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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 986


Pecans Grown in the States of Alabama, Arkansas, Arizona, California, Florida, Georgia, Kansas, Louisiana, Missouri, Mississippi, North Carolina, New Mexico, Oklahoma, South Carolina, and Texas; Establishment of Reporting Requirements and New Information Collection

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This rule implements a recommendation made by the American Pecan Council (Council) to establish reporting requirements under the Federal marketing order for pecans (Order). These reporting requirements will enable collection of information from handlers on: Pecans received; pecans purchased outside the United States; shipments and inventory of pecans; pecans exported by country of destination; and pecans exported for shelling and returned to the United States. This information will be used to provide important statistical reports to the industry, meet requirements under the Order, and to help guide future marketing efforts.


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SUPPLEMENTARY INFORMATION: This final rule, pursuant to 5 U.S.C. 553, amends regulations issued to carry out a marketing order as defined in 7 CFR 900.2[j]. This final rule is issued under Marketing Agreement and Order No. 986, (7 CFR part 986), regulating the handling of pecans grown in the states of Alabama, Arkansas, Arizona, California, Florida, Georgia, Kansas, Louisiana, Missouri, Mississippi, North Carolina, New Mexico, Oklahoma, South Carolina, and Texas. Part 986 (referred to as “the order”) is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the “Act.”

The Department of Agriculture (USDA) is issuing this rule in conformance with Executive Orders 13563 and 13175. This action falls within a category of regulatory actions that the Office of Management and Budget (OMB) has exempted from Executive Order 12866 review. Additionally, because this rule does not meet the definition of a significant regulatory action it does not trigger the requirements contained in Executive Order 13771. See OMB’s Memorandum titled “Interim Guidance Implementing Section 2 of the Executive Order of January 30, 2017” titled “Reducing Regulation and Controlling Regulatory Costs” (February 2, 2017).

This rule has been reviewed under Executive Order 12988. Civil Justice Reform. Under the Order now in effect, pecan handlers are subject to assessments. Funds to administer the Order are derived from these assessments. The reporting requirements established herein will be applicable to all assessable pecans beginning October 1, 2017.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 606c(15)(A) of the Act, any handler subject to an Order may file a petition with USDA a petition stating that the Order, any provision of the Order, or any obligation imposed in connection with the Order is not in accordance with law and request a modification of the Order or to be exempted therefrom. A handler is afforded the opportunity for a hearing on the petition. After the hearing, USDA would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review USDA’s ruling on the petition, provided an action is filed not later than 20 days after the date of the entry of the ruling.

This final rule establishes reporting requirements under the Order. This action will require all pecan handlers to submit to the Council reports on pecans received, shipped, held in inventory, exported for sale or shelling, and purchased from outside the United States. This information will be used by the Council to provide statistical reports to the industry, meet requirements under the Order, and help guide future marketing efforts. This action was unanimously recommended by the Council at its April 17, 2017, meeting. Section 2(4) of the Act specifies that one of its stated policies is to establish and maintain orderly marketing conditions for certain agricultural commodities that will provide, in the interests of producers and consumers, an orderly flow of the supply of such commodities to market to avoid unreasonable fluctuations in supply and prices. Section 8(d)(1) of the Act specifies that the Secretary may require all handlers subject to a marketing order to provide USDA with such information as is necessary for it to ascertain and determine the degree to which the agreement has been carried out or effectuated the declared policy of the Act.

Sections 986.75, 986.76, and 986.77 of the Order provide authority to the Council to require handlers to submit reports of inventory, merchantable pecans handled, and pecans received by handlers, respectively, on such dates as the Council may prescribe. Section 986.78 further provides, with the approval of the Secretary, authority for the Council to collect other reports and information from handlers needed to perform its duties. This rule uses these authorities to establish new §§ 986.177 and 986.178 under the administrative provisions of the Order. These new
sections will require handlers of pecans to report to the Council on a monthly basis: Pecans received, shipped, held in inventory, exported for sale or shelling, and purchased from outside the United States, using five specific Council forms.

At its November 16, 2016, meeting, the first meeting following the promulgation of the Order, the Council discussed its initial budget, assessment rates, and necessary reporting requirements to establish a program that is efficient and responsive to industry needs. During these discussions, the Council appointed a Statistics and Reporting Committee (Committee) to develop reporting requirements.

Members of the Committee discussed the reporting needs of the industry, reviewed examples of reporting forms from other marketing orders, and met and worked with the staff of another marketing order in developing the proposed reporting requirements. The Committee also worked with USDA to ensure the recommended information collection would provide the information necessary to facilitate the administration of the Order.

At its February 23, 2017, meeting, the Council reviewed drafts of seven reporting forms as developed and recommended by the Committee. The Council expressed its interest in having as much electronic reporting as possible, but recognized that many handlers may prefer a paper submission. The Council also considered the timing of when forms would be due and submission dates that would work for all parts of the industry. After a thorough review and some modifications, seven forms were approved by the Council.

At a meeting on April 17, 2017, the Council revisited the recommended reporting requirements and the accompanying forms. Acknowledging that the industry was more than halfway through the fiscal year at that time, the Council recommended dividing the reporting requirements into the five forms needed beginning with the 2017–2018 fiscal year and the two forms needed beginning with the 2016–2017 fiscal year. The two forms required for the 2016–2017 fiscal year were established in a separate rulemaking action.

This final rule adds five new reporting requirements and five new forms to the administrative provisions under the Order by adding §§ 986.177 and 986.178. During the formal rulemaking hearing to promulgate the Order, it was stated that the data collected by the Council was one of the most important aspects of the Order.

Concerns were also expressed regarding the accuracy and availability of industry data, and the impact those have on making good business decisions.

Currently, most available reports on domestic pecan production are issued annually and often long after the marketing year has been completed. The reporting of this information is currently voluntary, so not all handlers are reporting, which impacts the accuracy of the available information. Some aggregate import and export data are available, but this information is usually available on an annual basis, or reported several months after the shipments have been made. Additionally, some domestic production is shipped outside of the country for shelling and then returned to the United States for sale or further processing. There is concern this volume is not being properly accounted for, and is negatively impacting the accuracy of the industry information currently available.

The Council agreed these reporting requirements would be necessary to develop a more accurate reporting system regarding pecans being produced and handled in the United States, and recognized the value to the industry of such reports. Having accurate and timely information on the total supply of pecans moving into and out of the country will also assist the industry in managing available supply and in making marketing decisions. Further, collecting this information monthly will allow the Council to provide key data regarding total supply and inventory to the industry in a more timely fashion throughout the season.

The Council also recognized that § 986.65 of the Order requires the Council to provide a report and recommendation to the Secretary on the Council’s proposed marketing policy for the next fiscal year. The report is required to include, in part, an estimate of production; improved, native, and substandard pecans; handler inventory; and trade supply, taking into consideration imported pecans. In addition to providing important information for industry reports, the reporting requirements covered in this action would provide the information needed to develop the marketing policy.

Two specific monthly reporting requirements will be added to the administrative provisions under the Order in a new § 986.177, a summary report of domestic pecans received, and a report of pecans purchased outside the United States. The summary report of domestic pecans received includes information on the handler submitting the form along with the report, the total weight and type of inshell pecans received, and the weight by variety of improved pecans received. In addition, the form also includes information regarding total assessments owed and total pounds reported to date.

The information on this form will provide the Council with the volume of pecans received by handlers each month throughout the season. This information will be used to track the available supply of pecans each month, and the overall crop as it is delivered to handlers. The Council will then be able to use the information to develop its own reports that would provide the industry with an overview of market information for the predominant varieties, including volume by variety, which will assist in the development of marketing strategies.

The Council also intends to use this form to facilitate the collection of assessments on a monthly basis throughout the season. Using the form, handlers will be able to calculate their assessments due each month based on the pecans received as listed on the report. Handlers will then be required to pay to the Council the assessments owed on the pecans received by the due date of the summary report.

In its discussion of the report of pecans purchased outside the United States, the Council agreed it would be important to have information regarding the volume of pecans being imported by production area. The monthly report of pecans purchased outside the United States includes the name of the handler importing pecans, the month covered by the report, the date imported, country of origin, volume, and variety of pecans imported.

As production of pecans abroad has increased, there has been an increase in pecans imported into the United States. One Council member stated that the domestic industry is currently shelling and processing as much as 70 to 75 percent of Mexican-grown pecans, and that Mexican pecans now account for nearly 50 percent of sales in the United States. Consequently, having information regarding the volume of imported pecans is essential when calculating available supply. Collecting this information will greatly improve the accuracy of reports to the industry as it includes information regarding both domestic and imported pecans.

One of the Council’s main goals in developing these reporting requirements is to deliver to the industry accurate reports regarding the marketplace and supply of pecans to assist the industry in making its marketing decisions throughout the year. The Council believes having information regarding imported pecans is an essential part of reaching this goal.
Further, collecting this information will provide the industry with valuable data regarding the timing and volume of pecans imported into the United States. Members also agreed having this information will assist the Council in developing its marketing policy as required under the Order.

Three additional reporting requirements will be added to the administrative provisions in a new § 986.178: Reports of shipments and inventory, exports by country of destination, and inshell pecans exported to Mexico for shelling. The report of shipments and inventory will include information on the handler submitting the report, the month covered by the report, shipments of shelled and inshell pecans, current inventory, and pecans in inventory already committed for shipment.

The Council believes this form will provide beneficial information regarding shipments completed and volume in inventory. While there is currently some limited information available regarding pecans in cold storage, this information does not delineate between available inventory and inventory that is already committed for shipment. By collecting this information from handlers, this report, in conjunction with the data regarding pecans received, will allow the Council to provide the industry with inventory reports that are more accurate, and that provide a clearer picture of available supply. This data on the available volume of pecans will provide the industry with the information needed to make better marketing decisions.

When discussing a reporting requirement for exported pecans, the Council expressed the industry’s need for more information concerning international trade markets and export trends. The report of exports by country of destination includes information on the handler submitting the report, the month of the report, the weight of all shipments of pecans, inshell or shelled, by classification, and by country of destination.

The Council estimated that prior to 2005, around 10 percent of domestic production was being exported. Since then, exports have grown considerably and now account for between 40 and 50 percent of production. The recommended form will be used to generate reports throughout the season providing industry members with information on where product is being sold and in what volume. Further, the Council will use this information to determine the effectiveness of any international promotional efforts and to consider opportunities for promotion and market expansion.

Some of the pecans shipped outside the United States are exported just for shelling and then returned to the United States for further use. The Council recommended an additional reporting form to capture this information. Specifically, the Council recommended collecting information on pecans exported to Mexico for shelling and then returned to the United States. The Council decided to limit the reporting to Mexico since the vast majority of pecans exported for this purpose are being sent to Mexico because of its proximity and cost efficiencies. The report of inshell pecans exported to Mexico for shelling includes information on the handler submitting the report, the month covered by the report, dates of shipments, the total weight of inshell pecans shipped for shelling, and the weight of shelled pecans returned to the United States.

In discussing this reporting requirement, the Council recognized that in addition to shelling some pecans from the production area, Mexico also exports pecans to the United States. This makes it difficult to determine how much of the import volume reported from Mexico is represented by domestic product after shelling. It was expressed that without this report, the accuracy of data regarding both reported exported and imported product could be compromised. Pecans exported for shelling could be counted as exports, and then counted again as imports when returned to the United States. This reporting requirement will help reduce the possibility of double counting of these pecans, and will help improve the accuracy of the overall information on supply.

The Council selected the tenth day of the month following the month of the activity as the due date for all five reports. Should the tenth day of the month fall on a weekend or holiday, reports will be due by the first business day following the tenth day of the month. The five monthly reports will be used during the 2017–2018 and subsequent seasons.

This action requires pecan handlers to provide the Council with monthly reports on pecans received, shipped, held in inventory, exported for sale or shelling, and purchased from outside the United States. By establishing these reporting requirements, the Council will be able to gather and disseminate this information in accurate market reports. Further, this information will be used to create a marketing policy each year as required under the Order.

Final Regulatory Flexibility Analysis

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), the Agricultural Marketing Service (AMS) has considered the economic impact of this action on small entities. Accordingly, AMS has prepared this final regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf.

There are approximately 2,500 growers of pecans in the production area and approximately 250 handlers subject to regulation under the pecan marketing Order. Small agricultural growers are defined by the Small Business Administration as those having annual receipts less than $750,000, and small agricultural service firms are defined as those whose annual receipts are less than $7,500,000 (13 CFR 121.201).

According to information from the National Agricultural Statistics Service (NASS), the average grower price for pecans during the 2015–2016 season was $2.20 per pound and 254 million pounds were utilized. The value for pecans that year totaled $558.8 million ($2.20 per pound multiplied by 254 million pounds). Taking the total value of production for pecans and dividing it by the total number of pecan growers provides an average return per grower of $223,520. Using the average price and utilization information, and assuming a normal bell-curve distribution of receipts among growers, the majority of growers receive less than $750,000 annually.

Evidence presented at the formal rulemaking hearing indicates an average handler margin of $0.58 per pound. Adding this margin to the average grower price of $2.20 per pound of inshell pecans results in an estimated handler price of $2.78 per pound. With a total 2015 production of 254 million pounds, ($2.78 per pound multiplied by 254 million pounds) the total value of production in 2015 was $706.12 million. Taking the total value of production for pecans and dividing it by the total number of pecan handlers provides an average return per handler of $2,244,480. Using this estimated price, the utilization volume, number of handlers, and assuming a normal bell-
curve distribution of receipts among handlers, the majority of handlers have annual receipts of less than $7,500,000. Thus, the majority (a substantial number) of growers and handlers of pecans grown in the states of Alabama, Arkansas, Arizona, California, Florida, Georgia, Kansas, Louisiana, Missouri, Mississippi, North Carolina, New Mexico, Oklahoma, South Carolina, and Texas may be classified as small entities.

This final rule establishes reporting requirements under the Order. This action requires pecan handlers to provide the Council with reports of pecans received, shipped, held in inventory, exported for sale or shelling, and purchased from outside the United States. The Council will use this information to provide important statistical reports to the industry, to meet requirements under the Order, and to help guide future marketing efforts. This rule establishes new §§ 986.177 and 986.178 under the administrative provisions of the Order. The authority for this action is provided for in Section 8(d)(1) of the Act and §§ 986.75, 986.76, 986.77, and 986.78 of the Order.

Requiring monthly reports of pecans received, shipped, held in inventory, exported for sale or shelling, and purchased from outside the United States will impose an increase in the reporting burden on all pecan handlers. However, this data is already recorded and maintained by handlers as a part of their daily business. Handlers, regardless of size, should be able to readily admit and submit this information. Consequently, any additional costs associated with this change would be minimal (not significant) and apply equally to all handlers.

This action should also help the entire industry by providing comprehensive data on pecans received, shipped, held in inventory, exported for sale or shelling, and purchased from outside the United States. Collection of this data was one of the industry’s goals in promulgating the Order as there is no other source for this type of data. This information should provide accurate information regarding available inventory, help with marketing and planning for the industry, provide important information for the collection of assessments, and assist with preparing the annual marketing policy required by the Order. The benefits of this action are expected to be equally available to all pecan growers and handlers, regardless of their size.

The Council considered listing additional varieties on the summary report of pecans received. However, after discussion the Council determined a simpler version with the major commercial varieties and room for handlers to enter additional varieties as needed would be less burdensome. The Council also considered different due dates for these monthly reports, including a due date of the first, the third and the fifth day after the month of the activity. However, after some discussion, it was determined some handlers may have difficulty meeting these time frames. The 15th day of the month was also suggested, but Council members thought this would delay the issuance of reports, and negatively impact their value. Consequently, the Council agreed to set the due date for all five forms at the tenth of the month. The Council also considered the value and importance of each of the forms, and if all should be recommended. However, the Council agreed each of the recommended forms provides important information for the industry and for administering the Order. Therefore, the alternatives were rejected.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), this collection has been submitted to OMB with the reference number 0575-0036. Upon approval, the collection will be merged with OMB No. 0581-0291, “Federal Marketing Order for Pecans.” This final rule establishes the use of five new Council forms, which impose a total annual burden increase of 2,234.4 hours. The forms, “Summary Report U.S. Pecans Received for Your Own Account,” “Pecans Purchased Outside the United States,” “Report of Shipments and Inventory on Hand,” “Exports by Country of Destination,” and “Inshell Pecans Exported to Mexico for Shelling and Returned to the United States as Shelled Meats,” require the minimum information necessary to effectively carry out the requirements of the Order. The information would enable the Council to provide statistical reports to the industry, meet requirements under the Order, and help guide future marketing efforts.

As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies.

As noted in the initial regulatory flexibility analysis, USDA has not identified any relevant Federal rules that duplicate, overlap, or conflict with this rule. Further, the public comments received concerning the proposal did not address the initial regulatory flexibility analysis.

AMS is committed to complying 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.

Further, the Council’s meetings were widely publicized throughout the pecan industry and all interested persons were invited to attend the meetings and participate in Council deliberations on all issues. Additionally, the Council’s Committee meetings held February 23, 2017, and April 17, 2017, were also public meetings and all entities, both large and small, were able to express views on this issue.

A proposed rule concerning this action was published in the Federal Register on December 4, 2017 (82 FR 57166). Copies of the rule were sent via email to Council members and known pecan handlers. Finally, the rule was made available through the internet by USDA and the Office of the Federal Register. A 60-day comment period ending February 2, 2018, was provided to allow interested persons to respond to the proposal. Two comments were received in support of the proposed information collection. One commenter stated that, while he worried about the cost of pecans going up, he would consider the cost worthwhile if the information made the pecan industry more transparent. Another commenter stated she appreciated that the regulation could help improve the production and transportation of pecans.

Accordingly, no changes will be made to the rule as proposed, based on the comments received.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: http://www.ams.usda.gov/rules-regulations/maa/small-businesses. Any questions about the compliance guide should be sent to Richard Lower at the previously-mentioned address in the FOR FURTHER INFORMATION CONTACT section.

After consideration of all relevant matter presented, including the information and recommendation of the Council and other available information, it is hereby found that this rule, as hereinafter set forth, will tend to effectuate the declared policy of the Act.

List of Subjects in 7 CFR Part 986

Marketing agreements, Nuts, Pecans, Reporting and recordkeeping requirements.
§ 986.177 Reports of pecans received by handlers.

(a) Summary report U.S. pecans received for your own account. Handlers shall submit to the Council, by the tenth day of the month, a summary report of inshell domestic pecans received during the preceding month. Should the tenth day of the month fall on a weekend or holiday, reports are due by the first business day following the tenth day of the month. The report shall be submitted to the Council on APC Form 1 and contain the following information:

1. The name and address of the handler;
2. The month covered by the report;
3. The total weight and type of inshell pecans received, and the weight by variety for improved pecans received during the reporting period;
4. The total weight and type of inshell pecans imported during the preceding month and year to date; and,
5. Assessments due on pecans received during the reporting period to be paid by the due date of the report.

(b) Pecans purchased outside the United States. Handlers shall submit to the Council, by the tenth day of the month, a summary report of shelled pecans imported during the preceding month. Should the tenth day of the month fall on a weekend or holiday, reports are due by the first business day following the tenth day of the month. The report shall be submitted to the Council on APC Form 6 and contain the following information:

1. The name and address of the handler;
2. The month covered by the report;
3. The date the pecans were imported;
4. The country of origin; and,
5. The total weight of shelled and inshell pecans received, and the weight by variety for improved pecans received.

§ 986.179 Other reports.

(a) Report of shipments and inventory on hand. Handlers shall submit to the Council, by the tenth day of the month following the month of activity, a report of all shipments, inventory, and committed inventory for pecans. Should the tenth day of the month fall on a weekend or holiday, reports are due by the first business day following the tenth day of the month. The report shall be submitted to the Council on APC Form 2 and contain the following information:

1. The name and address of the handler;
2. The month covered by the report;
3. The weight of all shipments of pecans, inshell and shelled, and inter-handler transfers shipped and received during the reporting period;
4. The weight of all shipments of pecans, inshell and shelled, and inter-handler transfers shipped and received in the previous month and year to date;
5. Total inventory held by handler;
6. All the inventory committed (pecans not shipped, but sold or otherwise obligated) whether for domestic sale or export; and,
7. The weight of all shelled or inshell pecans under contract for purchase from other handlers.

(b) Exports by country of destination. Handlers shall submit to the Council, by the tenth day of the month following the month of shipment, a report of exports. Should the tenth day of the month fall on a weekend or holiday, reports are due by the first business day following the tenth day of the month. The report shall be reported to the Council on APC Form 3 and contain the following information:

1. The name and address of the handler;
2. The month covered by the report;
3. The total weight of pecans shipped for export, whether inshell, shelled, or substandard during the reporting period;
4. The total weight of pecans shipped for export, whether inshell, shelled, or substandard during the previous period and year to date; and,
5. The destination(s) of such exports.

(c) Inshell pecans exported to Mexico for shelling and returned to the United States as shelled meats. Handlers shall submit to the Council, by the tenth day of the month following the month of shipment, a report of all inshell pecans exported to Mexico for shelling and returned to the United States as shelled pecans. Should the tenth day of the month fall on a weekend or holiday,
Adjustment Act of 1990, Public Law 101–410, 104 Stat 890 (the 1990 Inflation Adjustment Act), to improve the effectiveness of civil monetary penalties and to maintain their deterrent effect. The 2015 Inflation Adjustment Improvements Act required agencies to issue an interim final rule by August 1, 2016, to adjust the level of civil monetary penalties with an initial “catch-up” adjustment, and to annually adjust these monetary penalties for inflation by January 15 of each subsequent year. The act authorizes agencies to implement the annual adjustments without regard to the requirements for public notice and comment or delayed effective date under the Administrative Procedures Act (the APA), 5 U.S.C. 553(b)(3)(B) and (d)(3), respectively.

In addition, based on the definition of a “civil monetary penalty” in the 1990 Inflation Adjustment Act, agencies are to make adjustments only to the civil penalties that (i) are for a specific monetary amount as provided by Federal law or have a maximum amount provided for by Federal law; (ii) are assessed or enforced by an agency; and (iii) are enforced or assessed in an administrative proceeding or a civil action in the Federal courts. Therefore, penalties that are stated as a percentage of an indeterminate amount or as a function of a violation (penalties that encompass actual damages incurred) are not to be adjusted.

On May 19, 2016, SBA published an interim final rule with its initial adjustments to the civil monetary penalties, including an initial “catch-up” adjustment. 81 FR 31489. These adjusted penalties became effective on August 1, 2016. SBA published its first annual adjustments to the monetary penalties in the Federal Register on February 9, 2017 (82 FR 9967), with an immediate effective date. This rule will establish the adjusted penalty amounts for 2018.

According to the 2015 Inflation Adjustment Improvements Act and the Office of Management and Budget implementing guidance in M–18–03, Implementation of Penalty Inflation Adjustments for 2018, Pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, (December 15, 2017), the formula for calculating the annual adjustments is based on the Consumer Price Index for all Urban Consumers (CPI–U) for the month of October preceding the adjustment, and specifically on the change between the October CPI–U preceding the adjustment and the prior year’s CPI–U. Based on this methodology, the 2018 civil monetary penalty adjustment is 1.02041 (October 2017 CPI–U (246.663)/October 2016 CPI–U (241.729) = 1.02041). The annual adjustments identified in this rule were obtained by applying this multiplier to the most recently adjusted penalty amounts that were published on February 9, 2017 (82 FR 9967).

II. Civil Money Penalties Adjusted by This Rule

This rule makes adjustments to civil monetary penalties authorized by the Small Business Act, the Small Business Investment Act of 1958 (SBIAct), the Program Fraud Civil Remedies Act, and the Byrd Amendment to the Federal Regulation of Lobbying Act. These penalties and the implementing regulations are discussed below.

1. 13 CFR 107.665—Civil Penalties

SBA licenses, regulates and provides financial assistance to financial entities called small business investment companies (SBICs). Pursuant to section 315 of the SBIAct, 15 U.S.C. 687g, SBA may impose a penalty on any SBIC for each day that it fails to comply with SBA’s regulations or directives governing the filing of regular or special reports. The penalty for non-compliance is incorporated in § 107.665 of the SBIC program regulations.

This rule amends § 107.665 to adjust the current civil penalty from $254 to $259 for each day an SBIC fails to file a required report. The current civil penalty amount of $254 was multiplied by the multiplier of 1.02041 to reach a product of $259, rounded to the nearest dollar.

2. 13 CFR 120.465—Civil Penalty for Late Submission of Required Reports

According to the regulations at § 120.465, any SBA Supervised Lender, as defined in 13 CFR 120.10, that violates a regulation or written directive issued by the SBA Administrator regarding the filing of any regular or special report is subject to the civil penalty amount stated in § 120.465(b) for each day the company fails to file the report, unless the SBA Supervised Lender can show that there is reasonable cause for its failure to file. This penalty is authorized by section 23(j)(1) of the Small Business Act, 15 U.S.C. 650(j)(1).

This rule amends § 120.465 to adjust the current civil penalty to $6,460 per day for failure to file. The current civil penalty amount was calculated by multiplying the civil penalty amount of $259 for each day an SBIC fails to file the required disclosure forms or to make prohibited expenditures or fail to file the required disclosure forms or to amend such forms, if necessary. This rule amends § 120.465(b), to adjust the current civil penalty amounts to “not less than $19,639 and not more than $196,387.” The current civil penalty amounts of $19,246 and $196,387 were multiplied by the multiplier of 1.02041 to reach a product of $19,639 and to adjust the civil penalty that may be imposed for a first time violation of § 142.1(b) to a maximum of $10,781, for each statement or claim. Therefore, this final rule makes the required adjustment for 2018 based on the correct published amount of $10,957. Accordingly, the rule amends § 142.1(b) to adjust the current civil penalty to $11,181 per statement or claim. The adjusted civil penalty amount was calculated by multiplying the civil penalty amount of $10,957 by the multiplier of 1.02041 to reach a product of $11,181, rounded to the nearest dollar.

3. 13 CFR 142.400—Overview of Regulations

SBA has promulgated regulations at 13 CFR part 142 to implement the civil penalties authorized by the Program Fraud Civil Remedies Act of 1986 (PF CRA), 31 U.S.C. 3801–3812. The current electronic Code of Federal Regulations (eCFR) at § 142.1(b) states that a person who submits, or causes to be submitted, a false claim or a false statement to SBA is subject to a civil penalty of not more than $10,781, for each statement or claim. However, this amount reflected in the eCFR is incorrect. Rather, the correct adjusted amount for 2017, as published in the Federal Register on August 9, 2017, was $10,957 (the product of $10,781 and the multiplier of 1.0636). Therefore, this final rule makes the required adjustment for 2018 based on the correct published amount of $10,957. Accordingly, the rule amends § 142.1(b) to adjust the current civil penalty to $11,181 per statement or claim. The adjusted civil penalty amount was calculated by multiplying the civil penalty amount of $10,957 by the multiplier of 1.02041 to reach a product of $11,181, rounded to the nearest dollar.
respectively, rounded to the nearest dollar.

III. Justification for Final Rule

The Inflation Adjustment Act provides that agencies shall annually adjust civil monetary penalties for inflation notwithstanding Section 553 of the APA. Additionally, the Inflation Adjustment Act provides a nondiscretionary cost-of-living formula for annual adjustment of the civil monetary penalties. For these reasons, the requirements in sections 553(b), (c), and (d) of the APA, relating to notice and comment and requiring that a rule be effective 30 days after publication in the Federal Register, are inapplicable.

IV. Justification for Immediate Effective Date

Section 553(d) requires agencies to publish their rules at least 30 days before their effective dates, except if the agency finds for good cause that the delay is impracticable, unnecessary, or contrary to the public interest. By expressly exempting this rule from section 553, the 2015 Inflation Adjustment Improvements Act has provided SBA with the good cause justification for this rule to become effective on the date it is published in the Federal Register.

Compliance With Executive Orders 12866, 12988, 13132, 13771, and the Paperwork Reduction Act (44 U.S.C. Ch. 35) and the Regulatory Flexibility Act (5 U.S.C. 601–612)

Executive Order 12866

The Office of Management and Budget has determined that this final rule is not a significant regulatory action under Executive Order 12866. This is also not a major rule under the Congressional Review Act, 5 U.S.C. 800.

Executive Order 12988

This action meets applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden. The action does not have retroactive or preemptive effect.

Executive Order 13132

For the purpose of Executive Order 13132, SBA has determined that the rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, this final rule has no federalism implications warranting preparation of a federalism assessment.

Executive Order 13771

This rule is not an Executive Order 13771 regulatory action because this rule is not significant under Executive Order 12866.

Paperwork Reduction Act

SBA has determined that this rule does not impose additional reporting or recordkeeping requirements.

Regulatory Flexibility Act (RFA)

The RFA requires agencies to consider the effect of their regulatory actions on small entities, including small nonprofit businesses, and small local governments. Pursuant to the RFA, when an agency issues a rule the agency must prepare an analysis that describes whether the impact of the rule will have a significant economic impact on a substantial number of such small entities. However, the RFA requires such analysis only where notice and comment rulemaking is required. As stated above, SBA has express statutory authority to issue this rule without regard to the notice and comment requirement of the Administrative Procedure Act. Since notice and comment is not required before this rule is issued, SBA is not required to prepare a regulatory analysis.

List of Subjects

13 CFR Part 107

Investment companies, Loan programs—business, Reporting and recordkeeping requirements, Small businesses.

13 CFR Part 120

Loan programs—business, Reporting and recordkeeping requirements, Small businesses.

13 CFR Part 142

Administrative practice and procedure, Claims, Fraud, Penalties.

13 CFR Part 146

Government contracts, Grant programs, Loan programs, Lobbying, Penalties, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, SBA amends 13 CFR parts 107, 120, 142, and 146 as follows:

PART 107—SMALL BUSINESS INVESTMENT COMPANIES

1. The authority citation for part 107 continues to read as follows:

Authority: 15 U.S.C. 681, 683, 687(c), 687b, 687d, 687g, 687m.

§ 107.665 [Amended]

2. In § 107.665, remove “$254” and add in its place “$259”.

PART 120—BUSINESS LOANS

3. The authority citation for part 120 continues to read as follows:


§ 120.465 [Amended]

4. In § 120.465, amend paragraph (b) by removing “$6,331” and adding in its place “$6,460”.

PART 142—PROGRAM FRAUD CIVIL REMEDIES ACT REGULATIONS

5. The authority citation for part 142 continues to read as follows:

Authority: 15 U.S.C. 634(b); 31 U.S.C. 3803(g)(2).

§ 142.1 [Amended]

6. In § 142.1, amend paragraph (b) by removing “$10,781” and adding in its place “$11,181”.

PART 146—NEW RESTRICTIONS ON LOBBYING

7. The authority citation for part 146 continues to read as follows:


§ 146.400 [Amended]

8. In § 146.400, amend paragraphs (a), (b), and (e) by removing “$19,246” wherever it appears and adding in its place “$19,639” and by removing “$192,459” and adding in its place “$196,387”.

Linda E. McMahon, Administrator.
[FR Doc. 2018–03490 Filed 2–20–18; 8:45 am]
BILLING CODE 8025–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71


Amendment of Class E Airspace; Hanford, CA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.
SUMMARY: This action amends Class E airspace extending upward from 700 feet above the surface at Hanford Municipal Airport, Hanford, CA, by enlarging the airspace to accommodate area navigation (RNAV) procedures at the airport, removing the Visalia VOR omnidirectional range/distance measuring equipment (VOR/DME) from the airspace description, and amending the geographic coordinates of the airport. This action also removes Blair Airport from the airport description as the airport no longer exists. This action is necessary for the safety and management of instrument flight rules (IFR) operations at the airport.

DATES: Effective 0901 UTC, May 24, 2018. The Director of the Federal Register approves this incorporation by reference action under Title 1, Code of Federal Regulations, part 51, subject to the annual revision of FAA Order 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order 7400.11B, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at http://www.faa.gov/air_traffic/publications/. For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741–6030, or go to https://www.archives.gov/federal-register/cfr/ibr-locations.html. FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

FOR FURTHER INFORMATION CONTACT: Tom Clark, Federal Aviation Administration, Operations Support Group, Western Service Center, 1601 Lind Avenue SW, Renton, WA 98057; telephone (425) 203–4511.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA’s authority to issue rules regarding 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, Subpart 1, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it amends Class E airspace at Hanford Municipal Airport, Hanford, CA, to support instrument flight rules (IFR) operations at the airport.

History

The FAA published a notice of proposed rulemaking (NPRM) in the Federal Register for Docket No. FAA–2017–0856 (82 FR 50594; November 1, 2017) proposing to amend Class E airspace extending upward from 700 feet above the surface at Hanford Municipal Airport, Hanford, CA, to support instrument flight rules (IFR) operations at the airport.

The Rule

The FAA is amending title 14 Code of Federal Regulations (14 CFR) part 71 by amending Class E airspace extending upward from 700 feet above the surface at Hanford Municipal Airport, Hanford, CA, to accommodate area navigation (RNAV) procedures at the airport. The Class E airspace area is modified to within 1.8 miles southwest and 3.2 miles northeast of the 332° bearing from the airport extending to 6.2 miles northwest of the airport (from within a 2.6-mile radius), and within 1.8 miles southwest and 3.2 miles northeast (from within 1.5 miles each side) of the 152° bearing from the airport extending to 6.2 miles southeast of the airport (from 5 miles southeast), and within 1.3 miles each side of the 067° bearing from the airport (from 1.8 miles north and 2.3 miles south of the Visalia VOR/DME) extending to 7.7 miles northeast of the airport.

Also, this action amends the geographic coordinates for the airport, removes the reference to the Visalia VOR/DME in the legal description as the FAA transitions from ground-based to satellite-based navigation; and removes Blair Airport from the legal description as the airport no longer exists.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial and unlikely to result in adverse or negative comments. It, therefore: (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); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1F, “Environmental Impacts: Policies and Procedures,” paragraph 5–6.5a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:
PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

1. The authority citation for part 71 continues to read as follows:


§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11B, Airspace Designations and Reporting Points, dated August 3, 2017, and effective September 15, 2017, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

AWP CA E5 Hanford, CA [Amended]

Hanford Municipal Airport, CA

(Lat. 36°19’00” N, long. 119°37’40” W)

That airspace extending upward from 700 feet above the surface within 1.8 miles southwest and 3.2 miles northeast of a 332° bearing from Hanford Municipal Airport extending to 6.2 miles northwest of the airport, and within 1.8 miles southwest and 3.2 miles northeast of a 152° bearing from the airport extending to 6.2 miles southeast of the airport, and within 1.3 miles each side of a 067° bearing from the airport extending to 7.7 miles northeast of the airport.


B.G. Chew,

Acting Manager, Operations Support Group, Western Service Center.

[FR Doc. 2018–04349 Filed 2–20–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

(Docket No. FAA–2017–0972; Airspace Docket No. 16–AMN–9)

Establishment of Class E Airspace, Rangely, CO

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes Class E airspace extending upward from 700 feet above the surface, at Rangely Airport, Rangely, CO, to accommodate new area navigation (RNAV) procedures at the airport. This action ensures the safety and management of instrument flight rules (IFR) operations within the National Airspace System.

DATES: Effective 0901 UTC, May 24, 2018. The Director of the Federal Register approves this incorporation by reference action under Title 1, Code of Federal Regulations, part 51, subject to the annual revision of FAA Order 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order 7400.11B, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at http://www.faa.gov/air_traffic/publications/. For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741–6030, or go to https://www.archives.gov/federal-register/cfr/ibr-locations.html.

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15 each year.

FOR FURTHER INFORMATION CONTACT: Tom Clark, Civil Aviation Administration, Operations Support Group, Western Service Center, 2200 S 216th Street, Des Moines, WA 98198; telephone (206) 231–2253.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA’s authority to issue rules regarding 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, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it establishes Class E airspace extending upward from 700 feet above the earth at Rangely Airport, Rangely, CO, to support IFR operations at the airport.

History

The FAA published a notice of proposed rulemaking in the Federal Register (82 FR 57534; December 6, 2017) for Docket No. FAA–2017–0972 to establish Class E airspace extending upward from 700 feet above the surface at Rangely Airport, Rangely, CO.

Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Class E airspace designations are published in paragraph 6005 of FAA Order 7400.11B, dated August 3, 2017, and effective September 15, 2017, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order 7400.11B, Airspace Designations and Reporting Points, dated August 3, 2017, and effective September 15, 2017. FAA Order 7400.11B is publicly available as listed in the ADDRESSES section of this document. FAA Order 7400.11B lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

The FAA is amending Title 14 Code of Federal Regulations (14 CFR) part 71 by establishing Class E airspace extending upward from 700 feet above the surface at Rangely Airport, Rangely, CO, within an area approximately 10 miles wide, from north to south, and extending to approximately 10 miles east and 12 miles west of the airport.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial and unlikely to result in adverse or negative comments. It, therefore: (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); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA
Order 1050.1F, “Environmental Impacts: Policies and Procedures,” paragraph 5–6.5a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

§ 71.1 [Amended]

1. The authority citation for part 71 continues to read as follows:


§ 71.1 [Amended] 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11B, Airspace Designations and Reporting Points, dated August 3, 2017, and effective September 15, 2017, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

ANM CO E5 Rangely, CO [New]

Rangely Airport, CO (Lat. 40°05′38″ N, long. 108°45′47″ W)

That airspace extending upward from 700 feet above the surface of Rangely Airport within the area bounded by lat. 40°04′58″ N, long. 109°01′51″ W; to lat. 40°12′20″ N, long. 108°35′41″ W; to lat. 40°09′07″ N, long. 108°32′59″ W; to lat. 40°01′42″ N, long. 108°36′14″ W; to lat. 39°59′18″ N, long. 108°45′00″ W; to lat. 40°00′25″ N, long. 109°01′00″ W; thence to the point of beginning.


B.G. Chew,

Acting Manager, Operations Support Group, Western Service Center.

[FR Doc. 2016–03401 Filed 2–20–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 807, 812, and 814

[Docket No. FDA–2013–N–0080]

RIN 0910–AG48

Human Subject Protection; Acceptance of Data From Clinical Investigations for Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or we) is amending its regulations on acceptance of data from clinical investigations for medical devices. We are requiring that data submitted from clinical investigations conducted outside the United States intended to support an investigational device exemption (IDE) application, a premarket notification (510(k)) submission, a request for De Novo classification, a premarket approval (PMA) application, a product development protocol (PDP) application, or a humanitarian device exemption (HDE) application be from investigations conducted in accordance with good clinical practice (GCP), which includes obtaining and documenting the review and approval of the clinical investigation by an independent ethics committee (IEC) and obtaining and documenting freely given informed consent of subjects, which includes individuals whose specimens are used in investigations of medical devices.

The final rule updates the criteria for FDA acceptance of data from clinical investigations conducted outside the United States to help ensure the quality and integrity of data obtained from these investigations and the protection of human subjects. As part of this final rule, we are also amending the IDE, 510(k), and HDE regulations to address the requirements for FDA acceptance of data from clinical investigations conducted outside the United States.

The final rule provides consistency in FDA requirements for acceptance of data from clinical investigations, whatever the application or submission type.

DATES: This rule is effective February 21, 2019. See section III of this document for additional explanation of the effective date of this final rule.

FOR FURTHER INFORMATION CONTACT: Soma Kalb, Director, Investigational Device Exemptions Staff, Office of Device Evaluation, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1534, Silver Spring, MD 20993, 301–796–6359; and Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911.

SUPPLEMENTARY INFORMATION:

Executive Summary

Purpose of the Final Rule

Through this rule, FDA is updating the standards for FDA acceptance of data from clinical investigations conducted outside the United States to help ensure the quality and integrity of data obtained from these investigations and the protection of human subjects. In this rule, FDA is amending the regulations for PMA applications, IDE applications, IDE applications, and premarket notification submissions. As part of this rule, FDA also is amending the IDE regulations and the premarket notification regulations to address the requirements for FDA acceptance of data from clinical investigations conducted inside the United States. The amendments are intended to provide consistency in FDA requirements for acceptance of clinical data, whatever the application or submission type.

Legal Authority

FDA is issuing this rule under the authority of the provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) that apply to medical devices (21 U.S.C. 301 et seq.), including section 520(g) regarding IDEs (21 U.S.C. 360(g)), section 515(c)(1)(A) and (d)(2) regarding PMAs (21 U.S.C. 360e(c)(1)(A) and (d)(2)), sections 510(k) and 513(i) regarding premarket notifications and determinations of substantial equivalence (21 U.S.C. 360(k) and 360c(i), respectively), section 520(n) regarding IDEs, section 513(f)(2) regarding De Novo classifications, section 509B regarding acceptance of data from clinical investigations conducted outside the United States (21 U.S.C. 360bbb–8b), and section 701(a) regarding regulations for the efficient enforcement of the FD&C Act (21 U.S.C. 371(a)).

Summary of the Major Provisions of the Final Rule

This rule requires that sponsors and applicants of submissions and applications that include clinical investigations conducted outside the United States and submitted to support an IDE application or premarket approval application or submission provide statements and information regarding how the...
investigations conform with GCP. FDA defines GCP as a standard for the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical investigations in a way that provides assurance that the data and results are credible and accurate and that the rights, safety, and well-being of subjects are protected. GCP includes review and approval by an IEC before initiating an investigation, continuing IEC review of ongoing investigations, and obtaining and documenting the freely given informed consent of subjects. FDA also is including requirements for the acceptance of data from clinical investigations conducted in the United States submitted to support an IDE application, an HDE application, or a premarket notification submission. The changes require a statement regarding compliance with FDA regulations for human subject protection, institutional review boards, and IDEs when the investigations are conducted in the United States. With the above described changes, the rule is intended to update the standards for FDA acceptance of data from clinical investigations and to help ensure the quality and integrity of data obtained from these investigations and the protection of human subjects.

Summary of Costs and Benefits
The total estimated annualized costs of complying with these requirements, over 10 years, range from $0.8 million to $22.1 million with a 7 percent discount rate and range from $0.7 million to $22.0 million with a 3 percent discount rate. We lack data to quantify benefits, but expect the final rule will provide greater assurance of clinical data quality and integrity and human subject protection.

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I. Background
In the Federal Register of February 25, 2013 (78 FR 12664), FDA issued a proposed rule to revise the regulations in parts 807, 812, and 814 (21 CFR parts 807, 812, and 814) on the conditions under which FDA will accept data from clinical studies as support for an IDE application, a 510(k) submission, a PMA application, a PDP application, or an HDE application. The proposed rule addressed revisions to update the criteria for acceptance of data from clinical studies to help ensure the quality and integrity of data obtained from those studies and the protection of human subjects. In particular, the proposed rule addressed revisions to part 814 to update the criteria for acceptance of data from clinical studies conducted outside the United States. The proposed rule also addressed revisions to parts 807, 812, and 814, subpart H, to identify criteria for acceptance of data from clinical studies conducted both inside and outside the United States. The proposed rule identified similar criteria for acceptance of clinical data for all application and submission types for medical devices.

FDA received comments on the proposed rule from 13 entities: 7 medical device manufacturers, 2 academias, 2 associations, 1 drug manufacturer, and 1 consumer. The comments were supportive of GCP for medical devices as a mechanism to help ensure the quality and integrity of the data obtained from clinical investigations and human subject protection. Comments generally supported FDA’s efforts to clarify the criteria for acceptance of clinical data submitted to FDA to support an IDE or a device marketing application or submission. Many comments, however, raised concerns about the proposed rule and some believed the rule was premature.

II. Overview of the Final Rule
FDA considered all comments received on the proposed rule and we have made several important changes, primarily for clarity and accuracy, to reduce burden, and to provide flexibility in meeting regulatory requirements. The main changes from the proposed rule include:

• Deleting proposed § 812.2(e) because comments received indicated confusion regarding the scope of the rule. Proposed § 812.2(e) described the principles of good clinical practice applicable to clinical investigations that are conducted outside the United States that will be submitted to FDA in support of an IDE or device marketing application or submission. Including this information within the applicability section of the IDE regulations led some to believe that FDA intended for part 812 to apply to all clinical investigations conducted outside the United States. We have deleted proposed § 812.2(e) and included the supporting information requirements for clinical investigations conducted outside the United States in new § 812.28(a)(2).

• Clarifying that the rule applies to clinical data from “investigations” as defined in § 812.3(b) rather than using other terms, such as “clinical study” and “clinical trial,” in an interchangeable manner.

• Clarifying that the rule applies to the acceptance of data from clinical investigations conducted outside the United States when submitted to support an IDE or a device marketing application or submission rather than to all clinical data contained in such applications or submissions.

• Adding new § 812.28(a)(2), which identifies different supporting information requirements based on whether the investigation is for a significant risk device or a non-significant risk device, or meets the exemption criteria in § 812.2(c). Also, for investigations meeting the exemption criteria in § 812.2(c), the specified supporting information is required to be maintained and be made available for Agency review upon request by FDA.

• Adding a requirement in new § 812.28(a)(2) that the sponsor’s or applicant’s rationale for considering an investigation to be of a non-significant risk device or to meet the exemption criteria in § 812.2(c) be made available upon request by FDA. We also clarify in the preamble that we do not expect foreign IECs to provide oversight of the significant risk versus non-significant risk device determination and that sponsors and applicants may proceed based upon their own determination or based on a determination by FDA.

• Changing the requirements related to supporting information on incentives provided to subjects to require that the information be maintained for all clinical investigations but only require submission for significant risk device investigations. For investigations of non-significant risk devices and investigations meeting the exemption criteria in § 812.2(c), the final rule requires that information on incentives be made available upon FDA’s request. We made this change because of comments that can affect data integrity for all investigations. We do not believe this requirement will be
overly burdensome. Informed consent documents usually describe incentives and the IEC reviews this information. Therefore, providing the description of incentives to FDA should not be a burden. FDA will allow some flexibility in how sponsors or applicants comply with this provision. If the informed consent form includes an explanation of any incentives provided to subjects, a sponsor or applicant could submit a model consent form to meet the requirement. Alternatively, a sponsor or applicant could also satisfy the requirement by submitting a description of any incentives provided to subjects to participate in the investigation.

- Adding a waiver provision in new §812.28(c) to allow sponsors and applicants to request a waiver of any applicable requirements under §812.28(a)(1) and (b) if adequate justification can be provided. Although we believe the rule is flexible enough to address concerns about compliance with the laws and regulations of other countries and in situations when the sponsor or applicant did not initiate or conduct the clinical investigations, this revision will allow sponsors and applicants to request a waiver if they can provide adequate justification.

Although the proposed rule included provisions that would allow a sponsor or applicant to explain why a clinical investigation was not conducted in accordance with GCP, §812.28(e) makes this clear.

- Modifying the definition of an IEC in §812.3(l) by changing the reference to the definition of an institutional review board (IRB). In the proposed rule, we referenced §56.102(g) (21 CFR 56.102(g)). In the final rule, we reference §812.3(f), which incorporates §56.102(g), because §812.3(f) is specific to devices. While these definitions vary slightly, we interpret the definitions as having the same meaning. We have elected to reference the definition in §812.3(f) in order to reference definitions in part 812 whenever possible.

- Changing the requirement in proposed §812.28(a)(2), now §812.28(a)(3), that a statement is provided assuring the availability of the data from the study to FDA for validation through an onsite inspection to a requirement that FDA is able to validate the data from the investigation through an onsite inspection if the Agency deems it necessary.

- Amending §§812.28 and 812.140(d) to clarify that these provisions apply to requests for De Novo classifications, which are a type of device marketing submission. FDA intended for §§812.28 and 812.140(d) to encompass all device marketing applications and submissions. As stated in the proposed rule, “FDA believes that the requirements for FDA’s acceptance of data from clinical studies should be consistent regardless of the type of submission or application in which the data are submitted to FDA” (78 FR 12664 at 12665). This amendment will provide for consistency by ensuring that FDA requirements for acceptance of data from clinical investigations conducted outside the United States are the same for all device marketing applications and submissions, and will help to provide greater assurance of the quality and integrity of the data from such investigations submitted in support of this type of device marketing submission.

IV. Comments on the Proposed Rule

A summary of the comments submitted to the docket and our responses follow. To make it easier to identify comments and our responses, the word “Comment,” in parentheses, will appear before each comment; and the word “Response,” in parentheses, will appear before each response. We have numbered the comments to make it easier to distinguish between comments. The numbers are for organizational purposes only and do not reflect the order in which we received the comments or any value associated with them. We have combined similar comments under one numbered comment.

A. International Harmonization

Section 812.28(a) of the proposed rule would identify criteria for FDA acceptance of data from clinical studies conducted outside the United States and submitted in support of an IDE or a device marketing application or submission. Those criteria would require that such studies be conducted in accordance with GCP. This
stakeholders having an equal voice. They state that such guidelines do not exist for medical devices and that FDA should first seek a collaborative global approach and establishment of a harmonized guidance through the IMDRF organization, or similar group, with industry participation.

(Response) FDA disagrees. The rule only addresses the criteria for FDA acceptance of clinical data submitted to FDA that support an IDE or a device marketing application or submission. The rule does not address other aspects of medical device regulations, such as when an application or submission must be supported by clinical data, the type of clinical data needed, etc.

FDA has and will continue to promote global harmonization in many aspects of medical device development and regulation. With respect to medical device good clinical practice, FDA’s international activities include harmonizing regulatory requirements with our foreign counterparts, industry, and other international stakeholders. For example, FDA plays a key role in forums such as the International Medical Device Regulators Forum (IMDRF) where global medical device good clinical practice was discussed during the IMDRF meeting in Florianopolis, Brazil, in September 2016. Additionally, FDA continues to be directly involved in good clinical practice standard development, including those of the International Organization for Standardization (ISO) and the International Conference on Harmonisation (ICH).

(Response) FDA disagrees. The rule does not identify a specific GCP standard for sponsors and applicants to follow. Instead, the rule includes a definition of GCP in § 812.28(a)(1), which is consistent with the definition in § 312.120 (21 CFR 312.120), that embodies well recognized GCP principles and has been generally accepted. This allows sponsors of clinical investigations conducted outside the United States to determine an appropriate GCP standard to use for clinical investigations that will produce data to support an IDE or a device marketing application or submission to FDA. The rule helps to ensure that the data and results from such investigations are credible and accurate and that the rights, safety, and well-being of human subjects are adequately protected, while also being sufficiently flexible to accommodate differences in how countries regulate the conduct of clinical investigations.

(Response) FDA disagrees with this suggestion. The rule includes a definition of data from clinical investigations conducted outside the United States to support an IDE or a device marketing application or submission, the rule requires, among other things, that sponsors and applicants provide a statement that the investigation was conducted in accordance with GCP and provide supporting information. If these requirements were waived, a submission or application would not contain information regarding the sponsor’s or applicant’s conformity with GCP. The fact that the country where the investigation is conducted had adopted a GCP guideline would only identify the GCP guideline that should be followed but would not provide information regarding conformity of the clinical investigation with the GCP guideline.

(Response) FDA does not intend to regulate clinical investigations conducted outside the United States. The rule only identifies the criteria for FDA acceptance of clinical data submitted to FDA to support an IDE or a device marketing application or submission. We have modified the rule by removing proposed § 812.2(e) to clarify that the rule does not apply part 812 to investigations conducted outside the United States but rather addresses the conditions for FDA acceptance of clinical data when submitted to support an IDE or device marketing application or submission. FDA expects that foreign clinical investigations will be conducted in accordance with local laws and regulations. The application of a GCP standard would be in addition to the local laws and regulations to the extent that the local laws and regulations do not incorporate such a standard.

FDA’s rule does not identify a specific GCP standard for sponsors and applicants to follow. Instead, the rule includes a definition of GCP in § 812.28(a)(1), which is consistent with the definition in § 312.120 (21 CFR 312.120), that embodies well recognized GCP principles and has been generally accepted. Although the rule does not identify a specific GCP standard, we note that ISO 14155:2011, a GCP standard for medical devices, was recognized by most of the members of the IMDRF (Australia, Brazil, Canada, European Union, Japan, and the United States) as well as other countries, including Indonesia, Malaysia, Singapore, Thailand, and Taiwan.

FDA’s rule does not identify a specific GCP standard for sponsors and applicants to follow. Instead, the rule includes a definition of GCP in § 812.28(a)(1), which is consistent with the definition in § 312.120 (21 CFR 312.120), that embodies well recognized GCP principles and has been generally accepted. Although the rule does not identify a specific GCP standard, we note that ISO 14155:2011, a GCP standard for medical devices, was recognized by most of the members of the IMDRF (Australia, Brazil, Canada, European Union, Japan, and the United States) as well as other countries, including Indonesia, Malaysia, Singapore, Thailand, and Taiwan.

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believes that sponsors and applicants who follow ISO 14155:2011 in the conduct of clinical investigations will be able to meet the requirement in §812.28(a)(1) of this rule as well as the local laws and regulations of the countries where the investigations are conducted.

FDA believes the requirements outlined in the rule allow the flexibility needed to accommodate the laws and regulations of other countries. We also believe that conducting a clinical investigation according to a standard that meets the definition of GCP as provided in the rule will help to ensure the integrity and quality of the data and the protection of subjects. If needed, the rule allows sponsors and applicants to explain why GCP was not followed and to describe the steps taken to ensure that the data and results are credible and accurate and that the rights, safety, and well-being of human subjects have been adequately protected. Additionally, we have added a waiver provision to allow sponsors and applicants to request a waiver from any applicable requirement in §812.28(a)(1) and (b) of the rule (see new §812.28(c)). If a country’s clinical investigation requirements are not congruent with the GCP definition in this rule or with a GCP standard and the sponsor or applicant cannot meet GCP for the investigation, they may provide an explanation of the departure from GCP or request a waiver. FDA will take this information into account when considering the extent to which the Agency can rely on the data from these clinical investigations on a case-by-case basis.

B. Application of the Rule

(Comment 5) Several comments raised concerns that the rule may be interpreted as expanding the types of studies required to be included in applications and submissions and requiring GCP for all studies. Some comments requested clarification of the use of the terms “clinical investigation,” “clinical study,” and “clinical trial” in a seemingly interchangeable manner. The comments noted that the terms “clinical study” and “clinical trial” are not defined but the term “investigation” is defined in §812.3(h).

(Response) While FDA intended that “clinical study” and “clinical trial” have the same meaning as “clinical investigation,” to avoid any confusion, FDA has revised the rule to use the term “clinical investigation” with the meaning as defined in §812.3(h) (“Investigation means a clinical investigation of research involving one or more subjects to determine the safety or effectiveness of a device.”). We have also revised the rule to clarify that it applies when data from clinical investigations are provided to support an IDE or a device marketing application or submission; for example, when clinical data are submitted in: (1) A 510(k) submission to demonstrate substantial equivalence, (2) a PMA application to demonstrate a reasonable assurance of safety and effectiveness, or (3) an HDE application to demonstrate reasonable assurance of safety and probable benefit. When clinical data from investigations are included in applications and submissions as supplementary information and not as support, demonstration of conformity with GCP is not required.

(Comment 6) One comment noted that the proposed rule identified different requirements for acceptability of results from clinical investigations depending on the location of the study, that is, inside or outside the United States. The comment indicated applying this differential regimen would be difficult when a multicenter clinical investigation has sites both inside and outside the United States. The comment recommended that the requirements should not apply to clinical investigations per se but to clinical data. This would allow data originating from within the United States to be subject to existing GCP regulations (for example, parts 50, 56, and 812 (21 CFR parts 50, 56, and 812)) and data originating from outside the United States to be subject to the new GCP provisions even if the data were part of the same clinical investigation.

(Response) FDA notes that for a multicenter investigation with sites both inside and outside the United States, each site would need to comply with the local requirements. Clinical investigations conducted in the United States to determine the safety or effectiveness of a device are subject to parts 50, 56, and 812. The rule does not govern investigational sites located outside the United States, but rather specifies the criteria for FDA acceptance of data from investigations conducted outside the United States to support an IDE or device marketing application or submission. When a multicenter investigation includes sites both inside and outside the United States, the sponsor or applicant may provide a statement regarding the international nature of the investigation, the compliance of sites with their applicable local requirements, and a statement regarding conformance with GCP along with the required supporting information.

(Comment 7) Two comments noted that §812.2(e) identifies requirements for non-significant risk device investigations but IECs from other countries may not be familiar with this terminology and classification and may be unable to provide oversight of the sponsor’s determination as in the United States. One comment recommended that sponsors use their own determinations.

(Response) FDA agrees with these comments and notes that the significant risk versus non-significant risk determination in the rule relates only to the supporting information required to be submitted and maintained by sponsors and applicants while the requirement to follow GCP applies to all investigations submitted to FDA in support of device applications and submissions. As discussed previously, we have removed proposed §812.2(e) but we have maintained the provisions for different supporting information requirements in new §812.28(a)(2).

FDA does not intend that foreign IECs provide oversight of the significant risk versus non-significant risk determination. FDA recognizes that IECs outside the United States may not be familiar with FDA’s terminology related to significant risk and non-significant risk device investigations. Under the IDE regulations, sponsors may make an initial determination. Similarly, sponsors and applicants may make an initial determination for investigations conducted outside the United States. If the sponsor or applicant proceeds based on their own determination, they should maintain documentation of the rationale for their determination because FDA may request it, as stipulated at §812.28(a)(2).

For multinational investigations that include sites in the United States, the determination of the IRBs overseeing the sites in the United States should be used. In addition, sponsors and applicants may request a determination from FDA, just as they may for investigations conducted in the United States.

Note that any determination made by FDA, whether requested or not, will supersede any determination made by the sponsor or applicant (or IRB, if the sponsor or applicant relied on an IRB’s determination). If FDA determines that an investigation is of a significant risk device that was submitted as an investigation of a non-significant risk device or exempt investigation, FDA may request the additional supporting information required for significant risk device investigations. Likewise, if FDA determines that an investigation is of a non-significant risk device that was submitted as an exempt investigation, FDA may request the additional
supporting information required for non-significant risk device investigations.

(Comment 8) One comment recommended that the same requirements for IDE exempt studies apply regardless of where the study sites are located. The comment stated that studies exempt under §812.2(c) are not required to meet any requirements of part 812 except §812.119 when conducted in the United States, while the proposed rule levies a long list of requirements for these same studies when conducted outside the United States.

(Comment 9) One comment questioned the need for a statement in IDE applications and 510(k) submissions regarding compliance of clinical studies conducted in the United States with parts 50, 56, and 812. The comment stated that FDA must approve IDE applications, so it is not clear why data from a study conducted according to an approved IDE would not be acceptable for clinical studies conducted inside the United States.

(Comment 9) One comment recommended that any regulatory requirements are solely a compliance matter. As a result of FDA's determination on an application or submission, it is not clear why data from a study conducted according to an approved IDE would not be acceptable for clinical studies conducted outside the United States.

(Comment 9) One comment recommended that the same information be made available upon request. That is, the information is not required to be included in an IDE or device marketing application or submission when data from clinical investigations conducted inside the United States that meet the exemption criteria in §812.2(c) are provided to support an IDE or device marketing application or submission.

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alternative submission or course of action that satisfies the purpose of the requirement; or other information justifying a waiver.

Through these mechanisms, sponsors and applicants can provide information for FDA’s consideration in deciding whether to accept, on a case-by-case basis, data from a clinical investigation that is not conducted in accordance with GCP or for which the sponsor or applicant does not have information on how the investigation was conducted. (Comment 12) Two comments noted that sponsors and applicants may not be able to conduct all studies according to GCP due to requirements in the country where the study is conducted. The comments noted that in at least one country, ethics committees will not review post-market on-label studies because their scope is limited to investigational studies even though such studies may be submitted in support of applications and submissions to FDA.

(Response) FDA agrees that there may be situations where full conformity with GCP may be difficult or not feasible. FDA believes that conducting a clinical investigation in accordance with GCP will help to ensure that the data and results are credible and accurate and that the rights, safety, and well-being of human subjects are adequately protected. If the sponsor or applicant cannot meet GCP for the investigation, the sponsor or applicant may provide an explanation of the departure from GCP or request a waiver, as noted previously. FDA will take this information into account when considering the extent to which the Agency can rely on the data from these investigations on a case-by-case basis.

D. In Vitro Diagnostic (IVD) Devices

(Comment 13) Several comments recommended that FDA exempt from the informed consent provisions IVD studies conducted with de-identified samples consistent with FDA’s “Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable.” The comments state that application of GCP in this context would provide no additional protection and could deter innovation. One comment suggested that the concepts in the guidance be codified in the final rule.

(Response) The “Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable” does not exempt any clinical investigations from the informed consent requirements. In that guidance, FDA stated that we intend to exercise enforcement discretion with regard to the requirement for informed consent under the circumstances described in section 4 of the guidance. FDA issued the guidance to address concerns about obstacles to the development of IVDs and to facilitate development in a manner consistent with the principles of good clinical practice, including human subject protection. In addition to sponsors being able to apply the “Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable” to certain IVD investigations conducted in the United States, FDA does not intend to object if sponsors and applicants follow this guidance for similar IVD investigations conducted outside the United States provided there is no conflict with local laws and regulations.

The 21st Century Cures Act (Cures Act) (Pub. L. 114–255) was enacted on December 13, 2016. Title III, section 3023 of the Cures Act requires the Secretary of Health and Human Services (HHS), to the extent practicable and consistent with other statutory provisions, to harmonize the differences between the HHS human subject regulations and FDA’s human subject regulations. FDA will be working with others at HHS in carrying out this statutory directive, including with respect to de-identified human specimens.

(Comment 14) Three comments indicated that the rule should not apply to technical and analytical (or bench) studies that support IVD devices, especially when de-identified leftover specimens are used. Two comments indicated that these studies are subject to Good Laboratory Practices regulations and are conducted with IRB oversight and informed consent except under the circumstances described in the FDA’s “Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable.” These comments stated that application of GCP would provide no additional protection and would slow or deter innovation.

(Response) FDA disagrees with these comments. FDA considers investigations that use human specimens, including leftover specimens that are de-identified, to be clinical investigations. The definition of subject in § 812.3(p) includes individuals on whose specimens an investigational device is used. Data from investigations using human specimens are subject to the GCP rule when submitted as support of an IDE or a device marketing application or submission. FDA disagrees that the application of GCP would provide no additional protection. The application of GCP helps to ensure the quality and integrity of data from investigations using human specimens. We agree that these investigations should be conducted with IEC oversight and informed consent. However, as stated previously, in addition to sponsors being able to apply the “Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable” to certain IVD investigations conducted in the United States, FDA does not intend to object to object to sponsors and applicants following the guidance for similar IVD investigations conducted outside the United States, provided that there is no conflict with local laws and regulations.

As noted above, investigations using human specimens are considered clinical investigations. The Good Laboratory Practices regulation (part 58 (21 CFR part 58)) does not apply to clinical investigations, including investigations using human specimens. Further explanation of the applicability of part 58 is provided in FDA’s “Guidance for Industry and FDA Staff: In Vitro Diagnostic (IVD) Device Studies—Frequently Asked Questions.” (Comment 15) One comment noted that there is no harmonized, international IVD GCP guideline.

(Response) FDA recognizes that the ISO 14155:2011 standard states that it does not apply to IVD medical devices. FDA, however, considers conformity with the principles of GCP important for all clinical investigations, including those of IVD devices, to help ensure that the data and results from clinical investigations are credible and accurate and that the rights, safety, and well-being of human subjects are adequately protected. As stated above, FDA does not intend to object to sponsors and applicants following the “Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable,” provided that there is no conflict with local laws and regulations.

(Comment 16) One comment noted that the United States classifies IVDs as medical devices but other countries, for example, countries within the European Union, have separate directives governing medical devices and IVDs. Additionally, the Global Harmonization Task Force guidance documents on Clinical Evidence for IVD Medical Devices differentiate IVDs from other medical devices and the proposed regulations do not reflect these differences.
Although we have not identified specific requirements for the membership of an IEC in the rule, we note that the definition of an IEC references an IRB subject to the requirements of part 56 as one type of IEC. Another example would be the description provided in ICH E6.

F. Acceptance of Data From Clinical Investigations Conducted Outside the United States

Proposed § 812.28(a) would identify requirements for the acceptance of information from clinical investigations conducted outside the United States. FDA agrees that these requirements are adequate for regulation. We recognize that informed consent will be obtained before initiating the subject’s participation in the study.

Comment 20 One comment suggested adding to the end of proposed § 812.28(a)(1): “For the purpose of definition, device GCP does not include a requirement for sponsor collection and analysis of (i) adverse events beyond those specified in the protocol and those that would meet the definition of a UADE, (ii) concomitant medications and concomitant therapies beyond those specified in the protocol, (iii) any other data not specifically required of clinical investigations conducted under an IDE or not specified in the protocol.” The change is intended to clarify that the requirements for a drug clinical study are not being systematically required for medical device studies conducted outside the United States.

Response FDA disagrees with the suggested change. FDA has written the rule to be flexible to accommodate the laws and regulations of the countries where investigations are conducted. FDA expects that clinical investigations will be conducted in compliance with the local laws and regulations of the countries where the investigations take place and such laws and regulations may address collection and analysis of adverse events, concomitant medications and therapies, and other data. FDA considers the suggested language too restrictive because, during the course of an investigation, additional data may be collected that would be important to establishing the safety and effectiveness of a medical device or to subject safety. Moreover, the suggested language relies on FDA’s investigational device exemptions regulations by using a term (unanticipated adverse device effect or UADE) used in FDA’s regulations and limits “collection and analysis” by not requiring “any other data not specifically required of clinical investigations conducted under an IDE or not specified in the protocol.” These changes would modify the definition of GCP based on FDA’s regulations and it may appear that FDA is imposing its own GCP regulations on other countries. Additionally, the revisions could raise problems for investigations of combination products.

Adverse event reporting is an important aspect of GCP. The requirements related to collection and analysis of adverse events would be those identified in the GCP standard the sponsor uses. For example, ISO 14155:2011 includes the definition of adverse event documentation, reporting, and analysis in several sections.
including sections 6.4, 8.2.4, 8.2.5, and 9.8. A sponsor could request a waiver from any applicable requirement if the sponsor can justify why it is unnecessary, cannot be achieved, or can be satisfied through an alternative course of action.

(Comment 21) One comment noted that the text in proposed § 812.28(a) uses the term “data are valid” but stated this term is vague and recommends changing it to “relevant and credible.”

(Response) FDA agrees that the language in proposed § 812.28(a) regarding “data are valid” should be revised but disagrees with the suggested revision. The term “data are valid” was used in previous § 814.15(b) to indicate the data must represent valid scientific evidence, which is appropriate for PMA applications. Section 812.28, however, addresses data supporting other applications and submissions, including clinical data supporting an IDE application. Therefore, we have revised § 812.28(a) to read “FDA will accept information on clinical investigations conducted outside the United States to support an IDE or a device marketing application or submission if the investigations are well-designed and well-conducted . . .” consistent with § 312.120, which similarly applies to investigational applications in addition to marketing applications for drugs and biological products.

(Comment 22) One comment stated that phrases like “compliance with good clinical practice” might lead the reader to interpret FDA as expecting compliance with ICH E6 versus the phrase “compliance with the principles of good clinical practice,” which more readily relates to the concepts described in ISO 14155:2011.

(Response) FDA disagrees with this comment. Both ICH E6 and ISO 14155:2011 use the term “principles of good clinical practice.” FDA did use the term “principles of good clinical practice” in proposed § 812.2(e); however, we have removed this proposed section from the final rule to eliminate potential misinterpretation that part 812 applies to clinical investigations conducted outside the United States. Section 812.28(a)(1) uses the phrase “conducted in accordance with good clinical practice.” This section defines GCP and requires a sponsor or applicant to provide a statement regarding the conduct of the investigation submitted. The sponsor or applicant would indicate conformity with a specific GCP standard but the rule does not specify the GCP standard to use. FDA believes the language in the rule is appropriate in the context in which it is used.

(Comment 23) One comment asked whether the Agency looked at the differences between ICH E6 and ISO 14155:2011, related to device stakeholders’ requirements, to identify if there are any differences and considered the potential burden to adopt both standards.

(Response) FDA has not identified a specific GCP standard that sponsors must follow. Instead, FDA is allowing sponsors of device clinical investigations conducted outside the United States to follow a GCP standard of their choice, provided it meets the definition provided in § 812.28(a)(1). Although FDA believes that ICH E6 and ISO 14155:2011 represent similar approaches to GCP, we note that ICH E6 addresses drug and biological products, while ISO 14155:2011 addresses medical devices. We believe the differences are appropriate to the different products addressed.

G. Onsite Inspection

Proposed § 812.28(a)(2), as a condition for acceptance of data from a clinical investigation submitted under this section, would require a statement assuring the availability of the data from the clinical investigation to FDA for validation through an onsite inspection if the Agency deems it necessary or through other appropriate means.

(Comment 24) One comment stated that FDA has no authority to inspect foreign clinical study institutions and recommended that proposed § 812.28(a)(2) be struck. Another comment indicated that providing a statement as required by proposed § 812.28(a)(2) would be problematic because of foreign privacy laws.

(Response) FDA disagrees with striking proposed § 812.28(a)(2), now § 812.28(a)(3), because, in some cases (for example, to resolve any uncertainties about whether the investigation was conducted in accordance with GCP), to accept the data from a clinical investigation conducted outside the United States, FDA may need to validate the data through an onsite inspection. Historically, when needed to validate data from clinical investigations conducted outside the United States, FDA has been able to inspect the records of these investigations. When conducting foreign inspections, FDA obtains the consent of foreign governments.

FDA understands that a sponsor cannot disclose foreign records that are prohibited from disclosure by foreign law. If the Agency believes that access to records is necessary to verify certain data or to validate the investigation, and such records are not available because of foreign law, the sponsor and FDA will need to agree upon an alternative means for validation if the Agency is to rely on the data. Such alternative means for validation might entail FDA partnering with other regulatory authorities or other mutually agreed upon means for validation.

(Comment 25) One comment recommended keeping the language the same as in § 312.120(a)(1)(ii): That is, “FDA is able to validate the data from the study through an onsite inspection if the agency deems it necessary.” Another comment recommended modifying the language to “authorized by local law” and deleting “or through other appropriate means” unless FDA can clarify what it means and what types of activities would satisfy this requirement.

(Response) FDA partially agrees and has modified the language in proposed § 812.28(a)(2), now § 812.28(a)(3), to more closely follow the language in § 312.120. We have modified the requirement that a statement be provided assuring the availability of the data from the study to FDA for validation through an onsite inspection to a requirement that FDA is able to validate the data from the investigation through an onsite inspection. We have also determined that the phrase “if otherwise authorized by law” is unnecessary because FDA obtains the consent of foreign governments to do inspections. Therefore, the phrase has been deleted.

We are keeping the phrase “or through other appropriate means.” Essentially the same phrase is used in current § 814.15(d)(3) regarding validation of foreign clinical data. This language recognizes that foreign data present unique challenges not usually associated with domestic data. One such challenge may be that FDA is unable to conduct an onsite inspection. If the Agency believes that validation is necessary but is unable to conduct an onsite inspection, the sponsor and FDA will need to agree upon an alternative means for validation if the Agency is to rely on the data. Such alternative means for validation might entail FDA partnering with other regulatory authorities or other mutually agreed upon means for validation. If an agreement cannot be reached that satisfies FDA’s need for validation, then the data might not be accepted to support the application or submission.

(Comment 26) One comment noted that the preamble of the proposed rule identifies documents that articulate GCP principles but that these documents have broad differences in the
scope, level of detail, and formulation of actual requirements and that no individual document was identified as the authoritative set of enforceable requirements. The comment stated that, if GCP compliance will be subject to FDA inspection, the rule must clearly identify not only the applicable requirements in terms of general principles but also provide a sufficient level of detail to allow an objective basis for a uniform assessment of compliance by the sponsor as well as the Agency.

(Response) FDA disagrees with this comment. Similar to §312.120, the rule does not identify a specific GCP standard that sponsors must follow. Instead, the rule includes a definition of GCP in §812.28(a)(1), which is consistent with the definition in §312.120, and embodies well recognized GCP principles. FDA is allowing sponsors of clinical investigations conducted outside the United States to follow a GCP standard of their choice, provided it meets the definition provided in §812.28(a)(1). One example of a GCP standard that meets the definition provided in §812.28(a)(1) is ISO 14155:2011, “Clinical Investigation of Medical Devices for Human Subjects—Good Clinical Practice.” FDA has recognized this standard (77 FR 15765). In addition to following a GCP standard, sponsors would need to comply with the local requirements where the investigational sites are located.

H. Supporting Information

Proposed §812.28(b) would require a sponsor or applicant submitting data from clinical investigations conducted outside the United States in support of an IDE or device marketing application or submission to submit, in addition to information required elsewhere in parts 807, 812, and 814, supporting information that describes the actions taken to ensure that the research conducted to GCP.

1. General Comments

(Comment 27) One comment stated that the list of supporting information in §812.28(b) should reflect the approval standard for devices, which is a reasonable assurance of safety and effectiveness.

(Response) FDA disagrees with the comment. The supporting information is not used to establish a reasonable assurance of safety and effectiveness. Instead, the supporting information is used to assess whether the investigation conformed to GCP, which helps to ensure that the data and results submitted are credible and accurate and that the rights, safety, and well-being of human subjects are adequately protected. Data from clinical investigations conducted in accordance with GCP may be used to establish a reasonable assurance of safety and effectiveness for purposes of a PMA application, but may also be used to support other device applications and submissions, including an IDE. Section 812.28(a)(2) of the rule identifies different supporting information requirements based on the level of risk of the clinical investigation, with significant risk device investigations requiring more supporting information and device investigations presenting less risk, as well as those that meet the exemption criteria in §812.2(c), requiring less supporting information. (Comment 28) One comment noted that the preamble to the proposed rule states that many of the requirements in §812.28(b) parallel the requirements in §312.120(b) for drug applications but the list, in many cases, is more restrictive than the requirements for drug studies, and identified the request for certified copies in §812.28(b)(4) as an example.

(Response) FDA, in general, disagrees with the comment. Although the comment indicates that the list of supporting information in §812.28(b) is more restrictive in many cases than in §312.120(b), only one example is provided, the request for “certified copies” in §812.28(b)(4). Based on concerns raised by this and other similar comments, we have removed the term “certified copies” from §812.28(b)(4), as further discussed in response to comment 33 below.

There are only a few other differences between §§812.28(b) and 312.120(b). In §312.120(b)(1) and (2), the investigator’s qualifications and a description of the research facilities are required, respectively. In §812.28(b)(1), we require the names of investigators and the names and addresses of research facilities and sites where records relating to the investigation are maintained, separate from the requirement for the investigators’ qualifications in §812.28(b)(2) and the description of the research facilities in §812.28(b)(3). We believe this difference is appropriate because the information on names of investigators and names and addresses of research facilities and sites where records relating to the investigation are maintained is needed for all clinical investigations of medical devices. However, the information on investigators’ qualifications and the descriptions of research facilities is needed for significant risk device investigations but not for exempt and non-significant risk device investigations. These items are discussed further in comments 29 and 30 below.

The required information in §812.28(b)(5), describing the device used in the investigation, is also different from §312.120(b)(4), describing the drug substance and drug product. The difference is appropriate because it relates to the differences in information needed to adequately describe devices and drugs.

The difference between §§812.28(b)(6) and 312.120(b)(5) is related to different regulatory requirements for FDA decisions on device applications, as described in §860.7 (21 CFR 860.7), and drug applications, as described in §314.126. Therefore, FDA believes this difference is appropriate.

The last difference concerns the information required for the IEC that reviewed the investigation. In §812.28(b)(7), we do not specify that records of the IEC members’ names be maintained as required in §312.120(b)(6). We decided not to require that records of the IEC members’ names be maintained because drug sponsors and applicants reported occasional problems fulfilling this requirement due to foreign laws. Therefore, FDA considers the supporting information identified in §812.28(b) to be similar to the supporting information required for drug applications in §312.120(b), with the few differences being appropriate and not more restrictive.

2. Investigators and Research Facilities

Proposed §812.28(b)(1) would require the names and addresses of the investigators and research facilities; proposed §812.28(b)(2) would require the qualifications of investigators; and proposed §812.28(b)(3) would require a description of the research facilities. (Comment 29) One comment disagreed with providing investigators’ addresses and noted that personal details like this are not usually obtained and could be subject to more stringent foreign regulations. A second comment stated that the European Union Privacy Directive would protect from transfer to the United States the names and addresses of foreign investigators and that investigators would have to agree to this information sharing in advance or at the time of submission to FDA. The comment further stated that difficulties currently exist with obtaining investigators’ names for certain foreign sites, even when the data collection is part of an IDE.
address information to maintain on investigator and research facility selection. For example, ISO 14155:2011 addresses verification and documentation of the qualifications of the principal investigator(s) and the adequacy of the research facility and the rationale for selecting the facility in sections 5.8, 9.2, and 9.3.

The investigator’s qualifications and the description of the research facilities will also help us to assess the need for an onsite inspection.

3. Detailed Summary of Protocol and Results of Investigation

Proposed § 812.28(b)(4) would require submission of a detailed summary of the protocol and results of the investigation. In addition, the sponsor or applicant would be required to submit certified copies of case records maintained by the investigator or additional background data, such as hospital records or other institutional records, if requested by FDA.

(Comment 31) Several comments stated that stricter privacy laws outside the United States may partially or completely restrict the ability of sponsors and applicants to provide records to FDA. The comments noted that investigational sites typically archive the originals of completed case records and these records would generally not be available to sponsors. Two comments noted that the records may be available through an inspection at the investigational site. One comment noted that providing redacted patient information to a regulatory authority may be possible but would require changes to clinical trial agreements and informed consent documents and would impose significant burden and costs. Comments recommended modifying or deleting the requirement for providing records.

(Response) FDA acknowledges that in some instances there may be difficulties providing records should FDA request them but disagrees with deleting the requirement. FDA understands that a sponsor cannot disclose foreign records that are prohibited from disclosure by foreign law. If FDA requests case records or other records but these documents cannot be provided as required by § 812.28(b)(4) because disclosure is prohibited by governing law, the sponsor or applicant should document this disclosure prohibition by the foreign entity. For example, the sponsor or applicant should document the countries that prohibit such disclosure, the nature of the prohibitions, and the extent to which these prohibitions may impede sponsors or applicants in carrying out other obligations regarding record access. The sponsor or applicant can then submit such information in a waiver request to FDA. For FDA to rely on the affected data, the sponsor or applicant and FDA would need to agree on an alternative means for validation. Such alternative means for validation might entail FDA partnering with other regulatory authorities or other mutually agreed upon means for validation.

Additionally, in the informed consent documents, it may be helpful to notify subjects that regulatory authorities will have direct access to the subject’s medical records for verification of clinical investigation procedures and data, which is consistent with ISO 14155:2011, section 4.7.4(d3).

If FDA needs source documents such as hospital records to verify certain data or to validate the investigation and such records are not available because of foreign law, and an alternative means for validation is not available, FDA might not accept the data from the clinical investigation as support for an IDE or device marketing application or submission.

(Comment 32) Two comments requested clarification of the term “case record.”

(Response) FDA clarifies that the term “case record” as used in § 812.28(b)(4) is used to indicate records investigational sites commonly maintain in relation to clinical investigations. The term includes records as described in § 812.140(a)(3).

(Comment 33) Two comments requested that the term “certified copies” be defined.

(Response) FDA has reevaluated the provision related to “certified copies.” We acknowledge that the term has different meanings in other countries and have determined that this term is not needed. We have amended the rule accordingly.

(Comment 34) One comment recommended modifying § 812.28(b)(4) to require that the clinical investigation report, as described in ISO 14155:2011 Annex D, be included in the supporting information because it provides the relevant information from the protocol as well as the results of the clinical investigation.

(Response) FDA disagrees with modifying the requirement to specify providing the clinical investigation report as described in ISO 14155:2011. We believe that the supporting information required by the rule is sufficient for its purpose. Additionally, the rule does not require following ISO 14155:2011; however, if a sponsor or applicant chooses, FDA would accept the full clinical investigation report as
described in Annex D of ISO 14155:2011 as a detailed summary of the protocol and results of the investigation.

(Comment 35) One comment asked about FDA’s procedure and methods for review, retention, and destruction of the detailed summaries and records identified in § 812.28(b)(4) and the reasons why records would be needed and the intent of review.

(Response) FDA may request records to help understand the conduct of the investigation, to verify certain data, and to validate the investigation and the results obtained. When records from investigations conducted outside the United States are submitted, FDA will review and handle those records in the same manner as records from investigations conducted in the United States.

4. Valid Scientific Evidence

Proposed § 812.28(b)(6) would require a discussion demonstrating that the data and information, when intended to support the safety and effectiveness of a device, constitute valid scientific evidence.

(Comment 36) One comment stated that § 812.28(b)(6) is redundant and should be struck. A study complying with the principles of GCP is a well-controlled study conducted by qualified experts.

(Response) FDA disagrees that § 812.28(b)(6) is redundant. Section 812.28(b)(6) requires that the sponsor or applicant provide a discussion demonstrating that the data and information constitute valid scientific evidence within the meaning of § 860.7. FDA relies upon only valid scientific evidence to determine whether there is reasonable assurance that the device is safe and effective (see § 860.7).

Although there may be some overlap, the principles addressing valid scientific evidence more readily relate to the types of evidence that may support the safety and effectiveness of a device, while the principles of GCP relate more to the conduct of the investigation.

(Comment 37) Two comments opposed the requirement that a statement be provided that the IEC meets the definition in § 812.3(t). One comment indicated that sponsors may not know whether an IEC meets a given definition. Another comment recommended requiring a statement obtained from the IEC that it meets the definition in § 812.3(t) and is organized and operates according to applicable laws and regulations.

(Response) FDA agrees that a statement from the IEC would also be acceptable. To satisfy this requirement, FDA will accept a statement from the IEC indicating it meets the definition of an IEC in the rule. We also added a waiver provision (see new § 812.28(c)) to the rule that sponsors and applicants may consider using when they are unable to meet the requirements in § 812.28(a)(1) and (b) of the rule. For example, a waiver may be requested when the sponsor cannot submit a statement that the IEC meets the definition in § 812.3(t). A waiver request could be an alternative to the statement that the IEC meets the definition in § 812.3(t), a statement that the IEC is organized and operates according to the applicable laws and regulations of the country where it operates and provide a description of the laws and regulations under which the IEC is organized and operates. FDA will decide whether to grant or deny a waiver on a case-by-case basis, taking into account all appropriate circumstances.

(Comment 38) Three comments stated that the proposed rule requires sponsors to qualify IECs but there is no parallel requirement for a sponsor to qualify an IRB for a study in the United States. One comment noted that no rationale was provided for requiring greater regulation outside the United States than is required in the United States. Another comment indicated the requirement is likely because FDA recognized it does not have the authority to verify and document the adequacy of a foreign IEC but failed to recognize that sponsors do not have such authority and would face legal challenges to meet this requirement.

(Comment 39) Several comments indicated sponsors may have difficulty obtaining and documenting the qualifications of IEC members and making the records available to the Agency upon request. One comment noted that the term “qualification” is open to interpretation. Another comment indicated it may not be feasible to obtain the names of IEC members. A third comment noted that the European Union Privacy Directive may protect from transfer to the United States the information sought for the IEC.

(Response) FDA believes that oversight of a clinical investigation by an adequately constituted IEC is an essential component of human subject protection. Information about the adequacy of an IEC is important in assessing the competence of the committee to protect the rights, safety, and well-being of human subjects. To satisfy this requirement, FDA will accept a statement from the IEC indicating it meets the definition of an IEC in the rule. We also added a waiver provision to the rule that sponsors and applicants may consider using when they are unable to meet the requirements in § 812.28(a)(1) and (b) of the rule. For example, a waiver may be requested when the sponsor cannot submit a statement that the IEC meets the definition in § 812.3(t).

5. IEC Information

Proposed § 812.28(b)(7) would require the name and address of the IEC that reviewed the study and a statement that the IEC meets the definition in § 812.3(t). The sponsor or applicant would be required to maintain records supporting such statement, including records describing the qualifications of IEC members and would be required to make these records available for Agency review upon request.

(Comment 40) FDA acknowledges that the sponsor of an investigation under an IDE is not required to qualify and submit information on the adequacy of the reviewing IRBs. FDA routinely obtains information about IRBs in the United States through onsite inspections of the IRBs. To obtain information on the adequacy of the reviewing IEC for foreign investigations, given that inspections of foreign IECs are usually not feasible, FDA believes it is appropriate to ask the sponsor to document the adequacy of the reviewing IEC because the sponsor already interacts with the IEC, either directly or through the investigators, to obtain IEC review.

FDA believes that the oversight of a clinical investigation by an adequately constituted IEC is an essential component of human subject protection. Information about the adequacy of an IEC is important in assessing the competence of the committee to protect the rights, safety, and well-being of human subjects. To satisfy this requirement, FDA will accept a statement from the IEC indicating it meets the definition of an IEC in the rule. We also added a waiver provision to the rule that sponsors and applicants may consider using when they are unable to meet the requirements in § 812.28(a)(1) and (b) of the rule.
the sponsor or applicant clearly document attempts made to obtain the qualifications of IEC members along with an explanation as to why the qualifications cannot be obtained. Such information can be submitted to FDA in a waiver request.

(Comment 40) One comment questioned how FDA would review information on the qualifications of IEC members stating that, without a harmonized, globally accepted definition of “qualification,” there will be variability in interpretation of acceptable qualification based on reviewer interpretation or bias and may place FDA in the position of accepting or rejecting qualifications of IEC members from foreign nations.

(Response) FDA disagrees with the comment. We recognize that the membership of IECs may differ among countries because of local needs of the host country. Such variation is acceptable as long as the IEC can ensure the protection of the rights, safety, and well-being of human subjects involved in the clinical investigation. As we do for IRBs located in the United States, in its review FDA will be looking to see that, collectively, the IEC members have the qualifications needed to review and evaluate the science, medical aspects, and ethics of the proposed clinical investigation.

6. Summary of IEC’s Decision

Proposed § 812.28(b)(8) would require submission of a summary of the IEC’s decision to approve or modify and approve the study, or to provide a favorable opinion.

(Comment 41) One comment recommended changing proposed § 812.28(b)(8) to require the correspondence relating to the IEC’s decision to approve the investigation because the approval letter would be clearer and less ambiguous than a summary, which could be interpreted differently by different people.

(Response) FDA agrees with the comment; however, FDA believes that providing the approval letter(s) from the IEC(s) would be one way to provide a summary of the IEC’s decision to approve or provide a favorable opinion. We note that these letters are usually issued in the local language of the country in which the investigation is conducted and official translations may need to be provided.

7. Description of Informed Consent Process

Proposed § 812.28(b)(9) would require submission of a description of how informed consent was obtained.

(Comment 42) One comment recommended that § 812.28(b)(9) require that the blank informed consent document approved by the IEC or IRB be submitted instead of a “description of how” consent was obtained.

(Response) FDA disagrees that the blank informed consent document approved by each IEC or IRB should be submitted instead of a description of how consent was obtained. Providing information about how informed consent is obtained is important in ensuring transparency and accountability for the ethical conduct of the investigation. The description should address such concerns as who obtained informed consent (ensuring that the person obtaining informed consent was knowledgeable about the investigation and capable of answering all questions), when was consent obtained (ensuring that consent was obtained prior to a subject’s participation in the investigation, for example, prior to any research procedures), and the conditions under which consent was obtained (ensuring that consent was obtained under conditions that minimized coercion or undue influence).

(Comment 43) One comment recommended revising § 812.28(b)(9) to state “a description of how informed consent was obtained, and that this method was approved by the IEC.”

(Response) FDA disagrees with the comment. FDA defines GCP to include the review and approval (or provision of a favorable opinion) by an IEC that is responsible for ensuring the protection of the rights, safety, and well-being of human subjects involved in a clinical investigation. Ensuring the protection of human subjects would include review and approval of how informed consent is obtained. An applicant’s statement that an investigation was conducted in accordance with GCP would indicate that an IEC had approved (or provided a favorable opinion) of how informed consent was obtained. Therefore, FDA believes the proposed revision is unnecessary.

8. Description of Incentives to Subjects

Proposed § 812.28(b)(10) would require submission of a description of what incentives, if any, were provided to subjects to participate in the study. (Comment 44) One comment recommended deleting § 812.28(b)(10) because this is a new requirement, not required for investigations in the United States, and may lead to unnecessary burden of review for FDA. The comment stated that the review by the IRB or IEC as part of consent and is held by the sponsor as part of their records and subject to audit by the Agency.

(Response) FDA disagrees with the comment and does not believe this requirement will be overly burdensome. Informed consent documents usually describe incentives and the IEC reviews this information. Therefore, providing the description of incentives to FDA should not be a burden. FDA will allow some flexibility in how sponsors or applicants comply with § 812.28(b)(10). If the informed consent form includes a description of any incentives provided to subjects, a sponsor or applicant could submit a model consent form to meet the requirement. Alternatively, a sponsor or applicant could also satisfy the requirement by submitting a description of any incentives provided to subjects to participate in the investigation, or if such a description was included elsewhere, such as in the detailed summary of the protocol required under § 812.28(b)(4), the sponsor or applicant could reference where the description may be found to meet the requirement under § 812.28(b)(10).

FDA is requiring this information because incentives can affect data integrity. In the proposed rule, FDA only required the submission of information about incentives for significant risk device investigations. In the final rule, FDA is requiring that information about incentives be made available upon request for non-significant risk and exempt device investigations. FDA has made this change because incentives could affect the integrity of all investigations.

(Comment 45) One comment recommended revising § 812.28(b)(10) to state, “a description of what incentives, if any, were provided to subjects to participate in the study, and that these incentives, if any, were approved by the IEC.”

(Response) FDA disagrees with the comment. FDA defines GCP to include the review and approval (or provision of a favorable opinion) by an IEC that is responsible for ensuring the protection of the rights, safety, and well-being of human subjects involved in a clinical investigation. Ensuring the protection of human subjects would include review and approval of the incentives to be provided to subjects. An applicant’s statement that an investigation was conducted in accordance with GCP would indicate that an IEC had approved (or provided a favorable opinion) of the incentives provided to subjects. Therefore, FDA believes the proposed revision is unnecessary.
9. Description of Study Monitoring

Proposed § 812.28(b)(11) would require submission of a description of how the sponsor monitored the study and ensured that the study was carried out consistently with the study protocol. [Comment 48] One comment recommended including a statement supporting a sponsor’s performance of a risk assessment to determine the approach to monitoring for sites outside the United States, as they would for sites in the United States, because standardization may cause more burdens (for example, resources, time, and cost) related to the requirement to increase monitoring.

(Response) FDA has not identified a specific GCP standard that sponsors and applicants must follow. Instead, the rule defines GCP and allows sponsors and applicants to determine an appropriate GCP standard for their investigations that produce data to support device research and marketing applications and submissions to FDA. Sponsors and applicants may use a risk-based approach to monitoring, as described in FDA’s guidance document entitled “Oversight of Clinical Investigations—A Risk-Based Approach to Monitoring.” Provided it is consistent with the laws and regulations of the countries where the investigation takes place.

10. Description of Investigator Training and Signed Written Commitments

Proposed § 812.28(b)(12) would require submission of a description of how investigators were trained to comply with GCP and to conduct the study in accordance with the study protocol, and a statement on whether written commitments by investigators to comply with GCP and the protocol were obtained.

[Comment 47] One comment recommended that § 812.28(b)(12) only require that the investigator agree to comply with the protocol and with institutional and legal requirements. The principles of GCP do not require the sponsor to train investigators in GCP compliance.

(Response) FDA disagrees. Simply obtaining the investigator’s agreement to comply with the protocol and institutional and legal requirements may not be adequate. Protocols may be complex and additional steps may be needed to prepare investigators and to standardize performance of the investigation. A description of the steps taken to ensure consistent conduct of the investigation and recording of data among investigators is needed. Such a description may identify investigator meetings or other steps that the sponsor took to ensure compliance with GCP and the protocol.

I. Record Retention

Proposed § 812.28(c), now § 812.28(d) in the final rule, would require a sponsor or applicant to maintain records for a clinical investigation conducted outside the United States. If the investigation supported an IDE, the records would be retained for 2 years after the termination or completion of the IDE. If the investigator supported a device marketing application or submission, the records would be retained for 2 years after an Agency decision on that submission or application.

The proposed rule would amend § 812.140(d) to include humanitarian device exemption applications and premarket notification submissions as types of applications and submissions that would require the maintenance of IDE records.

[Comment 48] One comment indicated that FDA should clarify in § 812.28(c)(2) (now § 812.28(d)(2)) that the requirements only apply to studies sponsored by the sponsor or applicant of the submission or application in which the data were submitted.

(Response) FDA disagrees with the comment. The requirement to maintain appropriate records is to ensure that FDA will be able to validate an investigation through an onsite inspection, if necessary. Therefore, the record retention requirement must apply to all investigations from which clinical data are submitted to FDA in support of an application or submission, whether or not the investigation was sponsored by the sponsor or applicant. If a sponsor or applicant submits data from a clinical investigation they did not sponsor, they should obtain the commitment of the sponsor and investigators to retain the records. If FDA needs access to the records and the records are not available, FDA may not accept the data in support of an IDE or device marketing application or submission.

[Comment 49] One comment recommended that proposed § 812.140(d) be changed to read similarly to proposed § 812.28(c), namely, “The date on which the investigation is terminated or completed or for 2 years after an agency decision on that submission or application.”

(Response) FDA disagrees with the proposed change. As noted in the preamble to the proposed rule, we are revising § 812.140(d) to indicate that retention requirements for IDE records apply to those records used to support IDE applications and 510(k) submissions, as well as the application types already listed. In the final rule, we also clarify that the retention requirements apply to records used to support requests for De Novo classifications. We do not intend to further change the record retention requirements for IDEs.

J. Denial or Withdrawal of PMA

Proposed §§ 814.45(a)(5) and 814.46(a)(4) would allow FDA to deny or withdraw approval of a PMA if any clinical investigation subject to GCP referenced in § 814.15(a) and described in § 812.28(a) was not conducted in compliance with those regulations such that the rights or safety of human subjects were not adequately protected or the supporting data were determined to be otherwise unreliable.

[Comment 50] Several comments stated that the proposed rule should allow denial or withdrawal of a PMA based only on clinical investigations relied on for a determination of safety and effectiveness. One comment noted that, for PMAs, reporting of all prior studies is required despite not relying on all studies for a determination of safety and effectiveness. Two comments indicated that denial and withdrawal of approval should not be extended to other applications and submissions such as IDEs and 510(k)s.

(Response) FDA agrees that the rule should allow denial or withdrawal of a PMA for noncompliance with GCP referenced in § 814.15(a) and described in § 812.28(a) with respect to those clinical investigations conducted outside the United States that were relied upon for a determination of the safety and effectiveness of the device. FDA notes that the PMA regulations (see § 814.20(b)(8)) require the applicant to provide, among other things, an identification, discussion, and analysis of any other data, information, or report relevant to an evaluation of the safety and effectiveness of the device, known to or that should reasonably be known to the applicant from any source, foreign or domestic, including information derived from investigations other than those proposed in the application and from commercial marketing experience. While this information is required to be submitted, the applicant or sponsor may not have been involved in the conduct of the investigation and may not know the conditions under which the investigation was conducted (for example, a previous developer or competitor may have been involved in the conduct of the investigation).

As explained elsewhere in this document, § 812.28(a) requires demonstration of conformity with GCP.
when data from clinical investigations conducted outside the United States are provided to support an IDE or a device marketing application or submission; for example, when clinical data are submitted in a PMA application to demonstrate a reasonable assurance of safety and effectiveness. When clinical data from investigations are included in applications and submissions as supplementary information and not as support, demonstration of conformity with GCP is not required. FDA also notes that the rule only addresses denial and withdrawal of approval related to PMAs and does not address denial or withdrawal of authorization for other types of applications and submissions. However, if FDA determines that any clinical investigation conducted outside the United States and submitted in support of an IDE or a device marketing application or submission was represented to have been conducted in conformity with GCP but was not, FDA may take appropriate action under the FD&C Act and FDA regulations.

Comment 51) Two comments noted data collected outside the United States but not in compliance with the principles of GCP may nevertheless be relevant data for determining the safety and effectiveness of a device. One comment noted that, elsewhere in the proposed rule, the use of non-GCP compliant studies is allowed where appropriate justification is provided. (Response) As discussed in section IV.C, FDA agrees that clinical data from investigations conducted outside the United States that were not conducted in conformity with GCP may be relevant. FDA believes, however, that clinical data that are submitted to support a PMA should be credible, accurate, and ethically derived and that conducting a clinical investigation in accordance with GCP will help to ensure the integrity and quality of the data and the protection of subjects. If a country’s laws require less than GCP and the applicant does not or cannot meet GCP for the investigation, the applicant may provide an explanation of the departure from GCP or request a waiver. FDA will take this information into account when considering the extent to which it will rely on the data from these investigations in support of a premarket submission or application on a case-by-case basis, depending on whether the clinical data are credible, accurate, and ethically derived. In such situations, when an applicant requests a waiver and FDA grants the waiver and accepts a PMA clinical data from an investigation that was not conducted in conformity with GCP, FDA generally will not deny or withdraw approval of the PMA under § 814.45(a)(5) or § 814.46(a)(4).

Comment 52) One comment stated that the sections on denial and withdrawal of a PMA use the term “unreliable” without clarifying this term and could make a determination of “unreliable” potentially arbitrary, variable, and inconsistent. (Response) FDA disagrees with this comment. FDA has used the term “unreliable” in regulations such as in § 812.119 and 312.70 regarding investigator disqualification. FDA uses the term according to its common meaning and may consider data unreliable, for example, if the data are fraudulent or if there was a lack of rigor in the conduct of the investigation, such as not following the protocol.

K. Implementation

Comment 53) Several comments raised concerns with the implementation of the rules and recommended that the rule not be applied retrospectively to investigations begun prior to the effective date. Two comments recommended that the effective date be established as 18 months after publication. The comments noted that adequate time will be needed to allow for preparation for implementation, such as to revise internal operating procedures, for training, for study planning, and for negotiating and contracting with the necessary parties for future studies conducted outside the United States that are intended to support an application or submission to FDA. One comment recommended that FDA allow requests for waivers of certain requirements for investigations conducted prior to the effective date that are technically out of compliance but did not compromise public health or patient safety. (Response) FDA agrees that the rule should not be applied to clinical investigations begun prior to the effective date. FDA is implementing the rule for clinical investigations that enroll the first subject on or after the effective date of the rule. FDA also agrees that sponsors may need additional time to prepare to meet the new requirements. Therefore, the effective date is established as 1 year after the publication of the rule in the Federal Register to provide additional time for sponsors and applicants to make any changes necessary, for example, to their internal operating procedures, study planning, etc., to incorporate the principles of GCP and compliance with the requirements of the rule for investigations that will support an IDE or device marketing application or submission. We believe that this will provide adequate time for sponsors and applicants to implement changes in their processes to accommodate the new requirements.

In addition, FDA has added a waiver provision to § 812.28. Under this provision, a sponsor or applicant may submit waiver requests and FDA will decide whether to grant or deny waivers on a case-by-case basis, taking into account all appropriate circumstances. For the purposes of this rule, we will consider a subject enrolled when the subject agrees to participate in a clinical investigation as indicated by the subject (or a subject’s legally authorized representative, if the subject is unable to provide informed consent) signing the informed consent document(s) or participating in a clinical investigation meeting the requirements of § 50.24.

If an investigation conducted outside the United States enrolled the first subject prior to the rule’s effective date, then the requirements in § 814.15 prior to the rule’s effective date would apply. Specifically, if data from clinical investigations conducted outside the United States that enrolled the first subject prior to the effective date of this rule are submitted in support a PMA application, FDA will accept the data if the data are valid and the investigator has conducted the studies in conformance with the “Declaration of Helsinki” or the laws and regulations of the country in which the research is conducted, whichever accords greater protection to the human subjects. If the standards of the country are used, the applicant shall state in detail any differences between those standards and the “Declaration of Helsinki” and explain why they offer greater protection to the human subjects. (See § 814.15(b).)

L. Guidance Needed

Comment 54) Two comments recommended that FDA develop guidance and training on GCP and compliance with the requirements. One comment recommended that FDA develop a guidance document similar to the one available for investigational new drug applications (INDs), “Guidance for Industry and FDA Staff: Acceptance of Foreign Clinical Studies Not Conducted Under an IND, Frequently Asked Questions,” to provide clarification and definitions to the regulations. Another comment suggested that FDA develop guidance documents and training programs, or sanction third-party training programs, for physicians and IRBs on GCP as it relates to medical devices. The training programs should
provide opportunities to eliminate misinterpretations while raising the standard for GCPs.

(Response) FDA agrees with some of these comments and believes our responses to comments on the proposed rule provide clarification on many issues. FDA intends to issue guidance that explains the requirements of the rule in plain language and how sponsors and applicants can comply with the requirements.

On its website, FDA has provided materials related to GCP training opportunities, including information about the annual GCP training course that FDA has conducted.\(^1\) All of these training materials focus on the regulations governing FDA-regulated clinical investigations. In addition, FDA has been participating, through the Clinical Trials Transformation Initiative, in the development of recommendations identifying principles for GCP training for investigators.\(^2\)

V. Legal Authority

We are issuing this rule under the authority of the provisions of the FD&C Act that apply to medical devices (21 U.S.C. 301 et seq.).

To permit devices to be shipped for investigational use, section 520(g) of the FD&C Act authorizes the exemption of investigational devices from otherwise applicable provisions of the FD&C Act relating to misbranding, registration, premarket notification, performance standards, premarket approval, banned devices, records and reporting requirements, good manufacturing practice requirements, and requirements relating to the use of color additives in devices. Under section 520(g) of the FD&C Act, the procedures and conditions that FDA is authorized to prescribe for granting an IDE include the requirement that an application be submitted to FDA, in such form and manner as the Agency shall specify, and other requirements necessary for the protection of the public health and safety. Section 520(g) also requires that the information submitted in support of an IDE application be “adequate to justify the proposed clinical testing.” In investigations involving human subjects, the person applying for the

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1. Further information is available at: https://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/EducationalMaterials/ucm112925.htm.
3. In light of section 1003(d) of the FD&C Act (21 U.S.C. 393(d)) and the Secretary of Health and Human Services’ delegation to the Commissioner of Food and Drugs, statutory references to “the Secretary” in the discussion of legal authority have been changed to “FDA” or the “Agency.”
clinical data and adequate protection of human subjects.

Section 569B of the FD&C Act, which was added by the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) in 2012, requires FDA to accept data from clinical investigations conducted outside the United States, if the applicant demonstrates that such data are adequate under FDA’s applicable standards to support clearance or approval of the device.

Section 701(a) of the FD&C Act authorizes the Agency to issue regulations for the efficient enforcement of the FD&C Act.

These statutory provisions authorize us to issue regulations describing when we may consider data from clinical investigations, whether conducted inside or outside the United States, as reliable evidence supporting an IDE, PMA, 510(k), PDP, request for De Novo classification, or HDE application or submission.

VI. Analysis of Environmental Impact

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

VII. Economic Analysis of Impacts

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, Executive Order 13771, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 13771 requires that the costs associated with significant new regulations “shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.” We believe that this final rule is not a significant regulatory action as defined by Executive Order 12866. This final rule is not considered an Executive Order 13771 regulatory action.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because small entities are not likely to incur more than one percent of their revenue in costs to comply with the final rule, we certify that the final rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is $148 million, using the most current (2016) Implicit Price Deflator for the Gross Domestic Product. This final rule would not result in an expenditure in any year that meets or exceeds this amount.

We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the final rule. The full analysis of economic impacts is available in the docket for this final rule (Ref. 1, Docket No. FDA–2013–N–0080) and at https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.

The final rule will require that data submitted by sponsors and applicants from clinical investigations conducted outside the United States to support an IDE application, a 510(k) submission, a request for De Novo classification, a PMA application, a PDP application, or an HDE application be from investigations conducted in accordance with GCP. We define GCP as a standard for the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical investigations in a way that provides assurance that the data and results are credible and accurate and that the rights, safety, and well-being of subjects are protected. GCP includes the review and approval by an IEC before initiating an investigation, continuing IEC review of ongoing investigations, and obtaining and documenting the freely given informed consent of subjects. The changes require a statement regarding compliance with our regulations for human subject protection, IRBs, and IDEs when the investigations are conducted in the United States. With the above described changes, the rule is intended to update our standards of acceptance of data from clinical investigations and to help ensure the quality and integrity of data obtained from these investigations and the protection of human subjects.

We have not quantified the benefits of the final rule that would come from the greater assurance of clinical data quality and integrity and human subject protection, particularly as it pertains to clinical investigations conducted outside the United States. One-time costs would arise to learn the requirements of the rule, and annually recurring costs would arise from increased labor associated with obtaining, documenting, and maintaining records to meet the rule’s requirements for those that did not already meet the requirements. Total estimated annualized costs of complying with these requirements, over 10 years, range from $0.8 million to $22.1 million with a 7 percent discount rate and range from $0.7 million to $22.0 million with a 3 percent discount rate.

Table 1 summarizes our estimate of the annualized costs and the annualized benefits of the final rule.

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<th>Category</th>
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Table 1—Summary of Benefits, Costs and Distributional Effects of the Rule

[$ millions]
Table 2 presents a summary of the Executive Order 13771 impacts of the final rule over an infinite time horizon.

<table>
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<tr>
<th>Table 2—E.O. 13771 SUMMARY TABLE</th>
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<tr>
<td>[In $ millions 2016 dollars, over an infinite time horizon]</td>
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<td>Annualized Net Costs ...</td>
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### VIII. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection provisions are shown in the following paragraphs with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

**Title:** Human Subject Protection; Data Requirements for Medical Device Related Clinical Investigations (OMB control number 0910–0741)

**Description:** In this document is a discussion of the regulatory provisions we believe are subject to the PRA and the probable information collection burden associated with these provisions.

**Description of Respondents:** The reporting and recordkeeping requirements referenced in this document are imposed on a medical device sponsor or applicant.

**Section 807.87—Information Required in a Premarket Notification Submission (OMB Control Number 0910–0741)**

Section 807.87 is being amended to address requirements for 510(k) submissions supported by clinical data. For clinical investigations conducted in the United States, submitters will be required to submit a statement as described in § 807.87(j)(1). For clinical investigations conducted outside the United States, submitters will be...
required to submit the information as described in § 807.87(j)(2).

Section 812.27—Report of Prior Investigations (OMB Control Number 0910–0078)

Section 812.27 is being amended to address requirements for IDE applications supported by clinical data. For clinical investigations conducted in the United States, sponsors will be required to submit a statement as described in § 812.27(b)(4)(1). For clinical investigations conducted outside the United States, sponsors will be required to submit the information as described in § 812.27(b)(4)(ii).

Section 812.28—Acceptance of Data From Clinical Investigations Conducted Outside the United States (OMB Control Number 0910–0078)

Section 812.28 is being added to address the requirements for acceptance of foreign clinical data to support an IDE or a device marketing application or submission. The sponsor or applicant will be required to submit a statement as described in § 812.28(a)(1); provide a description of the actions the sponsor or applicant took to ensure that the research conformed to GCP that includes the information in § 812.28(b)(1) through (12) or a cross-reference to another section of the application or submission where the information is located; submit requests for waivers as described in § 812.28(c); and retain the records as described in § 812.28(d).

Section 812.28—Acceptance of Data From Clinical Investigations Conducted Outside the United States (OMB Control Number 0910–0078)

Section 812.28 is being added to address record retention requirements for investigators and sponsors. An investigator or sponsor will be required to maintain records as described in § 812.140(d).

Section 814.20—Application (OMB Control Number 0910–0231)

Section 814.20 is being amended to address requirements for a PMA application supported by data from clinical investigations conducted outside the United States. The applicant will be required to submit the information as described in § 814.20(b)(6)(ii)(C).

Section 814.104—Original Applications (OMB Control Number 0910–0332)

Section 814.104 is being amended to address record submission requirements for IDE applications supported by data from clinical investigations, the applicant will be required to include the information and statements as described in § 814.104(b)(4)(i).

TABLE 3—Estimated Annual Reporting Burden 1

<table>
<thead>
<tr>
<th>21 CFR section/activity</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Total annual responses</th>
<th>Average burden per response</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>807.87(j)—Human subject protection statement and information in a premarket notification submission supported by clinical data.</td>
<td>1,500</td>
<td>1</td>
<td>1,500</td>
<td>.25 (15 minutes)</td>
<td>375</td>
</tr>
<tr>
<td>812.27(b)(4)(i)—Report of prior investigations; U.S</td>
<td>400</td>
<td>1</td>
<td>400</td>
<td>1</td>
<td>400</td>
</tr>
<tr>
<td>812.27(b)(4)(i)—Report of prior investigations; outside the U.S.</td>
<td>100</td>
<td>1</td>
<td>100</td>
<td>.25 (15 minutes)</td>
<td>25</td>
</tr>
<tr>
<td>812.28(a)(1)—Data from clinical investigations 2</td>
<td>1,500</td>
<td>1</td>
<td>1,500</td>
<td>.25 (15 minutes)</td>
<td>375</td>
</tr>
<tr>
<td>812.28(b)—Description regarding GCP 2</td>
<td>1,500</td>
<td>1</td>
<td>1,500</td>
<td>10</td>
<td>15,000</td>
</tr>
<tr>
<td>812.28(c)—Waivers 2</td>
<td>10</td>
<td>1</td>
<td>10</td>
<td>1</td>
<td>10</td>
</tr>
<tr>
<td>814.20—Application information</td>
<td>10</td>
<td>1</td>
<td>10</td>
<td>.50 (30 minutes)</td>
<td>5</td>
</tr>
<tr>
<td>814.104—Original applications statements and information</td>
<td>10</td>
<td>1</td>
<td>10</td>
<td>8</td>
<td>80</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>16,270</td>
</tr>
</tbody>
</table>

1 There are no capital costs or operating and maintenance costs associated with this collection of information.
2 No precise data is available for requests for De Novo classifications.

TABLE 4—Estimated Annual Recordkeeping Burden 1

<table>
<thead>
<tr>
<th>21 CFR section/activity</th>
<th>Number of recordkeepers</th>
<th>Number of records per recordkeeper</th>
<th>Total annual records</th>
<th>Average burden per recordkeeping</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>812.28(d)—Records from clinical investigations conducted outside the United States 2</td>
<td>1,500</td>
<td>1</td>
<td>1,500</td>
<td>1</td>
<td>1,500</td>
</tr>
<tr>
<td>814.140—Retention period</td>
<td>10</td>
<td>1</td>
<td>10</td>
<td>1</td>
<td>10</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1,510</td>
</tr>
</tbody>
</table>

1 There are no capital costs or operating and maintenance costs associated with this collection of information.
2 No precise data is available for requests for De Novo classifications.

The total estimated burden imposed by these information collection requirements is 17,780 annual hours. The estimated burden is based on the most recent empirical data in the relevant collections with the numbers updated to reflect the current burden of these requirements.

It should be noted that while the information collection requirements referenced in this document are revisions to current approved information collections, these collection requirements are being submitted to OMB as a new information collection (OMB control number 0910–0741), with the expectation the currently approved requirements will be amended. As such the following collections of information will be amended and submitted to OMB for approval as revisions to currently approved information collections once the rule is finalized and the collections are due for renewal. The collections to

The information collection provisions in this final rule have been submitted to OMB for review as required by section 3507(d) of the PRA. Before the effective date of this final rule, FDA will publish a notice in the Federal Register announcing OMB’s decision to approve, modify, or disapprove the information collection provisions in this final rule. 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.

IX. Federalism

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

X. Reference

The following reference is on display in the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at https://www.regulations.gov.


List of Subjects

21 CFR Part 807

Confidential business information, Imports, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 812

Health records, Medical devices, Medical research, Reporting and recordkeeping requirements.

21 CFR Part 814

Administrative practice and procedure, Confidential business information, Medical devices, Medical research, Reporting and recordkeeping requirements.

PART 807—ESTABLISHMENT REGISTRATION AND DEVICE LISTING FOR MANUFACTURERS AND INITIAL IMPORTERS OF DEVICES

1. The authority citation for part 807 is revised to read as follows:


2. Section 807.87 is amended by redesignating paragraphs (j), (k), and (l) as paragraphs (k), (l), and (m), respectively, and by adding new paragraph (j) to read as follows:

§ 807.87 Information required in a premarket notification submission.

* * * * *

(j) For a submission supported by clinical data:

(1) If the data are from clinical investigations conducted in the United States, a statement that each investigation was conducted in compliance with applicable requirements in the protection of human subjects regulations in part 50 of this chapter, the institutional review boards regulations in part 812 of this chapter, or if the investigation was not conducted in compliance with those regulations, a brief statement of the reason for the noncompliance.

(2) If the data are from clinical investigations conducted outside the United States, the requirements under § 812.28 of this chapter apply. If any such investigation was not conducted in accordance with good clinical practice (GCP) as described in § 812.28(a) of this chapter, include either a waiver request in accordance with § 812.28(c) of the chapter or a brief statement of the reason for not conducting the investigation in accordance with GCP and a description of steps taken to ensure that the data and results are credible and accurate and that the rights, safety, and well-being of subjects have been adequately protected.

* * * * *

PART 812—INVESTIGATIONAL DEVICE EXEMPTIONS

3. The authority citation for part 812 is revised to read as follows:


4. Section 812.3 is amended by adding paragraph (t) to read as follows:

§ 812.3 Definitions.

* * * * *

(t) Independent ethics committee (IEC) means an independent review panel that is responsible for ensuring the protection of the rights, safety, and well-being of subjects involved in a clinical investigation and is adequately constituted to ensure that protection. An institutional review board (IRB), as defined in paragraph (f) of this section and subject to the requirements of part 56 of this chapter, is one type of IEC.

5. Section 812.27 is amended by adding paragraph (b)(4) to read as follows:

§ 812.27 Report of prior investigations.

* * * * *

(b) * * *

(4)(i) If data from clinical investigations conducted in the United States are provided, a statement that each investigation was conducted in compliance with applicable requirements in the protection of human subjects regulations in part 50 of this chapter, the institutional review boards regulations in part 56 of this chapter, or was not subject to the regulations under § 56.104 or § 56.105, and the investigational device exemptions regulations in this part, or if any such investigation was not conducted in compliance with those regulations, a brief statement of the reason for the noncompliance. Failure or inability to comply with these requirements does not justify failure to provide information on a relevant clinical investigation.

(ii) If data from clinical investigations conducted outside the United States are provided to support the IDE, the requirements under § 812.28 apply. If any such investigation was not conducted in accordance with good clinical practice (GCP) as described in § 812.28(a), the report of prior investigation shall include either a waiver request in accordance with § 812.28(c) or a brief statement of the
reason for not conducting the investigation in accordance with GCP and a description of steps taken to ensure that the data and results are credible and accurate and that the rights, safety, and well-being of subjects have been adequately protected. Failure or inability to comply with these requirements does not justify failure to provide information on a relevant clinical investigation.

6. Section 812.28 is added to subpart B to read as follows:

§ 812.28 Acceptance of data from clinical investigations conducted outside the United States.

(a) Acceptance of data from clinical investigations conducted outside the United States to support an IDE or a device marketing application or submission (an application under section 515 or 520(m) of the Federal Food, Drug, and Cosmetic Act, a premarket notification submission under section 510(k) of the Federal Food, Drug, and Cosmetic Act, or a request for De Novo classification under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act). FDA will accept information on a clinical investigation conducted outside the United States to support an IDE or a device marketing application or submission if the investigation is well-designed and well-conducted and the following conditions are met:

(1) A statement is provided that the investigation was conducted in accordance with good clinical practice (GCP). For the purposes of this section, GCP is defined as a standard for the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical investigations in a way that provides assurance that the data and results are credible and accurate and that the rights, safety, and well-being of subjects are protected. GCP includes review and approval (or provision of a favorable opinion) by an independent ethics committee (IEC) before initiating an investigation, continuing review of an ongoing investigation by an IEC, and obtaining and documenting the freely given informed consent of the subject (or a subject’s legally authorized representative, if the subject is unable to provide informed consent) before initiating an investigation. GCP does not require informed consent in life-threatening situations when the IEC reviewing the investigation finds, before initiation of the investigation, that informed consent is not feasible and either that the conditions present are consistent with those described in § 50.23 or § 50.24(a) of this chapter, or that the measures described in the protocol or elsewhere will protect the rights, safety, and well-being of subjects.

(2) In addition to the information required elsewhere in parts 807, 812, and 814 of this chapter, as applicable, the information in paragraph (b) of this section is submitted, as follows:

(i) For an investigation of a significant risk device, as defined in § 812.3(m), the supporting information as described in paragraph (b) of this section is submitted.

(ii) For an investigation of a device, other than a significant risk device, the supporting information as described in paragraphs (b)(1), (4), (5), (7) through (9), and (11) of this section is submitted, and the supporting information as described in paragraph (b)(10) of this section and the rationale for determining the investigation is of a device other than a significant risk device are made available for agency review upon request by FDA.

(iii) For a device investigation that meets the exemption criteria in § 812.2(c), the supporting information as described in paragraphs (b)(1), (4), (5), (7) through (11) of this section and the rationale for determining the investigation meets the exemption criteria in § 812.2(c) are made available for agency review upon request by FDA.

(3) FDA is able to validate the data from the investigation through an onsite inspection, or through other appropriate means, if the agency deems it necessary.

(b) Supporting information. A sponsor or applicant who submits data from a clinical investigation conducted outside the United States to support an IDE or a device marketing application or submission, in addition to information required elsewhere in parts 807, 812, and 814 of this chapter, as applicable, shall provide a description of the actions the sponsor or applicant took to ensure that the research conducted to GCP as described in paragraph (a)(1) of this section. The description is not required to duplicate information already submitted in the application or submission. Instead, the description must provide either the following information, as specified in paragraph (a)(2) of this section, or a cross-reference to another section of the application or submission where the information is located:

(1) The names of the investigators and the names and addresses of the research facilities and sites where records relating to the investigation are maintained;

(2) The investigator’s qualifications;

(3) A description of the research facility(ies);

(4) A detailed summary of the protocol and results of the investigation and, should FDA request, case records maintained by the investigator or additional background data such as hospital or other institutional records;

(5) Either a statement that the device used in the investigation conducted outside the United States is identical to the device that is the subject of the submission or application, or a detailed description of the device and each important component (including all materials and specifications), ingredient, property, and principle of operation of the device used in the investigation conducted outside the United States and a comparison to the device that is the subject of the submission or application that indicates how the device used in the investigation is similar to and/or different from the device that is the subject of the submission or application;

(6) If the investigation is intended to support the safety and effectiveness of a device, a discussion demonstrating that the data and information constitute valid scientific evidence within the meaning of § 860.7 of this chapter;

(7) The name and address of the IEC that reviewed the investigation and a statement that the IEC meets the definition in § 812.3(t). The sponsor or applicant must maintain records supporting such statement, including records describing the qualifications of IEC members, and make these records available for agency review upon request;

(8) A summary of the IEC’s decision to approve or modify and approve the investigation, or to provide a favorable opinion;

(9) A description of how informed consent was obtained;

(10) A description of what incentives, if any, were provided to subjects to participate in the investigation;

(11) A description of how the sponsor(s) monitored the investigation and ensured that the investigation was carried out consistently with the protocol; and

(12) A description of how investigators were trained to comply with GCP (as described in paragraph (a)(1) of this section) and to conduct the investigation in accordance with the protocol, and a statement on whether written commitments by investigators to comply with GCP and the protocol were obtained. Any signed written commitments by investigators must be maintained by the sponsor or applicant and made available for agency review upon request.

(c) Waivers. (1) A sponsor or applicant may ask FDA to waive any applicable
requirements under paragraphs (a)(1) and (b) of this section. A waiver request may be submitted in an IDE or in an amendment or supplement to an IDE, in a device marketing application or submission (an application under section 515 or 520(m) of the Federal Food, Drug, and Cosmetic Act, a premarket notification submission under section 510(k) of the Federal Food, Drug, and Cosmetic Act, or a request for De Novo classification under section 513(i)(2) of the Federal Food, Drug, and Cosmetic Act) or in an amendment or supplement to a device marketing application or submission, or in a pre-submission. A waiver request is required to contain at least one of the following:

(i) An explanation why the sponsor’s or applicant’s compliance with the requirement is unnecessary or cannot be achieved;

(ii) A description of an alternative submission or course of action that satisfies the purpose of the requirement; or

(iii) Other information justifying a waiver.

2. FDA may grant a waiver if it finds that doing so would be in the interest of the public health.

(d) Records. A sponsor or applicant must retain the records required by this section for a clinical investigation conducted outside the United States as follows:

(1) If the investigation is submitted in support of an IDE, for 2 years after the termination or completion of the IDE; and

(2) If the investigation is submitted in support of a premarket approval application, a notice of completion of a product development protocol, a humanitarian device exemption application, a premarket notification submission, or a request for De Novo classification, for 2 years after an agency decision on that submission or application.

(e) Clinical investigations conducted outside of the United States that do not meet conditions. For clinical investigations conducted outside the United States that do not meet the conditions under paragraph (a) of this section, FDA may accept the information from such clinical investigations to support an IDE or a device marketing application or submission if FDA believes that the data and results from such clinical investigation are credible and accurate and that the rights, safety, and well-being of subjects have been adequately protected.

7. Section 812.140 is amended by revising paragraph (d) to read as follows:

§812.140 Records.

(d) Retention period. An investigator or sponsor shall maintain the records required by this subpart during the investigation and for a period of 2 years after the latter of the following two dates: The date on which the investigation is terminated or completed, or the date that the records are no longer required for purposes of supporting a premarket approval application, a notice of completion of a product development protocol, a humanitarian device exemption application, a premarket notification submission, or a request for De Novo classification.

PART 814—PREMARKET APPROVAL OF MEDICAL DEVICES

8. The authority citation for part 814 is revised to read as follows:


9. Section 814.15 is amended by revising paragraph (a); by removing paragraphs (b) and (c); by redesignating paragraphs (d) and (e) as paragraphs (b) and (c), respectively; and by removing the parenthetical sentence at the end of the section to read as follows:

§814.15 Research conducted outside the United States.

(a) Data to support PMA. If data from clinical investigations conducted outside the United States are submitted to support a PMA, the applicant shall comply with the provisions in §812.28 of this chapter, as applicable.

(b) For clinical investigations conducted outside the United States that are intended to support the PMA, the requirements under §812.28 of this chapter apply. If any such investigation was not conducted in accordance with good clinical practice (GCP) as described in §812.28(a), include either a waiver request in accordance with §812.28(c) or a brief statement of the reason for not conducting the investigation in accordance with GCP and a description of steps taken to ensure that the data and results are credible and accurate and that the rights, safety, and well-being of subjects have been adequately protected. Failure or inability to comply with these requirements does not justify failure to provide information on a relevant clinical investigation.

10. Section 814.20 is amended by revising paragraphs (b)(6)(ii)(A) and (B) and adding paragraph (b)(6)(ii)(C) to read as follows:

§814.20 Application.

(A) For clinical investigations conducted in the United States, a statement with respect to each investigation that it either was conducted in compliance with the institutional review board regulations in part 56 of this chapter, or was not subject to the regulations under §56.104 or §56.105, and that it was conducted in compliance with the informed consent regulations in part 50 of this chapter; or if the investigation was not conducted in compliance with those regulations, a brief statement of the reason for the noncompliance. Failure or inability to comply with these requirements does not justify failure to provide information on a relevant clinical investigation.

(B) For clinical investigations conducted in the United States, a statement that each investigation was conducted in compliance with part 812 of this chapter concerning sponsors of clinical investigations and clinical investigators, or if the investigation was not conducted in compliance with those regulations, a brief statement of the reason for the noncompliance. Failure or inability to comply with these requirements does not justify failure to provide information on a relevant clinical investigation.

11. Section 814.45 is amended by revising paragraph (a)(5) to read as follows:

§814.45 Denial of approval of a PMA.

(a) * *

(5) Any clinical investigation involving human subjects described in the PMA, subject to the institutional review board regulations in part 56 of this chapter or informed consent regulations in part 50 of this chapter or GCP referenced in §814.15(a) and described in §812.28(a) of this chapter, was not conducted in compliance with those regulations such that the rights or safety of human subjects were not adequately protected or the supporting data were determined to be otherwise unreliable.

* * * * *
12. Section 814.46 is amended by revising paragraph (a)(4) to read as follows:

§ 814.46 Withdrawal of approval of a PMA.

(a) * * *

(4) Any clinical investigation involving human subjects described in the PMA, subject to the institutional review board regulations in part 56 of this chapter or informed consent regulations in part 50 of this chapter or GCP referenced in § 814.15(a) and described in § 812.28(a) of this chapter, was not conducted in compliance with those regulations such that the risks or safety of human subjects were not adequately protected or the supporting data were determined to be otherwise unreliable.

* * * * *

13. Section 814.104 is amended by revising paragraph (b)(4)(i) to read as follows:

§ 814.104 Original applications.

* * * * *

(b) * * *

(4) * * *

(i) In lieu of the summaries, conclusions, and results from clinical investigations required under § 814.20(b)(3)(v)(B), (b)(3)(vi), and the introductory text of (b)(6)(ii), the applicant shall include the summaries, conclusions, and results of all clinical experience or investigations (whether adverse or supportive) reasonably obtainable by the applicant that are relevant to an assessment of the risks and probable benefits of the device and to the extent the applicant includes data from clinical investigations, the applicant shall include the statements described in § 814.20(b)(6)(i)(A) and (B) with respect to clinical investigations conducted in the United States and the information described in § 814.20(b)(6)(i)(C) with respect to clinical investigations conducted outside the United States; and

* * * * *


Leslie Kux,
Associate Commissioner for Policy.

Associate Commissioner for Policy.

[FR Doc. 2018–03244 Filed 2–20–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 202

[Docket No. FR–6048–F–01]

Streamlining the Office of Inspector General’s Freedom of Information Act Regulations and Implementing the FOIA Improvement Act of 2016

AGENCY: Office of Inspector General, HUD.

ACTION: Final rule.

SUMMARY: This final rule amends the Freedom of Information Act (FOIA) regulations for the U.S. Department of Housing and Urban Development (HUD) Office of Inspector General (OIG) to align with HUD’s FOIA regulations, to implement the FOIA Improvement Act of 2016, and to explain current OIG policies and practices with respect to FOIA.


FOR FURTHER INFORMATION CONTACT:
Maura Malone; Deputy Counsel to the Inspector General; Department of Housing and Urban Development; 451 Seventh Street SW, Room 8260, Washington, DC 20410; 202–708–1613 (this is a toll-free number). Persons with hearing or speech impairments may access this number through TTY by calling the Federal Relay Service at 800–877–8339 (this is a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

In July 1967, HUD issued regulations at 24 CFR part 15 containing the policies and procedures governing public access to HUD records under the Freedom of Information Act (FOIA) (5 U.S.C. 552) (Pub. L. 89–487, approved July 4, 1966). The Inspector General Act of 1978 (5 U.S.C. App. 3) was enacted to “create independent and objective units” to perform investigative and monitoring functions within Executive agencies of the Federal Government, including HUD. HUD’s regulations regarding public access to HUD records under the FOIA are at 24 CFR part 15. To further its independence, OIG officials, as opposed to HUD officials, make determinations concerning the release of OIG records. In 1984, the HUD OIG published 24 CFR part 202, which explains the procedures for requesting information from the OIG under the FOIA. Part 2002 cross-referenced several of HUD’s regulations at 24 CFR part 15. The OIG last amended its FOIA regulations in July 2002 (67 FR 47216). Subsequently, HUD made several changes to its FOIA regulation, which has affected some of the regulations referenced in part 2002 (80 FR 49140).

On June 30, 2016, the President signed into law the FOIA Improvement Act of 2016 (2016 Act) (Pub. L. 114–185). The 2016 Act addresses a range of procedural issues, including requirements that agencies establish a minimum of 90 days for requesters to file an administrative appeal and that agencies provide dispute resolution services at various times throughout the FOIA process. The 2016 Act also codifies a “foreseeable harm” standard, amends a FOIA disclosure exemption, creates a new Chief FOIA Officer Council within the Executive Branch, and adds two new elements to agency Annual FOIA Reports. The amendments apply to any request made after the date of enactment. The 2016 Act also requires agencies to review and issue updated regulations on procedures for the disclosure of records under FOIA, in accordance with the amendments made by the 2016 Act. On January 12, 2017, HUD issued a direct final rule amending its FOIA regulation to reflect the 2016 Act amendments (82 FR 3619).

II. Changes Made in This Final Rule

In this final rule, the HUD OIG seeks to amend its FOIA regulations to address the 2016 Act changes, conform its regulations with HUD’s, and simplify its regulations to make the process clearer to the requesting public. The following is an overview of nontechnical changes made in this final rule:

Section 2002.3 OIG’s Overall Policy Concerning Disclosable Records

The OIG adds the title and contact information for the FOIA Public Liaison that is available to answer questions for FOIA requesters, as required by the 2016 Act.

Section 2002.5 How To Make a Request for OIG Records; Records Produced

This section is updated to provide for requests to be made in writing, which aligns with HUD’s FOIA regulations, and provides that such requests may be made using the OIG public website. The regulations also reflect the requirement that the requestor, when requesting records on themselves, may be required to identify themselves when making a request or such a request may be found insufficient and closed. Lastly, the OIG also clarifies that for purposes of reasonably describing a record, a more specific FOIA request will likely result in the OIG locating the records requested. The OIG notes that a request for “any and all” records over an
extended period of time may be rejected for not reasonably describing the record.

Section 2002.7 OIG Processing of Requests, Multi-Tracking, and Expedited Processing

This rule provides the tracking process for requests that qualify as unusual circumstances under the definition at 5 U.S.C. 552(a)(6)(B)(iii). In the definition, the OIG adds an example of audit work papers under the definition of “unusual circumstances” to clarify that requests for audit work papers usually qualify as unusual circumstances and take longer than 20 working days to process because work papers related to an audit, if it is accepted for processing as a proper request, generally take weeks or months to process.

Section 2002.9 Proactive Disclosures of Records

The 2016 Act requires agencies to “make available for public inspection in an electronic format” records that, because of their subject matter, the agency determines “have become or are likely to become the subject of subsequent requests for substantially the same records,” or that have been requested 3 or more times. The 2016 Act also adds new reporting requirements for agencies by requiring that agencies submit an Annual FOIA Report, which covers the preceding fiscal year, to be submitted to the Director of the Office of Government Information Services. The raw statistical data used in each report must be made available without charge, license, or registration requirement; in an aggregated, searchable format, and in a format that may be downloaded in bulk. Both the report and the raw statistical data used in the report must be made available for public inspection in an electronic format. In response, the OIG is amending § 2002.9 to comply with these requirements.

Section 2002.13 Fee Schedule, Advance Payment, Interest Charges, and Waiving or Reducing Fees

This rule amends § 2002.13 to adopt HUD’s fee schedule and policies in their entirety through cross-reference to HUD’s FOIA regulation at § 15.106. Incorporated in HUD’s regulations are the 2016 Act new provisions regarding agencies’ ability to assess search and duplication fees. First, the 2016 Act provides that an agency shall not assess any search fees, or in some cases, duplication fees, if the agency has failed to comply with any time limit described at 5 U.S.C. 552(a)(6), which are set out in OIG’s FOIA regulations at § 2002.15, with limited exceptions. Second, if an agency determines that unusual circumstances apply to the processing of a FOIA request, the agency has provided timely written notice to the requester, and the agency has provided timely written notice to the requester, then a delayed response time is excused for an additional 10 days; however, if the agency fails to comply with the extended time limit, it may not charge search fees, or, in some cases, duplication fees, with limited exceptions. Third, the 2016 Act provides an exception allowing agencies to charge search fees, or in some cases, duplication fees, if unusual circumstances apply, more than 5,000 pages are necessary to respond to the request, timely written notice has been made to the requester, and the agency has discussed with the requester via written mail, electronic mail, or telephone (or made not less than three good-faith attempts to do so) how the requester could effectively limit the scope of the request. Fourth, the 2016 Act maintains that if a court determines that “exceptional circumstances” exist, as defined in 5 U.S.C. 552(a)(6)(C), the agency’s failure to comply with a time limit “shall be excused for the length of the time provided by the court order.”

As for the definition of “commercial requesters” adopted from HUD’s regulation, the OIG clarifies that as a policy, it will treat owners of websites that contain advertisements, or that charge fees in any way, to be “commercial requesters,” if they do not use editorial skills to turn the posted materials into a distinct work, or provide significant editorial comments. Owners of websites that do not contain advertisements, but that post requested documents without altering such documents or providing editorial comments, will be considered “other requesters,” unless the websites are used to advertise or publicize the skills or expertise of the owners.

This rule also removes OIG’s existing FOIA regulations at § 2002.13 because the collecting of interest charges on any unpaid bills is consistent with HUD’s FOIA regulations at § 15.106(g).

Section 2002.15 Time Limitations

When a FOIA request involves “unusual circumstances,” agencies have long been required to provide written notice to the requester, and in those instances where an extension of time of more than 10 working days is specified, agencies have been required to provide the requester with the opportunity to limit the scope of the request so that it can be processed more quickly or to arrange an alternative time to respond. The 2016 Act adds an additional requirement that when unusual circumstances exist and an agency extends the time limits by more than 10 additional working days, in the written notice to the requester they must notify the requester of their right to seek dispute resolution services from the FOIA Public Liaison of the agency or the Office of Government Information Services. To address this requirement, the OIG is revising § 2002.15 to incorporate the change enacted by the 2016 Act.

The OIG is also using this final rule to update several specific provisions of § 2002.15 to more accurately reflect the statutory language in 5 U.S.C. 552(a)(6)(A)(i). First, the OIG is amending § 2002.15(a) to state that OIG will generally “make a determination whether to comply with a FOIA request within 20 working days.” Second, the OIG is amending the provision that addresses when OIG may extend the time periods for processing a FOIA request, to remove the sentence that limits extensions to 10 working days. The OIG is removing this language as inconsistent with the plain reading of the statute, the logic of the rest of the language in § 2002.15, and Department of Justice guidance.

Finally, in accordance with 5 U.S.C. 552(a)(6)(B)(ii), the OIG is updating § 2002.15 to include the provision that the OIG shall make available its FOIA Public Liaison, who shall assist in the resolution of any disputes between the requester and the OIG. When an agency makes a determination regarding whether to comply with a FOIA request, the 2016 Act provides that the agency is required to immediately notify the requester of such determination and the reasons therefore, and notify the requester that they have a right to seek assistance from the agency’s FOIA Public Liaison. For adverse determinations, the 2016 Act requires that agencies afford the requester no less than 90 days from the date of the adverse determination on the request to file an appeal. In addition, the 2016 Act requires that agencies notify the requester that they may seek dispute resolution services from the FOIA Public Liaison or from the Office of Government Information Services. Consistent with this requirement, the OIG has revised § 2002.15 to provide that, once OIG makes a determination regarding compliance, the OIG will

1 Under FOIA, agencies are also required to submit an Annual FOIA Report to the Attorney General of the United States (5 U.S.C. 552(e)(1)).

immediately notify the requester of such determination, the reasons therefore, and their right to seek assistance from the FOIA Public Liaison.

Section 2002.19 Authority To Deny Requests for Records and Form of Denial, Exemptions, and Exclusions

The 2016 Act requires that agencies withhold information under FOIA “only if the agency reasonably foresees that disclosure would harm an interest protected by an exemption” or if disclosure is prohibited by law. The 2016 Act further directs agencies to consider whether partial disclosure of information is possible whenever the agency determines that a full disclosure of a requested record is not possible, and to take reasonable steps necessary to segregate and release nonexempt information. The 2016 Act does not require disclosure of information that is otherwise prohibited from disclosure by law or otherwise exempted from disclosure under Exemption 3.

Consistent with these changes, the OIG is amending § 2002.19 to provide that the OIG shall withhold information only if it is reasonably foreseeable that disclosure would harm an interest protected by an exemption, or if disclosure is prohibited by law. The OIG will also consider whether partial disclosure of information is possible if it determines that a full disclosure of a requested record is not possible and will take reasonable steps necessary to segregate and release nonexempt information.

In addition, the 2016 Act amends Exemption 5 of FOIA to provide that the deliberative process privilege does not apply to records created 25 years or more before the date on which the records were requested. In accordance with the 2016 Act, the OIG is revising § 2002.19 to state that the deliberative process privilege “shall not apply to records created 25 years or more before the date on which the records were requested.”

For adverse determinations, the OIG is amending § 2002.19 to provide that the OIG will notify the requester of their right to file an appeal no less than 90 days after the date of receiving the adverse determination. Finally, the OIG is amending § 2002.19 to provide that the OIG will notify the requester of their right to seek dispute resolution services from the FOIA Public Liaison or from the Office of Government Information Services.

Section 2002.23 Administrative Review

The OIG amends § 2002.23, consistent with the 2016 Act to provide that the OIG will notify requesters of dispute resolution services in its FOIA appeal determination response letter and that they have 90 days to seek an appeal. The OIG is also amending § 2002.23 to clarify that appeals may be submitted electronically and lists the items that a requester should include in an appeal, such as a copy of the original request and the written denial.

III. Justification for Final Rulemaking

In general, OIG publishes a rule for public comment before issuing a rule for effect, in accordance with OIG’s regulations on rulemaking at 24 CFR part 10. Section 10.1, however, provides an exception from that general rule where OIG 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.”

The OIG finds that good cause exists to publish this rule for effect without first soliciting public comment because prior public comment is unnecessary. This final rule follows the statutory directive in section 3 of the 2016 Act, which requires agencies to review and issue updated regulations on procedures for the disclosure of records under FOIA, in accordance with the amendments made by the 2016 Act. The 2016 Act codifies a number of transparency and openness principles and enacts a number of procedural requirements, including requiring that agencies establish a minimum of 90 days for requesters to file an administrative appeal and that they provide dispute resolution services at various times throughout FOIA process. This final rule reflects the changes required by the 2016 Act. Additionally, this final rule makes technical amendments to align the OIG’s FOIA regulation with HUD’s FOIA regulation at 24 CFR part 15 and clarifies current OIG FOIA procedures to streamline and simplify the process of filing FOIA requests.

IV. Findings and Certifications

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. This final rule incorporates changes enacted by the 2016 Act and makes other minor procedural changes that align this OIG regulation to HUD’s FOIA regulation at 24 CFR part 15. As a result, this rule was determined to not be a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and therefore was not reviewed by OMB.

Environmental Review

This final rule is categorically excluded from environmental review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321). The revision of the FOIA-related provisions of 24 CFR part 2002 falls within the exclusion provided by 24 CFR 50.19(c)(1), in that it does not direct, provide for assistance or loan and mortgage insurance for, or otherwise govern or regulate real property acquisition, disposition, leasing, rehabilitation, alteration, demolition, or new construction; or establish, revise, or provide for standards for construction or construction materials, manufactured housing, or occupancy.

Regulatory Flexibility Act

Executive Order 13132 (entitled “Federalism”) prohibits an agency, to the extent practicable and permitted by law, 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 agency meets the relevant requirements of section 6 of the Executive Order. This final 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) establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. This final rule does not impose any Federal mandates on any State, local, or tribal governments or the private sector within the meaning of the

List of Subjects in 24 CFR Part 2002

Release of information under the Freedom of Information Act.

Accordingly, for the reasons stated above, OIG revises 24 CFR part 2002 to read as follows:

PART 2002—AVAILABILITY OF INFORMATION TO THE PUBLIC

Sec.

2002.1 Scope of this part and applicability of other HUD regulations.

2002.3 OIG’s overall policy concerning disclosable records and requests for OIG records.

2002.5 How to make a request for OIG records; records produced.

2002.7 OIG processing of requests, multi-tracking, and expedited processing.

2002.9 Proactive disclosures of records.

2002.11 Agency review of records and aggregating requests.

2002.13 Fee schedule, advance payment, and waiving or reducing fees.

2002.15 Time limitations.

2002.17 Authority to release records or production or disclosure of information in the possession of the OIG, except as limited in paragraph (c) of this section or otherwise expressly stated in this part.

2002.19 Authority to deny requests for OIG records.

2002.21 Effect of denial of request.

2002.23 Administrative review.


§ 2002.1 Scope of this part and applicability of other HUD regulations.

(a) General. This part contains the regulations of the Office of Inspector General (OIG) that implement the Freedom of Information Act (FOIA) (5 U.S.C. 552). It informs the public how to request records and information from the OIG and explains the procedure to use if a request is denied. Requests made by individuals for records about themselves under the Privacy Act of 1974, 5 U.S.C. 552a, are processed in accordance with 24 CFR part 2003 as well as this part. Requests for documents made by subpoena or other demands of courts or other authorities are governed by procedures contained in part 2004 of this chapter. These rules should be read in conjunction with the text of the FOIA and the Uniform Freedom of Information Fee Schedule and Guidelines published by the Office of Management and Budget. This policy does not create any right enforceable in court.

(b) Applicability of HUD’s FOIA regulations. In addition to the regulations in this part, §§ 15.2 and 15.106 of this title apply to the production or disclosure of information in the possession of the OIG, except as limited in paragraph (c) of this section or otherwise expressly stated in this part.

(c) Limited applicability of §§ 15.2 and 15.106 of this title. The OIG has different people and entities involved in the FOIA process than those defined in §15.2 and these people and entities are specifically identified in this part. For purposes of this part, when the words “HUD” or “Department” are used in §15.2 or §15.106, the term means the OIG. The OIG will follow the fee schedule at §15.106 except as otherwise provided in this part. Where §15.106 references §15.103, the OIG reference in this part is §2002.15.

§ 2002.3 OIG’s overall policy concerning disclosable records.

(a) The OIG will administer its FOIA program with a presumption of openness. This policy does not create any right enforceable in court. The OIG will fully and responsibly disclose its identifiable records and information consistent with competing public interests, such as national security, personal privacy, grand jury and investigative secrecy, complainant confidentiality, and agency deliberative process, as are recognized by FOIA and other Federal statutes. The OIG will apply the FOIA exemptions if release could foreseeably harm an interest protected by a FOIA exemption. Release of records will be made as promptly as possible.

(b) The OIG FOIA Public Liaison is the Deputy Counsel to the Inspector General. Requesters who have questions or concerns about their FOIA request may contact the FOIA Public Liaison at 202–708–1613, or through the FOIA email at FOIARequests@hudoig.gov.

§ 2002.5 How to make a request for OIG records; records produced.

(a) Any request for OIG records must be made in writing. The easiest way to make a FOIA request is electronically through our public website at www.hudoig.gov. A request may also be made by submitting the written request to The Office of Inspector General; Department of Housing and Urban Development; 451 Seventh Street SW, Suite 8260, Washington, DC 20410. The envelope should indicate it is a FOIA request. A request for OIG records may also be made in person during normal business hours at any office where OIG employees are permanently stationed.

(b) Each request must reasonably describe the desired record, including the title or name, author, subject matter, and number or date, where possible, so that the record may be identified and located. The more specific the FOIA request for records, the more likely OIG officials will be able to locate the records requested. The request should also include the name, address and telephone number of the requester, the fee category that the requester believes applies to the request, and the form or format in which the requester would like the desired record to be reproduced, if the requester has a preference. In order to enable the OIG to comply with the time limitations set forth in §2002.15, both the envelope containing a written request and the letter itself should clearly indicate that the subject is a Freedom of Information Act request.

(c) The request must be accompanied by the fee or an offer to pay the fee as determined in §15.106 of this title and §2002.13.

(d) The OIG may require information verifying the requester’s identity, if the requester requests agency records pertaining to the requester, a minor, or an individual who is legally incompetent. Failure to provide the information when requested will result in the request being found insufficient and closed. It will not prevent the future refiling of the request.

(e) Duplication of available records will be made as promptly as possible. Such duplication can take the form of paper copy, audiovisual materials, or machine-readable documentation (e.g., electronic documents on CD, DVD, flash drive, etc.). Records that are published or available for sale will not be reproduced.

(f) The OIG shall honor a requester’s specified preference of form or format of disclosure if the record is readily reproducible with reasonable efforts in the requested form or format by the office responding to the request.

(g) If the requester makes a request for expedited processing, the request must provide a detailed explanation of the basis for the request. The requester should also include a statement certifying the truth of the circumstances supporting the requester’s compelling need. Requests for expedited processing that simply recite the statutory language are generally not granted.

§ 2002.7 OIG processing of requests, multi-tracking, and expedited processing.

(a) Tracking number. FOIA requests will be logged in the order that they are received and be assigned a tracking number, except as provided in paragraph (c) of this section. A requester should use the tracking number to identify his or her request when contacting the FOIA office for any reason. An acknowledgement of receipt of the request, with the assigned
tracking number, will be sent to the requester by the FOIA office.

(b) Multi-track processing—(1) Types of tracks. For requests that do not qualify for expedited processing, the OIG places each request in one of two tracks, simple or complex, based on the amount of work and time involved in processing the request. In doing so, the OIG will consider whether the request involves the processing of voluminous documents or responsive documents from more than one organizational unit. Within each track, the OIG processes requests in the order in which they are received.

(2) Unusual circumstances. Requests for audit work papers are considered complex requests and generally qualify as an unusual circumstance under 5 U.S.C. 552(a)(6)(B)(iii), taking longer than 20 working days to process. Requests for “all” specified records over a span of time, if they are accepted as reasonably describing a specific group of records, are considered complex requests and usually qualify as an unusual circumstance under 5 U.S.C. 552(a)(6)(B)(iii), taking longer than 20 working days to process. Requesters who make requests qualifying as unusual circumstances will be offered an opportunity to narrow the scope of their request or arrange for an alternative time period.

(3) Misdirected requests. For requests that have been sent to the wrong office, the OIG will assign the request within each track using the earlier of either:

(i) The date on which the request was referred to the appropriate office; or

(ii) The end of the 10 working-day period in which the request should have been referred to the appropriate office.

(c) Expedited processing. (1) The OIG may take your request or appeal out of normal order if the OIG determines that you have a compelling need for the records or in other cases as determined by the OIG. Any requester may ask for expedited processing at any time. If expedited processing is requested, the OIG will notify the requester within 10 working days whether it will grant expedited processing.

(2) The OIG will grant requests for expedited processing if it finds a compelling need under 5 U.S.C. 552(a)(6)(E). Evidence of a compelling need by a person making a request for expedited processing must be made in a statement certified by such person to be true and correct to the best of such person’s knowledge and belief. A compelling need exists if:

(i) You reasonably believe that the records sought are likely to have an imminent threat to the life or physical safety of an individual;

(ii) You are primarily engaged in disseminating information and there is an urgency to inform the public concerning actual or alleged Federal Government activity; or

(iii) Your failure to obtain the requested records on an expedited basis could result in the loss of substantial due process rights.

(3) If the OIG grants the request for expedited processing, the OIG will give the requester priority and will process it as soon as practicable.

§ 2002.9 Proactive disclosures of records.

(a) You may review records that section 552(a)(2) of FOIA requires the OIG to make available to the public in the electronic FOIA Reading Rooms identified in paragraph (b) of this section. That is the preferable method; however, you may also ask to review those documents that are in hardcopy at the Headquarters offices at HUD’s Library, 451 Seventh Street SW, Suite 8141, Washington, DC 20410. This request should be coordinated through Office of Legal Counsel, Office of Inspector General, Suite 8254. Local offices may coordinate local requests for hardcopy reviews.

(b) As required by 5 U.S.C. 552(a)(2), the OIG makes records created on or after November 1, 1996, available through its Electronic FOIA Reading Room located at https://www.hudoig.gov/foia. These records include:

(1) Copies of all records, regardless of form or format that have been released to any person under this part; and

(j) Because of the nature of their subject matter, the agency determines that the records have become or are likely to become the subject of subsequent requests for substantially the same records; or

(ii) Have been requested three or more times.

(2) Report for the preceding fiscal year submitted to the U.S. Attorney General and the Director of the Office of Government Information Services as required by 5 U.S.C. 552(e) and the raw statistical data used in each report. This report will be made available:

(i) Without charge, license, or registration requirement;

(ii) In an aggregated, searchable format; and

(iii) In a format that may be downloaded in bulk.

(c) The OIG also makes other documents, such as audits and semiannual reports, available to the public at https://www.hudoig.gov/.

§ 2002.11 Agency review of records and aggregating requests.

(a) Review of records. Only requesters who are seeking documents for commercial use may be charged for the time the OIG spends reviewing records to determine whether the records are exempt from mandatory disclosure. Charges will be assessed only for the initial review; i.e., the review undertaken the first time the OIG reviews a particular record or portion of a record to apply an exemption. The OIG will not charge for review at the administrative appeal level of an exemption already applied. However, records or portions of records withheld under an exemption that is subsequently determined not to apply may be reviewed again to determine the applicability of other exemptions not previously considered. The costs for such a subsequent review would be properly assessable. Review time will be assessed at the same rates established for search time in §§ 2002.13 and 15.106 of this title.

(b) Aggregating requests. (1) The OIG may aggregate multiple requests in cases where unusual circumstances exist and the OIG determines that:

(i) Certain requests from the same requester or from a group of requesters acting in concert actually constitute a single request; and

(ii) The requests involve clearly related matters.

(2) Aggregation of requests for this purpose will be conducted independent of aggregation of requests for fee purposes under § 15.106(h) of this title.

§ 2002.13 Fee schedule, advance payment, interest charges, and waiving or reducing fees.

The OIG will charge for processing requests under the FOIA in accordance with § 15.106 of this title, except where those provisions conflict with provisions of this part; more specifically, where § 15.106 references § 15.103 of this title replace such reference with § 2002.15.

§ 2002.15 Time limitations.

(a) General. Upon receipt of a request for records, the appropriate Assistant Inspector General or an appointed designee will generally make a determination whether to comply with a FOIA request within 20 working days. The Assistant Inspector General or designee will immediately notify the requester in writing of the determination and the reason(s) for such determination and the right of the person to request assistance from the FOIA Public Liaison. The 20-day period will begin on the day the request is
received by the OIG, but in any event not later than 10 working days after the request is received by any component designated to receive FOIA requests, and after any fees or advance payment of fees under §2002.13 has been made.

(b) Scope of responsive records. In determining which records are responsive to a request, an agency ordinarily will include only records in its possession as of the date that it begins its search. If any other date is used, the agency must inform the requester of that date. A record that is excluded from the requirements of the FOIA pursuant to 5 U.S.C. 552(c) is not considered responsive to a request.

(c) Unusual circumstances. Under unusual circumstances, as specified in this paragraph (c), the OIG may extend the time period for processing a FOIA request. In such circumstances, the OIG will provide the requester with written notice setting forth the unusual circumstances for the extension and the date on which a determination is expected to be made. This date will not exceed 10 working days beyond the general time established in paragraph (a) of this section. If processing a request would require more than 10 working days beyond the general time limit established in paragraph (a) of this section, the OIG will offer the requester an opportunity to reduce or limit the scope of the request in order to allow the OIG to process it within the extra 10-day working period or arrange an alternative time period within which the FOIA request will be processed. To aid the requester, the OIG shall make available its FOIA Public Liaison, who shall assist in the resolution of any disputes between the requester and the OIG, and notify the requester of the right of the requester to seek dispute resolution services from the Office of Government Information Services.

Unusual circumstances mean that there is a need:

(1) To search for and collect the requested records from field facilities or other establishments that are separate from the office processing the request;

(2) To search for, collect, and appropriately examine a voluminous amount of separate and distinct records that are demanded in a single request (e.g. audit work papers); or

(3) For consultation, which shall be conducted with all practicable speed, with another agency having a substantial interest in the determination of the request or among two or more offices of the OIG, or with the Inspector General having a substantial interest in the subject matter of the request.

§2002.17 Authority to release records or duplications.

Any Assistant Inspector General or an appointed designee is authorized to release any record (or duplication) pertaining to activities for which he or she has primary responsibility, unless disclosure is clearly inappropriate under this part. No authorized person may release records for which another officer has primary responsibility without the consent of the officer or his or her designee.

§2002.19 Authority to deny requests for records and form of denial, exemptions, and exclusions.

(a) Process for denying requests. An Assistant Inspector General or the Counsel to the Inspector General, or their designees, may deny a request for a record. Any denial will:

(1) Be in writing;

(2) State simply the reasons for the denial;

(3) Provide an estimate of the volume of records or information withheld, when appropriate, in number of pages or in some other reasonable form of estimation. This estimate does not need to be provided if the volume is otherwise indicated through deletions on records disclosed in part, or if providing an estimate would harm an interest protected by an applicable exemption;

(4) Identify the person(s) responsible for the denial by name and title;

(5) Provide notice of the right of the requester to appeal to the Deputy Inspector General, within a period determined by the head of the agency that is not less than 90 days after the date of such adverse determination, consistent with §2002.23; and

(6) Provide notice of the right of the requester to seek dispute resolution services from the FOIA Public Liaison of the agency or the Office of Government Information Services.

(b) Denying requests generally. The OIG shall withhold information only if the OIG reasonably foresees that disclosure would harm an interest protected by an exemption as provided in this section, or disclosure is prohibited by law. The OIG will consider whether partial disclosure of information is possible whenever the OIG determines that a full disclosure of a requested record is not possible and will take reasonable steps necessary to segregate and release nonexempt information. Nothing in this section requires disclosure of information that is otherwise prohibited from disclosure by law or otherwise exempted from disclosure as provided in this section.

(c) FOIA exemptions. The FOIA contains nine exemptions (5 U.S.C. 552(b)) that authorize agencies to withhold various records from disclosure, and two exclusions to the statute that may be used by the OIG. With regard to the records normally requested, the OIG generally applies the exemptions and exclusions as follows:

(1) Classified documents. Exemption 1 (5 U.S.C. 552(b)(1)) protects classified national defense and foreign relations information. The OIG seldom relies on this exception to withhold documents. However, where applicable, the OIG will refer a request for records classified under Executive Order 13526 and the pertinent records to the originating agency for processing. The OIG may refuse to confirm or deny the existence of the requested information if the originating agency determines that the fact of the existence of the information itself is classified.

(2) Internal agency rules and practices. Exemption 2 (5 U.S.C. 552(b)(2)) protects records relating to internal personnel rules and practices.

(3) Information prohibited from disclosure by another statute. Exemption 3 (5 U.S.C. 552(b)(3)) protects information that is prohibited from disclosure by another Federal law. Some investigatory records contain information that could reveal grand jury proceedings, which are protected from disclosure by Federal Rule of Criminal Procedure 6(e). Section 7 of the Inspector General Act of 1978 prohibits the OIG from disclosing the identity of employees who make protected disclosures. The OIG generally will not disclose competitive proposals prior to contract award, competitive proposals that are not set forth or incorporated by reference into the awarded contract, (see 41 U.S.C. 4702), or, during the selection process, any covered selection information regarding such selection, either directly or indirectly (see 42 U.S.C. 3537a).

(4) Commercial or financial information. Exemption 4 (5 U.S.C. 552(b)(4)) protects trade secrets and commercial or financial information obtained from a person that is privileged and confidential. The OIG frequently obtains this information through its audits. The OIG will process the release of this category of information pursuant to Executive Order 12600 and give notice to the affected business and an opportunity for the business to present evidence of its confidentiality claim. If the OIG is sued by a requester under the FOIA for nondisclosure of commercial or financial business information, the OIG expects the affected business to cooperate to the
fullest extent possible in defending such a decision.

(5) Certain interagency or intra-agency communications. Exemption 5 (5 U.S.C. 552(b)(5)) protects interagency or intra-agency communications that are protected by legal privileges, such as the attorney-client privilege, attorney work-product privilege, or communications reflecting the agency’s deliberative process. These communications may include communications with the Department of Justice and with HUD. The deliberative process privilege shall not apply to records created 25 years or more before the date on which the records were requested.

(6) Personal privacy. Exemption 6 (5 U.S.C. 552(b)(6)) protects information involving matters of personal privacy. This information may be found in personnel, medical, and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy. Names, addresses, telephone numbers, and email addresses of persons identified in audits or complaints generally will not be disclosed. The OIG has learned through experience that some of its employees (i.e., Hotline employees) will be harassed if their identities are known, and the OIG will protect the identities of these employees. As a law enforcement agency, the OIG finds individuals generally have a heightened privacy interest for not having their identities associated with the OIG.

(7) Law enforcement records. Exemption 7 (5 U.S.C. 552(b)(7)) protects certain records or information compiled for law enforcement purposes. This exemption protects records where the production could reasonably be expected to interfere with enforcement proceedings. The protection of this exemption also encompasses, but is not limited to, information in law enforcement files that could reasonably be expected to constitute an unwarranted invasion of personal privacy; the names of confidential informants; and techniques and procedures for law enforcement investigations, or guidelines for law enforcement investigations if such disclosure could reasonably be expected to risk circumvention of the law. It is the policy of the OIG in responding to all FOIA requests for investigative records pertaining to specifically named individuals to refuse to confirm or deny the existence of such records. Lacking the subject individuals consent, proof of death, an official acknowledgement of an investigation, or an overriding public interest, even acknowledging the existence of such records could reasonably be expected to constitute an unwarranted invasion of personal privacy.

(8) Supervision of financial institutions. Exemption 8 (5 U.S.C. 552(b)(8)) protects information relating to the supervision of financial institutions. It is unlikely that the OIG will have these documents.

(9) Wells. Exemption 9 (5 U.S.C. 552(b)(9)) protects geological information on wells. It is unlikely that the OIG will have these documents.

(d) FOIA exclusion. Some law enforcement records are excluded from the FOIA. 5 U.S.C. 552(c)(1) permits a law enforcement agency to exclude a document from the FOIA if there is reason to believe that:

(1) The subject of the investigation or proceeding is not aware of its pendency; and

(2) Disclosure of the existence of the records could reasonably be expected to interfere with enforcement proceedings, in which case the agency may, during only such time as that circumstance continues, treat the records as not subject to the requirements of the FOIA. Section 552(c)(2) of FOIA allows the exclusion of informant records, unless the existence of the informant has been officially confirmed.

§ 2002.21 Effect of denial of request.

Denial of a request shall terminate the authority of the Assistant Inspector General or his or her designee to release or disclose the requested record, which thereafter may not be made publicly available except with express authorization of the Inspector General, Deputy Inspector General, or Counsel to the Inspector General.

§ 2002.23 Administrative review.

(a) Review is available only from a written determination denying a request for a record and only if a written request for review is filed within 90 days after issuance of the written determination. If mailed, the requester’s letter of appeal must be postmarked within 90 calendar days of the date of the letter of determination. If the letter of appeal is transmitted electronically or by a means other than the United States Postal Service, it must be received in the appropriate office by the close of business on the 90th calendar day after the date of the letter of determination. Before seeking court review of an adverse determination, a requester must exhaust their administrative remedies under this section.

(b) A review may be initiated by sending a request for review to the Office of Inspector General; Department of Housing and Urban Development; 451 Seventh Street SW, Room 8256, Washington, DC 20410 or to FOIArequests@hudigo.gov. In order to enable the OIG to comply with the time limitations set forth in § 2002.17, both the envelope containing the request for review and the letter itself should clearly indicate that the subject is a Freedom of Information Act request for review. Each request for review must contain the following:

(1) A copy of the original request;

(2) A copy of the written denial; and

(3) A statement of the circumstances, reasons, or arguments advanced in support of disclosure of the original records requested.

(c) Review will be made promptly by the Deputy Inspector General, or designee, on the basis of the written record. The OIG will decide an appeal of a denial of a request to expedite processing of a FOIA request within 10 working days of receipt of the appeal. The OIG will make a determination on all other appeals within 20 working days of receipt, unless unusual circumstances require the OIG to extend the time for an additional 10 working days.

(d) The time of receipt for processing of a request is the time it is received by the Inspector General. If a request is misdirected by the requester and is received by one other than the Inspector General, the OIG official who receives the request will forward it promptly to the Inspector General and will advise the requester about the delayed time of receipt.

(e) The decision after review will be in writing, will constitute final agency action on the request, and, if the denial of the request for records is in full or in part upheld, the Inspector General will notify the person making the request of his or her right to seek judicial review under 5 U.S.C. 552(a)(4).

(f) Adverse decisions will include the name and contact information of dispute resolution services that offer mediation services to resolve disputes between FOIA requester and Federal agencies as a nonexclusive alternative to litigation.

Dated: January 18, 2018.

Helen M. Albert,
Acting Inspector General.

[PR Doc. 2018–03400 Filed 2–20–18; 8:45 am]
DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117
[Docket No. USCG–2018–0097]

Drawbridge Operation Regulation; Mianus River, Greenwich, CT

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulation.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the Metro-North Bridge across the Mianus River, mile 1.0 at Greenwich, Connecticut. The deviation is necessary to repair the superstructure and replace timber ties. This deviation allows the bridge to be closed to navigation.

DATES: This deviation is effective from 8 a.m. on April 10, 2018 to 8 a.m. on May 14, 2018.

ADDRESSES: The docket for this deviation, USCG–2018–0097 is available at 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 deviation.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email Mr. Jeffrey Stieb, First Coast Guard District Bridge Branch, Coast Guard; telephone 617–223–8364, email Jeffrey.D.Stieb@uscg.mil.

SUPPLEMENTARY INFORMATION: The owner of the bridge, the Connecticut Department of Transportation (CT DOT), requested a temporary deviation to conduct superstructure repair and timber ties replacement. The Metro-North Bridge across the Mianus River, mile 1.0, at Greenwich Connecticut has a vertical clearance in the closed position of 20 feet at mean high water and 27 feet at mean low water. The existing bridge operating regulations are found at 33 CFR 117.209.

This temporary deviation allows the bridge to operate from 8 a.m. April 10, 2018 to 8 a.m. on Monday, May 14, 2018 as follows: From 8 a.m. Monday through 4 p.m. Friday, the draw is authorized to remain closed to navigation; from 4:01 p.m. Friday to 7:59 a.m. Monday, the draw shall open with 24 hours advance notice. The deviation will have negligible effect on vessel navigation. The waterway is transited primarily by seasonal recreational vessels and small commercial fishing vessels. In 2016 there were six openings and in 2017 there were 19 openings between the effective dates. CT DOT has notified waterway users, the harbormaster, and town officials of the requested deviation. No objections to the proposed closure were received. Vessels that can pass through the bridge in the closed position may continue to do so. The bridge will not be able to open for emergencies and there is no immediate alternate route for vessels to pass. CT DOT will issue a press release announcing the closure. The Coast Guard will inform waterway users of the closure through Local and Broadcast Notices to Mariners.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the effective period of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.


Christopher J. Bisignano,
Supervisory Bridge Management Specialist,
First Coast Guard District.

BILLING CODE 9110–04–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 1, 4, 9, and 20
[WT Docket No. 16–240; FCC 17–167]

Requirements for Licensees To Overcome a CMRS Presumption

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document, the Federal Communications Commission adopts rules to harmonize and streamline the Commission’s regulations regarding the classification of commercial and private mobile radio services, primarily by removing provisions in the Commission’s rules that were outdated or unnecessary. The rules in question list various services or subservices that the Commission had classified as “commercial mobile services” and determined to be “any mobile service . . . that is interconnected service available (A) to the public or (B) to such classes of eligible users as to be effectively available to a substantial portion of the public[.]” “Private mobile service” is defined in the negative as “any mobile services are regulated as commercial or private, and instead allows licensees to rely on the statutory definitions of those terms to identify the nature and regulatory treatment of their mobile services, consistent with applicable service rules.


FOR FURTHER INFORMATION CONTACT: Thomas Reed at thomas.reed@fcc.gov, of the Wireless Telecommunications Bureau, Mobility Division, (202) 418–0531.


Alternative formats are available for people with disabilities (Braille, large print, electronic files, audio format), by sending an email to FCC504@fcc.gov or calling the Consumer and Government Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY).

The Commission will send a copy of the Order in a report to be sent to Congress and the Government Accountability Office pursuant to the Congressional Review Act, see 5 U.S.C. 801(a)(1)(A).

I. Report and Order

1. The Commission adopted §§ 20.7 and 20.9 in 1994 as part of its implementation of Sections 3(n) and 332 of the Communications Act, which Congress amended in the Omnibus Budget Reconciliation Act of 1993 (OBRA). Congress, seeking to bring mobile services that were similar in nature under a consistent regulatory framework, created the statutory classifications of “commercial mobile services” and “private mobile services” (referred to in Commission rules as commercial mobile radio service and private mobile radio service, respectively). The Communications Act defines commercial mobile service as “any mobile service . . . that is provided for profit and makes interconnected service available (A) to the public or (B) to such classes of eligible users as to be effectively available to a substantial portion of the public[,]” “Private mobile service” is defined in the negative as “any mobile
service . . . that is not a commercial mobile service or the functional equivalent of a commercial mobile service[.]” In the 1994 CMRS Second Report and Order (GN Docket No. 93–252) (59 FR 18493), the Commission mirrored these definitions in §20.3 of its rules. Thus, §20.3 defines “commercial mobile radio service” as a for-profit, interconnected mobile service that is available to the public; or to such classes of eligible users as to be effectively available to a substantial portion of the public; or the functional equivalent of such a for-profit, interconnected mobile service. “Private mobile radio service” is defined as a mobile service that is neither a commercial mobile radio service nor the functional equivalent of a commercial mobile radio service. Similarly, the Commission largely mirrored the statutory definition of “mobile services” in its definition in the rules.

2. The Commission, in adopting §§20.7 and 20.9, conducted an extensive review of the 1993 OBRA, its legislative history, and developments in the regulation of wireless services. The Commission noted that Congress “replaced the common carrier and private radio definitions that evolved under the prior version of section 332 of the Act with two newly defined categories of mobile services: Commercial mobile radio service (CMRS) and private mobile radio service (PMRS),” and “replaced traditional regulation of mobile services with an approach that brings all mobile service providers under a comprehensive, consistent regulatory framework and gives the Commission flexibility to establish appropriate levels of regulation for mobile radio service providers.” Two Congressional objectives appeared to drive these statutory changes: (1) Ensuring that “similar [mobile] services would be subject to consistent regulatory classification[,]” and (2) establishing and administering for CMRS providers “an appropriate level of regulation.”

3. Applying the purpose of the legislation to include all existing mobile services within the ambit of section 332 and in view of the goal of achieving regulatory symmetry, the Commission stated that all existing mobile services will be included within the ambit of section 332 as well as all auxiliary services and ancillary fixed communications offered by such service providers. In addition, the Commission stated that “unlicensed PCS and part 15 devices will not be included under the definition of mobile services,” but other unlicensed services meeting the definition of CMRS, such as the resale of CMRS, are mobile services within the meaning of sections 3(n) and 332 of the Communications Act. Section 20.7 memorialized these and listed the existing mobile services.

4. In addition, applying the statutory criteria to the existing common carrier mobile services at the time, the Commission identified in §20.9(a) thirteen specific mobile service bands (or subsets thereof) that met the definition of CMRS and would be treated as common carrier services. At the time, in the wake of the 1993 OBRA, the list served as a clear, easily applied tool for implementing the new CMRS classification and creating certainty about which regulatory regime would apply to a given license band. The primary reason this approach worked well was because many of the service-specific wireless rule parts drew clear lines between commercial and private operation in terms of service rules, obligations, and usage, and the licensed operations within a given service were often limited by rule either to common or private carriage. If a licensee of a service band identified in §20.9(a) wished to provide service on a private basis, it would have needed to seek a waiver of §20.9(a). Section 20.9(b) identifies three services that are specifically presumed to be CMRS (rather than deemed to be regulated as CMRS in §20.9(a)) and prescribes a certification process for overcoming that presumption in cases where the provider intends to operate on a PMRS basis.

5. In crafting the §20.9(a) approach, the Commission also noted that Congress was concerned with the “disparate regulatory treatment” that had evolved across services, and it observed that Congress’s intent for the Commission to establish consistent regulations was reflected in the statutory requirement that any service that amounted to the “functional equivalent” of CMRS be treated as such, even if it did not meet the strict definition. At the same time, the Commission “anticipated that very few mobile services that do not meet the definition of CMRS will be a close substitute for a [CMRS].” Because the Commission expected that the functional equivalency test would be applied only rarely, it decided to create another presumption—i.e., to “presume that a mobile service that does not meet the definition of CMRS is a [PMRS].” To rebut that presumption, a challenger to a PMRS claim could file a petition for declaratory ruling attempting to show that the service at issue met the definition of CMRS or was the functional equivalent of CMRS. Section 20.9(a)(14) memorializes this presumption and the process for overcoming the presumption.

6. For the services listed in §20.9(b), the rules state that service may be provided on a PMRS basis only if the licensee or applicant overcomes the presumption that those services are CMRS through a specific certification process. Specifically, §20.9(b) requires licensees of, or applicants for, Personal Communications Service (PCS), VHF Public Coast Stations, and Automated Maritime Telecommunications Systems (AMTS) that want to operate on a PMRS basis to include a certification as part of an authorization, modification, transaction, or spectrum leasing application demonstrating that the proposed service does not fall within the definition of CMRS. The application is placed on public notice for 30 days, during which interested parties may file petitions to deny.

7. While §20.9’s regulatory treatment of certain service bands may well have been a reasonable tool when it was adopted, it was based on assumptions that no longer apply—namely that a licensee would offer a service restricted either to CMRS or PMRS use rather than seek to have the flexibility to operate as both. In recent years, the Commission’s spectrum regulation has turned toward a flexible use model that no longer supports this particular treatment embedded in the Commission’s rules. Section 20.9 was adopted at a time when there were far fewer wireless licensees and services than exist today. Dramatic changes have occurred in the wireless industry since then. Notably, licensees of spectrum bands not identified in §20.9 are governed by service-specific rules that afford entities greater flexibility in how operations can be provided and that do not presume them to be CMRS or PMRS. Applicants and licensees in these newer services can select whether they will be providing common carrier service, non-common carrier service, and/or private, internal communications on FCC Form 601 or in other applications. Moreover, the continuing demand for PMRS use of spectrum—including spectrum that providers, in the past, had primarily sought for CMRS use—has altered another of the underlying assumptions of §20.9(a), i.e., that the demand to operate services referenced in §20.9 is primarily a demand to offer such services on a CMRS basis.

8. In light of the broadened interest in and need for spectrum covered by §20.9 by an increased diversity of licensees, the Commission has sought to provide greater flexibility to applicants,
licensees, and spectrum lessees subject to § 20.9, but these efforts have nonetheless left some entities with burdens that their counterparts in other spectrum bands do not face. In 2005, for example, the Commission eliminated the restriction that entities must operate as common carriers in order to hold a part 22 license. Despite this change, part 22 applicants, licensees, and spectrum lessees are still required to seek a waiver of § 20.9(a) if they plan to operate on a non-CMRS basis. In recent years, applicants, licensees, and spectrum lessees in many services presumed to be CMRS have requested waiver of § 20.9(a) as part of an initial authorization, modification, transaction, or spectrum leasing application, and the inclusion of the waiver request often increases the time it takes the Commission to process the application. For example, a paging assignment application in which the assignee includes a waiver request must go on public notice for a minimum of 14 days. Absent the waiver request, the application otherwise might be subject to overnight grant under the Commission’s processing rules. Similarly, the § 20.9(b) process for PCS, VHS Public Coast station services, and AMTS licensees to certify that their proposed operations are not commercial is cumbersome and time-consuming. Applications that include a § 20.9(b) certification often could be granted on an overnight basis absent § 20.9(b)’s public notice requirement.

9. To address these inefficiencies, the Commission in July 2016 released a Notice of Proposed Rulemaking (WT Docket No. 16–240) (NPRM) (81 FR 55161) recognizing that § 20.9’s approach to the regulatory status of certain bands was not the only way to administer the CMRS/PMRS statutory framework, and seeking comment on whether to eliminate this approach by removing § 20.9 from its rules. The Commission tentatively concluded that doing so would streamline application processing and promote comparable treatment of wireless applicants and licensees operating in different spectrum bands. The Commission anticipated that this revision of its rules would shorten the processing time for a number of applications and eliminate the obligation of licensees and applicants in the specified § 20.9 bands to make a showing—even if brief—regarding their intent to operate on a PMRS-basis. It tentatively concluded that this, in turn, would lead to more efficient and timely use of spectrum, without imposing more regulatory burdens than necessary for the Commission to oversee spectrum usage. The Commission sought comment on its tentative conclusions and on the costs and benefits of its proposed rule elimination. Five parties filed comments and two parties filed reply comments in response to the NPRM, all of which generally support elimination of § 20.9.

10. The Commission also sought comment in the NPRM on eliminating § 20.7’s list of certain services that meet the statutory definition of “mobile service” as used in sections 3(n) and 332 of the Act. This list is under-inclusive—it does not include all the services that are, in fact, “mobile services” under the statutory language and the § 20.3 definition. The Commission tentatively concluded that § 20.7 no longer serves a useful purpose and stressed that eliminating § 20.7 would not change the definition of “mobile service” contained in § 20.3 of the rules.

II. Streamlining Part 20 of the Commission’s Rules

11. Elimination of § 20.9. The Commission removes § 20.9 from its rules, eliminating that section’s approach for determining whether services provided in the specified frequency bands are CMRS. There is unanimous support for this rule change, with every commenter addressing this issue supportive of the Commission removing § 20.9 in its entirety. This action is also consistent with the Commission’s recent steps in the WRS Second Report and Order and Further Notice of Proposed Rulemaking, released on August 3, 2017 (WT Docket No. 10–112) (82 FR 41580), to harmonize renewal and other regulatory requirements across services and to simplify regulatory processes. Going forward, licensees and applicants whose services were subject to § 20.9 can rely on the relevant definitions in the Communications Act and the Commission’s rules—which articulate with sufficient clarity what constitutes CMRS and PMRS—to identify the nature of their services in relevant Commission applications. Akin to their counterparts operating in other frequency bands that already accommodate flexible use, these entities may provide any service that is consistent with the technical rules of the band in which they operate. Licensees will no longer need to seek waivers or submit certifications to the Commission before they can provide non-commercial services; they need only look to the definitions of CMRS and PMRS to determine their regulatory status and proceed accordingly.

12. Eliminating § 20.9 is consistent with the Commission’s ongoing efforts to facilitate flexible use of spectrum, and will allow licensees to respond more quickly to consumer demand and competitive forces. Moreover, removing § 20.9 will help eliminate uneven and disparate regulation of wireless applicants and licensees in different spectrum bands. The Commission finds that the public interest is best served by treating similarly situated entities on a more equal, comparable basis. As previously discussed, Congress’s intent in creating the CMRS and PMRS umbrella service definitions was to ensure that similarly situated service providers were operating on the same regulatory footing, and the Commission aimed to effectuate this intent by adopting § 20.9. But as a result of the changes that have occurred in the preceding two decades, entities operating in frequency bands subject to § 20.9 are not treated the same as their competitors in other bands. Rather, if they wish to use the spectrum for non-commercial services, this subset of licensees and applicants must file requests for waivers of § 20.9(a) or certifications that operations are not CMRS under § 20.9(b), and they must endure delays associated with the required public notice periods, even though the requests and certifications are usually granted on a routine basis. Several commenters highlight how elimination of § 20.9 will reduce burdens for such entities, enabling them to put their spectrum to efficient use more quickly.

13. The Commission also expects that removing § 20.9 will enable service providers to more easily meet the continuing demand for PMRS and other non-traditional CMRS operations that serve the public interest. The Commission concludes that elimination of § 20.9 will help bring beneficial services to businesses, state and local governments, and the public safety community, while reducing the administrative burdens and processing delays that certain providers of these services currently face.

14. A few commenters caution the Commission that any rule changes should not substantively alter CMRS and PMRS licensees’ respective regulatory obligations or expectations regarding their licenses. Nothing here is intended to substantively change the definitions of CMRS and PMRS in § 20.3 of the Commission’s rules, which generally track the statutory definitions and which provide sufficiently clear guidance to enable providers to...
continue to determine the nature of their services accurately. Nor does the Commission take any action in this Order to change the regulatory obligations that attach to CMRS operations or to PMRS operations. Entities may continue to provide both CMRS and PMRS under the same license, to the extent allowed by, and subject to, the statutes, rules, and requirements that otherwise apply to the particular service at issue. 15. As the Commission proposed in the NPRM, applicants and licensees that were subject to § 20.9 and that utilize ULS can inform Commission staff in initial, modification, transaction, or spectrum leasing applications whether they seek authorization to provide or use their service for any of the applicable service offerings—"common carrier," "non-common carrier," and/or "private, internal communications"—without any additional showing, as applicants and licensees already do in spectrum bands that already accommodate flexible use. In other words, they can select "non-common carrier" and/or "private, internal communications," as applicable, without needing to include a waiver request or certification to prove that their service is not CMRS. There is no opposition to this approach from commenters. Importantly, this will not place any additional burdens on applicants and licensees. The Commission's rules already permit entities to self-identify their regulatory status but, because of § 20.9, entities using spectrum in identified frequency bands had to go through the additional administrative processes discussed above. Based on the foregoing, the Commission eliminates the need for them to do so.

16. PMRS Presumption and Rebuttal Process. As discussed above, § 20.9(a)(14) sets forth a rebuttable presumption that "[a] mobile service that does not meet the definition of commercial mobile radio service is presumed to be a private mobile service," and it sets out the process for rebutting such a presumption. This only acts as a presumption, however, with respect to an "interested party's" challenge to a provider's claim that its service is PMRS, in light of the implicit factual assertion that the service does not meet the definition of CMRS. If the challenger cannot overcome the presumption of the validity of the provider's claim that its service does not, as a factual matter, meet the § 20.3 definition of CMRS, then the PMRS status of the operation at issue has been established as a definitional matter under the rule and statute, and this challenge will fail. 17. In the NPRM, the Commission observed that the rules do not need to identify several bands that will be treated as CMRS in order to establish a framework within which a provider can claim PMRS status (presumptively or otherwise). There are other approaches for identifying whether a licensee's proposed or existing operations should be classified one way or another, such as allowing the licensee, in the first instance, to make that determination with respect to its individualized operations, based on the existing definitions of PMRS and CMRS. The Commission observed that § 20.3 of the rules defines CMRS to include mobile services that are the "functional equivalent" of CMRS, and therefore—in combination with other Commission rules and processes—ensures that any service that amounts to the "functional equivalent" of CMRS is treated as such. 18. The Commission recognized, however, that elimination of § 20.9 in its entirety would also include deletion of § 20.9(a)(14)(ii), which enumerates several factors that the Commission may consider in determining whether a mobile service is the "functional equivalent" of CMRS in cases where an interested party challenges a claim that operations are presumptively classified as PMRS. The Commission sought comment on whether retaining § 20.9(a)(14) or any of its subsections would be useful "as a practical and procedural set of guidelines" for both mobile service providers and the Commission when applying the definitions of CMRS and PMRS, and whether it should move this language to § 20.3 or another section in part 20. Only two commenters addressed the issue. One argued for the removal of the PMRS presumption while the other requested that the Commission maintain sufficient clarity in the definition of, and requirements for, PMRS and CMRS classifications.

19. The Commission retains the key aspects of the PMRS presumption by revising its definition of Private Mobile Radio Service in § 20.3 to provide a party with a presumption that it meets that definition (as against a challenge that the service is CMRS), if the service in question does not meet the three specific elements for qualifying as a CMRS under paragraph (a) of the § 20.3 CMRS definition. In such a case, a challenger would bear the burden of proving that the service meets paragraph (b) of the CMRS definition (i.e., that it is the functional equivalent of a service that satisfies the paragraph (a) elements) and therefore does not qualify as PMRS. While the rules thus continue to recognize that a service not meeting the specific paragraph (a) elements of the CMRS definition is presumptively PMRS, the Commission declines otherwise to carve out the rebuttal process from its elimination of section 20.9. The Commission anticipates that the CMRS and PMRS definitions in § 20.3 as revised in this Order will provide sufficient clarity to enable the Commission, licensees and spectrum lessees, and members of the public to differentiate between CMRS and PMRS and, relatedly, to assess whether a licensee is offering a service that is the "functional equivalent" of CMRS. At the same time, The Commission has identified various benefits of eliminating the use of the scheme embodied in § 20.9, which has discouraged the flexible use of spectrum in the identified frequency bands and created unnecessary hurdles for a subset of mobile service providers. 20. In sum, the Commission sees no need to retain any of the § 20.9 provisions about whether service being provided in a particular frequency band is commercial or private, or to retain rebuttal procedures crafted as part of the § 20.9 approach. Even so, § 20.9(a)(14), interested parties will continue to have avenues available to

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2 As the Commission explained in the NPRM, such CMRS obligations include, but are not limited to, provisions of E911 services, obligations pursuant to the Communications Assistance for Law Enforcement Act, and compliance with hearing aid compatibility requirements.

3 This subsection's reference to the definition of CMRS is stated without limitation and therefore includes a service that is defined as CMRS under either the "(a)" or "(b)" paragraphs of the § 20.3 definition of CMRS.

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4 Note that this definition includes services meeting the three elements of the definition's (a) paragraph and services meeting the definition's (b) paragraph covering services that are the functional equivalent of satisfying the three elements of paragraph (a).

47 CFR 20.3 (defining Private Mobile Radio Service as a "mobile service that is neither a commercial mobile radio service nor the functional equivalent of a service that meets the definition of commercial mobile radio service"); 47 U.S.C. 332(d)(3) (defining "private mobile service" as "any mobile service . . . that is not a commercial mobile service or the functional equivalent of a commercial mobile service, as specified by regulation by the Commission").
challenge whether an entity’s operation is “non-common carrier” or “private internal communications.” Elimination of the § 20.9(a)(14) process thus neither materially affects the opportunity for interested parties to challenge an entity’s claim of private status, nor alters the distribution of the burden of proof in adjudicating such a challenge (i.e., a party challenging a licensee’s claim of private status bears the burden of presenting sufficient allegations of fact to overcome the presumptive validity of that claim). Similarly, the exemplary factors for determining whether a service is the “functional equivalent” of CMRS, discussed in the CMRS Second Report and Order, remain probative in potential challenges, even if they are no longer memorialized in the Commission’s rules. Nonetheless, given concerns raised by commenters, and for ease of future reference for parties seeking to rely on them as illustrative examples, the Commission moves the “functional equivalent” exemplary factors to the definition of CMRS in § 20.3 and slightly revise the rule to indicate that reliance on these examples is permissible but not required. Finally, nothing in this action alters the Commission’s authority, independent of § 20.9, to take enforcement action against a licensee that tries to avoid CMRS regulation by misrepresenting that its service is or will be operated on a “non-common carrier” or “private, internal communications” basis.

21. Elimination of § 20.7. Most commenters do not address the Commission’s proposal to remove § 20.7, which lists certain services in various Commission rules parts that meet the statutory definition of “mobile services.” T-Mobile is the only party that raises a concern with removal of a specific subclass of the rule, § 20.7(h). Section 20.7(h) includes within the list of mobile services “[u]nlicensed services meeting the definition of [CMRS] in § 20.3, such as the resale of [CMRS], but excluding unlicensed radio frequency devices under part 15 of this chapter (in radio unlicensed personal communications service devices).” T-Mobile argues that this language represents an intentional decision by the Commission to exclude part 15 unlicensed services from the definition of “mobile service” in § 20.7. T-Mobile asks the Commission to either preserve § 20.7(h) or incorporate its wording into § 20.3.

22. The Commission eliminates § 20.7, which provides an outdated and incomplete list of some, but not all, services that meet the definition of “mobile service” as used in the Act. This approach is consistent with the Commission’s elimination of § 20.9, in favor of relying instead on the definition of CMRS in § 20.3. As is the case with respect to the definition of CMRS, § 20.3 clearly articulates the definition of “mobile service,” consistent with the statutory definition. Elimination of § 20.7 will thus not affect the Commission’s understanding or application of the term “mobile service” in the Act or under the Commission’s rules.

23. Regarding the concern raised by T-Mobile about the regulatory categorization of part 15 unlicensed devices, the Commission found, in the CMRS Second Report and Order, that the definition of “mobile service” in the 1993 OBRA includes “service for which a license is required in a personal communications service,” and therefore concluded that “mobile service” does not include unlicensed PCS and part 15 devices. This action should in no way be construed as affecting the Commission’s findings in the CMRS Second Report and Order. Nonetheless, to ensure that there is no confusion on this issue, the Commission revises § 20.3 to make clear that the term “mobile service” explicitly excludes unlicensed radio frequency devices under part 15 of the Commission’s rules.

24. Edits to parts 1, 4, and 9 of the Rules. Consistent with the Commission’s proposal in the NPRM and its efforts to streamline its rules, the Commission makes corrective edits to rule parts that errantly cross-reference § 20.9 for the definition of CMRS, rather than cross-referencing the definition in § 20.3, the definitions section for part 20. Specifically, § 4.3(f) of the rules, which defines “wireless service providers” that are subject to outage reporting requirements, cross-references section 20.9 for a definition of CMRS. Section 9.3, related to the provision of interconnected VoIP services, similarly defines CMRS as “Commercial Mobile Radio Service, as defined in § 20.9 of this chapter.” The Commission amends both sections to remove the reference to § 20.9 and refer instead to the definition of CMRS in § 20.3.

25. CTIA requested changes to § 1.907’s definitions of Private Wireless Services and Wireless Telecommunications Services to remove cross-references to other CFR rule parts that appear in those definitions. The CMRS proceeding has focused on the treatment of services defined and regulated as PMRS and CMRS under part 20 of the Commission’s rules and cross-references in several other related rules. While the definitions for which CTIA seeks modification are not coextensive with the definitions of PMRS and CMRS, the Commission sought broad comment in the CMRS proceeding on whether to eliminate the itemized, service-by-service approach to classifying wireless services that the Commission had superimposed over the statutory definitions, in favor of an approach that enabled applicants and licensees themselves to classify—under straightforward statutory definitions—what type of permitted flexible operations they had chosen to provide (rather than forcing them to proceed under a categorical framework that requires parties to seek an exception from the Commission when their choice of flexible operations will not line up with the correct statutorily-defined wireless classification that the rules are forcing them into). CTIA’s proposal for eliminating the categorical list of services classified as Wireless Telecommunications Services under the § 1.907 definitions is virtually indistinguishable in these regards from the proposal the Commission made for CMRS, as the elimination of these categories from the Wireless Telecommunications Service definition will remove the needless inefficiency and reduce the rigidity of such a categorical approach, while leaving intact in the rule the critical classification benchmark—i.e., the definition of “telecommunications service” in section 3 of the Act—on which applicants and licensees can rely in choosing to provide Wireless Telecommunications Service. In contrast, the Commission does not, in the CMRS proceeding, modify the § 1.907 definition of Private Wireless Service because this aspect of CTIA’s proposals addresses a definition in the rules that does not expressly invoke a statutory definition to provide a ready benchmark that can replace the categories of service that are listed categorically as comprising (and defining) the Private Wireless Services. Accordingly, CTIA’s proposal for this definition, whatever the merits, is not part of the regulatory changes that the Commission envisioned in this proceeding, and the Commission therefore denies this aspect of CTIA’s request without prejudice.

26. Regulatory Status on FCC Forms. In the NPRM, the Commission requested comment on whether it would need to make changes to any of its forms if it were to eliminate § 20.9. For example, it noted that Form 603 (used for assignments and transfers of control) does not include an option for an assignee/transferee to indicate a different regulatory status for a license.
at issue in the proposed transaction, and suggested that, if the Commission eliminated § 20.9, it would need to revise Form 603 to permit such a designation. The Commission also sought comment on whether the regulatory status options provided on Form 601 and other forms—“common carrier,” “non-common-carrier,” and “private, internal communications”—were confusing, and asked whether they should be replaced with or altered to include the CMRS/PMRS terminology.

27. Only one party addresses the NPRM questions about forms, recommending that the Commission retain the three regulatory status categories currently used on Form 601 and other forms—“common carrier,” “non-common carrier,” and “private/ internal communications.” The Commission decides not to replace the current form designations of “common carrier,” “non-common carrier,” and “private, internal communications” with the alternatives of CMRS or PMRS. The Commission concludes that the change would create a less detailed description of regulatory status for certain licensees. Further, the current designations, in combination with a filer’s responses to form questions regarding the type of radio service being provided, are used by the Commission to determine, among other things, regulatory fees and which filings may need to go on an accepted for filing public notice. The Commission also declines to revise Form 601 or other forms to add an additional question asking an entity to distinguish whether it is providing, or plans to provide, “CMRS” and/or “PMRS.” Adding this to the Commission’s forms and to ULS would be costly, without providing the Commission with additional useful information beyond what it already obtains from the combination of questions about regulatory status and type of radio service being provided.

28. The current ULS Form 601 permits an applicant to select the status of its radio service operation as “common carrier,” “non-common carrier,” or “private, internal communications,” or some combination, to the extent applicable. This status must be selected when an applicant first files for an authorization. Under this action, applicants in services previously covered by § 20.9 will have the same flexibility as other licensees that utilize ULS to select the appropriate status or statuses, without additional regulatory requirements. A licensee also can use Form 601 to modify its regulatory status to add an additional status or change the status under which it was originally licensed. Applications on Form 601 to modify regulatory status are processed as a minor modification to the subject authorization.

29. The current Form 603 does not permit a proposed assignee or transferee to make any selection regarding regulatory status. Rather, the proposed assignee or transferee receives the license with the regulatory status as designated by the assignor or the pre-transfer licensee. Because a change to Form 603 would require corresponding changes to ULS, including costly reprogramming and additional time to implement, the Commission directs staff to explore an interim process for permitting a proposed assignee or transferee to modify the regulatory status for a license as part of the assignment or transfer of control application, perhaps by permitting the applicants to provide in an exhibit a request for change. In the interim and as can be done under the Commission’s current processes, assignees or transferees will be able to file a modification on Form 601 to change the regulatory status of a license obtained pursuant to a transaction after the transaction is consummated.

30. The current Form 608, Item 9, permits a proposed spectrum lessee to indicate at the time of filing an initial spectrum leasing application what regulatory status or statuses are applicable to its planned operations on the leased spectrum. Once a spectrum leasing arrangement is granted or accepted, as applicable, the spectrum lessee may file a lease modification on Form 608 to indicate a change in the regulatory status as application to its operations under the spectrum leasing arrangement.

31. Other issues. Several commenters raise issues that were not discussed in the NPRM. For example, MSI and NPPD highlight several part 22 rules that they argue are ripe for reform, and ask the Commission to initiate a separate rulemaking to review these and other part 22 rules. Those issues are beyond the scope of the CMRS proceeding and the Commission does not address them here.

I. Procedural Matters

A. Paperwork Reduction Act Analysis

32. This document does not contain new or modified information collection requirements 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 businesses or 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).

B. Congressional Review Act

33. The Commission will send a copy of the Order to Congress and the Government Accountability Office pursuant to the Congressional Review Act.

C. Final Regulatory Flexibility Certification

34. The Regulatory Flexibility Act of 1980, as amended (RFA), requires that an agency prepare a regulatory flexibility analysis for notice and comment rulemakings, unless the agency certifies that “the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities.” The Final Regulatory Flexibility Certification of the possible economic impact of the rule changes contained in the Report and Order was attached as Appendix B of the Order.

D. Contact Information

35. For further information regarding the Order, contact Kathy Harris at (202) 418–0609, Kathy.Harris@fcc.gov, or Thomas Reed at (202) 418–0531, Thomas.Reed@fcc.gov.

II. Ordering Clauses

36. Accordingly, it is ordered, pursuant to sections 1, 2, 4(i), 4(j), 7, 301, 303, 307, 308, 309, and 332 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 152, 154(j), 157, 301, 303, 307, 308, 309, and 332, that this report and order in WT Docket No. 16–240 is adopted.

37. It is further ordered that the report and order shall be effective 30 days after publication of a summary of the report and order in the Federal Register.

38. It is further ordered that part 1 of the Commission’s rules, 47 CFR part 1, part 4 of the Commission’s rules, 47 CFR part 4, part 9 of the Commission’s rules, 47 CFR part 9, and part 20 of the Commission’s rules, 47 CFR part 20, are amended as specified in Appendix A of the Order, effective 30 days after publication in the Federal Register.

39. It is further ordered that, pursuant to Section 801(a)(1)(A) of the Congressional Review Act, 5 U.S.C. 801(a)(1)(A), the Commission shall send a copy of the report and order to Congress and to the Government Accountability Office.

40. It is further ordered that the Commission’s Consumer and Governmental Affairs Bureau, Reference Information Center, shall send a copy of the report and order, including the Final Regulatory Flexibility Certification, to
the Chief Counsel for Advocacy of the Small Business Administration.

41. It is further ordered that, if no petitions for reconsideration or applications for review are timely filed, this proceeding shall be terminated and the docket closed.

List of Subjects in 47 CFR Parts 1, 4, 9, and 20

Commercial mobile services, Disruptions to communications, Interconnected voice over internet protocol services, Practice and procedure.

Federal Communications Commission.

Katura Jackson,
Federal Register Liaison Officer, Office of the Secretary.

Final rules

For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR Parts 1, 4, 9, and 20 as follows:

PART 1—PRACTICE AND PROCEDURE

§ 1.907 Definitions.

Wireless Telecommunications Services. Wireless Radio Services, whether fixed or mobile, that meet the definition of “telecommunications service” as defined by 47 U.S.C. 153, as amended, and are therefore subject to regulation on a common carrier basis.

PART 4—DISRUPTIONS TO COMMUNICATIONS

§ 4.3 Communications providers covered by the requirements of this part.

(f) Wireless service providers include Commercial Mobile Radio Service communications providers that use cellular architecture and CMRS paging providers. See § 20.3 of this chapter for the definition of Commercial Mobile Radio Service. Also included are affiliated and non-affiliated entities that maintain or provide communications networks or services used by the provider in offering such communications.

PART 9—INTERCONNECTED VOICE OVER INTERNET PROTOCOL SERVICES

§ 9.3 Definitions.

CMRS. Commercial Mobile Radio Service, as defined in § 20.3 of this chapter.

PART 20—COMMERCIAL MOBILE SERVICES

§ 20.3 Definitions.

Commercial mobile radio service.

§ 20.9 [Removed and Reserved]

§ 20.7 [Removed and Reserved]

§ 20.6 [Removed and Reserved]

§ 20.5 [Removed and Reserved]

§ 20.4 [Removed and Reserved]

§ 20.3 [Removed and Reserved]

§ 20.2 [Removed and Reserved]

§ 20.1 [Removed and Reserved]

§ 20.9 [Removed and Reserved]

§ 20.7 [Removed and Reserved]

§ 20.6 [Removed and Reserved]

§ 20.5 [Removed and Reserved]

§ 20.4 [Removed and Reserved]

§ 20.3 [Removed and Reserved]

§ 20.2 [Removed and Reserved]

§ 20.1 [Removed and Reserved]

DEPARTMENT OF VETERANS AFFAIRS

48 CFR Parts 816, 828, and 852

RIN 2900–AP82

Revise and Streamline VA Acquisition Regulation To Adhere to Federal Acquisition Regulation Principles (VAAR Case 2014–V002)

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: The Department of Veterans Affairs (VA) adopts as final the proposed rule published on March 13, 2017, as a final rule with five technical non-substantive changes.
DATES: This rule is effective on March 23, 2018.

FOR FURTHER INFORMATION CONTACT: Mr. Ricky Clark, Senior Procurement Analyst, Procurement Policy and Warrant Management Services, 003A2A, 425 I Street NW, Washington, DC 20001, (202) 632–5276 (this is not a toll-free telephone number).

SUPPLEMENTARY INFORMATION: This document adopts as a final rule without change a proposed rule amending the VA Acquisition Regulation (VAAR). On March 13, 2017, VA published a proposed rule in the Federal Register (82 FR 13418) which announced VA’s intent to amend regulations for parts 816 and 828. On April 4, 2017, VA published in the Federal Register a correction to the proposed rule at 82 FR 16322.

We provided a 60 day comment period for interested parties to submit comments to VA on or before May 12, 2017. Five respondents submitted comments to the proposed rule. A discussion of the comments is provided below. One commenter asserted that the restrictions imposed on VA regarding 38 U.S.C. 8127 can often impact the efficiency of using the combined synopsis/solicitation method. The commenter recommends: “Creating a policy and procedure for COs to utilize the commercial combo and still comply with the “purpose” of 38 U.S.C. 8127 but COs will need guidance and limitations.”

The parts in this final rule do not address acquisition of commercial items or simplified acquisition procedures set forth in the Federal Acquisition Regulation (FAR) parts 12 and 13 or VAAR parts 812 and 813. However, in response to the comment, VA does not concur. In order to satisfy the requirements of 38 U.S.C. 8127, VA must ensure that preference is given for awards to service-disabled veteran-owned small businesses and veteran-owned small businesses, even for acquisition of commercial items under FAR part 13. Accordingly, VA has revised its market research process to facilitate the identification of verified and qualified veteran-owned firms for contract awards. VA’s contracting officers will be able to perform the required market research and identify veteran-owned firms more quickly and efficiently as the learning curve diminishes. VA is committed to complying with 38 U.S.C. 8127, ensuring the mission is not compromised, and that contracting officers are making awards in a timely fashion. Additionally, implementation of 38 U.S.C. 8127, the Veterans Benefits, Healthcare, and Information Technology Act of 2006, does not prohibit the use of the combined synopsis/solicitation method set forth in FAR part 12.

One commenter expressed general support for veterans programs and complimented the revisions made in the rule. VA appreciates the commenter’s support of veterans.

One commenter noted that the proposed rule does not require formal rulemaking. VA removed the term “formal” in the description of its rulemaking process. However, in accordance with 41 U.S.C. 1707 (the Office of Federal Procurement Policy Act), a procurement policy, regulation, procedure, or form (including an amendment or modification thereto) may not take effect until 60 days after it is published for public comment in the Federal Register. During this process where VA is examining its VA Acquisition Regulation, proposed rules will be published for public comment in accordance with the Federal rulemaking process.

One commenter stated that this rule could benefit from further explanation as currently in VA there is confusion regarding how consignment agreements are entered into. The first sentence of section 816.770 has been changed from “A consignment agreement is not a contract” to “Consignment agreements shall only be established under a contract and by a contracting officer.”

The final rule informs the public that consignment agreements are permitted to be used at VA. As stated in the proposed rule: “This Proposed Rule will streamline the VAAR to implement and supplement the FAR only when required, and remove internal agency guidance as noted above in keeping with the FAR principles concerning agency acquisition regulations.” Internal agency guidance and procedures relating to consignment agreements are included in M816, the corresponding VA Acquisition Manual (VAAM) that will be issued within VA when the revised VAAR part 816 is published. The information included in the VAAM will address the concerns raised by the commenter.

One commenter recommends that VA consider the use of cascading set-asides in FAR part 16 related acquisitions. The commenter also takes issue with VA’s implementation of 38 U.S.C. 8127 in that it doesn’t explicitly allow cascading set-asides and believes that this slows the procurement process. We are making no change to VAAR Part 816 at this time based on this comment.

This comment was beyond the scope of the proposed rule. Guidance on cascading set-asides would more appropriately be placed in VAAR Part 819. VA will consider including guidance on cascading when VA proposes revisions to VAAR Part 819. VA is committed to complying with 38 U.S.C. 8127, ensuring the mission is not compromised, and that contracting officers are making awards in a timely fashion.

Technical Non-Substantive Changes to the Proposed Rule

This final rule removes the citation of 38 U.S.C. 501 from parts 828 and 852, 41 U.S.C. 1121 and 41 U.S.C. 1702 to the authority of parts 816, 828, and 852 which address overall direction of procurement policy, acquisition planning and management responsibilities.

This final rule revises subsection 816.203–4(f) to remove “or under a VA provider agreement.” This clarifies that the prescribed clause applies to VA contracts and should not be utilized for VA provider agreements that are not made under a contract. Clause 852.216–72, “Proportional Economic Price Adjustment of Contract Price(s) Based on a Price Index,” included in a footnote the sentence, “Selection of the wrong index may result in a claim and reformation of a contract.” This sentence has been removed. The deleted text represents internal VA guidance for VA contracting personnel and is not appropriate for inclusion in a regulation.

This final rule revises section 828.306(b) by replacing “VA Manual MP–1, Part II, Chapter 3” with “VA Policy” in reference to the policy document for emergency or sporadic ambulance services. This change was made to avoid the need to amend the regulation should VA place this policy in a different document in the future.

This final rule revises section 852.216–73(a) by including “by a contracting officer” at the end of the paragraph. This is to clarify that contract modifications must be performed by a contracting officer.

Sections 852.216–73(a) and 852.216–74 are revised to remove the terms “ALT #1” and “ALT #2” from the titles of the clauses as well as from their prescriptions at section 816.203–4(e)(3) and (4).

Based on the rationale set forth in the proposed rule and in this document, VA is adopting the provisions of the proposed rule as a final rule with the changes discussed above.

Paperwork Reduction Act

Although this action contains provisions constituting collections of
information at 48 CFR 828.306 and 852.228–71, under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521), no new or proposed revised collections of information are associated with this final rule. The information collection requirements for 48 CFR 828.306 and 852.228–71 are currently approved by the Office of Management and Budget (OMB) and have been assigned OMB control number 2900–0590.

Regulatory Flexibility Act

This final rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. This final rule will generally be small business neutral. The overall impact of the final rule will be of benefit to small businesses owned by veterans or service-disabled veterans as the VAAR is being updated to remove extraneous procedural information that applies only to VA’s internal operating procedures. VA estimates no cost impact to individual business resulting from these rule updates. On this basis, the adoption of this final rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. Therefore, under 5 U.S.C. 605(b), this final rule is exempt from the initial and final regulatory flexibility analysis requirements of sections 603 and 604.

Executive Orders 12866, 13563 and 13771

Executive Orders (E.O.) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits of reducing costs, of harmonizing rules, and of promoting flexibility. E.O. 12866, Regulatory Planning and Review defines “significant regulatory action” to mean any regulatory action that is likely to result in a rule that may: “(1) Have an annual effect on the economy of $100 million or more or adversely affect 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; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in this Executive Order.”

VA has examined the economic, interagency, budgetary, legal, and policy implications of this regulatory action, and it has been determined to be a significant regulatory action under E.O. 12866, because it raises novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in this Executive order. VA’s impact analysis can be found as a supporting document at http://www.regulations.gov, usually within 48 hours after the rulemaking document is published. Additionally, a copy of the rulemaking and its impact analysis are available on VA’s website at http://www.va.gov/orpm by following the link for VA Regulations Published from FY 2004 Through Fiscal Year to Date. This rule is not expected to be subject to the requirements of E.O. 13771, Reducing Regulation and Controlling Regulatory Costs, because this rule is expected to result in no more than de minimis costs.

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, and tribal Governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any one year. This final rule will have no such effect on State, local, and tribal Governments or on the private sector.

List of Subjects

48 CFR Part 816

Government procurement.

48 CFR Part 828

Government procurement, Insurance, Surety bonds.

48 CFR Part 852

Government procurement, Reporting and recordkeeping requirements.

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. Gina S. Farrisee, Deputy Chief of Staff, Department of Veterans Affairs, approved this document on December 15, 2017, for publication.


Consuela Benjamin,

Regulations Development Coordinator, Office of Regulation Policy & Management, Office of the Secretary, Department of Veterans Affairs.

For the reasons set out in the preamble, VA amends 48 CFR, chapter 8, parts 816, 828, and 852 as follows:

PART 816—TYPES OF CONTRACTS

■ 1. The authority citation for part 816 is revised to read as follows:


Subpart 816.1 [Removed and Reserved]

■ 2. Subpart 816.1 is removed and reserved.

■ 3. Subpart 816.2, consisting of section 816.203, is added to read as follows:

Subpart 816.2—Fixed-Price Contracts

816.203 Fixed-price contracts with economic price adjustment.

816.203–4 Contract clauses.

(e) The contracting officer shall, when contracting by negotiation, use the following clauses.

(1) The contracting officer shall insert the clause at 852.216–71, “Economic Price Adjustment of Contract Price(s) Based on a Price Index,” in solicitations and firm fixed price contracts, subject to FAR 16.203–4(d)(1) and when changes to a price index will be used to calculate corresponding changes to the total contract price or unit prices of the contract.

(i) Exceptions:

(A) Do not use this clause when changes to the price index will apply to only a component part of the contract price.

(B) Do not publish or include the footnotes in the solicitation, they are only included herein to provide guidance to contracting officers.

(2) The contracting officer shall insert the clause at 852.216–72, “Proportional Economic Price Adjustment of Contract Price(s) Based on a Price Index,” in solicitations and firm fixed price contracts, and subject to FAR 16.203–4(d)(1) when changes to an industry price index shall be used to calculate changes to only a portion of the contract price or the unit prices of the contract.

(i) Exceptions:
(A) The clause should not be used when a change in the index price will be applied directly and totally to the contract price or the unit prices, i.e., when the Consumer Price Index is used to calculate changes and a 5% increase in the CPI would result in a 5% increase in the total contract price of the unit prices.

(B) Do not publish or include the footnotes in the solicitation, as they are only provided for guidance to the contracting officer.

(3) The contracting officer shall insert the clause at 852.216–73, “Economic Price Adjustment—State Nursing Home Care for Veterans,” in solicitations and firm fixed price contracts subject to FAR 16.203–4(d)(1) and the following circumstance: When changes to the Medicaid rate, as authorized by the State Medicaid Agency (SMA), shall be used to calculate corresponding changes in the total contract price or the per diem prices of the agreement or contract.

(4) The contracting officer shall insert the clause at 852.216–74, “Economic Price Adjustment—Medicaid Labor Rates,” in solicitations and firm fixed price contracts when the conditions specified in FAR 16.203–4(c)(1) apply. The clause is modifiable by increasing the 10-percent maximum limit on aggregate increases specified in paragraph (c)(4) of this section, upon the approval by the Head of the Contracting Activity (HCA) or designee.

(5) The contracting officer shall insert the clause at 852.216–75, “Economic Price Adjustment—Fuel Surcharge,” in solicitations and firm fixed price contracts when contracting by negotiation is subject to changes in the cost of fuel increases. The clause is subject to the conditions at FAR 16.203–4(d)(1).

(f) The contracting officer shall follow procedures as prescribed in FAR 16.203–4(c) and 38 CFR 51.41(b)(1) for EPA fixed price contracts based on Medicaid rates. These procedures shall be used when contracting by negotiation between the VA and the State Veteran Home for making payments under contracts for nursing home care for Veterans.

816.504 [Removed]

8. Sections 816.101, 816.101–2, and 816.101–70 [Removed]

816.106–6 [Removed]

9. Section 816.106–6 is removed.

10. Section 816.106–70 is revised to read as follows:

816.106–70 Bond premium adjustment.

(a) The clause shall be inserted in all contracts, when performance and payment bonds or payment protection is required.

(b) Unless otherwise provided in the solicitation, the clause at 852.228–70, Bond Premium Adjustment, in solicitations and contracts when performance and payment bonds or payment protection is required.

816.505 Ordering.

(b)(8) Task-order and delivery-order ombudsman. The task-order contract and delivery-order ombudsman for VA is the Associate Deputy Assistant Secretary (ADAS) for Procurement Policy, Systems and Oversight. The VA Ombudsman shall review and resolve complaints from contractors concerning all task and delivery order actions. If any corrective action is needed after reviewing complaints from contractors, the VA Ombudsman shall provide a written determination of such action to the contracting officer. Contracting officers shall be notified of any complaints submitted to the VA Ombudsman.

8. Section 816.306 is amended by revising paragraph (a) to read as follows:

828.306 Insurance under fixed-price contracts.

(a) The contracting officer shall insert the clause at 852.228–71, Indemnification and Insurance, in solicitations when utilizing term contracts or contracts of a continuing nature for ambulance, automobile and aircraft service.

Subpart 828.71 [Redesignated as Subpart 828.70]

13. Subpart 828.71 is redesignated as subpart 828.70 and revised to read as follows:

Subpart 828.70—Indemnification of Contractors for Medical Research or Development Contracts

828.7000 Scope of subpart.

828.7001 Extent of indemnification.

828.7002 Financial protection.

828.7003 Indemnification clause.

828.7000 Scope of subpart.

(a) As used in this subpart, the term “contractor” includes subcontractors of any tier under a contract containing an indemnification provision under 38 U.S.C. 7317.

(b) This subpart sets forth the policies and procedures concerning indemnification of contractors performing contracts involving medical research or research and development that involve risks of an unusually hazardous nature, as authorized by 38 U.S.C. 7317.

(c) The authority to indemnify the contractor under this subpart does not create any rights to third parties that do not exist by law.

828.7001 Extent of indemnification.

(a) A contract for medical research or development authorized by 38 U.S.C. 7303, may provide that the Government will indemnify the contractor against losses or liability specified in paragraphs (b) and (c) of this section if all of the following apply:

1. The contract work involves a risk of an unusually hazardous nature.

2. The losses or liability arise out of the direct performance of the contract.

3. The losses or liability are not covered by the financial protection required under 828.7002.

(b) The Government may indemnify a contractor for liability (including reasonable expenses of litigation or settlement) to third persons for death, bodily injury, or loss of or damage to property from a risk that the contract defines as unusually hazardous. The
indemnification will not cover liability under State or Federal worker’s injury compensation laws to employees of the contractor who are both:

(1) Employed at the site of the contract work; and
(2) Working on the contract for which indemnification is granted.

(c) The Government may indemnify the contractor for loss of or damage to property of the contractor from a risk that the contract defines as unusually hazardous.

(d) A contract that provides for indemnification in accordance with this subpart must also require that:

(1) The contractor must notify the contracting officer of any claim or suit against the contractor for death, bodily injury, or loss of or damage to property; and

(2) The Government may choose to control or assist in the defense of any suit or claim for which indemnification is provided in the contract. (38 U.S.C. 7317)

828.7002 Financial protection.

(a) A contractor shall have and maintain an amount of financial protection to cover liability to third persons and loss of or damage to the contractor’s property that meets one of the following:

(1) The maximum amount of insurance available from private sources; or

(2) A lesser amount that the Secretary establishes after taking into consideration the cost and terms of private insurance.

(b) Financial protection may include private insurance, private contractual indemnities, self-insurance, other proof of financial responsibility, or a combination that provides the maximum amount required. If a contractor elects to self-insure, the contractor must provide the contracting officer, before award, proof of financial responsibility up to the maximum amount required. (38 U.S.C. 7317)

828.7003 Indemnification clause.

The contracting officer shall include the clause, 852.228–72,

“Indemnification of Contractor—Hazardous Research Projects” in contracts and solicitations that indemnify a contractor for liability (including reasonable expenses of litigation or settlement) to third person for death, bodily injury, or loss of or damage to property from a risk that the contract defines in the performance work statement, the statement of work, or the statement of objectives as unusually hazardous.

PART 852—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

14. The authority citation for 48 CFR part 852 is revised to read as follows:


852.216–70 [Removed and Reserved]

15. Section 852.216–70 is removed and reserved.

16. Section 852.216–71 is added to read as follows:

852.216–71 Economic price adjustment of contract price(s) based on a price index.

As prescribed in 816.203–4(e)(1), insert the following clause:

ECONOMIC PRICE ADJUSTMENT OF CONTRACT PRICE(S) BASED ON A PRICE INDEX (DATE)

(a) To the extent that contract cost increases are provided for by this economic price adjustment clause, the Contractor warrants that the prices in this contract for the base period and any option periods do not include any amount to protect against such contingent cost increases.

(b) The Base and Adjusting Indexes, for the purpose of price adjustment under this clause, shall be the
to be published by .

1. All adjustments authorized under this clause shall be made by using the Base Index and Adjusting Indexes, which are published according to the following:

(1) The Base Index, for the purposes of price adjustment under this clause, shall be the most recent Index published prior to the date for receipt of offers, or the due date for receipt of best and final offers if discussions were held whichever is later. The Base Index shall remain constant for the entire term of the contract, including all option periods.

(2) The Adjusting Index shall be the most current Index published prior to the date of contract adjustment, as specified in paragraph (d) of this clause.

(c) The percentage difference between the Base Index and the Adjusting Index, rounded to the nearest .01 percent (e.g., 4.57%), will be used in calculating all adjustments to the following line items:

The prices for these line items will be multiplied by the percentage increase or decrease and the resulting amount will be added to or deducted from the original line item price for that contract period (e.g., Base Year) to arrive at the new contract price for those line items from the effective date of the adjustment to the beginning of the next contract adjustment period, rounded to the same number of decimal points as the prices originally bid. Calculations for option year contract terms will be based on the prices in the schedule for those option years.

(d) The dates of contract adjustment shall be and the starting dates of each option year, if not already included in these dates. The Contracting Officer shall retain a copy of the Base Index in the contract file and, on each date of adjustment specified in this paragraph (d), shall obtain a copy of the Adjusting Index. The Contracting Officer shall calculate the adjustment due and shall, within 5 business days, issue a modification to the contract adjusting the unit or contract prices, as specified in paragraph (c). The adjusted unit or contract prices shall be effective for all orders placed or services provided after the date of contract adjustment as specified in this paragraph (d) until the beginning of the next contract adjustment period. If the Contracting Officer fails to act, the Contractor shall request in writing a contract adjustment and any subsequent adjustment shall be retroactive to the applicable date of contract adjustment specified in this paragraph (d). The Contractor’s entitlement to price increases for a prior contract period (base year or option year) is waived unless the Contractor’s written request for an adjustment under this clause is received by the Contracting Officer no later than 30 days following the end of the base year for changes applicable to the base year, or 30 days following the end of each option year for changes applicable to that option year. The Government’s right to contract decreases for prior contract periods (base year or option year) is waived unless the Contracting Officer processes a contract modification no later than 30 days following the end of the base year for changes applicable to the base year, or 30 days following the end of each option year for changes applicable to that option year.

(e) An example of an adjustment calculation is provided herein for informational purposes only.

(1) The original contract price or line item prices for that contract term (e.g., base year) shall be used for all calculations during that particular contract term and new calculations

4. Enter the line items that will be subject to adjustment or revise this paragraph to otherwise state what prices are subject to adjustment under this clause.

5. Establish time periods for when the Contracting Officer will process adjustments. This could be “the first day of every quarter, January, April, July, and October” or “Annually on October 1st” or some other similar time periods. Since the contracting officer is responsible for initiating the change, the Contracting Officer must establish a reminder mechanism to ensure that the adjustments are accomplished within the time period specified.
Adjust Index for the current period ................................................................. 196.6
Minus the Base Index .................................................................................. −188.0
Equals the Index Point Change .................................................................... 8.6
Index Point Change Divided by the Base Index .............................................. 8.6/188.0 = 0.0457 *
Result Multiplied by 100 Equals the Percentage Change ............................... 4.57%

* This figure shall be rounded to the fourth decimal place. When the fifth decimal is 1 to 4, the figure shall be rounded down, 5 to 9, rounded up.

(3) For a line item with an original bid price of $25.00 and a 4.57 percent Index Point Change increase as of the first contract adjustment period, as shown above, the calculations for a new contract price for the first contract adjustment period would be as follows: $25.00 × 0.0457 = $1.14, $25 + $1.14 = $26.14 **. The new contract price for this line item from the beginning of that first contract adjustment period until the start of the next contract adjustment period would be $26.14 and the Contracting Officer would issue a contract modification reflecting this price change. ** The unit price adjustment shall be rounded up or down, as in paragraph (e)(1) of this clause, to match the number of decimal places in the original bid.

(4) If the Adjusting Index went down for the second adjustment period, reflecting only a 3 percent Index Point Change increase over the Base Index, the new price for this sample line item would be reduced for the second contract adjustment period from $26.14 to $25.75 as follows: $25 × .03 = $0.75, $25 + $0.75 = $25.75. Note that the calculations for the second contract adjustment period are based on the original contract price for that contract term of $25.00. The contract price for this line item is modified to reflect this new price for the second contract adjustment period.

(5) At the start of each option year and each subsequent option year period (as well as for each contract adjustment period specified in paragraph (d) during that option year, if different), the Contracting Officer shall recalculate the contract or unit prices for that first option year based on any change between Adjusting Index and the Base Index, from the original contract award date to the start of the first option period, and based on the Contractor’s new option year prices. Assume the Contractor’s bid price for the first option year for the above sample line item was $25.50 and the calculations shown in paragraph (e)(1) of this clause at the start of the first option period reflected a 6 percent Index Point Change. The new contract price for that line item at the start of the first option period would be calculated as follows: $25.50 × .06 = $1.53, $25.50 + $1.53 = $27.03. The Contracting Officer would process a contract modification reflecting a revised contract price of $27.03 for the first contract adjustment period in the first option year.

(f) Price adjustments pursuant to this clause, shall be documented by a contract modification issued by the Contracting Officer, show the Base Index (see paragraph (b)(1)), the Adjusting Index, the adjusted contract prices (see paragraph (c)), the mathematical calculations used to arrive at the adjusted contract prices, and the effective date of the adjustment (see paragraph (d)).

(g) At the start of each option year, the Contracting Officer shall, within 5 days of the start of the option year period, process a contract modification adjusting the option prices by the then current Index Point Change percentage, if any, reflecting the new adjusted prices for that first contract adjustment period in that option year.

(h) In the event that the Adjusting Index discontinues, or alters substantially, its method of calculating the Index cited herein, the parties shall mutually agree upon an appropriate substitute for determining the price adjustment described herein. If the Contracting Officer determines that the Index consistently and substantially fails to reflect market conditions, the Contracting Officer may modify the contract to specify the use of an appropriate substitute index, effective on the date the Index specified herein begins to consistently and substantially fail to reflect market conditions.

(i) Any dispute arising under this clause shall be resolved subject to the "Disputes" clause of the contract.

(End of clause)

17. Section 852.216–72 is added to read as follows:

852.216–72 Proportional economic price adjustment of contract price(s) based on a price index.

As prescribed in 816.203–4(e)(2), insert the following clause:

PROPORTIONAL ECONOMIC PRICE ADJUSTMENT OF CONTRACT PRICE(S) BASED ON A PRICE INDEX (DATE)

(a) To the extent that contract cost increases are provided for by this economic price adjustment clause, the Contractor warrants that the prices in this contract for any option periods do not include any amount to protect against such contingent cost increases.

(b) The cost index, for the purpose of price adjustment under this clause, shall

be __________% as contained in __________ as published by __________. All adjustments and upward, the percentage shall be made by using the Base Index and Adjusting Indexes, which are published __________.

(1) The Base Index, for the purposes of price adjustment under this clause, shall be the most recent Index published prior to the closing date for receipt of offers, or the due date for receipt of best and final offers if discussions are held. This Base Index shall remain constant throughout the life of the contract, including all option periods.

(2) The Adjusting Index shall be the most recent Index published prior to the date of contract adjustment, as specified in paragraph (f).

(3) At the start of each option period, the price of gasoline or diesel fuel. For example, in a solicitation for ambulance services, the Contracting Officer might enter into this block "the "Weekly U.S. Retail Gasoline Prices, Regular Grade" Index for New England" (or California or whichever index is most applicable).

4 Specify where the index can be found, such as an example for gasoline, "the Energy Information Administration website (see VAAM MR16.203–70)."

5 Provide the information on who publishes the index, such as, in an example for gasoline, "the U.S. Department of Energy."...

* Prior to issuing the solicitation, the Contracting Officer must conduct market research to determine an appropriate percentage to include in this paragraph. The percentage should reflect that portion of the unit price for the service being acquired that is applicable to the indexed commodity. For instance, in the case of an ambulance contract, research might indicate that, at the time of the solicitation being drafted and based on prior per-mile bid prices, the cost of gasoline accounts for 10% of the per mile cost of operating an ambulance. For example, if the prior bid price had been $.60 per mile, ambulances average 10 miles per gallon, and the cost of gasoline had been $1.55 per gallon, 1 mile’s worth of gasoline ($0.16) would be approximately ten (10) percent of the prior per mile bid price of $0.60 per mile. This percent must be stated in the solicitation so that the same figure applies to all bidders. This figure remains constant throughout the life of the contract.

* Enter in this block the percentage of the contract that will be subject to price adjustment, e.g., "each one-way mile of ambulance services," or the line items that will be subject to price adjustment.
Base Cost of \(^7\) and the resulting Base Cost will be the basis upon which adjustment will be made under this clause. This Base Cost will be used in calculating all adjustments to the following line items:

\(^a\) A new Base Cost will be calculated for each option year period based on the new option year prices.

(d) The percentage of the price of the indexed commodity (see paragraph (c)) remains fixed throughout the life of the contract and is not subject to modification under this clause. Any pricing actions pursuant to the “Changes” clause or other clause or provision of the contract, except for this clause, will be priced as though there were no provisions for economic price adjustment.

(e) All price adjustments shall be applicable only to the specific contract adjustment period to which the calculations are made. For every contract adjustment period, new calculations shall be made and new prices determined. Every adjustment during the Base Year will be based on the original contract prices for that contract year and every adjustment during an option year shall be based on the original contract prices for that option year. The Contracting Officer must make new calculations for each and every contract adjustment period specified in paragraph (f) and at the beginning of each new option year, if different.

(f) The dates of contract adjustment shall be \(^9\) and the starting dates of each option year, if not already included in these dates. The Contracting Officer shall retain a copy of the Base Index in the contract file and, on each date of adjustment specified herein, obtain a copy of the Adjusting Index. The Contracting Officer shall calculate the adjustment due and shall, within 5 business days, issue a modification to the contract adjusting the contract or unit price(s). The adjusted contract or unit price(s) shall be effective for all orders placed or services provided after the date of contract adjustment, as specified in this paragraph (f), until the date of the next contract adjustment. If the Contracting Officer fails to act, the Contractor shall request a contract adjustment in writing and any subsequent adjustment shall be retroactive to the applicable date of contract adjustment. The Contractor’s entitlement to price increases for a prior contract period (base year or option year) shall be waived unless the Contractor’s request for an adjustment under this clause is received by the Contracting Officer no later than 30 days following the end of the base year for changes applicable to the base year, or 30 days following the end of each option year for changes applicable to that option year. The Government’s right to contract decreases for prior contract periods (base year or option year) shall be waived unless the Contracting Officer processes a contract modification no later than 30 days following the end of the base year for changes applicable to the base year, or 30 days following the end of each option year for changes applicable to that option year.

(g) An example of an adjustment calculation is provided herein for informational purposes only.

(1) For purposes of this example, assume that a contract is for ambulance services, that the contract price is $2.10 per mile one way, that price adjustments will be made on the basis of the cost of gasoline, that the cost of gasoline represents 10% of the total cost per mile (the Base Cost is 10% of $2.10 (the per mile one way price in Line Item X)), or $0.21, and that contract adjustments will be made quarterly. If the Base Index (the price of gasoline the week prior to receipt of bids) is $1.559 per gallon and the price of gasoline at the first date of contract adjustment is $2.129 per gallon, the calculations for contract price adjustment would be as follows:

| Adjusting Index (most recent Index cost of gasoline as of the date of the first adjustment period) | \(-$1,559\) per gallon. |
| Minus the Base Index (Index cost of gasoline as of the date of receipt of offers) | \(0.570\). |
| Equals increase (or decrease) to the Base Index (see paragraph (c)) | \(0.570 + 1.559 = 1.656\) per gallon. |
| Divide increase (or decrease) to the Base Index by the Base Index | \((3.656\% \text{ increase})\). |
| Base Cost of $0.21 (10% of $2.10) multiplied by $0.768 = $2.1768 per mile (rounded to $2.18) \(*\) \(\text{**}\) | \(0.225\) (note that the original percent figure \(10\%\) multiplied by \(0.0706\) is \(0.706\%\) and rounded up to \(0.706\)). |
| This figure shall be rounded to the fourth decimal place. When the fifth decimal is 1 to 4, the figure shall be rounded down. 5 to 9, rounded up. | \(0.225\) (note that the original percent figure \(10\%\) multiplied by \(0.0706\) is \(0.706\%\) and rounded up to \(0.706\)). |
| ** The unit price adjustment shall be rounded up or down, as above, to match the number of decimal places in the original bid. |

(2) For the second contract adjustment period, all calculations would be based on the original contract bid price for that contract year, $2.10 per mile in this example. If the price of gasoline goes down during the second adjustment period to the original Base Index price of $1.559 per gallon, the adjusted contract price for that second period would return to $2.10 per mile (there would be a zero percent increase or decrease to the Base Cost and thus no change to the original bid price for that contract adjustment period). The Contracting Officer would then issue a contract modification returning the contract price from $2.18 to $2.10 per mile for that contract adjustment period. If, on the other hand, the price of gasoline actually went below the Base Index price, say to $1.449 per gallon, the calculations for the second economic price adjustment period would be as follows:

| Adjusting Index (most recent Index cost of gasoline as of the date of the second adjustment period) | \(-$1,449\) per gallon. |
| Minus the Base Index (Index cost of gasoline as of the date of receipt of offers) | \((0.110) (\text{a negative} \text{ S.}1)\). |
| Equals increase (or decrease) to the Base Index (see paragraph (c)) | \((0.110) + 1.559 = 0.469\) per gallon. |
| Divide increase (or decrease) to the Base Index by the Base Index | \((7.06\% \text{ decrease})\). |
| Base Cost of $0.21 (10% of $2.10) multiplied by \(0.0706\) = \($0.0148\) unit price decrease. | \(0.225\) (note that the original percent figure \(10\%\) multiplied by \(0.0706\) is \(0.706\%\) and rounded up to \(0.706\)). |
| New Unit price following the second economic price adjustment is $2.10 minus $0.0148 = $2.0852 per mile (rounded to $2.09). | \(0.225\) (note that the original percent figure \(10\%\) multiplied by \(0.0706\) is \(0.706\%\) and rounded up to \(0.706\)). |

(3) At the start of the first option year, the Contracting Officer shall recalculate the price per mile based on any changes in the price of gasoline from the original contract award date and based on the Contractor’s new first option year price per mile. Assuming the Contractor’s bid price per mile for the first option year was $2.25 per mile, the new Base Cost for gasoline would be 10% of $2.25, or \$0.225 (note that the original percent figure from paragraph (c) (10% in this sample) stays constant throughout the life of the contract), per mile for ambulance services for the base year and for each option year.

*Establish time periods for when the Contracting Officer will process adjustments. This could be “the first day of each month” or “the first day of every quarter, January, April, July, and October” or

\(^7\) Enter in this block the commodity applicable to the index being used, as in an example for an ambulance contract, “regular grade gasoline”.

\(^8\) Enter the line items that will be subject to adjustment, as in an example for an ambulance contract, the line items that reflect the one-way cost
Adjusting Index (most recent Index cost of gasoline as of the first day of the first option period). Minus the Base Index (Index cost of gasoline as of the date of receipt of offers) EQUALS increase (or decrease) to the Base Index. Divide the increase (or decrease) to the Base Index by the Index specified herein begins to date the Index. Contracting Officer determines that the Index has increased in this sample for the first option year from $2.10 to $2.25. Although the new unit price for the first contract adjustment period of the first option year following application of the economic price adjustment in this sample would be $2.30 per mile, all economic price adjustment calculations made during that first option year would be based on the original first option year bid price ($2.25 in this sample). If in the second contract adjustment period of the first option year, the calculations resulted in a unit price increase for gasoline of $0.0332, the adjusted price for that period would be $2.25 + $0.0332 = $2.2832, rounded to $2.28 per mile.

(h) Price adjustments pursuant to this clause, which shall be made by contract modification issued by the Contracting Officer, shall show the Base Index (see paragraph (b)(1)), the Adjusting Index, the mathematical calculations used to arrive at the adjusted contract unit price, and the effective date of the adjustment.

(i) In the event that the Disputes clause described herein, the parties shall mutually agree upon an appropriate substitute for determining the price adjustment described herein. If the Contracting Officer determines that the Index consistently and substantially fails to reflect market conditions, the Contracting Officer may modify the contract to specify use of an appropriate substitute index, effective on the date the Index specified herein begins to consistently and substantially fail to reflect market conditions.

(j) Any dispute arising under this clause shall subject to the “Disputes” clause of the contract.

(End of clause)

852.216–74 [Amended]

19. Subsection 852.216–74 is added to read as follows:

852.216–74 Economic price adjustment— Medicaid labor rates.

As prescribed in 816.203–4(e)(4), insert the following clause:

ECONOMIC PRICE ADJUSTMENT— MEDICAID LABOR RATES (DATE)

This clause does not apply to rates for non-Medicaid nursing homes.

(a) The Contractor shall notify the Contracting Officer if, at any time during contract performance, the Medicaid rate set by the State Medicaid Agency (SMA) for contract line item increases or decreases in the Schedule. The Contractor shall furnish this notice within 60 days after the increase or decrease, or within any additional period that the Contracting Officer may approve in writing, but not later than the date of final payment under this contract. The notice shall include the Contractor’s proposal for an adjustment in the contract unit prices to be negotiated under paragraph (b) of this clause, and shall include, in the form required by the Contracting Officer, supporting data explaining the cause, effective date, and the amount of the increase or decrease and the amount of the Contractor’s adjustment proposal.

(b) If the Contracting Officer and the Contractor shall negotiate a price adjustment to the contract’s unit prices and its effective date upon receipt of the notice and data under paragraph (a) of this clause. However, the Contracting Officer may postpone the negotiations until an accumulation of increases and decreases of the Medicaid labor rates (including fringe benefits) shown in the Schedule results in an adjustment allowable by the authorized nursing home official. Within ten days after this occurs, the Contracting Officer will execute an approval signature and date at the approximate locations of the nursing home official’s signature, the action of which will serve as the effective date of the adjusted rate. A copy of the fully executed document will be sent to the nursing home official for record keeping purposes.

(End of clause)
under paragraph (c)(3) of this clause. The Contracting Officer shall modify this contract as follows:

(1) Include the price adjustment and its effective date;

(2) Revise the Medicaid labor rates (including fringe benefits) as shown in the Schedule to reflect the increases or decreases resulting from the SMA adjustment. The Contractor shall continue performance pending agreement on, or determination of, any adjustment and its effective date.

(c) Any price adjustment under this clause is subject to the following limitations:

(1) Adjustment shall be limited to the effect on unit prices of the increases or decreases of the Medicaid rates of pay for labor (including fringe benefits) shown in the Schedule. There shall be no adjustment for changes in rates or unit prices other than those shown in the Schedule.

(2) No upward adjustment shall apply to supplies or services that are required to be delivered or performed before the effective date of the adjustment, unless the Contractor’s failure to deliver or perform according to the delivery schedule results from causes beyond the Contractor’s control and without its fault or negligence, within the meaning of the Default clause.

(3) There shall be no adjustment for any change in rates of pay for labor (including fringe benefits) or unit prices for material which would not result in a net change of at least three percent of the then-current total contract price. This limitation shall not apply, however, if, after final delivery of all contract line items, either party requests an adjustment under paragraph (b) of this clause.

The aggregate of the increases in any contract unit price made under this clause shall not exceed 10 percent of the original unit price. There is no percentage limitation on the amount of decreases made under this clause.

(d) The Contracting Officer, precluding certified cost and pricing data may examine the Contractor’s books, records, and other supporting data relevant to the cost of labor (including fringe benefits) and material during all reasonable times until the end of 3 years after the date of final payment under this contract or the time specified in Subpart 4.7 of the Federal Acquisition Regulation (FAR), whichever is earlier.

(End of clause)

852.216–75 [Amended]

20. Section 852.216–75 is added to read as follows:

852.216–75 Economic price adjustment clause—fuel surcharge.

As prescribed in 816.203–4(e)(5), insert the following clause:

ECONOMIC PRICE ADJUSTMENT CLAUSE—FUEL SURCHARGE (DATE)

(a) To the extent that contract fuel cost increases are provided for by this economic price adjustment clause, the Contractor warrants that the prices in this contract for any option periods do not include any amount to compensate for such contingent fuel cost increases.

(b) The fuel cost index, for the purpose of price adjustment under this clause, shall be the “Weekly Retail On-Highway Diesel Prices Index.”

(End of clause)

Example calculation of fuel price change: ….. 3rd QTR (3rd week June) first year. Fuel Price $3.05. Calculation: 3rd QTR Diesel Fuel Price decrease …….

$1.80 Calculation: ……

(f) Once approved, the date for contract fuel price adjustment will be the first Monday of the first month of each quarter unless otherwise designated at time of contract award.

(g) The Contracting Officer shall retain a copy of the Base Fuel Index establishing the Base Fuel Cost and the calculation of the price range incorporating the (+/−) x% adjustment in the contract file. All subsequent changes will be documented within the contract file and communicated to the Subsistence Prime Vendor (SPV) customers via email one week prior to the fuel price adjustment implementation.

(h) Any adjustments for fuel price changes will only be implemented if requested in writing, reviewed by both parties, and provided within the designated time frames. No retroactive cost adjustments will be made. A contract modification will be issued at inception of first increase or decrease detailing Base Fuel Cost, price range, and calculation of first fuel adjustment charge. Adjustment will remain in effect with quarterly calculation changes as needed until price falls within Base Fuel Cost price range. A contract modification will be issued to terminate the adjustment when price returns to Base Fuel Cost (+/−) x% price range.

(i) In the event that “the Energy Information Administration, Department of Energy” discontinues, or substantially alters its method of calculating the national average diesel fuel prices cited herein, the parties shall mutually agree upon an appropriate substitute for determining the price adjustment described herein. If the Contracting Officer determines the Index consistently and substantially fails to reflect market conditions, the Contracting Officer may modify the contract to specify use of an appropriate substitute Index, effective on the date the Index specified herein begins to consistently and substantially fail to reflect market conditions.

(j) Any dispute arising under this clause shall be determined in accordance with and subject to the “Disputes” clause of the contract.

(End of clause)

852.228–71 Indemnification and insurance.

As prescribed in 828.306, insert the following clause:

INDEMNIFICATION AND INSURANCE (DATE)

(a) Indemnification. The Contractor expressly agrees to indemnify and save the Government, its officers, agents, servants, and employees harmless from and against any and all claims, loss, damage, injury, and liability, however caused, resulting from, arising out of, or in any way connected with the performance of work under this contract. Further, it is agreed that any negligence or alleged negligence of the Government, its officers, agents, servants, and employees is the sole, competent, and exclusive producing cause of such claims, loss, damage, injury, and liability. At the option of the Contractor, and subject to the approval by the Contracting Officer, insurance coverage may be employed as guaranty of indemnification.
(b) Insurance. Satisfactory insurance coverage is a condition precedent to award of this contract. In general, a successful bidder must present satisfactory evidence of full compliance with State and local requirements, or those below stipulated, whichever are the greater. More specifically, workers’ compensation and employer’s liability coverage will conform to applicable State law requirements for the service defined, whereas general liability and automobile liability of comprehensive type shall, in the absence of higher statutory minimums, be required in the amounts per vehicle used of not less than $200,000 per person and $500,000 per occurrence for bodily injury and $20,000 per occurrence for property damage. State-approved sources of insurance coverage ordinarily will be deemed acceptable to the Department of Veterans Affairs, subject to timely certifications by such sources of the types and limits of the coverages afforded by the sources to the bidder. [Contracting Officer’s Note: In those instances where airplane service is to be used, substitute the word “aircraft” for “automobile” and “vehicle” and modify coverage to require aircraft public and passenger liability insurance of at least $200,000 per person and $500,000 per occurrence for bodily injury, other than passenger liability, and $200,000 per occurrence for property damage. Coverage for passenger liability bodily injury shall be at least $200,000 multiplied by the number of seats or passengers, whichever is greater.] (End of clause)

22. Section 852.228–73 is added to read as follows:

852.228–73 Indemnification of contractor—hazardous research projects.

As prescribed in 828.7003, insert the following clause:

INDEMNIFICATION OF CONTRACTOR—HAZARDOUS RESEARCH PROJECTS (DATE)

(a) This contract involves work with a risk of an unusually hazardous nature as specifically defined in the contract. The government shall indemnify the Contractor, including subcontractors of any tier, against losses or liability specified in paragraphs (b) and (c) of this clause if—

(1) The losses or liability arise out of or results from a risk defined in this contract as unusually hazardous; and

(2) The losses or liability are not covered by the financial protection required by paragraph (c).

(b) The Government shall indemnify a Contractor for—

(1) Liability (including reasonable expenses of litigation or settlement) to third persons for death, bodily injury, or loss of or damage to property from a risk that the contract defines as unusually hazardous. This indemnification shall not cover liability under State or Federal worker’s injury compensation laws to employees of the Contractor who are both:

(i) Employed at the site of the contract work; and

(ii) Working on the contract for which indemnification is granted.

(2) The Government shall also indemnify the Contractor for loss of or damage to property of the Contractor from a risk that the contract defines as unusually hazardous.

(c) A Contractor shall have and maintain an amount of financial protection to cover liability to third persons and loss of or damage to the Contractor’s property. Financial protection may include private insurance, private contractual indemnities, self-insurance, other proof of financial responsibility, or a combination that provides the maximum amount required. The financial protection provided must meet one of the following—

(1) The maximum amount of insurance available from private sources; or

(2) A lesser amount that the Secretary establishes after taking into consideration the cost and terms of private insurance.

(d) Actions in event of a claim—

(1) The Contractor shall notify the Contracting Officer of any claim or suit against the Contractor for death, bodily injury, or loss of or damage to property; and

(2) The Government may elect to control or assist in the defense of any suit or claim for which indemnification is provided in the contract.

(End of clause)

[FR Doc. 2018–03164 Filed 2–20–18; 8:45 am]

BILLING CODE 8320–01–P
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.

OFFICE OF PERSONNEL MANAGEMENT
5 CFR Part 890
RIN 3206–AN51
Federal Employees Health Benefits Program Regulations: Revised Guaranteed Issue Conversion Requirements and Technical Updates

AGENCY: Office of Personnel Management.

ACTION: Proposed rule.

SUMMARY: The Office of Personnel Management proposes to amend the guaranteed issue conversion requirements for the Federal Employees Health Benefits (FEHB) Program. Guaranteed issue insurance policies are available in all 50 states and the District of Columbia. These rules update the requirements and timeframes for FEHB Carriers to offer assistance to enrollees who may wish to enroll in guaranteed issue conversion contracts and ensure that terminating enrollees are able to receive assistance from FEHB Carriers if they choose to enroll in guaranteed issue non-group policies. This rule also updates the title of the Director for Retirement and Insurance.

DATES: Comments are due on or before April 23, 2018.

ADDRESSES: You may submit comments, identified by docket number and/or Regulatory Information Number (RIN) and title, by any of the following methods:


All submissions received must include the agency name and docket number or RIN for this document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing at http://www.regulations.gov as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT:
Delon Pinto, Senior Policy Analyst, at Delon.Pinto@opm.gov or (202) 606–0004.

SUPPLEMENTARY INFORMATION:
Authority for This Rulemaking
The Federal Employees Health Benefits (FEHB) Program is administered by the Office of Personnel Management (OPM) in accordance with Chapter 89 of Title 5 of the U.S. Code and our implementing regulations (title 5, part 890 and title 48, chapter 16). The statute establishes the basic rules for benefits, enrollment, and participation. OPM is authorized to contract with health insurance Carriers; approve health plans for participation in the program; negotiate with Carriers about benefit and premium levels; determine the times and conditions for an annual open enrollment period known as “open season” during which eligible individuals may elect coverage or change plans; make information available to employees concerning plan options; evaluate health plans on key parameters of clinical quality, customer service, resource use in comparison with national benchmarks and contract oversight requirements; apply administrative sanctions to health care providers that have committed certain violations; and administer the program’s financing.

OPM is also responsible for maintaining the funds that hold contingency reserves for the plans and the fund that receives premium payments from enrollees and Federal agencies, from which premiums are disbursed to participating plans. OPM determines whether retiring employees or survivor annuitants meet the requirements to continue health insurance coverage; takes the action necessary to terminate, accept, or continue enrollment; oversees the automatic deduction of premiums from monthly annuity checks and credits the premiums, along with the applicable Government contribution, to the proper account; processes all enrollment changes; notifies affected Carriers of enrollment changes; and keeps enrolled retirees advised of rate and benefit changes within their plan.

Background
Under Section 8902 of Title 5 of the U.S. Code, OPM may only contract with health insurance Carriers who offer terminating enrollees the opportunity to convert to a non-group policy without restrictions on pre-existing conditions. This was an additional protection to ensure that individuals could receive health insurance coverage if they no longer had access to group or non-group coverage. Currently, Carriers must offer a non-group policy to terminating enrollees. Subject to certain exceptions, all non-grandfathered health insurance policies offered in the individual market must be sold to individuals on a guaranteed issue basis.

Discussion of Proposed Changes
OPM has determined that the existing FEHB Program requirement that health insurance Carriers offer the option to convert to a non-group contract providing health benefits to FEHB enrollees and covered family members upon termination of their FEHB coverage can be revised to allow more flexibility to enrollees or covered family members and Carriers. As a result, in addition to or as an alternative to enrollment in a conversion plan offered by the Carrier when an enrollee’s or covered family member’s FEHB coverage is terminated, the enrollee or covered family member can enroll in a guaranteed issue non-group policy.

OPM will continue to offer enrollees and covered family members a 31-day extension of coverage, which may be extended to 60 days if the enrollee or covered family member can prove that the 31-day extension did not provide sufficient opportunity to convert to a non-group contract.

Additionally, the timeframe in which an agency must notify a terminating enrollee of his or her right to convert has been decreased from 60 days to 15 days to minimize the risk of a gap in coverage for the enrollee. OPM arrived at 15 days by reviewing the enrollment deadlines for non-group coverage options available to enrollees and calculating a reasonable time frame for notice that would allow terminating enrollees to subsequently enroll in coverage before the 30 day temporary extension of coverage expired.
Expected Impact of Proposed Changes

OPM expects the proposed deregulatory changes to increase the flexibility for Carriers to assist terminating enrollees in finding health insurance coverage and to reduce the costs for Carriers who will have additional options to assist enrollees with finding conversion coverage. Because we are proposing to decrease the timeline for notification by employing agencies, we expect individuals to expedite their transition from FEHB coverage to a conversion plan should they choose to enroll in conversion coverage. This increased flexibility will reduce the administrative costs for Carriers. Currently, Carriers must contract with a third party or provide an internal organization to accept any enrollees who may elect conversion coverage offered by the plan. This is a sunk cost regardless of whether enrollees actually elect conversion coverage. This can be a significant expense, particularly if the FEHBP is the only program for which the Carrier must provide this service. If the Carrier has additional flexibility regarding conversion coverage, the Carrier will no longer bear this expense. Depending on how the plan is rated, a portion of this cost will be passed on to the Government and will proportionally reduce premiums. OPM expects these proposed changes to increase the flexibility for Carriers to assist terminating enrollees in finding appropriate health insurance coverage.

OPM does not believe that this regulation will have a large impact on the broader health insurance market since FEHB generally constitutes a smaller percentage of the overall health insurance carrier's book of business. OPM also believes that employees and annuitants make their health care decisions based on a variety of factors, including networks, premiums, etc., so changes in plan enrollments will be determined by individual choice. However, because OPM does not have extensive data to determine the impact of this regulation, we are seeking comments on the following:

1. How will the changes made by this regulation impact the non-group health insurance market?
2. How will the changes made by this regulation impact the choices available to terminating FEHB enrollees?
3. How will the changes made by this regulation impact the administration of conversion coverage by FEHB Carriers?

Regulatory Impact Analysis

OPM has examined the impact of this proposed rule as required by Executive Order 12866 and Executive Order 13563, which directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public, health, and safety effects, distributive impacts, and equity). A regulatory impact analysis must be prepared for major rules with economically significant effects of $100 million or more in any one year. This rule has been designated as a "significant regulatory action," under Executive Order 12866.

E.O. 13771: Reducing Regulation and Controlling Regulatory Costs

This proposed rule is expected to be an E.O. 13771 deregulatory action. Details can be found in the “Expected Impact of the Proposed Changes” section of the rule.

Regulatory Flexibility Act

I certify that this regulation will not have a significant economic impact on a substantial number of small entities.

Federalism

We have examined this rule in accordance with Executive Order 13132, Federalism, and have determined that this rule will not have any negative impact on the rights, roles and responsibilities of State, local, or tribal governments.

List of Subjects in 5 CFR Part 890

Administration and general provisions, Administrative practice and procedure, Administrative sanctions imposed against health care providers, Benefits for former spouses, Benefits for United States hostages in Iraq and Kuwait and United States hostages captured in Lebanon, Benefits in medically underserved areas, Contributions and withholdings, Department of Defense Federal Employees Health Benefits Program demonstration project, Employee benefit plans, Enrollment, Government employees, Health benefits plans, Limit on inpatient hospital charges, physician charges, and FEHB benefit payments, Reporting and recordkeeping requirements, Retirement, Temporary continuation of coverage, Temporary extension of coverage and conversion, Transfers from retired FEHB Program, U.S. Office of Personnel Management.

Kathleen M. McGettigan,
Acting Director.

Accordingly, OPM proposes to amend title 5, Code of Federal Regulations as follows:

PART 890—FEDERAL EMPLOYEES HEALTH BENEFITS PROGRAM

1. The authority citation for part 890 continues to read as follows:


2. Amend § 890.401 by revising paragraphs (a)(1), (b)(2), and (c) to read as follows:

§ 890.401 Temporary extension of coverage and conversion.

(a) * * *

(1) An enrollee whose enrollment is terminated other than by cancellation of the enrollment or discontinuance of the plan, in whole or part, and a covered family member whose coverage is terminated other than by cancellation of the enrollment or discontinuance of the plan, in whole or in part, is entitled to a 31-day extension of coverage for self only, self plus one, or self and family, as the case may be, without contributions by the enrollee or the Government, during which period he or she is entitled to exercise the right of conversion provided for by this part. The 31-day extension of coverage and the right of conversion for any person ends on the effective date of a new enrollment under this part covering the person. In the event this 31-day temporary extension period provides insufficient opportunity for the enrollee to exercise his or her right to convert to a non-group contract with an effective date commencing before or immediately upon the end of the 31-day temporary extension of coverage, the Carrier may, on a case-by-case basis, provide an additional extension of coverage not to exceed a total of 60 days as appropriate to avoid an interruption in coverage. The enrollee or covered family member must explain to the Carrier in writing the circumstances for seeking additional extension, and the Carrier must notify the OPM Contracting Officer of any extension granted, or obtain prior approval of any extension request that is proposed for denial. * * * * *

(b) * * *

(2) Except when a plan is discontinued in whole or in part or the
Director orders an enrollment change, a person whose enrollment has been changed from one plan to another, or from one option of a plan to the other option of that plan, and who is confined to a hospital or other institution for care or treatment on the last day of enrollment under the prior plan or option, is entitled to continuation of the benefits of the prior plan or option during the continuance of the confinement. Continuation of benefits shall not extend beyond the 91st day after the last day of enrollment in the prior plan or option. The plan or option to which enrollment has been changed shall not pay benefits with respect to that person while he or she is entitled to any inpatient benefits under the prior plan or option. The gaining plan or option shall begin coverage according to the limits of its FEHB Program contract on the day after the day all inpatient benefits have been exhausted under the prior plan or option or the 92nd day after the last day of enrollment in the prior plan or option, whichever is earlier. For the purposes of this paragraph (b)(2), “exhausted” means paid or provided to the maximum benefit available under the contract.

(c)(1) The employing agency must notify the enrollee of the termination of the enrollment and of the right to convert to a non-group contract within 15 days after the date the enrollment terminates.

(2) The individual whose enrollment terminates must request conversion information from the losing Carrier within 15 days of the date of the agency notice of the termination of the enrollment and of the right to convert. The losing Carrier must provide information to the individual that will assist the individual in enrolling in a non-group contract for which the individual is eligible.

(3) When an agency fails to provide the notification required in paragraph (c)(1) of this section within 15 days of the date the enrollment terminates, or the individual fails for other reasons beyond his or her control to request conversion as required in paragraph (c)(2) of this section, he or she may request assistance with conversion to a non-group contract by writing directly to the Carrier. Such a request must be filed within 6 months after the individual became eligible to convert his or her group coverage and must be accompanied by verification of termination of the enrollment: e.g., an SF 50, showing the individual’s separation from the service. In addition, the individual must show that he or she was not notified of the termination of the enrollment and of the right to convert, and was not otherwise aware of it, or that he or she was unable, for cause beyond his or her control, to convert. The Carrier will determine if the individual is eligible to convert; and when the determination is affirmative, the individual may convert within 31 days of the determination. If the determination by the Carrier is negative, the individual may request a review of the Carrier’s determination from OPM.

(4) When an individual converts his or her coverage any time after the group coverage has ended, the non-group plan coverage is effective on the date governed by the rules applicable to the non-group plan.

(5) An individual who fails to exercise his or her rights to convert to non-group plan during the extension period is deemed to have declined the right to convert unless the Carrier, or, upon review, OPM determines the failure was for cause beyond his or her control.

[FR Doc. 2018–03510 Filed 2–20–18; 8:45 am]

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DEPARTMENT OF THE TREASURY
Office of the Comptroller of the Currency
12 CFR Part 45
RIN 1557–AE29
FEDERAL RESERVE SYSTEM
12 CFR Part 237
[Docket No. R–1596]
RIN 7100–AE96
FEDERAL DEPOSIT INSURANCE CORPORATION
12 CFR Part 349
RIN 3064–AE70
FARM CREDIT ADMINISTRATION
12 CFR Part 624
RIN 3052–AD28
FEDERAL HOUSING FINANCE AGENCY
12 CFR Part 1221
RIN 2590–AA92
Margin and Capital Requirements for Covered Swap Entities; Proposed Rule
AGENCY: Office of the Comptroller of the Currency, Treasury (OCC); Board of Governors of the Federal Reserve System (Board); Federal Deposit Insurance Corporation (FDIC); Farm Credit Administration (FCA); and the Federal Housing Finance Agency (FHFA).
ACTION: Notice of proposed rulemaking and request for comment.
SUMMARY: The Board, OCC, FDIC, FCA, and FHFA (each an Agency and, collectively, the Agencies) are seeking comment on proposed amendments to the minimum margin requirements for registered swap dealers, major swap participants, security-based swap dealers, and major security-based swap participants for which one of the Agencies is the prudential regulator (Swap Margin Rule). The Agencies are proposing these amendments in light of the rules recently adopted by the Board, the OCC, and the FDIC that impose restrictions on certain non-cleared swaps and non-cleared security-based swaps and other financial contracts (Covered QFCs) (the QFC Rules). The QFC Rules amend the definition of “Qualifying Master Netting Agreement” in the Federal banking agencies’ regulatory capital and liquidity rules to ensure that a Covered QFC is not prevented from being part of a Qualifying Master Netting Agreement solely because the Covered QFC conforms to the new requirements in the QFC Rules. The FCA also plans to propose amendments to its capital rules, including potential revisions to its regulatory definition of “Qualifying Master Netting Agreement,” which is expected to be identical to the definition used in the Federal banking agencies’ regulatory capital and liquidity rules.

The Agencies are proposing to amend the definition of “Eligible Master Netting Agreement” in the Swap Margin Rule so that it remains harmonized with the amended definition of “Qualifying Master Netting Agreement” in the Federal banking agencies’ regulatory capital and liquidity rules, and amendments to the capital rules that the FCA separately plans to propose. This proposed rule would also ensure that netting agreements of firms subject to the Swap Margin Rule are not excluded from the definition of “Eligible Master Netting Agreement” based solely on their compliance with the QFC Rules. The Agencies are also proposing that any legacy non-cleared swap or non-cleared security-based swap (i.e., a non-cleared swap or non-cleared security-based swap entered into before the applicable compliance date) that is not subject to the margin requirements of the Swap Margin Rule would not become subject to the provisions of the...
The Swap Margin Rule if the non-cleared swap or non-cleared security-based swap is amended solely to comply with the requirements of the QFC Rules.

**DATES:** Comments should be received by April 23, 2018.

**ADDRESSES:** Interested parties are encouraged to submit written comments jointly to all of the Agencies. Commenters are encouraged to use the title “Margin and Capital Requirements for Covered Swap Entities” to facilitate the organization and distribution of comments among the Agencies. Commenters are also encouraged to identify the number of the specific question for comment to which they are responding. Comments should be directed to:

**OCC:** You may submit comments to the OCC by any of the methods set forth below. Because paper mail in the Washington, DC area and at the OCC is subject to delay, commenters are encouraged to submit comments through the Federal eRulemaking Portal or email, if possible. Please use the title “Margin and Capital Requirements for Covered Swap Entities” to facilitate the organization and distribution of the comments. You may submit comments by any of the following methods:

- **Federal eRulemaking Portal—“Regulations.gov”:** Go to www.regulations.gov. Enter “Docket ID OCC–2018–0003” in the Search box and click “Search.” Click on “Open Docket Folder” on the right side of the screen. Comments and supporting materials can be viewed and filtered by clicking on “View all documents and comments in this docket” and then using the filtering tools on the left side of the screen.
- **Click on the “Help” tab on the Regulations.gov home page to get information on using Regulations.gov. The docket may be viewed after the close of the comment period in the same manner as during the comment period.**
- **Viewing Comments Personally:** You may personally inspect and photocopy comments at the OCC, 400 7th Street SW, Washington, DC 20219. For security reasons, the OCC requires that visitors make an appointment to inspect comments. You may do so by calling (202) 649–6700 or, for persons who are deaf or hearing impaired, TTY, (202) 649–5597. Upon arrival, visitors will be required to present valid government-issued photo identification and submit to security screening in order to inspect and photocopy comments.
- **Board:** You may submit comments, identified by Docket No. R–1596 and RIN 3064–AE70, by any of the following methods:
  - **Federal eRulemaking Portal:** http://www.regulations.gov. Follow the instructions for submitting comments.
  - **Email:** regs.comments@occ.treas.gov.
  - **Mail:** Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, 400 7th Street SW, Suite 3E–218, Washington, DC 20219.
  - **Hand Delivery/Courier:** 400 7th Street SW, Suite 3E–218, Washington, DC 20219.
  - **Fax:** (571) 465–4326.

**Instructions:** You must include “OCC” as the agency name and “Docket ID OCC–2018–0003” in your comment. In general, the OCC will enter all comments received into the docket and publish them on the Regulations.gov website without change, including any business or personal information that you provide such as name and address information, email addresses, or phone numbers. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

You may review comments and other related materials that pertain to this rulemaking action by any of the following methods:

- **Viewing Comments Electronically:** Go to www.regulations.gov. Enter “Docket ID OCC–2018–003” in the Search box and click “Search.” Click on “Open Docket Folder” on the right side of the screen. Comments and supporting materials can be viewed and filtered by clicking on “View all documents and comments in this docket” and then using the filtering tools on the left side of the screen.
- **Click on the “Help” tab on the Regulations.gov home page to get information on using Regulations.gov.**
- **Agency website:** http://www.fdic.gov/regulations/laws/federal. Follow instructions for submitting comments on the Agency website.
- **Email:** CommentsFDIC.gov. Include “RIN 3064–AE70” on the subject line of the message.
- **Mail:** Robert E. Feldman, Executive Secretary, Attention: Comments/RIN 3064–AE70, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.
- **Hand Delivery/Courier:** Comments may be hand delivered to the guard station at the rear of the 550 17th Street Building (located on F Street) on business days between 7 a.m. and 5 p.m. All comments received must include the agency name (FDIC) and RIN 3064–AE70 and will be posted without change to http://www.fdic.gov/regulations/laws/federal, including any personal information provided.

**FDIC:** You may submit comments, identified by RIN 3064–AE70, by any of the following methods:

- **Agency website:** http://www.fdic.gov/regulations/laws/federal. Follow instructions for submitting comments on the Agency website.
- **Email:** CommentsFDIC.gov. Include “RIN 3064–AE70” on the subject line of the message.
- **Mail:** Michael R. Thompson, Director, Office of Operations Policy, Farm Credit Administration, 1501 Farm Credit Drive, McLean, VA 22102–5090.
- **Hand Delivery/Courier:** Comments may be hand delivered to the guard station at the rear of the 550 17th Street Building (located on F Street) on business days between 7 a.m. and 5 p.m. All comments received must include the agency name (FDIC) and RIN 3064–AE70 and will be posted without change to http://www.fdic.gov/regulations/laws/federal, including any personal information provided.

**FGA:** We offer a variety of methods for you to submit your comments. For accuracy and efficiency reasons, commenters are encouraged to submit comments by email or through the FGA’s website. As facsimiles (fax) are difficult for us to process and achieve compliance with section 508 of the Rehabilitation Act, we are no longer accepting comments submitted by fax. Regardless of the method you use, please do not submit your comments multiple times via different methods.

You may submit comments by any of the following methods:

- **Email:** Send us an email at reg-comm@fga.gov.
- **FGA website:** http://www.fga.gov. Select “Public Commenters,” then “Public Comments,” and follow the directions for “Submitting a Comment.”
- **Federal eRulemaking Portal:** http://www.regulations.gov. Follow the instructions for submitting comments.
- **Mail:** Barry F. Mardock, Deputy Director, Office of Regulatory Policy, Farm Credit Administration, 1501 Farm Credit Drive, McLean, VA 22102–5090. You may review copies of all comments we receive at our office in McLean, Virginia or on our website at http://www.fga.gov. Once you are in the website, select “Public Commenters,” then “Public Comments,” and follow the directions for “Reading Submitted Public Comments.” We will show your comments as submitted, including any

I. Background

A. The Swap Margin Rule

The Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act) was enacted on July 21, 2010. Title VII of the Dodd-Frank Act established a comprehensive new regulatory framework for derivatives, which the Dodd-Frank Act generally characterizes as “swaps” (swap is defined in section 721 of the Dodd-Frank Act to include, among other things, an interest rate swap, commodity swap, equity swap, and credit default swap) and “security-based swaps” (security-based swap is defined in section 761 of the Dodd-Frank Act to include a swap based on a single security or loan or on a narrow-based security index). For the remainder of this preamble, the term “swaps” refers to swaps and security-based swaps unless the context requires otherwise. Sections 731 and 764 of the Dodd-Frank Act required the Office of the Comptroller of the Currency (OCC); Board of Governors of the Federal Reserve System (Board); Federal Deposit Insurance Corporation (FDIC); Farm Credit Administration (FCA); and the Federal Housing Finance Agency (FHFA) (collectively, the Agencies) to adopt rules jointly that establish capital and margin requirements for swap entities that are prudentially regulated by one of the Agencies (covered swap entities), to offset the greater risk to the


3 See 7 U.S.C. 6a; 15 U.S.C. 78o–10. Sections 731 and 764 of the Dodd-Frank Act add a new section 4s to the Commodity Exchange Act of 1936 as amended, and a new section, section 15F, to the Securities Exchange Act of 1934, as amended, respectively, which require registration with the Commodity Futures Trading Commission (CFTC) of swap dealers and major swap participants and the U.S. Securities and Exchange Commission (SEC) of security-based swap dealers and major security-based swap participants (each a swap entity and, collectively, swap entities). The CFTC is vested with primary responsibility for the oversight of the swaps market under Title VII of the Dodd-Frank Act. The SEC is vested with primary responsibility for the oversight of the security-based swaps market under Title VII of the Dodd-Frank Act. Section 712(d)(1) of the Dodd-Frank Act required the CFTC and SEC to issue joint rules further defining the terms swap, security-based swap, swap dealer, major swap participant, security-based swap dealer, and major security-based swap participant. The CFTC and SEC issued final joint rulemakings with respect to these definitions in May 2012 and August 2012, respectively, as codified at 77 FR 30596 (May 23, 2012); 77 FR 39826 (July 5, 2012) (corrected at 77 FR 48207 (August 13, 2012)). 17 CFR part 1; 17 CFR parts 230, 240 and 241.

4 Section 1a(39) of the Commodity Exchange Act of 1936, as amended, defines the term “prudential regulator” for purposes of the margin requirements applicable to swap dealers, major swap participants, security-based swap dealers and major security-based swap participants. The Board is the prudential regulator for any swap entity that is (i) a state-chartered bank that is a member of the Federal Reserve System, (ii) a state-chartered branch or agency of a foreign bank, (iii) a foreign bank which does not operate an insured branch, (iv) an organization operating under section 25A of the Federal Reserve Act of 1913, as amended, or having an agreement with the Board under section 25 of the Federal Reserve Act, or (v) a bank holding company, a foreign bank that is treated as a bank holding company under section 6(a) of the International Banking Act of 1978, as amended, or a savings and loan holding company (on or after the transfer date established under section 311 of the Dodd-Frank Act), or a subsidiary of such a company or foreign bank (other than a subsidiary for which the OCC or the FDIC is the prudential regulator or that is required to be registered with the CFTC or SEC as a swap dealer or major swap participant or a security-based swap dealer or major security-based swap participant, respectively). The OCC is the prudential regulator for any swap entity that is (i) a national bank, (ii) a federally chartered branch or agency of a foreign bank, or (iii) a Federal savings association. The FDIC is the prudential regulator for

Continued
covered swap entity and the financial system arising from swaps that are not cleared by a registered derivatives clearing organization or a registered clearing agency (non-cleared swaps).\(^{5}\) On November 30, 2015, the Agencies published a joint final rule (Swap Margin Rule) to establish minimum margin and capital requirements for covered swap entities.\(^{6}\)

In the Swap Margin Rule, the Agencies adopted a risk-based approach for initial and variation margin requirements for covered swap entities.\(^{7}\) To implement the risk-based approach, the Agencies established requirements for a covered swap entity to collect and post initial margin for non-cleared swaps with a counterparty that is either: (1) A financial end user with material swaps exposure,\(^{8}\) or (2) a swap entity.\(^{9}\) A covered swap entity must collect and post variation margin for non-cleared swaps with all swap entities and financial end user counterparties, even if such financial end users do not have material swaps exposure.\(^{10}\) Other counterparties, including nonfinancial end users, are not subject to specific, numerical minimum requirements for initial and variation margin.\(^{11}\)

The effective date for the Swap Margin Rule was April 1, 2016, but the Agencies established a phase-in compliance schedule for the initial margin and variation margin requirements.\(^{12}\) On or after March 1, 2017, all covered swap entities are required to comply with the variation margin requirements for transactions with other swap entities and financial end user counterparties. By September 1, 2020, all covered swap entities will be required to comply with the initial margin requirements for non-cleared swaps with all financial end users with a material swaps exposure and all swap entities.

The Swap Margin Rule’s requirements apply only to a non-cleared swap entered into on or after the applicable compliance date (covered swap); a non-cleared swap entered into prior to a covered swap entity’s applicable compliance date (legacy swap) is generally not subject to the margin requirements in the Swap Margin Rule.\(^{13}\) However, a legacy swap that is later amended or novated on or after the applicable compliance date would be deemed to be a covered swap, and therefore would become subject to the requirements of the Swap Margin Rule.\(^{14}\)

Whether a non-cleared swap is deemed to be a legacy swap or a covered swap also affects the treatment of a covered swap entity’s netting portfolios. The Swap Margin Rule permits a covered swap entity to (1) calculate initial margin requirements for covered swaps under an eligible master netting agreement (EMNA) with a counterparty on a portfolio basis in certain circumstances, if it does so using an initial margin model; and (2) calculate variation margin on an aggregate net basis under an EMNA.\(^{15}\) In addition, the Swap Margin Rule permits swap counterparties to identify one or more separate netting portfolios under an EMNA, including netting sets of covered swaps and netting sets of non-cleared swaps that are not subject to margin requirements.\(^{16}\) Specifically, a netting portfolio that contains only legacy swaps is not subject to the margin requirements set out in the Swap Margin Rule.\(^{17}\) However, if a netting portfolio contains any covered swaps, the entire netting portfolio is subject to the margin requirements of the Swap Margin Rule.\(^{18}\)

B. The QFC Rules

As part of the broader regulatory reform effort following the financial crisis to increase the resolvability and resiliency of U.S. global systemically important banking institutions\(^{19}\) (U.S. GSIBs) and the U.S. operations of foreign GSIBs (together, GSIBs),\(^{20}\) the Board, the OCC, and the FDIC adopted final rules that establish restrictions on and requirements for certain non-cleared swaps and other financial contracts (collectively, Covered QFCs) of GSIBs and their subsidiaries (the QFC Rules).\(^{21}\)

Subject to certain exemptions, the QFC Rules require U.S. GSIBs, together with their subsidiaries, and the U.S. operations of foreign GSIBs (each a Covered QFC Entity and, collectively, Covered QFC Entities) to conform Covered QFCs to the requirements of the rules.\(^{22}\) The QFC Rules generally require the Covered QFCs of Covered QFC Entities to contain contractual provisions that opt into the “temporary stay-and-transfer treatment” of the Federal Deposit Insurance Act (FDI Act)\(^{23}\) and Title II of the Dodd-Frank Act, thereby reducing the risk that the stay-and-transfer treatment would be challenged by a Covered QFC Entity’s counterparty or a court in a foreign jurisdiction.\(^{24}\) The temporary stay-and-transfer treatment is part of the special

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\(^{5}\) See 7 U.S.C. 1a(45).

\(^{6}\) Id.

\(^{7}\) See 12 CFR 252.82(c) (defining Covered QFC), 382.2(c) (same). See also 82 FR 56630 (November 29, 2017) (for OCC’s QFC Rule). See also 82 FR 50228 (October 30, 2017) (for FDIC’s QFC Rule). See also 82 FR 42882 (September 12, 2017) (for the Board’s QFC Rule). The effective date of the Board’s QFC Rule was November 13, 2017, and the effective date for the substance of the OCC’s and FDIC’s QFC Rules was January 1, 2018. The QFC Rules include a phased-in conformance period for a Covered QFC Entity that varies depending upon the counterparty type of the Covered QFC Entity. The first conformance date is January 1, 2019, and applies to Covered QFCs with GSIBs. The QFC Rules provide Covered QFC Entities an additional six months or one year to conform its Covered QFCs with other types of counterparties.

\(^{8}\) To the extent a U.S. GSIB, any of its subsidiaries, or the U.S. operations of a foreign GSIB include a swap entity for which one of the Agencies is a prudential regulator, a Covered QFC Entity may be a covered swap entity.

\(^{9}\) Id.

\(^{10}\) Id.

\(^{11}\) Id.

\(^{12}\) Id.

\(^{13}\) Id.

\(^{14}\) Id.


\(^{16}\) The U.S. operations of 20 foreign GSIBs are currently subject to the Board’s QFC Rule.

\(^{17}\) See 12 CFR 252.82(c) (defining Covered QFC), 382.2(c) (same). See also 82 FR 56630 (November 29, 2017) (for OCC’s QFC Rule). See also 82 FR 50228 (October 30, 2017) (for FDIC’s QFC Rule). See also 82 FR 42882 (September 12, 2017) (for the Board’s QFC Rule). The effective date of the Board’s QFC Rule was November 13, 2017, and the effective date for the substance of the OCC’s and FDIC’s QFC Rules was January 1, 2018. The QFC Rules include a phased-in conformance period for a Covered QFC Entity that varies depending upon the counterparty type of the Covered QFC Entity. The first conformance date is January 1, 2019, and applies to Covered QFCs with GSIBs. The QFC Rules provide Covered QFC Entities an additional six months or one year to conform its Covered QFCs with other types of counterparties.

\(^{18}\) To the extent a U.S. GSIB, any of its subsidiaries, or the U.S. operations of a foreign GSIB include a swap entity for which one of the Agencies is a prudential regulator, a Covered QFC Entity may be a covered swap entity.

\(^{19}\) 12 U.S.C. 1811 et. seq.

\(^{20}\) 82 FR 42882 (September 12, 2017); 82 FR 50228 (October 30, 2017); 82 FR 56630 (November 29, 2017).
resolution framework for failed financial firms created by the FDI Act and Title II of the Dodd-Frank Act. The stay-and-transfer treatment provides that the rights of a failed insured depository institution’s or financial company’s counterparties to terminate, liquidate, or net certain qualified financial contracts on account of the appointment of the FDIC as receiver for the entity (or the insolvency or financial condition of the entity for which the FDIC has been appointed receiver) are temporarily stayed when the entity enters a resolution proceeding to allow for the transfer of the failed firm’s Covered QFCs to a solvent party. The QFC Rules also generally prohibit Covered QFCs from allowing the exercise of default rights related, directly or indirectly, to the entry into resolution of an affiliate of the Covered QFC Entity (cross-default rights).

The Board’s QFC Rule applies to U.S. GSIBs and their subsidiaries, state branches, and state agencies, as well other U.S. operations of foreign GSIBs with the exception of banks regulated by the FDIC or OCC, Federal branches, or Federal agencies. The FDIC’s QFC Rule applies to GSIB subsidiaries that are state savings associations and state-chartered banks that are not members of the Federal Reserve System. The OCC’s QFC Rule applies to national bank subsidiaries and Federal savings association subsidiaries of GSIBs, and Federal branches and agencies of foreign GSIBs.

C. The Definitions of Qualifying Master Netting Agreement

As part of the QFC Rules, the Federal banking agencies amended the definition of qualifying master netting agreement (QMNA) in their capital and liquidity rules to prevent the QFC Rules from having disruptive effects on the treatment of netting sets of Board-regulated firms, OCC-regulated firms, and FDIC-regulated firms. The FCA plans to propose several technical and clarifying amendments to its capital regulations, including a possible revision to the definition of QMNA so that it continues to be identical to the definition in the regulations of the Federal banking agencies’ regulatory capital and liquidity rules.

The amendments to the Federal banking agencies’ capital and liquidity rules are necessary because the previous QMNA definition did not recognize some of the new close-out restrictions on Covered QFCs imposed by the QFC Rules. Pursuant to the previous definition of QMNA, a banking organization’s rights under a QMNA generally could not be stayed or avoided in the event of its counterparty’s default. However, the definition of QMNA permitted certain exceptions to this general prohibition to accommodate certain restrictions on the exercise of default rights that are important to the prudent resolution of a banking organization, including a limited stay under a special resolution regime, such as Title II of the Dodd-Frank Act, the FDIC Act, and comparable foreign resolution regimes. The previous QMNA definition did not explicitly recognize all the restrictions on the exercise of cross-default rights. Therefore, a master netting agreement that complies with the QFC Rules by limiting the rights of a Covered QFC Entity’s counterparty to close out against the Covered QFC Entity would not meet the previous QMNA definition. Thus, a failure to meet the definition of QMNA would result in a banking organization subject to one of the Federal banking agencies’ capital and liquidity rules losing the ability to net offsetting exposures under its applicable capital and liquidity requirements when its counterparty is a Covered QFC Entity. If netting were not permitted, the banking organization would be required to calculate its capital and liquidity requirements relating to certain Covered QFCs on a gross basis rather than on a net basis, which would typically result in higher capital and liquidity requirements. The Federal banking agencies do not believe that such an outcome would accurately reflect the risks posed by the affected Covered QFCs.

The amendments to the QMNA definition maintain the netting treatment for these contracts under the Federal banking agencies’ capital and liquidity rules. The amendments permit a master netting agreement to meet the definition of QMNA even if it limits the banking organization’s right to accelerate, terminate, and close-out on a net basis all transactions under the agreement and to liquidate or set-off collateral promptly upon an event of default of a counterparty that is a Covered QFC Entity to the extent necessary for the Covered QFC Entity to comply fully with the QFC Rules. The amended definition of QMNA continues to recognize that default rights may be stayed if the defaulting counterparty is in resolution under the Dodd-Frank Act, the FDI Act, a substantially similar law applicable to government-sponsored enterprises, or a substantially similar foreign law, or where the agreement is subject by its terms to, or incorporates, any of those laws. By recognizing these required restrictions on the ability of a banking organization to exercise close-out rights when its counterparty is a Covered QFC Entity, the amended definition allows a master netting agreement that includes such restrictions to continue to meet the definition of QMNA under the Federal banking agencies’ capital and liquidity rules.

II. Proposed Changes to the Swap Margin Rule

A. Proposed Amendment to the Definition of Eligible Master Netting Agreement

In the Swap Margin Rule, the Agencies explained that the current definition of EMNA was purposefully aligned with the Federal banking agencies’ then-current definition of QMNA in the capital and liquidity rules. This was to “minimize operational burden for a covered swap entity, which otherwise would have to make a separate determination as to whether its netting agreements meet the requirements of this [Swap Margin Rule] as well as comply with the regulatory capital rules.” In addition, the Agencies’ rationale for recognizing netting of non-cleared swap exposures pursuant to the Swap Margin Rule is quite similar to the Federal banking agencies’ rationale for recognizing netting of various asset and liability exposures pursuant to their capital and liquidity rules. Therefore, it is appropriate that the corresponding conditions for recognizing a robust
netting set under all three rules be the same.

Like the definition of QMNA, the definition of EMNA recognizes that default rights of the covered swap entity may be stayed pursuant to a special resolution regime such as Title II of the Dodd-Frank Act, the FIDC Act, the Federal Housing Enterprises Financial Safety and Soundness Act of 1992, the Farm Credit Act of 1971, and comparable foreign resolution regimes. However, as was the case with the previous definition of QMNA, the current EMNA definition does not explicitly recognize certain restrictions on the exercise of cross-default rights imposed under the QFC Rules. Therefore, a master netting agreement that is amended in order to address a Covered QFC Entity’s compliance with the QFC Rules will not meet the current definition of EMNA from the standpoint of a Covered QFC Entity’s counterparty that is also a swap entity. Failure to meet the definition of EMNA would require that covered swap entity to measure its exposures from covered swaps on a gross, rather than net, basis for purposes of the Swap Margin Rule. This outcome would be an unintended consequence of the QFC Rules and would be contrary to the policy decisions expressed in the Swap Margin Rule to permit initial margin to be calculated on a net basis for covered swaps subject to netting agreements.

Accordingly, the Agencies are proposing to add a new paragraph to the definition of “eligible master netting agreement” to make clear that a master netting agreement meets the definition under the Swap Margin Rule when the agreement limits “the right to accelerate, terminate, and close-out on a net basis all transactions under the agreement and to liquidate or set-off collateral promptly upon an event of default of the counterparty to the extent necessary for the counterparty to comply with the requirements of part 47, Subpart I of part 252 or part 382 of Title 12, as applicable.” This text is identical to the corresponding text used in the amended definition of QMNA in the Federal banking agencies’ capital and liquidity rules.

B. Proposed Amendment to the Meaning of “Swaps Entered Into”

As discussed above, the Swap Margin Rule’s requirements apply only to covered swaps. Legacy swaps will generally not be subject to the Swap Margin Rule’s initial and variation margin requirements. However, in the preamble to the Swap Margin Rule, the Agencies declined to include language extending legacy swap treatment to a swap if it is subsequently novated or amended after the applicable compliance date. At the time, the Agencies did not contemplate that legacy swaps might be amended solely to meet other regulatory requirements imposed by one or more of the Agencies, such as the QFC Rules.

As discussed above, Covered QFC Entities must conform to the requirements of the QFC Rules. Covered QFCs entered into on or after January 1, 2019 and, in some instances, Covered QFCs entered into before that date. To comply with the requirements governing the restrictions on Covered QFCs, a Covered QFC Entity may directly amend the contractual provisions of its Covered QFCs, or alternatively, cause its Covered QFCs to be subject to the International Swaps and Derivatives Association 2015 Resolution Stay Protocol (“Universal Protocol”) or a yet-to-be-developed protocol that is expected to be similar to the Universal Protocol. Therefore, in order to provide clarity to market participants as to the effects of an amendment that is required by the QFC Rules to a legacy QFC that is a legacy swap, the Agencies are proposing an amendment to the Swap Margin Rule that makes clear that a legacy swap will not be deemed a covered swap under the Swap Margin Rule if it is amended, either by a direct amendment or a modification causing the legacy swap to be governed by one of the aforementioned protocols, by either counterparty solely to conform to the QFC Rules.

This proposal is intended to provide certainty to a covered swap entity and its counterparties about the treatment of legacy swaps and any applicable netting arrangements in light of the QFC Rules. However, if in addition to amendments required to comply with the QFC Rules, any other amendments are contemporaneously entered into, the amended legacy swap will be treated as a covered swap in accordance with the application of the existing Swap Margin Rule.

III. Regulatory Analysis

A. Paperwork Reduction Act

FDIC: In accordance with section 3512 of the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521), the Board may not conduct or sponsor, and a respondent is not required to respond to, an information collection unless it displays a currently valid OMB control number. The FDIC reviewed the proposed rule and concluded that it contains no requirements subject to the PRA.

Board: In accordance with section 3512 of the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521), the Board may not conduct or sponsor, and a respondent is not required to respond to, an information collection unless it displays a currently valid OMB control number. The Board reviewed the proposed rule under the authority delegated to them by OMB. The proposed rule contains no requirements subject to the PRA.

B. Proposed Amendment to the Meaning of “Swaps Entered Into”

As discussed above, the Swap Margin Rule’s requirements apply only to covered swaps. Legacy swaps will generally not be subject to the Swap Margin Rule’s initial and variation margin requirements. However, in the preamble to the Swap Margin Rule, the Agencies declined to include language extending legacy swap treatment to a swap if it is subsequently novated or amended after the applicable compliance date. At the time, the Agencies did not contemplate that legacy swaps might be amended solely to meet other regulatory requirements imposed by one or more of the Agencies, such as the QFC Rules.

As discussed above, Covered QFC Entities must conform to the requirements of the QFC Rules. Covered QFCs entered into on or after January 1, 2019 and, in some instances, Covered QFCs entered into before that date. To comply with the requirements governing the restrictions on Covered QFCs, a Covered QFC Entity may directly amend the contractual provisions of its Covered QFCs, or alternatively, cause its Covered QFCs to be subject to the International Swaps and Derivatives Association 2015 Resolution Stay Protocol (“Universal Protocol”) or a yet-to-be-developed protocol that is expected to be similar to the Universal Protocol. Therefore, in order to provide clarity to market participants as to the effects of an amendment that is required by the QFC Rules to a legacy QFC that is a legacy swap, the Agencies are proposing an amendment to the Swap Margin Rule that makes clear that a legacy swap will not be deemed a covered swap under the Swap Margin Rule if it is amended, either by a direct amendment or a modification causing the legacy swap to be governed by one of the aforementioned protocols, by either counterparty solely to conform to the QFC Rules.

This proposal is intended to provide certainty to a covered swap entity and its counterparties about the treatment of legacy swaps and any applicable netting arrangements in light of the QFC Rules. However, if in addition to amendments required to comply with the QFC Rules, any other amendments are contemporaneously entered into, the amended legacy swap will be treated as a covered swap in accordance with the application of the existing Swap Margin Rule.

III. Regulatory Analysis

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Board: In accordance with section 3512 of the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521), the Board may not conduct or sponsor, and a respondent is not required to respond to, an information collection unless it displays a currently valid OMB control number. The Board reviewed the proposed rule under the authority delegated to them by OMB. The proposed rule contains no requirements subject to the PRA.

B. Proposed Amendment to the Meaning of “Swaps Entered Into”

As discussed above, the Swap Margin Rule’s requirements apply only to covered swaps. Legacy swaps will generally not be subject to the Swap Margin Rule’s initial and variation margin requirements. However, in the preamble to the Swap Margin Rule, the Agencies declined to include language extending legacy swap treatment to a swap if it is subsequently novated or amended after the applicable compliance date. At the time, the Agencies did not contemplate that legacy swaps might be amended solely to meet other regulatory requirements imposed by one or more of the Agencies, such as the QFC Rules.

As discussed above, Covered QFC Entities must conform to the requirements of the QFC Rules. Covered QFCs entered into on or after January 1, 2019 and, in some instances, Covered QFCs entered into before that date. To comply with the requirements governing the restrictions on Covered QFCs, a Covered QFC Entity may directly amend the contractual provisions of its Covered QFCs, or alternatively, cause its Covered QFCs to be subject to the International Swaps and Derivatives Association 2015 Resolution Stay Protocol (“Universal Protocol”) or a yet-to-be-developed protocol that is expected to be similar to the Universal Protocol. Therefore, in order to provide clarity to market participants as to the effects of an amendment that is required by the QFC Rules to a legacy QFC that is a legacy swap, the Agencies are proposing an amendment to the Swap Margin Rule that makes clear that a legacy swap will not be deemed a covered swap under the Swap Margin Rule if it is amended, either by a direct amendment or a modification causing the legacy swap to be governed by one of the aforementioned protocols, by either counterparty solely to conform to the QFC Rules.

This proposal is intended to provide certainty to a covered swap entity and its counterparties about the treatment of legacy swaps and any applicable netting arrangements in light of the QFC Rules. However, if in addition to amendments required to comply with the QFC Rules, any other amendments are contemporaneously entered into, the amended legacy swap will be treated as a covered swap in accordance with the application of the existing Swap Margin Rule.

III. Regulatory Analysis

A. Paperwork Reduction Act

FDIC: In accordance with section 3512 of the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521), the Board may not conduct or sponsor, and a respondent is not required to respond to, an information collection unless it displays a currently valid OMB control number. The FDIC reviewed the proposed rule and concluded that it contains no requirements subject to the PRA.

Board: In accordance with section 3512 of the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521), the Board may not conduct or sponsor, and a respondent is not required to respond to, an information collection unless it displays a currently valid OMB control number. The Board reviewed the proposed rule under the authority delegated to them by OMB. The proposed rule contains no requirements subject to the PRA.

B. Proposed Amendment to the Meaning of “Swaps Entered Into”

As discussed above, the Swap Margin Rule’s requirements apply only to covered swaps. Legacy swaps will generally not be subject to the Swap Margin Rule’s initial and variation margin requirements. However, in the preamble to the Swap Margin Rule, the Agencies declined to include language extending legacy swap treatment to a swap if it is subsequently novated or amended after the applicable compliance date. At the time, the Agencies did not contemplate that legacy swaps might be amended solely to meet other regulatory requirements imposed by one or more of the Agencies, such as the QFC Rules.

As discussed above, Covered QFC Entities must conform to the requirements of the QFC Rules. Covered QFCs entered into on or after January 1, 2019 and, in some instances, Covered QFCs entered into before that date. To comply with the requirements governing the restrictions on Covered QFCs, a Covered QFC Entity may directly amend the contractual provisions of its Covered QFCs, or alternatively, cause its Covered QFCs to be subject to the International Swaps and Derivatives Association 2015 Resolution Stay Protocol (“Universal Protocol”) or a yet-to-be-developed protocol that is expected to be similar to the Universal Protocol. Therefore, in order to provide clarity to market participants as to the effects of an amendment that is required by the QFC Rules to a legacy QFC that is a legacy swap, the Agencies are proposing an amendment to the Swap Margin Rule that makes clear that a legacy swap will not be deemed a covered swap under the Swap Margin Rule if it is amended, either by a direct amendment or a modification causing the legacy swap to be governed by one of the aforementioned protocols, by either counterparty solely to conform to the QFC Rules. This proposal is intended to provide certainty to a covered swap entity and its counterparties about the treatment of legacy swaps and any applicable netting arrangements in light of the QFC Rules. However, if in addition to amendments required to comply with the QFC Rules, any other amendments are contemporaneously entered into, the amended legacy swap will be treated as a covered swap in accordance with the application of the existing Swap Margin Rule. 
collections of information pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). Therefore, FHFA has not submitted any information to the Office of Management and Budget for review.

B. Initial Regulatory Flexibility Act Analysis

OCC: In general, the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.) requires that in connection with a rulemaking, an agency prepare and make available for public comment a regulatory flexibility analysis that describes the impact of the rule on small entities. Under section 605(b) of the RFA, this analysis is not required if an agency certifies that the rule will not have a significant economic impact on a substantial number of small entities and publishes its certification and a brief explanatory statement in the Federal Register along with its rule. The OCC currently supervises approximately 764 entities.

None of these entities is a covered swap entity. Moreover, because the OCC assumes that this proposal will be implemented before any OCC-supervised entities are required to comply with the QFC Rules, the OCC believes that the proposal will not result in savings—or more than de minimis costs—for OCC-supervised entities. Therefore, the OCC certifies that the proposed rule will not have a significant economic impact on a substantial number of small OCC-regulated entities.

Board: In accordance with section 3(a) of the Regulatory Flexibility Act, 5 U.S.C. 601 et seq. (RFA), the Board is publishing an initial regulatory flexibility analysis for the proposed rule. The RFA requires an agency to provide an initial regulatory flexibility analysis with the proposed rule or to certify that the proposed rule will not have a significant economic impact on a substantial number of small entities. The Board welcomes comment on all aspects of the initial regulatory flexibility analysis. A final regulatory flexibility analysis will be conducted after consideration of comments.

1. Description of the reasons why action by the Board is being considered and statement of the objectives of the proposal. The Board is proposing to amend the definition of Eligible Master Netting Agreement in the Swap Margin Rule so that it remains harmonized with the amended definition of “Qualifying Master Netting Agreement” in the Federal banking agencies’ regulatory capital and liquidity rules. The Board is also proposing an amendment that will make clear that a legacy swap (a non-cleared swap entered into before the applicable compliance date) that is not subject to the requirements of the Swap Margin Rule will not be deemed a covered swap under the Swap Margin Rule if it is amended solely to conform to the QFC Rules.

2. Small entities affected by the proposal. This proposal would apply to financial institutions that are covered swap entities that are subject to the requirements of the Swap Margin Rule. Under Small Business Administration (SBA) regulations, the finance and insurance sector includes commercial banking, savings institutions, credit unions, other depository credit intermediation and consumer card issuing institutions (financial institutions). With respect to financial institutions that are covered swap entities under the Swap Margin Rule, a financial institution generally is considered small if it has assets of $550 million or less. Covered swap entities would be considered financial institutions for purposes of the RFA in accordance with SBA regulations. The Board does not expect that any covered swap entity is likely to be a small financial institution, because a small financial institution is unlikely to engage in the level of swap activity that would require it to register as a swap dealer or a major swap participant with the CFTC and SEC, respectively. None of the current covered swap entities are small entities.

3. Reporting, recordkeeping and compliance requirements. The proposed amendments apply to covered swap entities. As a result of the proposals, the economic impact on covered swap entities will be positive as they will continue to be able to enter into netting agreements that allow margin to be calculated on a net basis, rather than a gross basis. In addition, absent this proposal, legacy swaps that are not currently subject to the margin requirements of the Swap Margin Rule would be required to comply with the provisions of the Swap Margin Rule solely because of amendments made to conform to the requirements of the QFC Rules.

4. Other Federal rules. Absent this proposal, the definition of EMNA would conflict with the definition of QMNA in the Federal banking agencies’ regulatory capital and liquidity rules. This would result in additional compliance costs for firms that are subject to both definitions. In addition, absent these amendments, there would be a conflict between what the QFC Rules require in Covered QFCs and the policy determination previously made by the Board about the application of the Swap Margin Rule to legacy swaps.

5. Significant alternatives to the proposed rule. As discussed above, the Agencies have requested comment on the scope of the proposed amendments and have solicited comment on any approaches that would reduce the burden on covered swap entities. The Board welcomes comment on any significant alternatives that would minimize the impact of the proposal on small entities.

FDIC: The Regulatory Flexibility Act (RFA), 5 U.S.C. 601 et seq., requires an agency to provide an initial regulatory flexibility analysis with a proposed rule, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities (defined by the Small Business Administration for purposes of the RFA to include banking entities with total assets of $550 million or less). According to the most recent data from the Consolidated Reports of Income and Condition (CALL Report), the FDIC supervised 3,674 institutions. Of those, 2,050 are considered “small,” according to the terms of the Regulatory Flexibility Act. The proposed rule primarily affects covered swap entities. The FDIC believes that FDIC-supervised small entities are unlikely to be a covered swap entity because such entities are unlikely to engage in the level of swap activity that would require them to register as a swap entity. The Swap Margin Rule implements sections 731 and 764 of the Dodd-Frank Act, as amended by the Terrorism Risk Insurance Program Reauthorization Act.

40 The OCC bases its estimate of the number of small entities on the Small Business Association’s size thresholds for commercial banks and savings institutions, and trust companies, which are $550 million and $38.5 million, respectively. Consistent with the General Principles of Affiliation 13 CFR 121.103(a), the OCC counts the assets of affiliated financial institutions when determining if we should classify an OCC-supervised institution a small entity. The OCC used December 31, 2016, to determine size because a “financial institution’s” assets are averaging the assets reported on its four quarterly financial statements for the preceding year.” See footnote 2 of the U.S. Small Business Administration’s Table of Size Standards.

41 See 13 CFR 121.201 (effective December 2, 2014); see also 13 CFR 121.103(a)(6) (noting factors that the SBA considers in determining whether an entity qualifies as a small business, including receipts, employees, and other measures of its domestic and foreign operations).

42 The CFTC has published a list of provisionally registered swap dealers as of November 20, 2017 that does not include any small financial institutions. See http://www.cftc.gov/ LawRegulation/DoddFrankAct/registerswapdealer. The SEC has not yet imposed a registration requirement on entities that meet the definition of security-based swap dealer or major security-based swap participant.
of 2015 ("TRIPRA"). Because TRIPRA excludes non-cleared swaps entered into for hedging purposes by a financial institution with total assets of $10 billion or less from the requirements of the Swap Margin Rule, when a covered swap entity transacts non-cleared swaps with a small entity supervised by the FDIC, and such swaps are used to hedge a commercial risk of the small entity, those swaps will not be subject to the Swap Margin Rule. The FDIC believes that it is unlikely that any small entity it supervises will engage in non-cleared swaps for purposes other than hedging. Therefore, it is unlikely that the amendments included in the proposed rule would result in a significant economic impact on a substantial number of small entities under its supervisory jurisdiction.

For these reasons, the FDIC certifies that the Proposed Rule, if adopted in final form, would not have a significant economic impact on a substantial number of small entities, within the meaning of those terms as used in the RFA. Accordingly, a regulatory flexibility analysis is not required.

FCA: Pursuant to section 605(b) of the Regulatory Flexibility Act, 5 U.S.C. 601 et seq., FCA hereby certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities. Each of the banks in the Farm Credit System, considered together with its affiliated associations, has assets and annual income in excess of the amounts that would qualify them as small entities; nor does the Federal Agricultural Mortgage Corporation meet the definition of "small entity." Therefore, System institutions are not "small entities" as defined in the Regulatory Flexibility Act.

FHFA: The Regulatory Flexibility Act (5 U.S.C. 601 et seq.) requires that a regulation that has a significant economic impact on a substantial number of small entities, small businesses, or small organizations must include an initial regulatory flexibility analysis describing the regulation’s impact on small entities. FHFA need not undertake such an analysis if the agency has certified the regulation will not have a significant economic impact on a substantial number of small entities. 5 U.S.C. 605(b). FHFA has considered the impact of the proposed rule under the Regulatory Flexibility Act, and certifies that the proposed rule, if adopted as a final rule, would not have a significant economic impact on a substantial number of small entities because the proposed rule is applicable only FHFA’s regulated entities, which are not small entities for purposes of the Regulatory Flexibility Act.

C. Solicitation of Comments on the Use of Plain Language

Section 722 of the Gramm-Leach-Bliley Act requires the U.S. banking agencies to use plain language in proposed and final rulemakings. The Agencies have sought to present the proposed rule in a simple and straightforward manner, and invite comment on the use of plain language in this proposal.

Question 1: Have the Agencies organized the proposal in a clear way? If not, how could the proposal be organized more clearly?

Question 2: Are the requirements of the proposed rule clearly stated? If not, how could they be stated more clearly?

Question 3: Does the proposal contain unclear technical language or jargon? If so, which language requires clarification?

Question 4: Would a different format (such as a different grouping and ordering of sections, a different use of section headings, or a different organization of paragraphs) make the regulation easier to understand? If so, what changes would make the proposal clearer?

Question 5: What else could the Agencies do to make the proposal clearer and easier to understand?

D. OCC Unfunded Mandates Reform Act of 1995 Determination

Section 202 of the Unfunded Mandates Reform Act of 1995 (Unfunded Mandates Act) (2 U.S.C. 1532) requires that the OCC prepare a budgetary impact statement before promulgating a rule that includes any Federal mandate that may result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year. If a budgetary impact statement is required, section 205 of the Unfunded Mandates Act also requires the OCC to identify and consider a reasonable number of regulatory alternatives before promulgating a rule. The OCC has determined that the proposed rule does not impose any new mandates and will not result in expenditures by State, local, and Tribal governments, or by the private sector of $100 million or more in any one year. Accordingly, the OCC has not prepared a budgetary impact statement or specifically addressed the regulatory alternatives considered.

E. Riegle Community Development and Regulatory Improvement Act of 1994

The Riegle Community Development and Regulatory Improvement Act of 1994 (RCDRIA) requires that each Federal banking agency, in determining the effective date and administrative compliance requirements for new regulations that impose additional reporting, disclosure, or other requirements on insured depository institutions, consider, consistent with principles of safety and soundness and the public interest, any administrative burdens that such regulations would place on depository institutions, including small depository institutions, and customers of depository institutions, as well as the benefits of such regulations. In addition, new regulations and amendments to regulations that impose additional reporting, disclosures, or other new requirements on insured depository institutions generally must take effect on the first day of a calendar quarter that begins on or after the date on which the regulations are published in final form. Each Federal banking agency has determined that the proposed rule would not impose additional reporting, disclosure, or other requirements; therefore the requirements of the RCDRIA do not apply.

List of Subjects

12 CFR Part 45
Administrative practice and procedure, Capital, Margin requirements, National banks, Federal savings associations, Reporting and recordkeeping requirements, Risk.

12 CFR Part 237
Administrative practice and procedure, Banks and banking, Capital, Foreign banking, Holding companies, Margin requirements, Reporting and recordkeeping requirements, Risk.

12 CFR Part 349
Administrative practice and procedure, Banks, Holding companies, Margin Requirements, Capital, Reporting and recordkeeping requirements, Savings associations, Risk.

12 CFR Part 624
Accounting, Agriculture, Banks, Banking, Capital, Cooperatives, Credit, Margin requirements, Reporting and recordkeeping requirements, Risk, Rural areas, Swaps.
12 CFR Part 1221

Government-sponsored enterprises, Mortgages, Securities.

DEPARTMENT OF THE TREASURY
Office of the Comptroller of the Currency

12 CFR Chapter I

Authority and Issuance

For the reasons stated in the preamble, the Office of the Comptroller of the Currency proposes to amend part 45 of chapter I of title 12, Code of Federal Regulations, as follows:

PART 45—MARGIN AND CAPITAL REQUIREMENTS FOR COVERED SWAP ENTITIES

§ 45.1 Authority, purpose, scope, exemptions and compliance dates.

(e) * * *

(7) For purposes of determining the date on which a non-cleared swap or a non-cleared security-based swap was entered into, a Covered Swap Entity will not take into account amendments to the non-cleared swap or the non-cleared security-based swap that were entered into solely to comply with the requirements of part 47, Subpart I of part 252 or part 382 of Title 12, as applicable.

§ 45.2 Definitions.

(2) The agreement provides the covered swap entity the right to accelerate, terminate, and close-out on a net basis all transactions under the agreement and to liquidate or set-off collateral promptly upon an event of default of the counterparty to the extent necessary for the counterparty to comply with the requirements of part 47, Subpart I of part 252 or part 382 of Title 12, as applicable.

§ 45.3 Authority and Issuance

For the reasons set forth in the preamble, the Board of Governors of the Federal Reserve System proposes to amend 12 CFR part 237 to read as follows:

PART 237—SWAPS MARGIN AND SWAPS PUSH-OUT

§ 237.1 Authority, purpose, scope, exemptions and compliance dates.

(e) * * *

(7) For purposes of determining the date on which a non-cleared swap or a non-cleared security-based swap was entered into, a Covered Swap Entity will not take into account amendments to the non-cleared swap or the non-cleared security-based swap that were entered into solely to comply with the requirements of part 47, Subpart I of part 252 or part 382 of Title 12, as applicable.

§ 237.4 Authority and Issuance

For the reasons set forth in the preamble, the Federal Deposit Insurance Corporation proposes to amend 12 CFR part 349 as follows:

FEDERAL DEPOSIT INSURANCE CORPORATION

12 CFR Chapter III

Authority and Issuance

For the reasons set forth in the preamble, the Federal Deposit Insurance Corporation proposes to amend 12 CFR part 349 as follows:
PART 349—DERIVATIVES

Subpart A—Margin and Capital Requirements for Covered Swap Entities

7. The authority citation for Subpart A continues to read as follows:


8. Section 349.1 is amended by adding paragraph (e)(7) as follows:

§ 349.1 Authority, purpose, scope, exemptions and compliance dates.

(e) * * *

(7) For purposes of determining the date on which a non-cleared swap or a non-cleared security-based swap was entered into, a Covered Swap Entity will not take into account amendments to the non-cleared swap or the non-cleared security-based swap that were entered into solely to comply with the requirements of part 47, Subpart I of part 252 or part 382 of Title 12, as applicable.

9. Section 349.2 is amended by revising the definition of “Eligible master netting agreement” to read as follows:

§ 349.2 Definitions.

Eligible master netting agreement means a written, legally enforceable agreement provided that:

1. The agreement creates a single legal obligation for all individual transactions covered by the agreement upon an event of default following any stay permitted by paragraph (2) of this definition, including upon an event of receivership, conservatorship, insolvency, liquidation, or similar proceeding, of the counterparty;

2. The agreement provides the covered swap entity the right to accelerate, terminate, and close-out on a net basis all transactions under the agreement and to liquidate or set-off collateral promptly upon an event of default, including upon an event of receivership, conservatorship, insolvency, liquidation, or similar proceeding, of the counterparty, provided that, in any such case,

(i) Any exercise of rights under the agreement will not be stayed or avoided under applicable law in the relevant jurisdictions, other than:

(A) In receivership, conservatorship, or resolution under the Federal Deposit Insurance Act (12 U.S.C. 1811 et seq.), Title II of the Dodd-Frank Wall Street Reform and Consumer Protection Act (12 U.S.C. 5381 et seq.), the Federal Housing Enterprises Financial Safety and Soundness Act of 1992, as amended (12 U.S.C. 4617), or the Farm Credit Act of 1971, as amended (12 U.S.C. 2183 and 2279cc), or laws of foreign jurisdictions that are substantially similar to the U.S. laws referenced in this paragraph (2)(i)(A) in order to facilitate the orderly resolution of the defaulting counterparty; or

(B) Where the agreement is subject by its terms to, or incorporates, any of the laws referenced in paragraph (2)(i)(A) of this definition; and

(ii) The agreement may limit the right to accelerate, terminate, and close-out on a net basis all transactions under the agreement and to liquidate or set-off collateral promptly upon an event of default of the counterparty to the extent necessary for the counterparty to comply with the requirements of part 47, Subpart I of part 252 or part 382 of Title 12, as applicable;

3. The agreement does not contain a walkaway clause (that is, a provision that permits a non-defaulting counterparty to make a lower payment than it otherwise would make under the agreement, or no payment at all, to a defaulter or the estate of a defaulter, even if the defaulter or the estate of the defaulter is a net creditor under the agreement); and

4. A covered swap entity that relies on the agreement for purposes of calculating the margin required by this part must:

(i) Conduct sufficient legal review to conclude with a well-founded basis (and maintain sufficient written documentation of that legal review) that:

(A) The agreement meets the requirements of paragraph (2) of this definition; and

(B) In the event of a legal challenge (including one resulting from default or from receivership, conservatorship, insolvency, liquidation, or similar proceeding), the relevant court and administrative authorities would find the agreement to be legal, valid, binding, and enforceable under the law of the relevant jurisdictions; and

(ii) Establish and maintain written procedures to monitor possible changes in relevant law and to ensure that the agreement continues to satisfy the requirements of this definition.

9. Section 349.2 is amended by adding paragraph (e)(7) as follows:

§ 624.2 Definitions.

(e) * * *

(7) For purposes of determining the date on which a non-cleared swap or a non-cleared security-based swap was entered into, a Covered Swap Entity will not take into account amendments to the non-cleared swap or the non-cleared security-based swap that were entered into solely to comply with the requirements of part 47, Subpart I of part 252 or part 382 of Title 12, as applicable.

10. The authority citation for part 624 continues to read as follows:


11. Section 624.1 is amended by adding paragraph (e)(7) as follows:

§ 624.1 Authority, purpose, scope, exemptions and compliance dates.

(e) * * *

(7) For purposes of determining the date on which a non-cleared swap or a non-cleared security-based swap was entered into, a Covered Swap Entity will not take into account amendments to the non-cleared swap or the non-cleared security-based swap that were entered into solely to comply with the requirements of part 47, Subpart I of part 252 or part 382 of Title 12, as applicable.

12. Section 624.2 is amended by revising paragraph (2) of the definition of Eligible master netting agreement to read as follows:

§ 624.2 Definitions.

(2) The agreement provides the covered swap entity the right to accelerate, terminate, and close-out on a net basis all transactions under the agreement and to liquidate or set-off collateral promptly upon an event of default, including upon an event of receivership, conservatorship, insolvency, liquidation, or similar proceeding, of the counterparty, provided that, in any such case,

(i) Any exercise of rights under the agreement will not be stayed or avoided under applicable law in the relevant jurisdictions, other than:

(A) In receivership, conservatorship, or resolution under the Federal Deposit Insurance Act (12 U.S.C. 1811 et seq.), Title II of the Dodd-Frank Wall Street Reform and Consumer Protection Act (12 U.S.C. 5381 et seq.), the Federal Housing Enterprises Financial Safety and Soundness Act of 1992, as amended (12 U.S.C. 4617), or the Farm Credit Act of 1971, as amended (12 U.S.C. 2183 and 2279cc), or laws of foreign jurisdictions that are substantially similar to the U.S. laws referenced in this paragraph (2)(i)(A) in order to
facilitate the orderly resolution of the defaulting counterparty; or

(B) Where the agreement is subject by its terms to, or incorporates, any of the laws referenced in paragraph (2)(i)(A) of this definition; and

(ii) The agreement may limit the right to accelerate, terminate, and close-out on a net basis all transactions under the agreement and to liquidate or set-off collateral promptly upon an event of default of the counterparty to the extent necessary for the counterparty to comply with the requirements of part 47, Subpart I of part 252 or part 382 of Title 12, as applicable;

* * * * *

FEDERAL HOUSING FINANCE AGENCY

Authority and Issuance

For the reasons set forth in the preamble, the Federal Housing Finance Agency proposes to amend chapter XII of title 12, Code of Federal Regulations, as follows:

PART 1221—MARGIN AND CAPITAL REQUIREMENTS FOR COVERED SWAP ENTITIES

13. The authority citation for part 1221 continues to read as follows:


14. Section 1221.1 is amended by adding paragraph (e)(7) to read as follows:

§ 1221.1 Authority, purpose, and scope, exemptions and compliance dates.

(e) * * * * *

(7) For purposes of determining the date on which a non-cleared swap or a non-cleared security-based swap was entered into, a Covered Swap Entity will not take into account amendments to the non-cleared swap or the non-cleared security-based swap that were entered into solely to comply with the requirements of part 47, Subpart I of part 252 or part 382 of Title 12, as applicable.

* * * * *

15. Section 1221.2 is amended by revising paragraph (2) of the definition of Eligible master netting agreement to read as follows:

§ 1221.2 Definitions.

(2) The agreement provides the covered swap entity the right to accelerate, terminate, and close-out on a net basis all transactions under the agreement and to liquidate or set-off collateral promptly upon an event of default, including upon an event of receivership, conservatorship, insolvency, liquidation, or similar proceeding, of the counterparty, provided that, in any such case,

(i) Any exercise of rights under the agreement will not be stayed or avoided under applicable law in the relevant jurisdictions, other than:

(A) In receivership, conservatorship, or resolution under the Federal Deposit Insurance Act (12 U.S.C. 1811 et seq.), Title II of the Dodd-Frank Wall Street Reform and Consumer Protection Act (12 U.S.C. 5381 et seq.), the Federal Housing Enterprises Financial Safety and Soundness Act of 1992, as amended (12 U.S.C. 4617), or the Farm Credit Act of 1971, as amended (12 U.S.C. 2183 and 2279cc), or laws of foreign jurisdictions that are substantially similar to the U.S. laws referenced in this paragraph (2)(i)(A) in order to facilitate the orderly resolution of the defaulting counterparty; or

(B) Where the agreement is subject by its terms to, or incorporates, any of the laws referenced in paragraph (2)(i)(A) of this definition; and

(ii) The agreement may limit the right to accelerate, terminate, and close-out on a net basis all transactions under the agreement and to liquidate or set-off collateral promptly upon an event of default of the counterparty to the extent necessary for the counterparty to comply with the requirements of part 47, Subpart I of part 252 or part 382 of Title 12, as applicable;

* * * * *


Joseph M. Otting,

Comptroller of the Currency.

By order of the Board of Governors of the Federal Reserve System, January 24, 2018.

Ann E. Misback,

Secretary of the Board.

Dated at Washington, DC, this 25th day of January 2018.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

Dated: January 26, 2018.

Melvin L. Watt,

Director, Federal Housing Finance Agency.


Dale L. Aultman,

Secretary, Farm Credit Administration Board.

ADDITIONAL INFORMATION

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39


RIN 2120–AA64

Airworthiness Directives; AgustaWestland S.p.A. Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for AgustaWestland S.p.A. Model AW189 helicopters. This proposed AD would require inspecting the tail gearbox (TGB) fitting for a crack. This proposed AD is prompted by a report of a crack on a TGB fitting that was found during a scheduled inspection. The actions of this proposed AD are intended to prevent an unsafe condition on these products.

DATES: We must receive comments on this proposed AD by April 23, 2018.

ADDRESSES: You may send comments by any of the following methods:

• Federal eRulemaking Docket: Go to http://www.regulations.gov. Follow the online instructions for sending your comments electronically.

• Fax: 202–493–2251.

• Mail: Send comments to the U.S. Department of Transportation, Docket Operations, M–30, West Building, Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590–0001.

• Hand Delivery: Deliver to the “Mail” address between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Examine the AD Docket

You may examine the AD docket on the internet at http://www.regulations.gov by searching for and locating Docket No. FAA–2017–0619; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the European Aviation Safety Agency (EASA) AD, the economic evaluation, any comments received, and other information. The street address for Docket Operations (telephone 800–647–5527) is in the ADDRESSES section. Comments will be available in the AD docket shortly after receipt.

For service information identified in this proposed rule, contact Leonardo

FOR FURTHER INFORMATION CONTACT: Matt Fuller, Senior Aviation Safety Engineer, Safety Management Section, Rotorcraft Standards Branch, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222–5110; email matthew.fuller@faa.gov.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to participate in this rulemaking by submitting written comments, data, or views. We also invite comments relating to the economic, environmental, energy, or federalism impacts that might result from adopting the proposals in this document. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should send only one copy of written comments, or if comments are filed electronically, commenters should submit only one time.

We will file in the docket all comments that we receive, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, we will consider all comments we receive on or before the closing date for comments. We will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. We may change this proposal in light of the comments we receive.

Discussion

EASA advises that this condition, if not detected and corrected, could lead to crack propagation up to a critical length. This condition could reduce the assembly’s ability to sustain loads from the TGB and tail rotor, possibly resulting to reduced helicopter control. The EASA AD consequently requires repetitive inspections of the fitting and replacing the fitting, depending on the inspections’ outcome. EASA considers these actions to be interim and that further AD action may follow.

The FAA is in the process of updating AgustaWestland’s name changes to Finmeccanica S.p.A., and then to Leonardo Helicopters, on its FAA type certificate. Because this name change is not yet effective, this AD specifies AgustaWestland.

FAA’s Determination

These helicopters have been approved by the aviation authority of Italy and are approved for operation in the United States. Pursuant to our bilateral agreement with Italy, EASA, its technical representative, has notified us of the unsafe condition described in its AD. We are proposing this AD because we evaluated all known relevant information and determined that an unsafe condition is likely to exist or develop on other products of the same type design.

Related Service Information Under 1

CFR Part 51

Leonardo Helicopters has issued Bollettino Tecnico No. 189–114, dated September 6, 2016 (BT), which specifies inspecting the TGB fitting within 30 flight hours or 1 month from the receipt of the BT, whichever comes first, and then at intervals not to exceed 150 flight hours. If a crack is found, the BT requires replacing the TGB fitting. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the ADDRESSES section.

Proposed AD Requirements

This proposed AD would require within 30 hours time-in-service (TIS) and thereafter at intervals not to exceed 150 hours TIS, cleaning the areas around the Hi-lok holes and inspecting the TGB fitting for a crack. If a crack exists, this proposed AD would require replacing the part before the next flight.

Differences Between This Proposed AD and the EASA AD

The EASA AD requires you to provide a compliance record and return parts to Leonardo Helicopters if a crack is found on the fitting. This proposed AD would require no such actions.

Interim Action

We consider this proposed AD to be an interim action. The design approval holder is expected to develop a modification that will address the unsafe condition identified in this AD. Once this modification is developed, approved, and available, we might consider additional rulemaking.

Costs of Compliance

We estimate that this AD affects 4 helicopters of U.S. Registry and that labor costs average $85 per work-hour. Based on these estimates, we expect the following costs:

- Inspecting the TGB fitting would require 4 work-hours and no parts for a cost per helicopter of $340 and $1,360 for the U.S. fleet each inspection cycle.
- Replacing the TGB fitting would require 48 work-hours and parts would cost $30,000 for a cost of $34,080 per helicopter.

According to Leonardo Helicopters’ service information, some of the costs of this AD may be covered under warranty, thereby reducing the cost impact on affected individuals. We do not control warranty coverage by Leonardo Helicopters. Accordingly, we have included all costs in our cost estimate.

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 products identified in this rulemaking action.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would 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, I certify this proposed regulation:
1. Is not a “significant regulatory action” under Executive Order 12866;
2. Is not a “significant rule” under the 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 proposed 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.

The Proposed Amendment
Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 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):


(a) Applicability
This AD applies to AgustaWestland S.p.A. Model AW189 helicopters, certificated in any category, with tail assembly part number 8G5350A00131 installed.

(b) Unsafe Condition
This AD defines the unsafe condition as a crack on a tail gearbox fitting. This condition could reduce the tail assembly’s ability to sustain loads from the tail rotor gearbox (TGB) and the tail rotor and result in loss of helicopter control.

(c) Comments Due Date
We must receive comments by April 23, 2018.

(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
Within 30 hours time-in-service (TIS) and thereafter at intervals not to exceed 150 hours TIS, clean and inspect the TGB fitting for a crack in the areas depicted in Figure 1 of Leonardo Helicopters Bollettino Tecnico No. 189–114, dated September 6, 2016. If there is a crack, replace the TGB fitting before further flight.

(f) Alternative Methods of Compliance (AMOCS)

(1) The Manager, Safety Management Section, Rotorcraft Standards Branch, FAA, may approve AMOCS for this AD. Send your proposal to: Matt Fuller, Senior Aviation Safety Engineer, Safety Management Section, Rotorcraft Standards Branch, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222–5110; email 9–ASW-FTW–AMOC-Requests@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

(h) Subject
Joint Aircraft Service Component (JASC) Code: 6520, Tail Rotor Gearbox. Issued in Fort Worth, Texas, on February 12, 2018.

Scott A. Horn,
Deputy Director for Regulatory Operations, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2018–03494 Filed 2–20–18; 8:45 am]
BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION
Federal Aviation Administration

14 CFR Part 39


RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for all The Boeing Company Model 737–100, –200, –200C, –300, –400, –500 series airplanes. This proposed AD was prompted by reports of cracking in certain flanges, and the adjacent web, of the wing outboard flap track at certain positions. This proposed AD would require an inspection to determine the part number of the wing outboard flap track assembly; repetitive inspections of each affected wing outboard flap track for discrepancies, and applicable on-condition actions; and repetitive overhaul of each wing outboard flap track. We are proposing this AD to address the unsafe condition on these products.

DATES: We must receive comments on this proposed AD by April 9, 2018.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.33 and 11.45, by any of the following methods:

• Federal eRulemaking Portal: Go to http://www.regulations.gov. Follow the instructions for submitting comments.

• Fax: 202–493–2251.


Hand Delivery: Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this NPRM, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&Ds), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; internet https://www.myboeingfleet.com. You may view this referenced service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available on the internet at http://www.regulations.gov by searching for and locating Docket No. FAA–2018–0112.

Examining the AD Docket
You may examine the AD docket on the internet at http://www.regulations.gov by searching for and locating Docket No. FAA–2018–0112; or in person at the Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations (phone: 800–647–5527) is listed above. Comments will be...
available in the AD docket shortly after receipt.


SUPPLEMENTARY INFORMATION:

Comments Invited
We invite you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the ADDRESSES section. Include “Docket No. FAA–2018–0112; Product Identifier 2017–NM–161–AD” at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this NPRM. We will consider all comments received by the closing date and may amend this NPRM because of those comments.

We will post all comments we receive, without change, to http://www.regulations.gov, including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion
We have received a report indicating that during the tear down of a Model 737–300 airplane, cracking was found in the inboard lower flange and adjacent web near the forward attachment of the outboard flap track at position 8. The cracked flap track had accumulated 1,579 flight cycles since it was installed on the airplane after the most recent overhaul, and approximately 20,000 flight cycles since new. The metallurgical evaluation of the cracked flap track found that stress corrosion cracking originated from a fastener hole in the flap track web with missing cadmium plating. There was not sufficient evidence to conclude that the missing cadmium plating was the cause or the result of the cracking. Boeing has since received one more report of cracking in the outboard lower flange and the adjacent web of the outboard flap track at position 8 on a different Model 737–300 airplane. The crack was also found near the forward attachment, but did not originate from a fastener hole. The cracked flap track had accumulated 1,175 flight cycles since it was installed on the airplane. Boeing determined that the existing inspection programs are not sufficient to find such cracks before failure of a flap track could occur.

Cracking in the area between the forward and rear spar attachments of the wing outboard flap tracks may lead to the inability of a principal structural element to sustain required flight load. Such cracking could result in loss of the outboard trailing edge flap and consequent reduced controllability of the airplane.

Related Rulemaking
AD 2013–09–02, Amendment 39–17443 (78 FR 27010, May 9, 2013) ("AD 2013–09–02"), requires operators to use Boeing Service Bulletin (SB) 737–57A1271, Revision 3, dated February 13, 2012 ("SB 737–57A1271 R3"), to accomplish the inspections required by paragraph (p) of that AD. Boeing SB 737–57A1271 was issued to address more than 30 reports of stress corrosion cracks in the wing outboard flap tracks at positions 2 and 7, and provides instructions to do detailed and non-destructive test (NDT) inspections of the flap track flanges and webs, and detailed and NDT inspections of the flap track at the rear spar attachment. Boeing SB 737–57A1271 also gives instructions to repair, overhaul, and replace the wing outboard flap tracks at positions 2 and 7. Boeing SB 737–57A1271 does not include NDT inspections of the flap track flanges at the attachment of the flap transmission and the hinge support assembly, or NDT inspections of the flap track webs forward of the rear spar attachment nor repair, overhaul, and replacement of the wing outboard flap tracks at positions 1 and 8. As discussed above, Boeing reported information that indicates additional areas of stress corrosion cracks in other positions of the wing outboard flap tracks and the adjacent web of the outboard flap tracks. Therefore, the existing requirements of AD 2013–09–02 do not fully address the unsafe condition.

Related Service Information Under 1 CFR Part 51
We reviewed Boeing Alert Requirements Bulletin 737–57A1338 RB, dated September 25, 2017. The service information describes procedures for repetitive inspections, repair, repetitive overhaul, and replacement of the wing outboard flap tracks, and applicable on-condition actions. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the ADDRESSES section.

FAA’s Determination
We are proposing this AD because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements
This proposed AD would require new NDT inspections of the flap track flanges and webs forward of the rear spar attachment, in areas not previously inspected using SB 737–57A1271 R3 (or previous revisions), to the existing requirements in AD 2013–09–02. The new and existing requirements would also apply to the wing outboard flap tracks at positions 1 and 8.

Accomplishment of the inspections, repair, overhaul, and replacement of the wing outboard flap tracks specified in Boeing Alert Requirements Bulletin 737–57A1338 RB, dated September 25, 2017, would replace the instruction in SB 737–57A1271 R3 (or previous revisions), and terminates the requirements of AD 2013–09–02.

This proposed AD would require accomplishment of the actions identified in the Boeing Alert Requirements Bulletin 737–57A1338 RB, dated September 25, 2017, described previously, except for any differences identified as exceptions in the regulatory text of this proposed AD.

For information on the procedures and compliance times, see this service information at http://www.regulations.gov by searching for and locating Docket No. FAA–2018–0112.

Explanation of Requirements Bulletin
The FAA worked in conjunction with industry, under the Airworthiness Directives Implementation Aviation Rulemaking Committee (AD ARC), to enhance the AD system. One enhancement is a process for annotating which steps in the service information are “required for compliance” (RC) with an AD. Boeing has implemented this RC concept into Boeing service bulletins. In an effort to further improve the quality of ADs and AD-related Boeing service information, a joint process improvement initiative was worked between the FAA and Boeing. The initiative resulted in the development of a new process in which the service information more clearly identifies the actions needed to address the unsafe condition in the “Accomplishment Instructions.” The new process results in a Boeing Requirements Bulletin, which contains only the actions needed to address the unsafe condition (i.e., only the RC actions).
Costs of Compliance

We estimate that this proposed AD affects 160 airplanes of U.S. registry. We estimate the following costs to comply with this proposed AD:

**ESTIMATED COSTS FOR REQUIRED ACTIONS**

<table>
<thead>
<tr>
<th>Action</th>
<th>Labor cost</th>
<th>Parts cost</th>
<th>Cost per product</th>
<th>Cost on U.S. operators</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inspection (positions 1 and 8; Group 2 and Group 3, configuration 2).</td>
<td>78 work-hours × $85 per hour = $6,630 per inspection cycle.</td>
<td>$0</td>
<td>$6,630 per inspection cycle.</td>
<td>$1,060,800 per inspection cycle.</td>
</tr>
<tr>
<td>Inspection (positions 1 and 8; Group 3, configuration 1).</td>
<td>89 work-hours × $85 per hour = $7,565 per inspection cycle.</td>
<td>0</td>
<td>$7,565 per inspection cycle.</td>
<td>$1,210,400 per inspection cycle.</td>
</tr>
<tr>
<td>Inspection (positions 2 and 7; Group 2 and Group 3, configuration 1).</td>
<td>83 work-hours × $85 per hour = $7,055 per inspection cycle.</td>
<td>0</td>
<td>$7,055 per inspection cycle.</td>
<td>$1,128,800 per inspection cycle.</td>
</tr>
<tr>
<td>Inspection (positions 2 and 7; Group 3, configuration 2).</td>
<td>86 work-hours × $85 per hour = $7,310 per inspection cycle.</td>
<td>0</td>
<td>$7,310 per inspection cycle.</td>
<td>$1,169,600 per inspection cycle.</td>
</tr>
</tbody>
</table>

We have received no definitive data that would enable us to provide cost estimates for the actions for Group 1 airplanes or the on-condition actions specified in this proposed AD.

**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 products identified in this rulemaking action.

This proposed AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs applicable to transport category airplanes to the Director of the System Oversight Division.

**Regulatory Findings**

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would 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 this proposed regulation:

(1) Is not a “significant regulatory action” under Executive Order 12866,

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

(3) Will not affect intrastate aviation in Alaska, 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.

**List of Subjects in 14 CFR Part 39**

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

**The Proposed Amendment**

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

**PART 39—AIRWORTHINESS DIRECTIVES**

§ 39.13 [Amended]

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):


**[a] Comments Due Date**

We must receive comments by April 9, 2018.

(b) Affected ADs


(c) Applicability

This AD applies to all The Boeing Company Model 737–100, –200, –200C, –300, –400, –500 series airplanes, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 57, Wings.

(e) Unsafe Condition

This AD was prompted by reports of cracking in certain flanges, and the adjacent web, of the wing outboard flap track at certain positions. We are issuing this AD to detect and correct cracking of the rear spar attachment, and cracking of the wing outboard flap tracks. Cracking in the area between the forward and rear spar attachments of the wing outboard flap tracks could lead to the inability of a principal structural element to sustain required flight load, and result in loss of the outboard trailing edge flap and consequent reduced controllability of the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Required Actions for Group 1 Airplanes

For airplanes identified as Group 1 in Boeing Alert Requirements Bulletin 737–57A1338 RB, dated September 25, 2017:

Within 120 days after the effective date of this AD, do actions to correct the unsafe condition using a method approved in accordance with the procedures specified in paragraph (l) of this AD.

(h) Required Actions

For airplanes not specified in paragraph (g) of this AD, Except as required by paragraph (i) of this AD, at the applicable times specified in the “Compliance” paragraph of Boeing Alert Requirements Bulletin 737–57A1338 RB, dated September 25, 2017, do all applicable actions identified in, and in accordance with, the Accomplishment Instructions of Boeing Alert Requirements.

Note 1 to paragraph (h) of this AD: Guidance for accomplishing the actions required by this AD can be found in Boeing Aircraft Service Bulletin 737–57A1338, dated September 25, 2017, which is referred to in Boeing Aircraft Repair Bulletins 737–57A1338 RB, dated September 25, 2017.

(i) Exceptions to Service Information Specifications

For purposes of determining compliance with the requirements of this AD, Boeing Aircraft Service Bulletin 737–57A1338 RB, dated September 25, 2017, uses the phrase “the original issue date of Requirements Bulletins 737–57A1338 RB,” this AD requires using “the effective date of this AD.”

(j) Terminating Action for Requirements of AD 2013–09–02

Accomplishment of the requirements specified in paragraph (b) of this AD terminates all of the requirements specified in AD 2013–09–02.

(k) Parts Installation Limitation

As of the effective date of this AD, no person may install, on any airplane, a wing outboard flap track having a part number listed in paragraph 1.B. of Boeing Aircraft Repair Bulletins 737–57A1338 RB, dated September 25, 2017, unless the inspections and corrective actions specified in the Accomplishment Instructions of Boeing Aircraft Repair Bulletins 737–57A1338 RB, dated September 25, 2017, are accomplished prior to the part’s installation on the airplane.

(l) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Los Angeles ACO Branch, FAA, has the authority to approve AMOCs for this AD, provided the inspections using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the FAA, has the authority to approve AMOCs on the airplane.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local Flight Standards district office/certificate holding district office.

(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Los Angeles ACO Branch, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(m) Related Information

(1) For more information about this AD, contact Payman Soltani, Aerospace Engineer, Airframe Section, FAA, Los Angeles ACO Branch, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 562–627–5313; fax: 562–627–5210; email: payman.soltani@faa.gov.

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; internet: https://www.myboeingfleet.com. You may view referenced service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3109.

Issued in Renton, Washington, on February 12, 2018.

Michael Kaszycki,
Acting Director, System Oversight Division,
Aircraft Certification Service.

[FR Doc. 2018–03433 Filed 2–20–18; 8:45 am]
BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71


Proposed Amendment of Class D and Class E Airspaces; Aurora, OR

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend Class D airspace, Class E surface area airspace, and Class E airspace extending upward from 700 feet above the surface, at Aurora State Airport, Aurora, OR. After a biennial review the FAA found modification necessary to accommodate airspace redesign for the safety and management of instrument flight rules (IFR) operations at the airport. Additionally, an editorial change would be made removing the city associated with the airport name in the airspace designations. Also, this proposal would make an editorial change to the Class D airspace legal description replacing Airport/Facility Directory with the term Chart Supplement.

DATES: Comments must be received on or before April 9, 2018.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE, West Building, Goldberg Floor, Room W12–140, Washington, DC 20590; telephone: 1–800–647–5527, or (202) 366–9826.


FAA Order 7400.11B, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at http://www.faa.gov/air_traffic/publications/. For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11B at NARA, call (202) 741–6030, or go to https://www.archives.gov/federal-register/cfr/ibr-locations.html.

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

FOR FURTHER INFORMATION CONTACT: Tom Clark, Federal Aviation Administration, Operations Support Group, Western Service Center, 1601 Lind Avenue SW, Renton, WA 98057; telephone (425) 293–4511.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA’s authority to issue rules regarding 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, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would amend Class D and Class E airspace at Aurora State Airport, Aurora, OR to support IFR operations at the airport.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments
are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Persons wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: “Comments to Docket No. FAA–2017–1034; Airspace Docket No. 17–ANM–23”. The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at http://www.regulations.gov. An electronic copy of this document may also be accessed through the FAA’s web page at http://www.faa.gov/air_traffic/publications/airspace_amendments/.

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the ADDRESSES section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Northwest Mountain Regional Office of the Federal Aviation Administration, Air Traffic Organization, Western Service Center, Operations Support Group, 1601 Lind Avenue SW, Renton, WA 98057.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order 7400.11B, Airspace Designations and Reporting Points, dated August 3, 2017, and effective September 15, 2017. FAA Order 7400.11B is publicly available as listed in the ADDRESSES section of this document. FAA Order 7400.11B lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 by modifying Class D airspace, Class E surface area airspace, and Class E airspace extending upward from 700 feet above the surface at Aurora State Airport, Aurora, OR. Class D airspace would be modified to a 4-mile radius of the airport and within 1.8 miles each side of the 007° bearing from the airport extending from the 4-mile radius to 5.1 miles north of the airport (from a 4.2-mile radius of the airport from the 64° bearing from the airport clockwise to the 142° bearing, extending to a 5-mile radius from the 142° bearing clockwise to the 64° bearing from the airport). Two excluded area cutouts for Lenhardt Airpark and McGee Airport, respectively, (both nearby satellite general aviation airports) would be modified by excluding that airspace below 1,500 feet MSL within the area bounded by lat. 45°11′51″ N, long. 122°45′45″ W; to lat. 45°12′50″ N, long. 122°44′34″ W; to the point where the 142° bearing from the airport intersects the 4-mile radius of the airport, thence clockwise along the airport 4-mile radius to the 174° bearing from the airport, thence to the point of beginning; and excluding that airspace below 1,500 feet MSL within the area bounded by lat. 45°15′37″ N, long. 122°51′14″ W; to the point where the 235° bearing from the airport intersects the 4-mile radius of the airport, thence clockwise along the airport 4-mile radius to the airport 281° bearing, thence to the point of beginning” (from “excluding that airspace below 1,200 feet beyond 3.3 miles from the airport from the 142° bearing clockwise to the 174° bearing, and that airspace below 1,200 feet beyond 3.3 miles from the airport from the 250° bearing clockwise to the 266° bearing from the airport.”)

The modification of the excluded areas within the Class D provides additional airspace for visual flight rules operations at the satellite airports while maintaining the required airspace to support IFR operations at Aurora State Airport. Also, an editorial change would be made to the Class D airspace legal description replacing Airport/Facility Directory with the term Chart Supplement.

Class E surface area airspace would be modified to be coincident with the dimensions of the Class D airspace except no exclusion would be provided in the vicinity of Lenhardt Airpark (“excluding that airspace below 1,500 feet MSL within the area bounded by lat. 45°11′51″ N, long. 122°45′45″ W; to lat. 45°12′50″ N, long. 122°44′34″ W; to the point where the 142° bearing from the airport intersects the 4-mile radius of the airport, thence clockwise along the airport 4-mile radius to the 174° bearing from the airport, thence to the point of beginning”). Class E surface area airspace is required within this Class D cutout to ensure Class E weather requirements exist from the surface and protect IFR arrival operations to Aurora State Airport.

Class E airspace extending upward from 700 feet would be modified to within a 6.5-mile radius (from a 7-mile radius) from the airport (043° bearing clockwise to the airport 350° bearing and within a 9-mile radius (from a 6.5-mile radius) from the airport 350° bearing clockwise to the airport 043° bearing, and within 1.6 miles each side of a 007° bearing from the airport extending from the 9-mile radius of the airport to 20.6 miles north of the airport (from within 1.6 miles either side of the 007° bearing from airport extending from the 7-mile radius to 20 miles northeast of the airport), and within 1.6 miles each side of a line extending from lat. 45°21′12″ N, long. 122°58′41″ W, to lat. 45°19′20″ N, long. 122°49′07″ W (from within 1.2 miles either side of the 306° bearing from airport extending from the 7-mile radius to 10.9 miles northwest of the airport).

A graphic illustration of the proposed airspace will be entered into Docket No. FAA–2017–1034, and available for download under the “Supporting/Related Materials” section.

The airport designations for the Class D and E airspace areas also would be amended by removing the name of the city associated with the airport to be in compliance with a recent change to FAA Order 7400.2L, Procedures for Handling Airspace Matters, effective October 12, 2017.

Class D and Class E airspace designations are published in paragraph 5000, 6002, and 6005, respectively, of FAA Order 7400.11B, dated August 3, 2017, and effective September 15, 2017, which is incorporated by reference in 14 CFR 71.1. The Class D and E airspace designations listed in this document will be published subsequently in the Order.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial and unlikely to result in adverse or negative comments. It, therefore; (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); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, “Environmental Impacts: Policies and Procedures” prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

§ 71.1 [Amended]

1. The authority citation for 14 CFR part 71 continues to read as follows:


§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11B, Airspace Designations and Reporting Points, dated August 3, 2017, and effective September 15, 2017, is amended as follows:

Paragraph 6005 Class E Airspace Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * * * * * *

ANM OR E2 Aurora, OR [Amended]

Aurora State Airport, OR

(Lat. 45°14′50″ N, long. 122°46′12″ W)

That airspace extending upward from the surface within a 4-mile radius of Aurora State Airport and within 1.8 miles each side of the 007° bearing from the airport extending from the 4-mile radius to 5.1 miles north of the airport, excluding that airspace below 1,500 feet MSL within the area bounded by lat. 45°15′37″ N, long. 122°51′14″ W; to the point where the 235° bearing from the airport intersects the 4-mile radius of the airport, thence clockwise along the airport 4-mile radius to the airport 281° bearing, thence to the point of beginning.

Paragraph 6005 Class E Airspace Designed as Surface Areas.

* * * * * * *

ANM OR E5 Aurora, OR [Amended]

Aurora State Airport, OR

(Lat. 45°14′50″ N, long. 122°46′12″ W)

That airspace extending upward from 700 feet above the surface within a 9-mile radius of the Aurora State Airport from a 350° bearing from the airport clockwise to a 043° bearing from the airport, and within a 6.5-mile radius of the airport from the airport 043° bearing clockwise to the airport 350° bearing, and within 1.6 miles each side of a 007° bearing from the airport extending from the 9-mile radius of the airport to 20.6 miles north of the airport, and within 1.8 miles each side of a line extending from lat. 45°21′12″ N, long. 122°58′41″ W; to lat. 45°19′20″ N, long. 122°49′07″ W.


B.G. Chew,

Acting Manager, Operations Support Group, Western Service Center

[FR Doc. 2018–03408 Filed 2–20–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71


Proposed Removal of Class E Airspace; Mercury, NV

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to remove Class E airspace extending upward from 700 feet above the surface at Desert Rock Airport, Mercury, NV. This airspace is not required, as there are no instrument flight rules (IFR) operations at the airport.

DATES: Comments must be received on or before April 9, 2018.


FAA Order 7400.11B, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at http://www.faa.gov/air_traffic/publications/. For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11B at NARA, call (202) 741–6030, or go to https://www.archives.gov/federal-register/cfr/ibr-locations.html.

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

FOR FURTHER INFORMATION CONTACT: Tom Clark, Federal Aviation Administration, Operations Support Group, Western Service Center, 1601 Lind Avenue SW, Renton, WA 98057; telephone (425) 203–4511.

SUPPLEMENTARY INFORMATION:
Authority for This Rulemaking

The FAA’s authority to issue rules regarding 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, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would support the removal of controlled airspace at Desert Rock Airport, Mercury, NV.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (Docket No. FAA–2017–1148; Airspace Docket No. 17–AWP–30) and be submitted in triplicate to DOT Docket Operations (see ADDRESSES section for address and phone number).

Persons wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: “Comments to Docket No. FAA–2017–1148, Airspace Docket No. 17–AWP–30.” The postcard will be date/time stamped and returned to the commenter.

All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at http://www.regulations.gov. Recently published rulemaking documents can also be accessed through the FAA’s web page at http://www.faa.gov/air_traffic/publications/airspace_amendments/.

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the ADDRESSES section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined between 8:00 a.m. and 4:30 p.m., Monday through Friday, except federal holidays, at the Northwest Mountain Regional Office of the Federal Aviation Administration, Air Traffic Organization, Western Service Center, Operations Support Group, 1601 Lind Avenue SW, Renton, WA 98057.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order 7400.11B, Airspace Designations and Reporting Points, dated August 3, 2017, and effective September 15, 2017. FAA Order 7400.11B is publicly available as listed in the ADDRESSES section of this document. FAA Order 7400.11B lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposed Amendment

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 by removing Class E airspace extending upward from 700 feet above the surface at Desert Rock Airport, Mercury, NV. Controlled airspace is no longer needed as there are no standard instrument approach or departure procedures for IFR operations at the airport.

Class E airspace designations are published in paragraph 6005 of FAA Order 7400.11B, dated August 3, 2017, and effective September 15, 2017, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in the Order.

Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial and unlikely to result in adverse or negative comments. It, therefore: (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); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, “Environmental Impacts: Policies and Procedures” prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:


§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11B, Airspace Designations and Reporting Points, dated August 3, 2017, and effective September 15, 2017, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

AWP CA E5 Mercury, NV [Removed]


B.G. Chew,
Acting Manager, Operations Support Group, Western Service Center.

[FR Doc. 2018–03405 Filed 2–20–18; 8:45 am]

BILLING CODE 4910–13–P
DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71


Proposed Revocation of Class E Airspace; Sunol, CA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to remove Class E airspace extending upward from 1,200 feet above the surface at Sunol, CA. This airspace is wholly contained within the Sacramento en route airspace area and duplication is not necessary.

DATES: Comments must be received on or before April 9, 2018.


FAA Order 7400.11B, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at http://www.faa.gov/air_traffic/publications/).

You may view the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the ADDRESSES section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined between 8:00 a.m. and 4:30 p.m., Monday through Friday, except federal holidays, at the Northwest Mountain Regional Office of the Federal Aviation Administration, Air Traffic Organization, Western Service Center, Operations Support Group, 1601 Lind Avenue SW, Renton, WA 98057.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order 7400.11B, Airspace Designations and Reporting Points, dated August 3, 2017, and effective September 15, 2017. FAA Order 7400.11B is publicly available as listed in the ADDRESSES section of this document. FAA Order 7400.11B lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

History

The FAA published a final rule in the Federal Register (82 FR 27968; June 20, 2017) for Docket No. FAA–2016–9476 establishing Class E en route airspace extending upward from 1,200 feet above the surface centered near Sacramento, CA. The FAA found that this airspace encompasses the Class E 1,200-foot airspace for Sunol, CA.

The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) Part 71 by removing Class E airspace extending upward from 1,200 feet above the surface at Sunol, CA. The existing airspace area designated for Sunol, CA, is wholly contained within the Sacramento en route airspace area, and duplication is not necessary.

Class E airspace designations are published in paragraph 6005 of FAA Order 7400.11B, dated August 3, 2017 and effective September 15, 2017, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in the Order.

Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an Authority for This Rulemaking

The FAA’s authority to issue rules regarding 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, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would remove Class E airspace at Sunol, CA.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (Docket No. FAA–2017–1147; Airspace Docket No. 17–AWP–29) and be submitted in triplicate to DOT Docket Operations (see ADDRESSES section for address and phone number).

Persons wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: “Comments to Docket No. FAA–2017–1147, Airspace Docket No. 17–AWP–29”. The postcard will be date/time stamped and returned to the commenter.

All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at http://www.regulations.gov. Recently published rulemaking documents can also be accessed through the FAA’s web page at http://www.faa.gov/air_traffic/publications/airspace_amendments/.
established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial and unlikely to result in adverse or negative comments. It, therefore: (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); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, “Environmental Impacts: Policies and Procedures” prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

1. The authority citation for 14 CFR part 71 continues to read as follows:


§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11B, Airspace Designations and Reporting Points, dated August 3, 2017, and effective September 15, 2017, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

AWP CA E5 Sunol, CA [Removed]


B.G. Chew,

Acting Manager, Operations Support Group, Western Service Center.

[FR Doc. 2018–03406 Filed 2–20–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71


Proposed Amendment of Class E Airspace; Kamuela, HI

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend Class E surface area airspace and Class E airspace extending upward from 700 feet above the surface at Waima–Kohala Airport, Kamuela, HI. The part-time Notice to Airmen (NOTAM) status would be removed from Class E surface area airspace, references to the Kamuela VOR/DME would be removed from all associated Class E airspace areas, and airspace boundaries would be modified to only that area necessary to contain instrument flight rules (IFR) operations at the airport. Airspace redesign is necessary as the FAA transitions from ground-based to satellite-based navigation for the safety and management of the national airspace system. Also, an editorial change would be made removing the airport name and replacing it with the city in the airspace designators for the above airspace areas.

DATES: Comments must be received on or before April 9, 2018.


FOR FURTHER INFORMATION CONTACT: Tom Clark, Federal Aviation Administration, Operations Support Group, Western Service Center, 1601 Lind Avenue SW, Renton, WA 98057; telephone (425) 203–4511.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA’s authority to issue rules regarding 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, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would amend Class E airspace at Waima–Kohala Airport, Kamuela, HI, to accommodate airspace redesign in support of IFR operations at the airport.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (Docket No. FAA–2017–1145; Airspace Docket No. 17–AWP–19) and be submitted in triplicate to DOT Docket Operations (see ADDRESSES section for address and phone number).
Persons wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: “Comments to Docket No. FAA–2017–1145; Airspace Docket No. 17–AWP–19.” The postcard will be date/time stamped and returned to the commenter.

All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at http://www.regulations.gov. Recently published rulemaking documents can also be accessed through the FAA’s web page at http://www.faa.gov/air_traffic/publications/airspace_amendments/.

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the ADDRESSES section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined between 8:00 a.m. and 4:30 p.m., Monday through Friday, except federal holidays, at the Northwest Mountain Regional Office of the Federal Aviation Administration, Air Traffic Organization, Western Service Center, Operations Support Group, 1601 Lind Avenue SW, Renton, WA 98057.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order 7400.11B, Airspace Designations and Reporting Points, dated August 3, 2017, and effective September 15, 2017. FAA Order 7400.11B is publicly available as listed in the ADDRESSES section of this document. FAA Order 7400.11B lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 by removing the part-time NOTAM status of Class E surface area airspace and defining its boundaries with reference to the Waimea-Kohala Airport, Kamuela, HI (instead of the Kamuela VOR/DME).

Class E airspace would extend upward from the surface within the 4.3-mile radius of Waimea-Kohala Airport, and within 2.4 miles north and 1.8 miles south of the 069° bearing from the airport extending from the 4.3-mile radius to 7.3 miles east of the airport (from 1.8 miles northwest of and 2.6 miles southeast of the Kamuela VOR 063° radial, extending from the 4.3-mile radius to 7.8 miles northeast of the Kamuela VOR/DME).

Class E airspace extending upward from 700 feet above the surface would be modified to within a 4.3-mile radius of Waimea-Kohala Airport (from a 6.4-mile radius) and within 4.1 miles each side of the 069° bearing from the airport extending from the 4.3-mile radius to 12.8 miles east of the airport, and within 1.3 miles each side of the 244° bearing from the airport extending from the 4.3-mile radius to 5.8 miles southwest of the airport (from 2 miles each side of the Kamuela VOR/DME 068° radial, extending from the 6.4-mile radius 12.6 miles northeast of the Kamuela VOR/DME, and within 2 miles each side of the Kamuela VOR/DME 246° extending from the 6.4-mile radius to 13.4 miles southwest of the Kamuela VOR/DME). This airspace redesign would expand the airspace areas slightly northeast and reduce the airspace from southeast clockwise to north to only that area necessary to contain IFR operations at the airport.

Additionally, an editorial change would be made replacing Waimea-Kohala Airport, HI, with Kamuela, HI, in the airspace designation of the above classes of airspace to comply with a recent change to FAA Order 7400.2L, Procedures for Handling Airspace Matters, dated October 12, 2017.

Class E airspace designations are published in paragraph 6002, and 6005, respectively, of FAA Order 7400.11B, dated August 3, 2017 and effective September 15, 2017, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial and unlikely to result in adverse or negative comments. It, therefore: (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); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, “Environmental Impacts: Policies and Procedures” prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11B, Airspace Designations and Reporting Points, dated August 3, 2017, and effective September 15, 2017, is amended as follows:

Paragraph 6002 Class E Airspace Areas Designated as Surface Areas.

AWP HI E2 Kamuela, HI [Amended]

Waimea-Kohala Airport, HI (Lat. 20°00′05″ N, long. 155°40′05″ W) That airspace extending upward from the surface within a 4.3-mile radius of Waimea-Kohala Airport, and within 2.4 miles north and 1.6 miles south of the 069° bearing from the airport extending from the 4.3-mile radius to 7.3 miles east of the airport.

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.
The Federal Register / Vol. 83, No. 35 / Wednesday, February 21, 2018 / Proposed Rules

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Proposed Amendment of Class D and Class E Airspace, and Removal of Class E Airspace; Lompoc, CA]

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend Class D airspace, Class E airspace extending upward from 700 feet above the surface, and remove Class E airspace designated as an extension at Vandenberg Air Force Base (AFB), Lompoc, CA. This action also proposes to modify Class E airspace extending upward from 700 feet above the surface at Lompoc Airport, Lompoc, CA, by enlarging the airspace and removing the part-time Notice to Airmen (NOTAM) status. This action would also amend the geographic coordinates of the airports to match the FAA’s aeronautical database. This action is necessary for the safety and management of instrument flight rules (IFR) operations at these airports. An editorial change would be made removing the city associated with the airport name in the airspace designator for Vandenberg AFB, as well as removing exclusionary language from the description. Additionally, this action would replace the outdated term “Airport/Facility Directory” with the term “Chart Supplement”.

DATES: Comments must be received on or before April 9, 2018.


FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

FOR FURTHER INFORMATION CONTACT: Tom Clark, Federal Aviation Administration, Operations Support Group, Western Service Center, 1601 Lind Avenue SW, Renton, WA 98057; telephone (425) 203–4511.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA’s authority to issue rules regarding 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, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is necessary to ensure the safety of aircraft and the efficient use of airspace.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at http://www.regulations.gov. Recently published rulemaking documents can also be accessed through the FAA’s web page at http://www.faa.gov/air_traffic/publications/air_traffic/airport_directories/

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the ADDRESSES section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined between 8:00 a.m. and 4:30 p.m., Monday through Friday, except federal holidays, at the Northwest Mountain Regional Office of the Federal Aviation Administration, Air Traffic Organization, Western Service Center, Operations Support Group, 1601 Lind Avenue SW, Renton, WA 98057.
Aviation Administration proposes to amend FAA Order 7400.11B, Airspace Designations and Reporting Points, dated August 3, 2017, and effective September 15, 2017. FAA Order 7400.11B is publicly available as listed in the ADDRESSES section of this document. FAA Order 7400.11B lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposed Amendment

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 by enlarging Class D airspace, reducing Class E airspace extending upward from 200 feet above the surface, and removing Class E airspace designated as an extension at Vandenberg Air Force Base (AFB), Lompoc, CA, and also would amend Class E airspace extending upward from 700 feet above the surface and remove part-time NOTAM status at Lompoc Airport, Lompoc, CA.

Class D airspace would be enlarged to within a 5-mile radius (from a 4.3-mile radius) of Vandenberg AFB. Additionally, an editorial change would remove the city associated with the airport name in the airspace designation to comply with a recent change to FAA Order 7400.2L, dated October 12, 2017. An editorial change also would be made to the Class D airspace legal description replacing “Airport/Facility Directory” with “Chart Supplement”.

Class E airspace designated as an extension would be removed, as this airspace is not required to protect IFR arrival and departure aircraft at Vandenberg AFB.

Class E airspace extending upward from 700 feet above the surface at Vandenberg AFB would be modified to a 7.3-mile radius of the airport with extensions to 11 miles north, 12.5-miles southeast, and 11 miles south of the airport (from a 7.8-mile radius of the airport and within 1.8 miles each side of the Vandenberg AFB ILS localizer southeast course, extending from 7.8 miles to 10.3 miles southeast of the airport). The exclusionary language contained in the legal description would be removed to comply with FAA Order 7400.2L, Procedures for Handling Airspace Matters.

This action also would amend Class E airspace extending upward from 700 feet above the surface at Lompoc Airport, Lompoc, CA, by enlarging the airspace to within a 6.4-mile radius of the airport, and within 4 miles each side of the 090° bearing from the airport extending from the 6.4-mile radius to 12.8 miles east of the airport, and within 4 miles each side of the 113° bearing from the airport extending from the 6.4-mile radius to 20.4 miles southeast of the airport (from a 4.3-mile radius of the airport and within 4.3 miles each side of the Gaviota VORTAC 293° radial extending from the 4.3-mile radius to 10.9 miles west of the Gaviota VORTAC and within 4 miles each side of the 083° bearing from the Lompoc NDB to 8 miles east of the NDB. Also, the part-time NOTAM status would be removed, since this airspace is effective continuously.

Finally, this action would update the geographic coordinates of these airports to match the FAA’s aeronautical database.

Class E airspace designations are published in paragraph 5000, 6004, and 6005, respectively, of FAA Order 7400.11B, dated August 3, 2017 and effective September 15, 2017, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial and unlikely to result in adverse or negative comments. It, therefore: (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); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, “Environmental Impacts; Policies and Procedures” prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).
That airspace extending upward from 700 feet above the surface within a 6.4-mile radius of Lompoc Airport, and within 4 miles each side of the 090° bearing from the airport extending to 12.8 miles east of the airport, and within 4 miles each side of the 113° bearing from the airport extending to 20.4 miles southeast of the airport.


B.G. Chew,
Acting Manager, Operations Support Group, Western Service Center.

[FR Doc. 2018–03415 Filed 2–20–18; 8:45 am]
Addiction Equity Act of 2008,3 the Newborns’ and Mothers’ Health Protection Act,4 the Women’s Health and Cancer Rights Act,5 the Genetic Information Nondiscrimination Act of 2008,6 the Children’s Health Insurance Program Reauthorization Act of 2009,7 Michelle’s Law,8 and the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (PPACA).9 PPACA reorganizes, amends, and adds to the provisions of Part A of title XXVII of the PHS Act relating to group health plans and health insurance issuers in the group and individual markets. PPACA added section 715 of ERISA and section 9815 of the Code to incorporate provisions of Part A of title XXVII of the PHS Act (generally, sections 2701 through 2728 of the PHS Act) into ERISA and the Code.

B. President’s Executive Order

On October 12, 2017, President Trump issued Executive Order 13813 entitled “Promoting Healthcare Choice and Competition Across the United States”.10 This Executive Order states in relevant part: “Within 60 days of the date of this order, the Secretary of the Treasury, the Labor, and the Health and Human Services shall consider proposing regulations or revising guidance, consistent with law, to expand the availability of [short-term, limited-duration insurance]. To the extent permitted by law and supported by sound policy, the Secretaries should consider allowing such insurance to cover longer periods and be renewed by the consumer.”

C. 2017 Tax Legislation

Section 5000A of the Code, added by PPACA, provides that all non-exempt applicable individuals must maintain minimum essential coverage or pay the individual shared responsibility payment.11 On December 22, 2017, the President signed tax reform legislation into law.12 This legislation includes a provision under which the individual shared responsibility payment included in section 5000A of the Code is reduced to $0, effective for months beginning after December 31, 2018.

D. Short-Term, Limited-Duration Insurance

Short-term, limited-duration insurance is a type of health insurance coverage that was designed to fill temporary gaps in coverage that may occur when an individual is transitioning from one plan or coverage to another plan or coverage. Although short-term, limited-duration insurance is not an excepted benefit,13 it is exempt from the PHS Act’s individual-market requirements because it is not individual health insurance coverage.14 Section 2791(b)(5) of the PHS Act provides “[t]he term ‘individual health insurance coverage’ means health insurance coverage offered to individuals in the individual market, but does not include short-term limited duration insurance.”15

The PHS Act does not define short-term, limited-duration insurance. Under regulations implementing HIPAA, and that continued to apply through 2016, short-term, limited-duration insurance was defined as “health insurance coverage provided pursuant to a contract with an issuer that has an expiration date specified in the contract (taking into account any extensions that may be elected by the policyholder without the issuer’s consent) that is less than 12 months after the original effective date of the contract.”16

To address the issue of short-term, limited-duration insurance being sold as a type of primary coverage, as well as concerns regarding possible adverse selection impacts on the risk pool for PPACA-compliant plans, the Department of the Treasury, the Department of Labor, and the Department of Health and Human Services (together, the Departments)17 published a proposed rule on June 10, 2016 in the Federal Register entitled “Expatriate Health Plans, Expatriate Health Plan Issuers, and Qualified Expatriates; Excepted Benefits; Lifetime and Annual Limits; and Short-Term, Limited-Duration Insurance.”18 The June 2016 proposed rule changed the definition of short-term, limited-duration insurance that had been in place for nearly 20 years by revising the definition to specify that short-term, limited-duration insurance could not provide coverage for 3 months or longer (including any renewal period(s)).19

The June 2016 proposed rule also included a requirement that the following notice be prominently displayed in the contract and in any application materials provided in connection with enrollment in short-term, limited-duration insurance, in 14 point type:

THIS IS NOT QUALIFYING HEALTH COVERAGE (“MINIMUM ESSENTIAL COVERAGE”) THAT SATISFIES THE

program established or maintained by an employer (or employee organization or both) for the purpose of providing medical care to employees or their dependents (as defined under the terms of the plan) directly, or through insurance, reimbursement, or otherwise. There is no corresponding provision excluding short-term, limited-duration insurance from the definition of group health coverage. Thus, any insurance that is sold in the group market and purports to be short-term, limited-duration insurance must comply with Part A of title XXVII of the PHS Act, part 7 of ERISA, and Chapter 100 of the Code.

16 62 FR 16894 at 16928, 16942, 16958 (April 8, 1997), 69 FR 77722 (December 30, 2004).

17 Note, however, that in section headings listing only 2 of the 3 Departments, the term “Departments” generally refers only to the 2 Departments listed in the heading.

18 81 FR 38019.

19 81 FR 38019, 38032–33.
HEALTH COVERAGE REQUIREMENT OF THE AFFORDABLE CARE ACT. IF YOU DON'T HAVE MINIMUM ESSENTIAL COVERAGE, YOU MAY OWE AN ADDITIONAL PAYMENT WITH YOUR TAXES.20

Some stakeholders who submitted comments on the June 2016 proposed rule supported the rule and the Departments’ stated goals. Several commenters agreed that the proposed rule would limit the number of consumers relying on short-term, limited-duration insurance as their primary form of coverage and improve the PPACA’s individual market single risk pools. However, other commenters expressed concerns about restricting the use of short-term, limited-duration insurance (as originally defined under the HIPAA regulations) because it provides an additional, often much more affordable coverage option than an insurance policy that complies with all of the requirements of the PPACA. Some commenters explained that individuals who do not qualify for premium tax credits and need temporary coverage, or who cannot afford Consolidated Omnibus Budget Reconciliation Act21 (COBRA) continuation coverage, or who missed an opportunity to sign up for coverage during open enrollment or special enrollment periods, might need to rely on short-term, limited-duration insurance coverage for 3 months or longer. Commenters highlighted how a person with just a less-than-3-month policy who develops a health condition might have no coverage options for the condition after their coverage expires until the beginning of the plan year that corresponds to the next individual market open enrollment period. Other commenters also expressed opposition to the proposed rule citing their belief that States are in the best position to regulate short-term, limited-duration insurance and that the proposed rule would limit State flexibility. Finally, several commenters observed that PPACA-compliant policies are often network-based but short-term, limited-duration insurance policies typically are not, thus offering consumers a greater choice of health care providers. This is particularly true in rural areas, one commenter stated.

After reviewing public comments and feedback received from stakeholders, on October 31, 2016, the Departments finalized the June 2016 proposed rule without change in a final rule published in the Federal Register entitled “Excepted Benefits; Lifetime and Annual Limits; and Short-Term, Limited-Duration Insurance”.22

On June 12, 2017, HHS published a request for information in the Federal Register entitled “Reducing Regulatory Burdens Imposed by the Patient Protection and Affordable Care Act & Improving Healthcare Choices to Empower Patients”,23 which solicited public comments about potential changes to existing regulations and guidance that could promote consumer choice, enhance affordability of coverage for individual consumers, and affirm the traditional regulatory authority of the States in regulating the business of health insurance, among other goals. Several commenters stated that changes to the October 2016 final rule may provide an opportunity to achieve these goals. Consistent with many comments submitted on the June 2016 proposed rule, commenters stated that shortening the permitted length of short-term, limited-duration insurance policies had deprived individuals of affordable coverage options. One commenter explained that due to the increased costs of PPACA-compliant major medical coverage, many financially-stressed individuals may be faced with a choice between short-term, limited-duration insurance coverage and going without any coverage at all. One commenter highlighted the need for short-term, limited-duration insurance coverage among individuals who are in-between jobs. Another commenter explained that States have the primary responsibility to regulate short-term, limited-duration insurance and opined that the October 2016 final rule was overreaching on the part of the Federal government.

The Departments are also aware that, while individuals who qualify for premium tax credits are largely insulated from significant premium increases (that is, the government, and thus federal taxpayers, largely bear the cost of the higher premiums), individuals who are not eligible for subsidies are particularly harmed by increased premiums in the individual market due to a lack of other, more affordable alternative coverage options. Based on CMS data on Exchange plan selections and data compiled from issuer regulatory filings at the State level, for the first quarters of 2016 and 2017, the number of off-Exchange and unsubsidized enrollees with individual market coverage fell by nearly 2 million, representing an almost 25 percent decrease.24 Further, in 2018, about 26 percent of enrollees (living in 52 percent of counties) have access to just one insurer in the Exchange.25 Short-term, limited-duration insurance has become increasingly attractive to some individuals as premiums have escalated for PPACA-compliant plans and affordable choices in the individual market have dwindled.

II. Overview of the Proposed Regulations

In light of Executive Order 13813 directing the Departments to consider proposing regulations or revising guidance to expand the availability of short-term, limited-duration insurance, as well as continued feedback from stakeholders expressing concerns about the October 2016 final rule, the Departments are proposing to amend the definition of short-term, limited-duration insurance so that it may offer a maximum coverage period of less than 12 months after the original effective date of the contract, consistent with the original definition in the 1997 HIPAA rule (that is, the proposed rule would expand the potential maximum coverage period by 9 months). This proposed definition states that the expiration date specified in the contract takes into account any extensions that may be elected by the policyholder without the issuer’s consent.

In addition, this proposed rule would revise the required notice that must appear in the contract and any application materials for short-term, limited-duration insurance. The Departments are concerned that short-term, limited-duration insurance policies that provide coverage lasting almost 12 months may be more difficult for some individuals to distinguish from PPACA-compliant coverage which is typically offered on a 12-month basis. Accordingly, under this proposed rule, one of two versions (as explained below) of the following notice would be required to be prominently displayed (in at least 14 point type) in the contract and in any application materials

21 82 FR 38032.
22 81 FR 75316.
23 81 FR 26885.
provided in connection with enrollment:

"THIS COVERAGE IS NOT REQUIRED TO COMPLY WITH FEDERAL REQUIREMENTS FOR HEALTH INSURANCE, PRINCIPALLY THOSE CONTAINED IN THE AFFORDABLE CARE ACT. BE SURE TO CHECK YOUR POLICY CAREFULLY TO MAKE SURE YOU UNDERSTAND WHAT THE POLICY DOES AND DOESN'T COVER. IF THIS COVERAGE EXPIRES OR YOU LOSE ELIGIBILITY FOR THIS COVERAGE, YOU MIGHT HAVE TO WAIT UNTIL AN OPEN ENROLLMENT PERIOD TO GET OTHER HEALTH INSURANCE COVERAGE. ALSO, THIS COVERAGE IS NOT "MINIMUM ESSENTIAL COVERAGE". IF YOU DON'T HAVE MINIMUM ESSENTIAL COVERAGE FOR ANY MONTH IN 2018, YOU MAY HAVE TO MAKE A PAYMENT WHEN YOU FILE YOUR TAX RETURN UNLESS YOU QUALIFY FOR AN EXEMPTION FROM THE REQUIREMENT THAT YOU HAVE HEALTH COVERAGE FOR THAT MONTH."

As stated below, the Departments are proposing that the applicability date for this proposed rule, if finalized, would be 60 days after the publication of the final rule, and that policies sold on or after that date would have to meet the requirements of the final rule in order to constitute short-term, limited-duration insurance. As previously discussed, the individual shared responsibility payment is reduced to $0 for months beginning after December 2018. Consequently, the Departments propose that the final two sentences of the notice must appear only with respect to policies sold on or after the applicability date of the rule, if finalized, that have a coverage start date before January 1, 2019. The Departments solicit comments on this revised notice, and whether its language or some other language would best ensure that it is understandable and sufficiently apprises individuals of the nature of the coverage.

The current definition of short-term, limited-duration insurance applies for policy years beginning on or after January 1, 2017. In the October 2016 final rule, the Departments recognized that State regulators may have approved short-term, limited-duration insurance products for sale in 2017 that met the definition in effect prior to January 1, 2017. Accordingly, HHS noted it would not take enforcement action against an issuer with respect to its sale of a short-term, limited-duration insurance product before April 1, 2017, on the ground that the coverage period is 3 months or more, provided that the coverage ended on or before December 31, 2017, and otherwise complies with the definition of short-term, limited-duration insurance in effect under the final rule.27 As stated in the October 2016 final rule, States may also elect not to take enforcement actions against issuers with respect to such coverage sold before April 1, 2017. The current definition in the October 2016 final rule, and the non-enforcement policy as applied to policies sold before April 1, 2017, and that end on or before December 31, 2017, would continue to apply unless and until this rule is finalized.

Effective Date and Applicability Date

The Departments propose that this rule, if finalized, would be effective 60 days after publication of the final rule. With respect to the applicability date, the Departments propose that insurance policies sold on or after the 60th day following publication of the final rule, if finalized, would have to meet the definition of short-term, limited-duration insurance in the final rule in order to be considered such insurance. The Departments propose that group health plans and group health insurance issuers, to the extent they must distinguish between short-term, limited-duration insurance and individual market health insurance (such as for purposes of determining whether an individual has moved out of a health maintenance organization (HMO) service area in the individual market, which would trigger a special enrollment right into a group health plan or for purposes of offering limited wraparound coverage (which wraps around individual health insurance or the Basic Health Plan as an excepted benefit 28), must apply the definition of short-term, limited-duration insurance in the final rule as of the 60th day following publication of the final rule. The current regulations specify the applicability date for the definition of short-term, limited-duration insurance at 26 CFR 54.9833–1; 29 CFR 2590.736, 45 CFR 146.125; and 45 CFR 148.102.

Therefore, the Departments propose conforming amendments to those rules as part of this rulemaking. The Departments also propose a technical update in 26 CFR 54.9833–1; 29 CFR 2590.736; and 45 CFR 146.125 to delete the reference to the applicability date for amendments to 26 CFR 54.9831–1(c)(5)(i)(C); 26 CFR 54.9832(c)(5)(i)(C); 29 CFR 2590.732(c)(5)(i)(C); and 45 CFR 146.145(c)(5)(i)(C) (regarding supplemental coverage excepted benefits).29 Given that the applicability date for the amendments to those sections has passed, it is no longer necessary to mention the "future" applicability date.30 HHS similarly proposes to amend §148.102 to remove the reference to the applicability date for amendments to §148.220(b)(7) (regarding supplemental coverage excepted benefits).31

Request for Comments

The Departments seek comments on all aspects of this proposed rule, including whether the length of short-term, limited-duration insurance should be some other duration. The Departments seek comments on any regulations or other guidance or policy that limits issuers’ flexibility in designing short-term, limited-duration insurance or poses barriers to entry into the short-term, limited-duration insurance market.

In addition, the Departments seek comments on the conditions under which issuers should be able to allow short-term, limited-duration insurance to continue for 12 months or longer with the issuer’s consent. Among other things, the Departments solicit comments on whether any processes for expedited or streamlined reapplication for short-term, limited-duration insurance that would simplify the reapplication process and minimize the burden on consumers may be appropriate; whether federal standards are appropriate for such processes; and whether any clarifications are needed regarding the application of the definition of short-term, limited-duration insurance in the proposed rule to such practices. For example, an expedited process could involve setting minimum federal standards for what must be considered as part of the streamlined reapplication process while allowing insurers to consider additional factors in accordance with contract terms. The Departments are also interested in information on any State approaches (including any approaches that States are considering adopting) to minimize the burden of the reapplication process for issuers and consumers.

26 81 FR 75316 through 75319.
27 This non-enforcement policy is limited to the requirement that short-term, limited-duration insurance must be less than 3 months. It does not relieve issuers of short-term, limited-duration insurance of the notice requirement, which applies for policy years beginning on or after January 1, 2017.
28 See footnote 14.
Because short-term, limited-duration insurance can be priced in an actuarially fair manner (by which the Departments mean that it is priced so that the premium paid by an individual reflects the risks associated with insuring the particular individual or individuals covered by that policy), subject to State law, individuals who are likely to purchase short-term, limited-duration insurance are likely to be relatively young or healthy. Allowing such individuals to purchase policies that are not in compliance with PPACA may impact the individual market single risk pools. As explained in section III, “Economic Impact and Paperwork Burden” of this proposed rule, the Departments estimate that in 2019, after the elimination of the individual shared responsibility payment, between 100,000 and 200,000 individuals previously enrolled in Exchange coverage would purchase short-term, limited-duration insurance policies instead. This would cause the average monthly individual market premiums and average monthly premium tax credits to increase, leading to an increase in total annual advance payments of the premium tax credit (APTC)\(^{32}\) in the range of $96 million to $168 million. The Departments seek comments on these estimates, and welcome other estimates of the increase in enrollment in short-term, limited-duration insurance under this proposal, and the health status and age of individuals who would purchase these policies.

The Departments also seek comments on the proposed effective and applicability dates of this rule, if finalized. The Departments seek comments on whether the proposed fixed applicability date, which would first impose the new definition of short-term, limited-duration insurance on group health plans and group health insurance issuers on a date that may occur in the middle of a plan year, would cause any special challenges for group health plans and group health insurance issuers.

III. Economic Impact and Paperwork Burden

A. Summary—Department of Labor and Department of Health and Human Services

This rule proposes to amend the definition of short-term, limited-duration insurance coverage so that the coverage (taking into account extensions elected by the policyholder without the issuer’s consent) has a maximum period of less than 12 months after the original effective date of the contract. This rule also seeks comments on all aspects of this proposed rule, including whether the maximum length of short-term, limited-duration insurance should be some other duration; under what conditions issuers should be able to allow short-term, limited-duration insurance to continue for 12 months or longer with the issuer’s consent; and on the proposed revisions to the notice that must appear in the contract and any application materials.


B. Executive Orders 12866 and 13563—Department of Labor and Department of Health and Human Services

Executive Order 12866 (58 FR 51735) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 (76 FR 3821, January 21, 2011) is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in Executive Order 12866.

Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a final rule—(1) having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also referred to as “economically significant”); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order.

A full regulatory impact analysis must be prepared for major rules with economically significant effects (for example, $100 million or more in any 1 year), and a “significant” regulatory action is subject to review by the Office of Management and Budget (OMB). The Departments anticipate that this regulatory action is likely to have economic impacts of $100 million or more in at least 1 year, and therefore meets the definition of “significant” rule under Executive Order 12866. Therefore, the Departments have provided an assessment of the potential costs, benefits, and transfers associated with this proposed rule. In accordance with the provisions of Executive Order 12866, this proposed rule was reviewed by OMB.

1. Need for Regulatory Action

This rule contains proposed amendments to the definition of short-term, limited-duration insurance for purposes of the exclusion from the definition of individual health insurance coverage. This regulatory action is taken in light of Executive Order 13813 directing the Departments to consider proposing regulations or revising guidance to expand the availability of short-term, limited-duration insurance, as well as continued feedback from stakeholders expressing concerns about the October 2016 final rule. While individuals who qualify for premium tax credits are largely insulated from significant premium increases, individuals who are not eligible for subsidies are harmed by increased premiums in the individual market due to a lack of other, more affordable alternative coverage options. The proposed rule would increase insurance options for individuals unable or unwilling to purchase PPACA-compliant plans.

2. Summary of Impacts

In accordance with OMB Circular A–4, Table 1 depicts an accounting statement summarizing the

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\(^{32}\) The Departments are using data on APTC as an approximation of premium tax credits since this is the data that is available for 2017.
Short-term, limited-duration insurance represents a small fraction of the health insurance market. Based on data from the National Association of Insurance Commissioners (NAIC), in 2016, before the October 2016 final rule became effective, total premiums earned for policies designated short-term, limited-duration by carriers were approximately $146 million for approximately 1,279,500 member months and with approximately 160,600 covered lives at the end of the year. During the same period, total premiums for individual market (comprehensive major medical) coverage were approximately $63.25 billion for approximately 175,689,900 member months with approximately 13.6 million covered lives at the end of the year. 

Some public comments received in response to the June 2016 proposed rule stated that the majority of the short-term, limited-duration insurance policies were sold as transitional coverage, particularly for individuals seeking to cover periods of unemployment or other gaps between employer-sponsored coverage, and that the policies typically provided coverage for less than 3 months. Accordingly, this proposed rule would have no effect on the consumers who purchase such coverage for less than 3 months and perhaps some issuers of those policies. While it is not clear how the October 2016 final rule affected the sales of short-term, limited-duration insurance, the sales of such coverage were increasing prior to the issuance of that rule. Given the prior trend and the recent increases in premiums in the individual market, the Departments anticipate that the rule, if finalized, would encourage more consumers to purchase short-term, limited-duration insurance for longer durations, including individuals who were previously uninsured and some who are currently enrolled in individual market plans, especially in 2019 and beyond, when the individual shared responsibility payment included in section 5000A of the Code is reduced to $0, as provided under Public Law 115–97.

Benefits

Consumers who would be likely to purchase short-term, limited-duration insurance for longer periods would benefit from increased insurance options at lower premiums, as the average monthly premium in the fourth quarter of 2016 for a short-term, limited-duration policy was approximately $124 compared to $393 for an unsubsidized PPACA-compliant plan. This proposed rule would also benefit individuals who need coverage for longer periods for reasons previously discussed in the preamble, such as needing more than 3 months to find new employment, or finding PPACA-compliant plans to be unaffordable. Individuals who purchase short-term, limited-duration insurance as opposed to being uninsured would potentially experience improved health outcomes and have greater protection from catastrophic health care expenses. Individuals purchasing short-term, limited-duration policies could obtain broader access to health care providers compared to those PPACA-compliant plans that have narrow provider networks. The Departments seek comments on how many consumers may purchase short-term, limited-duration insurance, rather than being uninsured or purchasing PPACA-compliant plans, and the benefits to


35 The ability of short-term limited-duration plans to provide broad provider networks has been touted by some in the insurance community. https://www.wsj.com/articles/sales-of-short-term-health-policies-surge-1460228539.
them from having short-term, limited-duration insurance, as well as any impacts on the PPACA individual market single risk pools.

Issuers of short-term, limited-duration insurance would benefit from higher enrollment. They are likely to experience an increase in premium revenues and profits because such policies can be priced in an actuarially fair manner (by which the Departments mean that it is priced so that the premium paid by an individual reflects the risks associated with insuring the particular individual or individuals covered by that policy) and are not required to comply with PPACA medical loss ratio requirements for group and individual health insurance coverage.

Costs and Transfers

Short-term, limited-duration insurance policies would be unlikely to include all the elements of PPACA-compliant plans, such as the preexisting condition exclusion prohibition, coverage of essential health benefits without annual or lifetime dollar limits, preventive care, maternity and prescription drug coverage, rating restrictions, and guaranteed renewability. Therefore, consumers who switch to such policies from PPACA-compliant plans would experience loss of access to some services and providers and an increase in out-of-pocket expenditures related to such excluded services, benefits that in many cases consumers do not believe are worth their cost (which could be one reason why many consumers, even those receiving subsidies for PPACA-compliant plans, may switch to short-term, limited-duration policies rather than remain in PPACA-compliant plans). The Departments seek comments on the value of such excluded services to individuals who switch coverage. Depending on plan design, consumers who purchase short-term, limited-duration insurance policies and then develop chronic conditions could face financial hardship as a result, until they are able to enroll in PPACA-compliant plans that would provide coverage for such conditions. Additionally, since short-term, limited-duration insurance does not qualify as minimum essential coverage, any individual enrolled in a short-term, limited-duration plan that lasts 3 months or longer in 2018 would potentially incur a tax liability for not having minimum essential coverage during that year. Starting in 2019, the individual shared responsibility payment included in section 5000A of the Code is reduced to $0, as provided under Public Law 115–97.

Because short-term, limited-duration insurance policies can be priced in an actuarially fair manner, subject to State law, individuals who are likely to purchase such coverage are likely to be relatively young or healthy. Allowing such individuals to purchase policies that do not comply with PPACA, but with term lengths that may be similar to those of PPACA-compliant plans with 12-month terms, could potentially weaken States’ individual market single risk pools. As a result, individual market issuers could experience higher than expected costs of care and suffer financial losses, which might prompt them to leave the individual market. Although choices of plans available in the individual market have already been reduced to plans from a single insurer in roughly half of all counties, this proposed rule may further reduce choices for individuals remaining in those individual market single risk pools. The Departments seek comments on these and any other potential costs.

The Departments anticipate that most of the individuals who switch from individual market plans to short-term, limited-duration insurance would be relatively young or healthy and would also not be eligible to receive APTC. If individual market single risk pools change as a result, it would result in an increase in premiums for the individuals remaining in those risk pools. An increase in premiums for individual market single risk pool coverage would result in an increase in Federal outlays for APTC.

Beginning in 2019, the individual shared responsibility payment included in section 5000A of the Code is reduced to $0, as provided under Public Law 115–97. This would compound the effects of the provisions of this proposed rule (one potential exception being the impact on APTC payments). In order to estimate the impact on the individual market and APTC payments, the Departments used enrollment, premium and APTC data for 2017, observed rate increases for 2018, and assumed that 2019 rates will increase in line with medical expenditures and assumed the relative morbidities of the individuals leaving the individual market single risk pool to those remaining in the risk pool to be 75 percent. The Congressional Budget Office estimates that 3 million people will drop coverage in 2019 from the individual market and premiums will increase 10 percent on average, as a result of the change to the individual shared responsibility payment. The Departments seek comments on how many of these individuals may purchase short-term, limited-duration insurance instead. Based on enrollment trends prior to the October 2016 final rule, the Departments project that approximately 100,000 to 200,000 additional individuals would shift from the individual market to short-term, limited-duration insurance in 2019. Most of these individuals would be young or healthy and only about 10 percent of them would have been subsidized by eligibility for APTC if they maintained their Exchange coverage. While the reduction in the number of subsidized enrollees would tend to reduce total APTC payments, increases in premiums would tend to increase them. The proposed rule’s net effect on total APTC payments is uncertain, but federal outlays for APTC are estimated to increase by between $96 million ($54,948 million – $54,852 million) and $168 million ($55,020 million – $54,852 million) annually.

Table 2 depicts the effects on average premiums and APTC payments.

### Table 2—Estimated Effect on Individual Market Exchanges in 2019

<table>
<thead>
<tr>
<th></th>
<th>Estimated number of subsidized enrollees in exchanges</th>
<th>Estimated number of unsubsidized enrollees in exchanges</th>
<th>Estimated average monthly premium</th>
<th>Estimated average monthly APTC</th>
<th>Estimated total monthly APTC</th>
<th>Estimated total annual APTC</th>
</tr>
</thead>
<tbody>
<tr>
<td>No change in policy</td>
<td>8,459,000</td>
<td>4,671,000</td>
<td>$649</td>
<td>$512</td>
<td>$4,331,000,000</td>
<td>$51,972,000,000</td>
</tr>
</tbody>
</table>


37 Percent Premium Increase = (Total Enrollment – (Morbidity(75%)) * Number Switching)) / (Total Enrollment – Number Switching).
There is significant uncertainty regarding these estimates, because changes in enrollment and premiums would depend on a variety of economic factors and it is difficult to predict how consumers and issuers would react to the proposed policy changes.

C. Regulatory Alternatives

One regulatory alternative would be to set the maximum duration for short-term, limited-duration insurance to a 6 month or 9 month period. However, this alternative would not adequately increase choices for individuals unable or unwilling to purchase PPACA-compliant plans.

D. Paperwork Reduction Act—Department of Health and Human Services

This proposed rule would require that the required notice be prominently displayed in the contract and in any application materials for short-term, limited-duration insurance. The Departments have proposed the exact text for this notice requirement and the language would not need to be customized. The burden associated with these notices is not subject to the Paperwork Reduction Act of 1995 in accordance with 5 CFR 1320.3(c)(2) because they do not contain a “collection of information” as defined in 44 U.S.C. 3502(3). Consequently, this document need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

E. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 et seq.) (RFA) imposes certain requirements with respect to Federal rules that are subject to the notice and comment requirements of section 553(b) of the Administrative Procedure Act (5 U.S.C. 551 et seq.) and that are likely to have a significant economic impact on a substantial number of small entities. Unless an agency certifies that a proposed rule is not likely to have a significant economic impact on a substantial number of small entities, section 603 of RFA requires that the agency present an initial regulatory flexibility analysis at the time of the publication of the notice of proposed rulemaking describing the impact of the rule on small entities and seeking public comment on such impact. Small entities include small businesses, organizations and governmental jurisdictions.

The RFA generally defines a “small entity” as—(1) a proprietary firm meeting the size standards of the Small Business Administration (13 CFR 121.201); (2) a nonprofit organization that is not dominant in its field; or (3) a small government jurisdiction with a population of less than 50,000. (States and individuals are not included in the definition of “small entity”). The Departments use as their measure of significant economic impact on a substantial number of small entities a change in revenues of more than 3 to 5 percent.

This proposed rule would impact health insurance issuers, especially those in the individual market. The Departments believe that health insurance issuers would be classified under the North American Industry Classification System code 524114 (Direct Health and Medical Insurance Carriers). According to SBA size standards, entities with average annual receipts of $38.5 million or less are considered small entities for these North American Industry Classification System codes. Issuers could possibly be classified in 621491 (Health Maintenance Organization Medical Centers) and, if this is the case, the SBA size standard is $32.5 million or less.38 The Departments believe that few, if any, insurance companies selling comprehensive health insurance policies (in contrast, for example, to travel insurance policies or dental discount policies) fall below these size thresholds. Based on data from Medical Loss Ratio (MLR) annual report submissions for the 2015 MLR reporting year,39 approximately 92 out of over 530 issuers of health insurance coverage nationwide had total premium revenue of $38.5 million or less, of which 64 issuers offer plans in the individual market. This estimate may overstate the actual number of small health insurance companies that may be affected, since almost 50 percent of these small companies belong to larger holding groups, and many if not all of these small companies are likely to have non-health lines of business that would result in their revenues exceeding $38.5 million. Therefore, the Departments certify that this proposed rule would not have a significant impact on a substantial number of small entities.

In addition, section 1102(b) of the Social Security Act requires agencies to prepare a regulatory impact analysis if a rule may have a significant economic impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. This proposed rule will not affect small rural hospitals. Therefore, the Departments have determined that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

F. Special Analysis—Department of the Treasury

Certain IRS regulations, including this one, are exempt from the requirements of Executive Order 12866, as supplemented and reaffirmed by Executive Order 13563. Therefore, a regulatory impact assessment is not required. Pursuant to Executive Order 13789, the Treasury Department and OMB are currently reviewing the scope and implementation of the existing

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exemption. Pursuant to section 7805(f) of the Code, this proposed rule has been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

G. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a proposed rule that includes any Federal mandate that may result in expenditures in any 1 year by a State, local, or Tribal governments, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. Currently, that threshold is approximately $148 million. This proposed rule does not include any Federal mandate that may result in expenditures by State, local, or tribal governments, or the private sector, that may impose an annual burden that exceeds that threshold.

H. Federalism—Department of Labor and Department of Health and Human Services

Executive Order 13132 outlines fundamental principles of federalism. It requires adherence to specific criteria by Federal agencies in formulating and implementing policies that have “substantial direct effects” on the States, the relationship between the national government and States, or on the distribution of power and responsibilities among the various levels of government. Federal agencies promulgating regulations that have these federalism implications must consult with State and local officials, and describe the extent of their consultation and the nature of the concerns of State and local officials in the preamble to the final regulation.

Federal officials have discussed the issue of the term length of short-term, limited-duration insurance with State regulatory officials. This proposed rule has no federalism implications to the extent that current State law requirements for short-term, limited-duration insurance are the same as or more restrictive than the Federal standard proposed in this proposed rule. States may continue to apply such State law requirements.

I. Congressional Review Act

This proposed rule is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 et seq.) and will be transmitted to the Congress and to the Comptroller General for review in accordance with such provisions.

J. Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771, entitled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017. This proposed rule, if finalized as proposed, is expected to be an Executive Order 13771 deregulatory action.

IV. Statutory Authority

The Department of the Treasury regulations are proposed to be adopted pursuant to the authority contained in sections 7805 and 9833 of the Code. The Department of Labor regulations are proposed to be adopted pursuant to the authority contained in 29 U.S.C. 1135 and 1191c; and Secretary of Labor’s Order 1–2011, 77 FR 1088 (Jan. 9, 2012).

The Department of Health and Human Services regulations are proposed to be adopted pursuant to the authority contained in sections 2701 through 2763, 2791, 2792 and 2794 of the PHS Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, 300gg–92 and 300gg–94), as amended.

List of Subjects

26 CFR Part 54

Pension excise taxes.

29 CFR Part 2590

Continuation coverage, Disclosure, Employee benefit plans, Group health plans, Health care, Health insurance, Medical child support, Reporting and recordkeeping requirements.

45 CFR Parts 144 and 146

Health care, Health insurance, Reporting and recordkeeping requirements.

45 CFR Part 148

Administrative practice and procedure, Health care, Health insurance, Penalties, Reporting and recordkeeping requirements.

Kirsten B. Wielobob,

Deputy Commissioner for Services and Enforcement, Internal Revenue Service.

Signed this 8th day of February 2018.

Preston Rutledge,

Assistant Secretary, Employee Benefits Security Administration, Department of Labor.

Dated: February 1, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: February 9, 2018.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

For the reasons stated in the preamble, 26 CFR part 54 is proposed to be amended as follows:

PART 54—PENSION AND EXCISE TAX

Par. 1. The authority citation for part 54 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

Par. 2. Section 54.9801–2 is amended by revising the definition of “Short-term, limited-duration insurance” to read as follows:

§ 54.9801–2 Definitions.

Short-term, limited-duration insurance means health insurance coverage provided pursuant to a contract with an issuer that:

1. Has an expiration date specified in the contract (taking into account any extensions that may be elected by the policyholder without the issuer’s consent) that is less than 12 months after the original effective date of the contract;

2. With respect to policies having a coverage start date before January 1, 2019, displays prominently in the contract and in any application materials provided in connection with enrollment in such coverage in at least 14 point type the following:

THIS COVERAGE IS NOT REQUIRED TO COMPLY WITH FEDERAL REQUIREMENTS FOR HEALTH INSURANCE, PRINCIPALLY THOSE CONTAINED IN THE AFFORDABLE CARE ACT. BE SURE TO CHECK YOUR POLICY CAREFULLY TO MAKE SURE YOU UNDERSTAND WHAT THE POLICY DOES AND DOESN’T COVER. IF THIS COVERAGE EXPIRES OR YOU LOSE ELIGIBILITY FOR THIS COVERAGE, YOU MIGHT HAVE TO WAIT UNTIL AN OPEN ENROLLMENT PERIOD TO GET OTHER HEALTH
INSURANCE COVERAGE. ALSO, THIS COVERAGE IS NOT “MINIMUM ESSENTIAL COVERAGE”. IF YOU DON’T HAVE MINIMUM ESSENTIAL COVERAGE FOR ANY MONTH IN 2018, YOU MAY HAVE TO MAKE A PAYMENT WHEN YOU FILE YOUR TAX RETURN UNLESS YOU QUALIFY FOR AN EXEMPTION FROM THE REQUIREMENT THAT YOU HAVE HEALTH COVERAGE FOR THAT MONTH.

and

(3) With respect to policies having a coverage start date on or after January 1, 2019, displays prominently the contract and in any application materials provided in connection with enrollment in such coverage in at least 14 point type the following:

THIS COVERAGE IS NOT REQUIRED TO COMPLY WITH FEDERAL REQUIREMENTS FOR HEALTH INSURANCE, PRINCIPALLY THOSE CONTAINED IN THE AFFORDABLE CARE ACT. BE SURE TO CHECK YOUR POLICY CAREFULLY TO MAKE SURE YOU UNDERSTAND WHAT THE POLICY DOES AND DOESN’T COVER. IF THIS COVERAGE EXPIRES OR YOU LOSE ELIGIBILITY FOR THIS COVERAGE, YOU MIGHT HAVE TO WAIT UNTIL AN OPEN ENROLLMENT PERIOD TO GET OTHER HEALTH INSURANCE COVERAGE.

Par. 3. Section 54.9833–1 is amended by revising the section heading and the last sentence to read as follows:

§ 54.9833–1 Applicability dates.

* * * * *

Notwithstanding the previous sentence, the definition of “short-term, limited-duration insurance” in § 54.9801–2 applies [DATE 60 DAYS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE FEDERAL REGISTER].

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Chapter XXV

For the reasons stated in the preamble, the Department of Labor proposes to amend 29 CFR part 2590 as set forth below:

PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS

§ 4. The authority citation for part 2590 continues to read as follows:


§ 2590.701–2 Definitions.

* * * * *

Short-term, limited-duration insurance means health insurance coverage provided pursuant to a contract with an issuer that:

(1) Has an expiration date specified in the contract (taking into account any extensions that may be elected by the policyholder without the issuer’s consent) that is less than 12 months after the original effective date of the contract;

(2) With respect to policies having a coverage start date before January 1, 2019, displays prominently in the contract and in any application materials provided in connection with enrollment in such coverage in at least 14 point type the following:

THIS COVERAGE IS NOT REQUIRED TO COMPLY WITH FEDERAL REQUIREMENTS FOR HEALTH INSURANCE, PRINCIPALLY THOSE CONTAINED IN THE AFFORDABLE CARE ACT. BE SURE TO CHECK YOUR POLICY CAREFULLY TO MAKE SURE YOU UNDERSTAND WHAT THE POLICY DOES AND DOESN’T COVER. IF THIS COVERAGE EXPIRES OR YOU LOSE ELIGIBILITY FOR THIS COVERAGE, YOU MIGHT HAVE TO WAIT UNTIL AN OPEN ENROLLMENT PERIOD TO GET OTHER HEALTH INSURANCE COVERAGE.

* * * * *

§ 2590.736 Applicability dates.

* * * Notwithstanding the previous sentence, the definition of “short-term, limited-duration insurance” in § 2590.701–2 applies [DATE 60 DAYS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE FEDERAL REGISTER].

DEPARTMENT OF HEALTH AND HUMAN SERVICES

For the reasons stated in the preamble, the Department of Health and Human Services proposes to amend 45 CFR parts 144, 146, and 148 as set forth below:

PART 144—REQUIREMENTS RELATING TO HEALTH INSURANCE COVERAGE

§ 144.103 Definitions.

* * * * *

Short-term, limited-duration insurance means health insurance coverage provided pursuant to a contract with an issuer that:

(1) Has an expiration date specified in the contract (taking into account any extensions that may be elected by the policyholder without the issuer’s consent) that is less than 12 months after the original effective date of the contract;

(2) With respect to policies having a coverage start date before January 1, 2019, displays prominently in the contract and in any application materials provided in connection with enrollment in such coverage in at least 14 point type the following:

THIS COVERAGE IS NOT REQUIRED TO COMPLY WITH FEDERAL REQUIREMENTS FOR HEALTH INSURANCE, PRINCIPALLY THOSE CONTAINED IN THE AFFORDABLE CARE ACT. BE SURE TO CHECK YOUR POLICY CAREFULLY TO MAKE SURE YOU UNDERSTAND WHAT THE POLICY DOES AND DOESN’T COVER. IF THIS COVERAGE EXPIRES OR YOU LOSE ELIGIBILITY FOR THIS COVERAGE, YOU MIGHT HAVE TO WAIT UNTIL AN OPEN ENROLLMENT PERIOD TO GET OTHER HEALTH INSURANCE COVERAGE.

* * * * *
ESSENTIAL COVERAGE.” IF YOU DON’T HAVE MINIMUM ESSENTIAL COVERAGE FOR ANY MONTH IN 2018, YOU MAY HAVE TO MAKE A PAYMENT WHEN YOU FILE YOUR TAX RETURN UNLESS YOU QUALIFY FOR AN EXEMPTION FROM THE REQUIREMENT THAT YOU HAVE HEALTH COVERAGE FOR THAT MONTH;

and

(3) With respect to policies having a coverage start date on or after January 1, 2019, displays prominently in the contract and in any application materials provided in connection with enrollment in such coverage in at least 14 point type the following:

THIS COVERAGE IS NOT REQUIRED TO COMPLY WITH FEDERAL REQUIREMENTS FOR HEALTH INSURANCE, PRINCIPALLY THOSE CONTAINED IN THE AFFORDABLE CARE ACT. BE SURE TO CHECK YOUR POLICY CAREFULLY TO MAKE SURE YOU UNDERSTAND WHAT THE POLICY DOES AND DOESN’T COVER. IF THIS COVERAGE EXPIRES OR YOU LOSE ELIGIBILITY FOR THIS COVERAGE, YOU MIGHT HAVE TO WAIT UNTIL AN OPEN ENROLLMENT PERIOD TO GET OTHER HEALTH INSURANCE COVERAGE.

PART 146—REQUIREMENTS FOR THE GROUP HEALTH INSURANCE MARKET

9. The authority citation for part 146 is revised to read as follows:

Authority: Secs. 2702 through 2705, 2711 through 2723, 2791, and 2792 of the Public Health Service Act (42 U.S.C. 300gg–1 through 300gg–5, 300gg–11 through 300gg–23, 300gg–91, and 300gg–92).

10. Section 146.125 is amended by revising the last sentence to read as follows:

§ 146.125 Applicability dates.

(b) * * * Notwithstanding the previous sentence, the definition of “short-term, limited-duration insurance” in § 144.103 of this subchapter applies [DATE 60 DAYS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE FEDERAL REGISTER].

PART 148—REQUIREMENTS FOR THE INDIVIDUAL HEALTH INSURANCE MARKET

11. The authority citation for part 148 continues to read as follows:

Authority: Secs. 2701 through 2763, 2791, and 2792 of the Public Health Service Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended.

12. Section 148.102 is amended by revising the section heading and the last sentence of paragraph (b) to read as follows:

§ 148.102 Scope and applicability date.

(b) * * * Notwithstanding the previous sentence, the definition of “short-term, limited-duration insurance” in § 144.103 of this subchapter is applicable [DATE 60 DAYS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE FEDERAL REGISTER].

DEPARTMENT OF COMMERCE
National Oceanic and Atmospheric Administration

50 CFR Part 622

RIN 0648–BG83

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Reef Fish Fishery of the Gulf of Mexico; Amendment 36A

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notification of availability; request for comments.

SUMMARY: The Gulf of Mexico (Gulf) Fishery Management Council (Council) has submitted Amendment 36A to the Fishery Management Plan for the Reef Fish Resources of the Gulf of Mexico (Reef Fish FMP) for review, approval, and implementation by NMFS. Amendment 36A would require owners or operators of federally permitted commercial Gulf reef fish vessels landing any commercially caught, federally managed reef fish from the Gulf to provide notification prior to landing and to land at approved locations; require shares of red snapper individual fishing quota (IFQ) (RS–IFQ) program and groupers tilefish IFQ (GT–IFQ) program from non-activated accounts to be returned to NMFS for redistribution; and allow NMFS to hold back a portion of IFQ allocation at the start of the fishing year in anticipation of a commercial quota reduction. The purpose of Amendment 36A is to improve compliance and increase management flexibility in the RS–IFQ and GT–IFQ programs, and increase the likelihood of achieving optimum yield (OY) for reef fish stocks managed under these programs.

DATES: Written comments on Amendment 36A must be received by April 23, 2018.

ADDRESSES: You may submit comments on the amendment identified by “NOAA–NMFS–2017–0060” by either 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-2017-0060, click the “Comment Now!” icon, complete the required fields, and enter or attach your comments.

• Mail: Submit written comments to Peter Hood, NMFS Southeast Regional Office, 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).

Electronic copies of Amendment 36A may be obtained from www.regulations.gov or the Southeast Regional Office website at http://sero.nmfs.noaa.gov/sustainable_fisheries/gulf_fisheries/reef_fish/2017/ A36A_comm_IFQ/am36Aindex.html. Amendment 36A includes an environmental assessment, fishery impact statement, regulatory impact review, and Regulatory Flexibility Act analysis.

FOR FURTHER INFORMATION CONTACT:
Peter Hood, NMFS Southeast Regional Office, telephone: 727–824–5305, or email: peter.hood@noaa.gov.

SUPPLEMENTARY INFORMATION: The Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) requires each regional fishery management council to submit any FMP or amendment to NMFS for review and approval, partial approval, or disapproval. The Magnuson-Stevens Act also requires that NMFS, upon receiving a plan or amendment, publish an announcement in the Federal Register notifying the public that the FMP or amendment is available for review and comment.

Amendment 36A to the Reef Fish FMP was prepared by the Council and, if approved, would be implemented by NMFS through regulations at 50 CFR...
part 622 under the authority of the Magnuson-Stevens Act.

**Background**

There are two commercial IFQ programs in the Gulf. Amendment 26 to the Reef Fish FMP established the RS–IFQ program, and Amendment 29 to the Reef Fish FMP established the GT–IFQ program. The RS–IFQ program manages commercial harvest of red snapper and was implemented on January 1, 2007 (71 FR 74447, November 22, 2006). The GT–IFQ program manages commercial harvest of multiple species of groupers and tilefishes, and was implemented on January 1, 2010 (74 FR 44732, August 31, 2009). Both IFQ programs share a single Web-based accounting and reporting system.

The Council began the development of Amendment 36 to the Reef Fish FMP in response to a 5-year review of the RS–IFQ Program completed in 2013. This review evaluated the progress of the RS–IFQ program towards achieving the stated goals of reducing overcapacity in the fishery and eliminating problems associated with race-to-fish (derby) fishing. The Council also received input on the program from some of their advisory panels as well as from the public. As a result, the suggested modifications to the RS–IFQ program became complex, and the Council split the numerous potential actions into two FMP amendments, Amendments 36A and 36B. The scope of the actions was also expanded to include revisions to the GT–IFQ program because management, as well as the goals and objectives, of this program are similar to the RS–IFQ program. Amendment 36A addresses compliance and program flexibility issues, while Amendment 36B addresses program participation and the distribution of IFQ shares and allocation in the programs.

**Actions Contained in Amendment 36A**

Amendment 36A includes actions to expand the requirement for vessels with a commercial Gulf reef fish permit to notify NMFS in advance of landing any reef fish species not managed under the IFQ programs and to land at approved locations, and addresses IFQ shares held in shareholder accounts that have not been activated, since the current Web-based system was put in place on January 1, 2010. Amendment 36A would return shares held in non-activated accounts to NMFS for future redistribution. In addition, Amendment 36A provides NMFS the authority to withhold annual allocation before distribution at the beginning of a year in which a commercial quota reduction is expected to occur.

**Landing Notification**

Currently, to improve compliance with the IFQ programs, vessel owners or operators with commercial Gulf reef fish permits are required to notify NMFS between 3 and 24 hours in advance of landing any commercially harvested reef fish species managed under the IFQ programs (IFQ species). In addition, vessels must land IFQ species at an approved landing location. Although the advance landing notifications help with the enforcement of the IFQ programs, one of the conclusions from a 5-year review of the RS–IFQ Program was additional enforcement efforts may be necessary to deter IFQ landing violations.

Amendment 36A would expand the requirement for an advance landing notification to all commercial trips that land Gulf reef fish species or Florida Keys/East Florida hogfish harvested in the Gulf even if no IFQ species are on board. Note that the single hogfish stock in the Gulf was recently split into a West Florida stock and a Florida Keys/East Florida stock, separated at 25°09' N lat. in Gulf Federal waters off the west coast of Florida (82 FR 34574 and 82 FR 34584, July 25, 2017). The management measures for the Florida Keys/East Florida stock are developed by the South Atlantic Fishery Management Council, but commercial vessels fishing for this stock in Gulf Federal waters are required to have a Federal commercial permit for Gulf reef fish and are required to follow the reporting requirements associated with this permit.

The vessel owner or operator would notify NMFS at least 3 hours, but no more than 24 hours, in advance of landing on each trip. Amendment 36A would also require owners and operators on such trips to land at approved landing locations. Requiring notification in advance of landing any federally managed reef fish from the Gulf and requiring landings at approved locations is expected to help deter fishermen from illegally landing IFQ species or reporting IFQ species as another species (e.g., red snapper reported as vermilion snapper), because law enforcement and port agents would be informed in advance of all reef fish trips returning to port and can meet vessels to inspect landings. If any IFQ species are to be landed, all regulations under the applicable IFQ program must be followed, including the more extensive advance notice of landing. Only one IFQ landing notification covering both IFQ and non-IFQ Gulf reef fish species or Florida Keys/East Florida hogfish harvested in the Gulf would be required on such a trip.

**Non-Activated IFQ Shareholder Accounts**

Amendment 36A also addresses RS–IFQ and GT–IFQ shareholder accounts that received shares through the initial apportionment when each IFQ program began, but the accounts have never been accessed by the shareholder since January 1, 2010, the initiation of the current IFQ system. NMFS and the Council have attempted to notify account holders with these non-activated IFQ accounts through phone calls, certified letters, and discussion at public meetings. Although shares in the non-activated accounts represent a small fraction of the total shares, annual allocation assigned to these non-activated IFQ accounts is not landed, and therefore, may prevent achieving OY if not made available for use. Amendment 36A would return RS–IFQ and GT–IFQ shares in these non-activated accounts to NMFS for redistribution. The Council intends to redistribute these shares to IFQ program participants through a mechanism determined in Amendment 36B.

**Allocation**

Amendment 36A also addresses how to distribute allocation to IFQ shareholders in a fishing year where there is an anticipated reduction of the commercial quota. Under the IFQ programs, annual allocation is distributed to IFQ shareholders on January 1, and most IFQ program participants begin to use or transfer their allocation early in the fishing year. After shareholders begin transferring or landing allocation, NMFS cannot retroactively withdraw allocation from shareholder accounts if a quota decrease became effective after the beginning of the fishing year. Amendment 36A would allow NMFS to anticipate a decrease in the quota of any IFQ species or multi-species share categories after the start of a fishing year and withhold distribution of quota equal to the amount of the expected decrease in commercial quota. NMFS would distribute the remaining portion of the annual allocation to shareholders on January 1. If the rulemaking associated with the commercial quota reduction is not effective by June 1 in the same fishing year, then NMFS would distribute the withheld quota back to the current shareholders.

**Proposed Rule for Amendment 36A**

A proposed rule that would implement Amendment 36A has been drafted. In accordance with the
Magnuson-Stevens Act, NMFS is evaluating the proposed rule to determine whether it is consistent with the Reef Fish FMP, the Magnuson-Stevens Act, and other applicable laws. If that determination is affirmative, NMFS will publish the proposed rule in the Federal Register for public review and comment.

Consideration of Public Comments

The Council has submitted Amendment 36A for Secretarial review, approval, and implementation. Comments on Amendment 36A must be received by April 23, 2018. Comments received during the respective comment periods, whether specifically directed to Amendment 36A or the proposed rule, will be considered by NMFS in its decision to approve, partially approve, or disapprove Amendment 36A. Comments received after the comment periods will not be considered by NMFS in this decision. All comments received by NMFS on Amendment 36A or the proposed rule during their respective comment periods will be addressed in the final rule.

Authority: 16 U.S.C. 1801 et seq.


Emily H. Menashes,
Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2018–03463 Filed 2–20–18; 8:45 am]
DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

February 15, 2018.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995. Public Law 104–13. Comments are requested regarding (1) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency’s estimate of burden including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by March 23, 2018 will be considered. Written comments should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Building, 725 17th Street NW, Washington, DC 20502. Commenters are encouraged to submit their comments to OMB via email to: OIRA_Submission@OMB.EOP.GOV or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Copies of the submission(s) may be obtained by calling (202) 720–8958.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Animal Plant and Health Inspection Service

Title: Self Certification Medical Statement.

OMB Control Number: 0579–0196.

Summary of Collection: The United States Department of Agriculture is responsible for ensuring consumers that food and farm products are moved from producer to consumer in the most efficient, dependable, economical, and equitable system possible. Each year, the United States Department of Agriculture’s Marketing and Regulatory Programs (MRP) agency hires individuals for commodity grading and inspection positions to ensure this process is efficient and effective. These positions often involve arduous conditions and require direct contact with meat, dairy, fresh or processed fruits and vegetables, and poultry intended for human consumption; and cotton and tobacco products intended for consumer use. 5 CFR part 339 authorizes an agency to request medical information from an applicant that may assist management with employment decisions concerning covered positions that have specific medical or physical fitness requirements. APHIS will collect the applicant’s medical information using MRP Form 5 (Self-Certification Medical Statement).

Need and Use of the Information: The information collected from prospective employees assists MRP officials, administrative personnel, and servicing Human Resources Offices in determining an applicant’s physical fitness and suitability for employment in positions with approved medical standards and physical requirements. If the information was not collected, APHIS would not be able to accurately determine the applicant’s fitness to safely perform the duties of the covered positions.

Description of Respondents: Individuals or households.

Number of Respondents: 606.

Frequency of Responses: Reporting: On occasion.

Total Burden Hours: 102.

Ruth Brown, Departmental Information Collection Clearance Officer.

[FR Doc. 2018–03522 Filed 2–20–18; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

Codex Alimentarius Commission: Codex Committee on Pesticide Residues (CCPR)

[DOCKET NO. FSIS–2018–0002]

AGENCY: Office of the Deputy Under Secretary for Food Safety, USDA.

ACTION: Notice of public meeting and request for comments.

SUMMARY: The Office of the Deputy Under Secretary for Food Safety and the EPA are sponsoring a public meeting on March 15, 2018. The objective of the public meeting is to provide information and receive public comments on agenda items and draft United States (U.S.) positions to be discussed at the 50th Session of the Codex Committee on Pesticide Residues (CCPR) of the Codex Alimentarius Commission (Codex), taking place in Haikou, China between April 9 and 14, 2018. The Acting Deputy Under Secretary for Food Safety and the EPA recognize the importance of providing interested parties the opportunity to obtain background information on the 50th Session of the CCPR and to address items on the agenda.

DATES: The public meeting is scheduled for Thursday, March 15, 2018, 1:00 p.m.–4:00 p.m.

ADDRESSES: The public meeting will take place at the EPA, Room PYS–4350, One Potomac Yard South, 2777 South Crystal Drive, Arlington, VA 22202.

Documents related to the 50th Session of the CCPR are accessible via the internet at the following address: http://www.fao.org/fao-whocodexalimentarius/meetings/en/.

Captain David Miller, U.S. Delegate to the 50th Session of the CCPR, and the USDA invite interested U.S. parties to submit their comments electronically to
the following email address:
Miller.Davidj@epa.gov.

Call-In-Number
If you wish to participate in the public meeting for the 50th Session of the CCPR by conference call, please use the call-in-number and participant code listed below:
Call-in-Number: 1–888–844–9904
Participant Code: 5126092

For Further Information About the 50th Session of the CCPR Contact:
Captain David Miller, Chief, Chemistry & Exposure Branch and Acting Chief, Toxicology & Epidemiology Branch, Health Effects Division, Ariel Rios Building, 1200 Pennsylvania Avenue NW, Washington, DC 20460. Telephone: (703) 305–5352, Fax: (703) 305–5147, Email: Miller.Davidj@epa.gov.

For Further Information About the Public Meeting Contact: Marie Maratos, U.S. Codex Office, 1400 Independence Avenue SW, South Agriculture Building, Room 4861, Washington, DC 20250. Telephone: (202) 205–7760, Fax: (202) 720–3157, Email: Marie.Maratos@fsis.usda.gov.

SUPPLEMENTARY INFORMATION:
Background
Codex was established in 1963 by two United Nations organizations, the Food and Agriculture Organization and the World Health Organization (FAO/WHO). Through adoption of food standards, codes of practice, and other guidelines developed by its committees, and by promoting their adoption and implementation by governments, Codex seeks to protect the health of consumers and ensure fair practices are used in trade.

The CCPR is responsible for establishing maximum limits for pesticide residues in specific food items or in groups of food; establishing maximum limits for pesticide residues in certain animal feeding stuffs moving in international trade where this is justified for reasons of protection of human health; preparing priority lists of pesticides for evaluation by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR); considering methods of sampling and analysis for the determination of pesticide residues in food and feed; considering other matters in relation to the safety of food and feed containing pesticide residues; and establishing maximum limits for environmental and industrial contaminants showing chemical or other similarity to pesticides, in specific food items or groups of food.

The CCPR is hosted by China. The U.S. attends this committee as a member country of the Codex Alimentarius.

Issues To Be Discussed at the Public Meeting
The following items on the Agenda for the 50th Session of the CCPR will be discussed during the public meeting:
- Proposed draft and draft revision of the Classification of Food and Feed for selected commodity groups (including seeds for beverages and sweets);
- Proposed draft tables on examples of representative commodities (including seeds for beverages and sweets);
- Electronic Working Group Outcomes on the Proposed New Work on the Possible Revision of the International Estimated Short-Term Intake (IESTI) equations;
- Establishment of Codex Schedules and Priority Lists of Pesticides for evaluation by JMPR;
- Electronic Working Group Outcomes on the possible establishment of a Codex database of national registration of pesticides; and
- Other Business and Future Work. Each issue listed will be fully described in documents distributed, or to be distributed, by the Secretariat before to the Meeting. Members of the public may access or request copies of these documents (see ADDRESSES).

Public Meeting
At the March 15, 2018, public meeting, draft U.S. positions on the agenda items will be described and discussed, and attendees will have the opportunity to pose questions and offer comments. Written comments may be offered at the meeting or sent to Captain David Miller, U.S. Delegate for the 50th Session of the CCPR (see ADDRESSES). Written comments should state that they relate to activities of the 50th Session of the CCPR.

Additional Public Notification
Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this Federal Register publication on-line through the FSIS web page located at: http://www.fsis.usda.gov/federal-register.

FSIS also will make copies of this publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, Federal Register notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The Update is available on the FSIS web page. Through the web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an email subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: http://www.fsis.usda.gov/subscribe. Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

USDA Non-Discrimination Statement
No agency, officer, or employee of the USDA shall, on the grounds of race, color, national origin, religion, sex, gender identity, sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, or political beliefs, exclude from participation in, deny the benefits of, or subject to discrimination any person in the United States under any program or activity conducted by the USDA.

How To File a Complaint of Discrimination
To file a complaint of discrimination, complete the USDA Program Discrimination Complaint Form, which may be accessed online at http://www.ocio.usda.gov/sites/default/files/docs/2012/Complain_combined_6_8_12.pdf, or write a letter signed by you or your authorized representative. Send your completed complaint form or letter to USDA by mail, fax, or email: Mail: U.S. Department of Agriculture, Director, Office of Adjudication, 1400 Independence Avenue SW, Washington, DC 20250–9410, Fax: (202) 690–7442, Email: program.intake@usda.gov.

Persons with disabilities who require alternative means for communication (Braille, large print, audiotape, etc.), should contact USDA’s TARGET Center at (202) 720–2600 (voice and TDD).

Done at Washington, DC, on February 14, 2018.

Marie Maratos,
Acting U.S. Manager for Codex Alimentarius.

[FR Doc. 2018–03465 Filed 2–20–18; 8:45 am]

BILLING CODE 3410–DM–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board
[B–12–2018]

Foreign-Trade Zone 135—Palm Beach, Florida; Application for Reorganization and Expansion Under Alternative Site Framework

An application has been submitted to the Foreign-Trade Zones (FTZ) Board by
the Port of Palm Beach District, grantee of FTZ 135, requesting authority to reorganize and expand the zone under the alternative site framework (ASF) adopted by the FTZ Board (15 CFR Sec. 400.2(c)). The ASF is an option for grantees for the establishment or reorganization of zones and can permit significantly greater flexibility in the designation of new subzones or “usage-driven” FTZ sites for operators/users located within a grantee’s “service area” in the context of the FTZ Board’s standard 2,000-acre activation limit for a zone. The application was submitted pursuant to the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the Board (15 CFR part 400). It was formally docketed on February 9, 2018.

FTZ 135 was approved by the FTZ Board on March 16, 1987 (Board Order 334, 52 FR 9903, March 27, 1987) and expanded on November 8, 2002 (Board Order 1258, 67 FR 70046, November 20, 2002). The current zone includes the following sites: Site 1 (25 acres)—Located at Port of Beach Miami Terminal, one mile from the Lake Worth Inlet to the Atlantic Ocean, Riviera Beach; Site 2 (37 acres)—industrial site located 2 miles due west of the terminal at I–95 and Highway 710, Riviera Beach; Site 3 (11 acres)—TravelPro USA, 700 Banyan Trail, Boca Raton; Site 4 (66 acres)—Martin County Airport, 1801 SE Airport Road, Stuart; Site 5 (24 acres total, three parcels)—Palm Beach International Airport, 1300 N. Perimeter Road, West Palm Beach; Site 6 (226 acres, three parcels)—North Beach County Airport, located adjacent to Beeline Highway (SR 710), North Palm Beach; Site 7 (3.56 acres, 155,000 sq. ft.)—warehouse, 1440 West Indiantown Road, Jupiter; Site 8 (170 acres)—within the Palm Beach Park of Commerce, located on the Beeline Highway (SR 710) near Pratt Whitney Road, south of Indiantown Road, Palm Beach; Site 9 (1.44 acres)—Team International Corporation, 6643 42nd Terrace, Riviera Beach; Site 10 (11.63 acres)—Viking Sport Cruisers, Inc., Palm Harbor Marina, 400 North Flagler Drive, West Palm Beach; Site 11 (31.56 acres)—Rybovich, 4200 North Flagler Drive, West Palm Beach; and Site 12 (1.66 acres)—Berth One International, 1 East 11th Street, Riviera Beach. Sites 9 through 12 were designated through minor boundary modifications pending the grantee’s submission of its application to reorganize and expand the zone (including Sites 9 through 12) under the ASF.

The grantee’s proposed service area under the ASF would be Palm Beach County, Martin County and St. Lucie County (with the exception of Sites 1 through 4 of FTZ 218, which are located in St. Lucie County), as described in the application. If approved, the grantee would be able to serve sites throughout the service area based on companies’ needs for FTZ designation. The application indicates that the proposed service area is within and adjacent to the West Palm Beach Customs and Border Protection port of entry.

The applicant is requesting authority to reorganize its existing zone to include Sites 1, 4, 5, 6 and 8 as “magnet” sites and Sites 2, 3, 7, 9, 10, 11 and 12 as “usage-driven” sites. The ASF allows for the possible exemption of one magnet site from the “sunset” time limits that generally apply to sites under the ASF, and the applicant proposes that Site 1 be so exempted.

In accordance with the FTZ Board’s regulations, Qahira El-Amin of the FTZ Staff is designated examiner to evaluate and analyze the facts and information presented in the application and case record and to report findings and recommendations to the FTZ Board. Public comment is invited from interested parties. Submissions shall be addressed to the FTZ Board’s Executive Secretary at the address below. The closing period for their receipt is April 23, 2018. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to May 7, 2018.

A copy of the application will be available for public inspection at the Office of the Executive Secretary, Foreign-Trade Zones Board, Room 21013, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230–0002, and in the “Reading Room” section of the FTZ Board’s website, which is accessible via www.trade.gov/ftz. For further information, contact Qahira El-Amin at Qahira.El-Amin@trade.gov or (202) 482–5928.

Andrew McGilvray,
Executive Secretary.
[FR Doc. 2018–00517 Filed 2–20–18; 8:45 am]
BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE
Bureau of Industry and Security
Proposed Information Collection; Comment Request; Request for Investigation Under Section 232 of the Trade Expansion Act


ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: To ensure consideration, written comments must be submitted on or before April 23, 2018.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW, Washington, DC 20230 (or via the internet at PRAcomments@doc.gov).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Mark Crace, BIS ICB Liaison, Regulatory Policy Division, (202) 482–8093 or at mark.crace@bis.doc.gov.

SUPPLEMENTARY INFORMATION:

I. Abstract

Upon request, BIS will initiate an investigation to determine the effects of imports of specific commodities on the national security, and within 270 days report to the President the findings and a recommendation for action or inaction. Within 90 days after receiving the report, the President shall determine whether to concur or not concur with the findings and recommendations. No later than 30 days after a decision, the determination will be published in the Federal Register and reported to Congress. The purpose of this collection is to account for the public burden associated with the surveys distributed to determine the effect of imports of specific commodities on the national security.

II. Method of Collection

Submitted electronically or in paper form.

III. Data

OMB Control Number: 0694–0120.

Form Number(s): None.

Type of Review: Regular submission.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 800.

Estimated Time per Response: 7.5 hours.

Estimated Total Annual Burden Hours: 6,000.

Estimated Total Annual Cost to Public: $0.


**SUPPLEMENTARY INFORMATION:**

**Background**
On September 1, 2017, Commerce published a notice of opportunity to request an administrative review of the antidumping duty order on certain cold-rolled steel flat products (CR Steel) from the U.K. for the period of review (POR) March 7, 2016, through August 31, 2017.\(^1\) On October 2, 2017, the petitioners, AK Steel Corporation, Steel Dynamics Inc., ArcelorMittal USA LLC, Nucor Corporation, and United States Steel Corporation, requested an administrative review of the order with respect to Caparo Precision Strip, Ltd., and Liberty Performance Steels Ltd.\(^2\) On November 13, 2017, in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act) and 19 CFR 351.221(c)(1)(i), we initiated an administrative review of the order on CR Steel from the U.K. with respect to Caparo Precision Strip, Ltd., and Liberty Performance Steels Ltd.\(^3\) On February 6, 2018, the petitioners timely withdrew their request for an administrative review of Caparo Precision Strip, Ltd., and Liberty Performance Steels Ltd.\(^4\) No other party requested a review.  

**Rescission of Review**
Pursuant to 19 CFR 351.213(d)(1), Commerce will rescind an administrative review “in whole or in part, if a party that requested a review withdraws the request within 90 days of the date of publication of notice of initiation of the requested review.” The petitioners withdrew their request for review within the 90-day time limit. Because we received no other requests for review of Caparo Precision Strip, Ltd., and Liberty Performance Steels Ltd., and no other requests for the review of the order on CR Steel from the U.K. with respect to other companies subject to the order, we are rescinding the administrative review of the order in full, in accordance with 19 CFR 351.213(d)(1).

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\(^1\) See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review, 82 FR 41595 (September 1, 2017).  
\(^3\) See Initiation of Antidumping and Countervailing Duty Administrative Reviews, 82 FR 52268 (November 13, 2017) (Initiation Notice). In the Initiation Notice, Commerce stated that it had previously determined that Liberty Performance Steels Ltd. is the successor-in-interest to Caparo Precision Strip, Ltd. See Initiation Notice at footnote 5.  

**Assessment**
Commerce will instruct U.S. Customs and Border Protection (CBP) to assess antidumping duties on all appropriate entries of CR Steel products from the U.K. during the POR at rates equal to the cash deposit rate of estimated antidumping duties required at the time of entry, or withdrawal from warehouse, for consumption, in accordance with 19 CFR 351.212(c)(1)(i). Commerce intends to issue appropriate assessment instructions to CBP 15 days after publication of this notice in the Federal Register.

**Notification to Importers**
This notice serves as a final 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 review period. Failure to comply with this requirement could result in Commerce’s presumption that reimbursement of antidumping duties occurred and the subsequent assessment of doubled antidumping duties.  

**Notification Regarding Administrative Protective Order**
This notice also serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). 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 the terms of an APO is a sanctionable violation.

This notice is issued and published in accordance with sections 751(a)(1) and 777(f)(1) of the Act and 19 CFR 351.213(d)(4).

James Maeder,  
Associate Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the duties of Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

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**DEPARTMENT OF COMMERCE**  
**International Trade Administration**  
[A–412–824]

**Certain Cold-Rolled Steel Flat Products From the United Kingdom: Rescission of Antidumping Duty Administrative Review; 2016–2017**

**AGENCY:** Enforcement and Compliance, International Trade Administration, Department of Commerce.  
**SUMMARY:** The Department of Commerce (Commerce) is rescinding the administrative review of the antidumping duty order on certain cold-rolled steel flat products from the United Kingdom (U.K.) for the period March 7, 2016, through August 31, 2017.  
**DATES:** Effective February 21, 2018.  
**FOR FURTHER INFORMATION CONTACT:** Joshua Poole or Thomas Schauer, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–1293 or (202) 482–0410, respectively.
ACTION: Notice of public meeting (webinar).

SUMMARY: The Pacific Fishery Management Council’s (Pacific Council) Ad hoc Community Advisory Board (CAB) will hold a one-day meeting in Rohnert Park, CA. The meeting is open to the public.

DATES: The meeting will be held on Friday, March 9, 2018, from 1 p.m. until business for the day has been completed.

ADDRESSES: The meeting will be held at the Oxford Suites Sonoma County, Redwood Ballroom, 67 Golf Course Drive West, Rohnert Park, CA 94928; telephone: (707) 584–0333.

Council address: Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220.

FOR FURTHER INFORMATION CONTACT: Dr. Jim Seger, Pacific Council; telephone: (503) 820–2416.

SUPPLEMENTARY INFORMATION: The primary purpose of the CAB meeting is to continue to work on ranges of alternatives for modifying the trawl catch share program pursuant to the results from the catch share program review (alternatives for follow-on actions). The CAB may also comment on purpose and need statements, priorities, and other matters related to the Council’s consideration of follow-on actions. The meeting will result in a report to be presented for Pacific Council consideration at the March 2018 Pacific Council meeting under Agenda Item H.6.

Although non-emergency issues not contained in the meeting agenda may be discussed, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically listed in this document and any issues arising after publication of this document that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Mr. Kris Kleinschmidt (503) 820–2411 at least 10 business days prior to the meeting date.
DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648-XG039

Marine Mammals; File No. 21251

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; receipt of application.

SUMMARY: Notice is hereby given that Waikiki Aquarium, 2777 Kalakaua Avenue, Honolulu, HI 96815 (Dr. Andrew Rossiter, Responsible Party), has applied in due form for a permit to conduct research on and enhancement of captive Hawaiian monk seals.

DATES: Written, telefaxed, or email comments must be received on or before March 23, 2018.

ADDRESSES: The application and related documents are available for review by selecting “Records Open for Public Comment” from the “Features” box on the Applications and Permits for Protected Species (APPS) home page, https://apps.nmfs.noaa.gov, and then selecting File No. 21251 from the list of available applications.

Those documents are also available upon written request or by appointment in the 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.

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.Prl.Comments@noaa.gov. Please include the File No. 21251 in the subject line of the email comment.

FOR FURTHER INFORMATION CONTACT: Jennifer Skidmore or Sara Young, (301) 427–8401.


The Waikiki Aquarium is requesting a 5-year permit to continue to maintain in captivity up to three male Hawaiian monk seals (Neomonachus schauinslandi) for research and enhancement purposes. The aquarium currently maintains two non-releasable seals. Research proposed includes continuation of a long-term diet study using voluntary behaviors to monitor changes in body mass. The Aquarium will continue its collaboration with the University of California Santa Cruz investigating underwater feeding behavior. The Aquarium will begin a new project with Dr. Christin Murphy of the Department of Defense and Woods Hole Oceanographic Institute studying ventral vissualisation. All activities will occur at the Waikiki Aquarium.

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.

Permit No.

<table>
<thead>
<tr>
<th>Permit No.</th>
<th>RIN</th>
<th>Applicant</th>
<th>Previous Federal Register notice</th>
<th>Permit or modification issuance date</th>
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<tbody>
<tr>
<td>18688–01</td>
<td>0648–XD505</td>
<td>NMFS Pacific Islands Regional Office (Responsible Party: Michael Tosatto), 1601 Kapio1ani Boulevard, Suite 1110, Honolulu, HI 96814.</td>
<td>0648–XD505; November 21, 2017</td>
<td>January 31, 2018</td>
</tr>
<tr>
<td>20626</td>
<td>0648–XF734</td>
<td>James H.W. Hain, Ph.D., Box 721, Woods Hole, MA 02543.</td>
<td>82 FR 51397; November 6, 2017</td>
<td>December 22, 2017</td>
</tr>
<tr>
<td>21315</td>
<td>0648–XF746</td>
<td>Alaska Department of Fish and Game, (Responsible Party: Lori Quakenbush), 1300 College Road, Fairbanks, AK 99701.</td>
<td>82 FR 48488; October 18, 2017</td>
<td>January 19, 2018</td>
</tr>
</tbody>
</table>
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 activities proposed are categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

As required by the ESA, as applicable, issuance of these permits was based on a finding that such permits: (1) Were applied for in good faith; (2) will not operate to the disadvantage of such endangered species; and (3) are consistent with the purposes and policies set forth in Section 2 of the ESA.

Authority: The requested permits have been issued under the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 et seq.), the regulations governing the taking and importing of marine mammals (50 CFR part 216), the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 et seq.), and the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR parts 222–226), as applicable.


Julia Harrison,
Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2018–03509 Filed 2–20–18; 8:45 am]
BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE
National Oceanic and Atmospheric Administration

Proposed Information Collection; Comment Request; Socio-Economic Survey of Hired Captains and Crew in New England and Mid-Atlantic Commercial Fisheries

AGENCY: National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments must be submitted on or before April 23, 2018.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW, Washington, DC 20230 (or via the internet at pracomments@doc.gov).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Lisa L. Colburn, (401) 782–3252 or lisa.l.colburn@noaa.gov.

SUPPLEMENTARY INFORMATION:

I. Abstract

This request is for a reinstatement with change of a previously approved collection.

The NOAA Fisheries, Northeast Fisheries Science Center, Social Science Branch (SSB) seeks to conduct surveys to provide for the ongoing collection of social and economic data related to the fishing industry in the New England and Mid-Atlantic States. The purpose of this survey is to assess the current social and economic conditions of commercial fishing crews for which little is known. The proposed survey is as a follow-up to a baseline study conducted in 2011/2012. The intent of the proposed study is to assess how and why commercial crew working conditions may have changed since the initial 2011/2012 assessment. Data needed for this assessment support fishery performance measures developed by the SSB, which include information on financial viability, distributional outcomes, stewardship, governance, and well-being. Data to be collected include demographic information on crew, wage calculations systems, individual and community well-being, fishing practices, job satisfaction, job opportunities, and attitudes toward fisheries management. The National Environmental Policy Act (NEPA) and Magnuson-Stevens Conservation and Management Act (MSA) both contain requirements for considering the social and economic impacts of fishery management decisions. There is a need to understand how such fishery management policies and programs will affect the social and economic characteristics of those involved in the commercial fishing industry. To help meet these requirements of NEPA and MSA, the SSB will collect data on an ongoing basis to track how socio-economic characteristics of fisheries are changing over time and the impact of fishery management policies and programs implemented in New England and the Mid-Atlantic regions.

II. Method of Collection

This information will be collected though in-person intercept surveys.

III. Data

OMB Control Number: 0648–0636.

Form Number(s): None.

Type of Review: Regular submission (reinstatement with change of a previously approved collection).

Affected Public: Individuals or households; Business or other for-profit organizations.

Estimated Number of Respondents: 500.

Estimated Time per Response: 20 minutes.

Estimated Total Annual Burden Hours: 167.

Estimated Total Annual Cost to Public: $0.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency’s estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

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<tr>
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</thead>
<tbody>
<tr>
<td>21431 ......</td>
<td>0648–XF787</td>
<td>Gregory Bossart, V.M.D., Ph.D., Georgia Aquarium, 225 Baker Street Northwest, Atlanta, GA 30313.</td>
<td>82 FR 50121; October 30, 2017 ......</td>
<td>January 19, 2018.</td>
</tr>
</tbody>
</table>
SUPPLEMENTARY INFORMATION:

INFORMATION
ADDRESSES:

ACTION:
Public Meetings

RIN 0648–XG031
National Oceanic and Atmospheric Administration
BILLING CODE 3510–22–P

[FR Doc. 2018–03542 Filed 2–20–18; 8:45 am]

NOAA PRA Clearance Officer.

Public Meetings


ACTION: Notice of public meetings.

SUMMARY: The Pacific Fishery Management Council (Pacific Council) and its advisory entities will hold public meetings.

DATES: The Pacific Council and its advisory entities will meet March 8–14, 2018. The Pacific Council meeting will begin on Friday, March 9, 2018 at 9 a.m. Pacific Standard Time (PST), reconvening at 8 a.m. each day through Wednesday, March 14, 2018. All meetings are open to the public, except a closed session will be held from 8 a.m. to 9 a.m. Friday, March 9 to address litigation and personnel matters. The Pacific Council will meet as late as necessary each day to complete its scheduled business.

ADDRESSES: Meetings of the Pacific Council and its advisory entities will be held at the Doubletree by Hilton Sonoma Wine Country, One Doubletree Drive, Rohnert Park, CA; telephone: (707) 584–5466.

Council address: Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220. Instructions for attending the meeting via live stream broadcast are given under SUPPLEMENTARY INFORMATION, below.

FOR FURTHER INFORMATION CONTACT: Mr. Chuck Tracy, Executive Director; telephone: (503) 820–2280 or (866) 806–7204 toll-free; or access the Pacific Council website, http://www.pcouncil.org for the current meeting location, proposed agenda, and meeting briefing materials.

SUPPLEMENTARY INFORMATION: The March 9–14, 2018 meeting of the Pacific Council will be streamed live on the internet. The broadcasts begin initially at 9 a.m. PST Friday, March 9, 2018 and continue at 8 a.m. daily through Wednesday, March 14, 2018. Broadcasts end daily at 5 p.m. PST or when business for the day is complete. Only the audio portion and presentations displayed on the screen at the Pacific Council meeting will be broadcast. The audio portion is listen-only; you will be unable to speak to the Pacific Council via the broadcast. To access the meeting online, please use the following link: http://www.gotomeeting.com/online/webinar/join-webinar and enter the November Webinar ID, 530–089–227, and your email address. You can attend the webinar online using a computer, tablet, or smart phone, using the GoToMeeting application. It is recommended that you use a computer headset to listen to the meeting, but you may use your telephone for the audio-only portion of the meeting. The audio portion may be attended using a telephone by dialing the toll number 1–562–247–8321 (not a toll-free number), audio access code 240–052–611, and entering the audio pin shown after joining the webinar.

The following items are on the Pacific Council agenda, but not necessarily in this order. Agenda items noted as “Final Action” refer to actions requiring the Council to transmit a proposed fishery management plan, proposed plan amendment, or proposed regulations to the U.S. Secretary of Commerce, under Sections 304 or 305 of the Magnuson-Stevens Fishery Conservation and Management Act. Additional detail on agenda items, Council action, advisory entity meeting times, and meeting rooms are described in Agenda Item A.4, Proposed Council Meeting Agenda, and will be in the advance March 2018 briefing materials and posted on the Pacific Council website at www.pcouncil.org no later than February 16, 2018.

A. Call to Order
1. Opening Remarks
2. Roll Call
3. Executive Director’s Report
4. Approve Agenda

B. Open Comment Period
1. Comments on Non-Agenda Items

C. Administrative Matters
1. Council Coordination Committee (CCC) Update
2. Marine Planning Update
3. National Marine Sanctuary Coordination Report
4. Legislative Matters
5. Approval of Council Meeting Record
6. Membership Appointments and Council Operating Procedures

D. Habitat
1. Current Habitat Issues

E. Salmon Management
2. Review of 2017 Fisheries and Summary of 2018 Stock Forecasts
3. Identification of Management Objectives and Preliminary Definition of 2018 Salmon Management Alternatives
4. Recommendations for 2018 Management Alternative Analysis
5. Further Council Direction for 2018 Management Alternatives
6. Adoption of 2018 Management Alternatives for Public Review
7. Appoint Salmon Hearings Officers

F. Ecosystem
1. California Current Ecosystem and Integrated Ecosystem Assessment Report and Science Review Topics
2. Fishery Ecosystem Plan Climate and Communities Initiative Update
3. Sablefish Ecosystem Indicators: Management Strategy Evaluation

G. Pacific Halibut Management
1. Annual International Pacific Halibut Commission Meeting Report
2. Incidental Catch Recommendations: Options for the Salmon Troll and Final Recommendations for Fixed Gear Sablefish Fisheries—Final Action

H. Groundfish Management
2. Trawl Catch Shares—Gear Switching and Trawl Sablefish Area Management
3. Implementation of the 2018 Pacific Whiting Fishery Under the U.S./Canada Agreement
4. Initial Stock Assessment Plan and Terms of Reference
5. Endangered Species Act Biological Opinion on the Take of Listed Salmon in Groundfish Fisheries
6. Trawl Catch Share—Final Range of Alternatives (ROA) for Follow-On Actions
7. Update on 2019–2020 Harvest Specifications and Management Measures
8. Final Insenson Management, Including Shorebased Carryover and Exempted Fishing Permits (EFPs)—Final Action

I. Highly Migratory Species Management
3. Proposed Deep-Set Buoy Gear Exempted Fishing Permits

Advisory Body Agendas
Advisory body agendas will include discussions of relevant issues that are
on the Pacific Council agenda for this meeting, and may also include issues that may be relevant to future Council meetings. Proposed advisory body agendas for this meeting will be available on the Pacific Council website http://www.pccouncil.org/council-operations/council-meetings/current-briefing-book/ no later than Friday, February 16, 2018.

Schedule of Ancillary Meetings

Day 1—Thursday, March 8, 2018
Ecosystem Advisory Subpanel—8 a.m.
Ecosystem Workgroup—8 a.m.
Habitat Committee—8 a.m.
Scientific and Statistical Committee—8 a.m.
Legislative Committee—1 p.m.
Tribal Policy Group—Ad Hoc
Tribal and Washington Technical Group—Ad Hoc

Day 2—Friday, March 9, 2018
California State Delegation—7 a.m.
Oregon State Delegation—7 a.m.
Washington State Delegation—7 a.m.
Ecosystem Advisory Subpanel—8 a.m.
Ecosystem Workgroup—8 a.m.
Groundfish Management Team—8 a.m.
Salmon Advisory Subpanel—8 a.m.
Salmon Technical Team—8 a.m.
Scientific and Statistical Committee—8 a.m.
Ad Hoc Community Advisory Board (Offsite: Oxford Suites)—1 p.m.
Enforcement Consultants—3 p.m.
Tribal Policy Group—Ad Hoc
Tribal and Washington Technical Group—Ad Hoc

Day 3—Saturday, March 10, 2018
California State Delegation—7 a.m.
Oregon State Delegation—7 a.m.
Washington State Delegation—7 a.m.
Groundfish Advisory Subpanel—8 a.m.
Groundfish Management Team—8 a.m.
Salmon Advisory Subpanel—8 a.m.
Salmon Technical Team—8 a.m.
Tribal Policy Group—Ad Hoc
Tribal and Washington Technical Group—Ad Hoc

Day 4—Sunday, March 11, 2018
California State Delegation—7 a.m.
Oregon State Delegation—7 a.m.
Washington State Delegation—7 a.m.
Groundfish Advisory Subpanel—8 a.m.
Groundfish Management Team—8 a.m.
Highly Migratory Species Advisory Subpanel—8 a.m.
Highly Migratory Species Management Team—8 a.m.
Salmon Advisory Subpanel—8 a.m.
Salmon Technical Team—8 a.m.
Tribal Policy Group—Ad Hoc
Tribal and Washington Technical Group—Ad Hoc

Day 5—Monday, March 12, 2018
California State Delegation—7 a.m.
Oregon State Delegation—7 a.m.
Washington State Delegation—7 a.m.
Groundfish Advisory Subpanel—8 a.m.
Groundfish Management Team—8 a.m.
Highly Migratory Species Advisory Subpanel—8 a.m.
Highly Migratory Species Management Team—8 a.m.
Salmon Advisory Subpanel—8 a.m.
Salmon Technical Team—8 a.m.
Tribal Policy Group—Ad Hoc
Tribal and Washington Technical Group—Ad Hoc

Day 6—Tuesday, March 13, 2018
California State Delegation—7 a.m.
Oregon State Delegation—7 a.m.
Washington State Delegation—7 a.m.
Highly Migratory Species Advisory Subpanel—8 a.m.
Highly Migratory Species Management Team—8 a.m.
Salmon Advisory Subpanel—8 a.m.
Salmon Technical Team—8 a.m.
Tribal Policy Group—Ad Hoc
Tribal and Washington Technical Group—Ad Hoc

Day 7—Wednesday, March 14, 2018
California State Delegation—7 a.m.
Oregon State Delegation—7 a.m.
Washington State Delegation—7 a.m.
Salmon Advisory Subpanel—8 a.m.
Salmon Technical Team—8 a.m.
Tribal Policy Group—Ad Hoc
Tribal and Washington Technical Group—Ad Hoc

Although non-emergency issues not contained in this agenda may come before the Pacific Council for discussion, those issues may not be the subject of formal Council action during these meetings. Council action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under Section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Pacific Council’s intent to take final action to address the emergency.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Mr. Kris Kleinschmidt, (503) 820–2280, ext. 411 at least 10 business days prior to the meeting date.
be submitted to the DFO for the Committee, and this individual will ensure that the written statements are provided to the membership for their consideration.


Aaron Siegel,
Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE
Office of the Secretary

Charter Establishment of Department of Defense Federal Advisory Committees

AGENCY: Department of Defense.

ACTION: Establishment of Federal Advisory Committee.

SUMMARY: The Department of Defense (DoD) is publishing this notice to announce that it is establishing the charter for the Government-Industry Advisory Panel ("the Panel").

FOR FURTHER INFORMATION CONTACT: Jim Freeman, Advisory Committee Management Officer for the Department of Defense, 703–692–5952.

SUPPLEMENTARY INFORMATION: This committee’s charter is being established in accordance with the Federal Advisory Committee Act (FACA) of 1972 (5 U.S.C., Appendix, as amended) and 41 CFR 102–3.50(d). The charter, once filed, along with contact information for the Panel’s Designated Federal Officer (DFO) can be found at http://www.facadatabase.gov/. The Panel, previously established as a non-discretionary advisory committee, is being reestablished as a discretionary advisory committee due to the lapse in legislative authority so it can complete its work. The Panel shall provide to the Secretary of Defense and the Deputy Secretary of Defense, through the Under Secretary of Defense for Personnel and Readiness, independent advice and recommendations on matters pertaining to military personnel testing for enlisted selection and classification.

The Committee is composed of no more than seven members who are eminent authorities in the fields of educational and psychological testing. All members of the Committee are appointed to provide advice on behalf of the Government on the basis of their best judgment without representing any particular point of view and in a manner that is free from conflict of interest. Except for reimbursement of official Committee-related travel and per diem, Committee members serve without compensation.

The public or interested organizations may submit written statements to the Committee membership about the Committee’s mission and functions. Written statements may be submitted at any time or in response to the stated agenda of planned meeting of the Committee. All written statements shall be submitted to the DFO for the Committee, and this individual will ensure that the written statements are provided to the membership for their consideration.


Aaron Siegel,
Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE
Office of the Secretary

Charter Renewal of Department of Defense Federal Advisory Committees

AGENCY: Department of Defense.

ACTION: Renewal of Federal Advisory Committee.

SUMMARY: The Department of Defense (DoD) is publishing this notice to announce that it is renewing the charter for the Department of Defense Advisory Committee on Military Personnel Testing ("the Committee").

FOR FURTHER INFORMATION CONTACT: Jim Freeman, Advisory Committee Management Officer for the Department of Defense, 703–692–5952.

SUPPLEMENTARY INFORMATION: The Committee’s charter is being renewed in accordance with the Federal Advisory Committee Act (FACA) of 1972 (5 U.S.C., Appendix, as amended) and 41 CFR 102–3.50(d). The Committee’s charter and contact information for the Committee’s Designated Federal Officer (DFO) can be found at http://www.facadatabase.gov/. The Committee provides the Secretary of Defense and the Deputy Secretary of Defense, through the Under Secretary of Defense for Personnel and Readiness, independent advice and recommendations on matters pertaining to military personnel testing for enlisted selection and classification.

The Committee is composed of no more than seven members who are eminent authorities in the fields of educational and psychological testing. All members of the Committee are appointed to provide advice on behalf of the Government on the basis of their best judgment without representing any particular point of view and in a manner that is free from conflict of interest. Except for reimbursement of official Committee-related travel and per diem, Committee members serve without compensation.

The public or interested organizations may submit written statements to the Committee membership about the Committee’s mission and functions. Written statements may be submitted at any time or in response to the stated agenda of planned meeting of the Committee. All written statements shall be submitted to the DFO for the Committee, and this individual will ensure that the written statements are provided to the membership for their consideration.


Aaron Siegel,
Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE
Office of the Secretary

Defense Advisory Committee on Women in the Services; Notice of Federal Advisory Committee Meeting

AGENCY: Under Secretary of Defense for Personnel and Readiness, Department of Defense (DoD).

ACTION: Notice of Federal Advisory Committee meeting.

SUMMARY: The Department of Defense (DoD) is publishing this notice to announce that the following Federal Advisory Committee meeting of the Defense Advisory Committee on Women in the Services (DACOWITS) will take place.

DATES: Day 1—Open to the public Tuesday, March 20, 2018 from 8:30 a.m. to 12:00 p.m. Day 2—Open to the public Wednesday, March 21, 2018 from 8:30 a.m. to 11:30 a.m.

ADDRESSES: The address of the open meeting is the Hilton Alexandria-Mark Center, 5000 Seminary Road, Alexandria, VA 22311.

FOR FURTHER INFORMATION CONTACT: Colonel Toya J. Davis, U.S. Army, (703) 697–2122 (Voice), 703–614–6233 (Facsimile), toya.j.davis.mil@mail.mil (Email). Mailing address is 4800 Mark Center Drive, Suite 04]25–01, Alexandria, VA 22350. Website: http://dacowits.defense.gov. The most up-to-date changes to the meeting agenda can be found on the website.

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 102–3.140 and 102–3.150.

Purpose of the Meeting: The purpose of the meeting is for the Committee to receive briefings and updates relating to their current work. The meeting will open with the Designated Federal Officer (DFO) giving a status update on the Committee’s requests for
information. This will be followed with a briefing on Marketing Strategies. Then the Committee will have two panel discussions on the following topics: Healthy Unit Climate, and Women’s Mental Health. The second day of the meeting will open with a panel discussion on Personal Protective Equipment/Gear for Women. This will be followed by an update briefing on Marine Corps Recruit Training. Day two will end with a public comment period.

**Agenda:**
Tuesday, March 20, 2018, from 8:30 a.m. to 12:00 p.m.—Welcome, Introductions, and Announcements; Request for Information Status Update; Briefing: Marketing Strategies; Panel Discussion: Healthy Unit Climate; Panel Discussion: Women’s Mental Health; Public Dismissed. Wednesday, March 21, 2018, from 8:30 a.m. to 11:30 a.m.—Welcome and Announcements; Panel Discussion: Personal Protective Equipment/Gear for Women; Briefing: Marine Corps Recruit Training Update; Public Comment Period; Public Dismissed.

**Meeting Accessibility:** Pursuant to 5 U.S.C. 552b, as amended, and 41 CFR 102–3.140 through 102–3.165, this meeting is open to the public, subject to the availability of space.

**Written Statements:** Pursuant to 41 CFR 102–3.140, and section 10(a)(3) of the Federal Advisory Committee Act of 1972, interested persons may submit a written statement for consideration by the DACOWITS. Individuals submitting a written statement must submit their statement to the point of contact listed at the address in **FOR FURTHER INFORMATION CONTACT** no later than 5:00 p.m., Monday, March 12, 2018. If a written statement is not received by Monday, March 12, 2018, prior to the meeting, which is the subject of this notice, then it may not be provided to or considered by the DACOWITS until its next open meeting. The DFO will review all timely submissions with the DACOWITS Chair and ensure they are provided to the members of the Committee. If members of the public are interested in making an oral statement, a written statement should be submitted. After reviewing the written comments, the Chair and the DFO will determine who of the requesting persons will be able to make an oral presentation of their issue during an open portion of this meeting or at a future meeting. Pursuant to 41 CFR 102–3.140(d), determination of who will be making an oral presentation is at the sole discretion of the Committee Chair and the DFO, and will depend on time availability. These topics are relevant to the Committee’s activities. Five minutes will be allotted to persons desiring to make an oral presentation. Oral presentations by members of the public will be permitted only on Wednesday, March 21, 2018 from 11:00 a.m. to 11:30 a.m. in front of the full Committee. The number of oral presentations to be made will depend on the number of requests received from members of the public.


**Aaron Siegel.**
Alternate OSD Federal Register Liaison Officer, Department of Defense.

**FOR INFORMATION CONTACT:**
Christopher Monsey, Naval Surface Warfare Center, Crane Div, Code OOL, Bldg 2, 300 Highway 361, Crane, IN 47522–5001. Email: Christopher.Monsey@navy.mil.

**DEPARTMENT OF DEFENSE**

**DEPARTMENT OF DEFENSE**

**Department of the Navy**

**Notice of Availability of Government-Owned Inventions; Available for Licensing**

**AGENCY:** Department of the Navy, DoD.

**ACTION:** Notice.

**SUMMARY:** The Department of the Navy (DoN) announces the availability of the inventions listed below, assigned to the United States Government, as represented by the Secretary of the Navy, for domestic and foreign licensing by the Department of the Navy.

**ADDITIONAL INFORMATION CONTACT:**
Mr. Christopher Monsey, Naval Surface Warfare Center, Crane Div, Code OOL, Bldg 2, 300 Highway 361, Crane, IN 47522–5001. Email: Christopher.Monsey@navy.mil.

**DEPARTMENT OF EDUCATION**

**DEPARTMENT OF EDUCATION**

**[Docket ID ED–2017–OPE–0085]**

**Request for Information on Evaluating Undue Hardship Claims in Adversary Actions Seeking Student Loan Discharge in Bankruptcy Proceedings**

**AGENCY:** Office of Postsecondary Education, U.S. Department of Education.

**ACTION:** Request for information.

**SUMMARY:** The U.S. Department of Education (Department) seeks to ensure that the congressional mandate to except student loans from bankruptcy discharge except in cases of undue hardship is appropriately implemented while also ensuring that borrowers for whom repayment of their student loans would be an undue hardship are not inadvertently discouraged from filing an adversary proceeding in their bankruptcy case. Accordingly, the Department is requesting public comment on factors to be considered in evaluating undue hardship claims asserted by student loan borrowers in adversary proceedings filed in bankruptcy cases, the weight to be given to such factors, whether the existence of two tests for evaluation of undue hardship claims results in inequities among borrowers seeking undue hardship discharge, and how all of these, and potentially additional, considerations should weigh into whether an undue hardship claim should be conceded by the loan holder.

**DATES:** Responses must be received by May 22, 2018.

**ADDRESSES:** Submit your comments through the Federal eRulemaking Portal or via U.S. mail, commercial delivery, or hand delivery. We will not accept comments by fax or by email or those submitted after the comment period. To ensure that we do not receive duplicate
copies, please submit your comments only once. In addition, please include the Docket ID and the term “Evaluating Undue Hardship Claims in Bankruptcy” at the top of your comments.

* Federal eRulemaking Portal: Go to www.regulations.gov to submit your comments electronically. Information on using Regulations.gov, including instructions for accessing agency documents, submitting comments, and viewing the docket, is available on the site under the “Help” tab.

U.S. Mail, Commercial Delivery, or Hand Delivery: If you mail or deliver your comments, address them to Jean-Didier Gaina, U.S. Department of Education, Office of Postsecondary Education, 400 Maryland Avenue SW, Washington, DC 20202–6110. Though this Request for Information (RFI) is not regulatory in nature, the Department has elected to use the Federal eRulemaking Portal for submissions to ensure the process is transparent to all interested parties.

Privacy Note: The Department’s policy for comments received from members of the public (including comments submitted by mail, commercial delivery, or hand delivery) is to make these submissions available for public viewing in their entirety on the Federal eRulemaking Portal at www.regulations.gov. Therefore, commenters should be careful to include in their comments only information that they wish to have made publicly available on the Internet.

Note: This RFI is issued solely for information and planning purposes and is not a request for proposal (RFP), a notice inviting applications (NIA), or a promise to award an obligation. Though an RFI may take the form of a request for information, the Department has not delegated to the Federal eRulemaking Portal the authority to do so. Federal courts have established a legal test (named after the case in which that test was first articulated, Brunner v. New York State Higher Educ. Serv. Corp., 831 F.2d 395 (2d Cir. 1987)) or Brunner test, the debtor

FOR FURTHER INFORMATION CONTACT:

SUPPLEMENTARY INFORMATION:

Background

A. Statutory Authority

The U.S. Bankruptcy Code, 11 U.S.C. 523(a)(8), currently provides that student loans can be discharged in bankruptcy only if excepting the debt from discharge would impose an “undue hardship” on the borrower and the borrower’s dependents:

Section 523 Exceptions to Discharge

(a) A discharge under . . . this title does not discharge an individual debtor from any debt—

(i) unless excepting such debt from discharge under this paragraph would impose an undue hardship on the debtor and the debtor's dependents for—

(A)(i) an educational benefit overpayment or loan made, insured, or guaranteed by a governmental unit, or made under any program funded in whole or in part by a governmental unit or nonprofit institution; or

(B) any other educational loan that is a qualified education loan, as defined in subsection (d)(1) of the Internal Revenue Code of 1986, incurred by a debtor who is an individual.


Congress has amended the student loan bankruptcy discharge provision several times, tightening the restrictions on discharge with each amendment.

B. “Undue Hardship” Case Law

Congress has never defined the term “undue hardship” in the Bankruptcy Code and has not delegated to the Department the authority to do so. Federal courts have established a legal standard for a student loan debtor to prove “undue hardship” as authorized by Congress. In general, the courts have used one of two tests to analyze whether undue hardship is proven: The Brunner test (named after the case in which that test was first articulated, Brunner v. New York State Higher Educ. Serv. Corp., 831 F.2d 395 (2d Cir. 1987)) or the Brunner test, the debtor

Under the Brunner test, the debtor must show that: (1) he or she cannot maintain, based on current income and expenses, a minimal standard of living for himself or herself and any dependents if forced to repay the loans; (2) additional circumstances exist indicating that this state of affairs is likely to persist for a significant portion of the repayment period of the student loans; and (3) he or she has made good faith efforts to repay the loans. Under the Brunner test, the court examines: (1) The borrower’s past, present, and likely future financial resources; (2) his or her reasonably necessary living expenses; and (3) any other relevant facts and circumstances. Regardless of which test is used, the burden of proof is on the debtor to meet the standard and prove undue hardship.

C. Regulatory Requirements: Direct 34 CFR 685.212(c), FELP 34 CFR 682.402(i)(1) & Perkins 34 CFR 674.49(c)

Department regulations currently require holders to evaluate each undue hardship claim to determine whether requiring repayment would constitute an undue hardship. If a holder determines that requiring repayment would impose an undue hardship, the holder must concede an undue hardship claim by the borrower in an adversary proceeding. The Department’s current guidance to guarantors and educational institutions in defending bankruptcy proceedings is summarized in a July 7, 2015 Dear Colleague Letter (GEN–15–13 https://ifap.ed.gov/dpletters/ GEN1513.html) and provides for a two-step analysis when evaluating whether or not to object to a borrower’s claim of undue hardship. The Department follows the same two-step analysis when defending bankruptcy proceedings for Direct loans. After receiving input from this notice, we will consider whether that analysis is still appropriate.

Context for Responses and Information Requested: The undue hardship standard established under either test requires a variety of factors to be evaluated when determining whether repaying a debt will cause a debtor and his or her dependents an undue hardship, such as, but not limited to, the debtor’s: Medical, work, or family history; history of mental illness; level of educational attainment; future employment prospects; payment history, including a borrower’s willingness to avoid himself or herself of all available repayment plans, including income-driven repayment plans; and necessary expenses in excess of ordinary unique to the debtor.

The Assistant Secretary for Postsecondary Education invites the public, including individuals, advocacy groups, and professional organizations, as well as other State or Federal agencies or components, to provide comment on, and offer information regarding: (1) Factors to be considered in evaluating undue hardship claims; (2) weight to be given to any such factors; (3) whether the use of two tests results in inequities among borrowers; (4) circumstances under which loan holders should concede an undue hardship claim by the borrower; and (5) whether and how the 2015 Dear Colleague Letter should be amended. The Department will review the data collected to determine whether there is any need to modify how undue hardship claims by student loan borrowers in bankruptcy are evaluated.
You may provide comments in any convenient format (i.e., bullet points, charts, graphs, paragraphs, etc.) and may also provide relevant information that is not responsive to a particular question but may nevertheless be helpful.

Accessible Format: Individuals with disabilities can obtain this document in an accessible format (e.g., braille, large print, audiotape, or compact disc) upon request to the person listed under FOR FURTHER INFORMATION CONTACT.

Electronic Access to This Document: The official version of this document is the document published in the Federal Register. Free internet access to the official edition of the Federal Register and the Code of Federal Regulations is available via the Federal Digital System at: www.gpo.govfdsys. At this site you can view this document, as well as all other documents of this Department published in the Federal Register, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the Federal Register by using the article search feature at: www.federalregister.gov. Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.


Frank T. Brogan,
Principal Deputy Assistant Secretary and Delegated the duties of the Assistant Secretary, Office of Planning, Evaluation and Policy Development, Delegated the duties of the Assistant Secretary, Office of Postsecondary Education.

[FR Doc. 2018–03537 Filed 2–20–18; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2017–ICCD–0133]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Consolidated State Performance Report Part I and Part II

AGENCY: Office of Elementary and Secondary Education (OESE), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing a revision of an existing information collection.

DATES: Interested persons are invited to submit comments on or before March 23, 2018.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use http://www.regulations.gov by searching the Docket ID number ED–2017–ICCD–0133. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at http://www.regulations.gov by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted. Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW, LBJ, Room 216–42, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Sarah Newman, 202–453–6956.

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: Consolidated State Performance Report Part I and Part II.

OMB Control Number: 1810–0724. Type of Review: A revision of an existing information collection.

Respondents/Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 14,653.

Total Estimated Number of Annual Burden Hours: 16,447.

Abstract: The Consolidated State Performance Report (CSPR) is the required annual reporting tool for each State, the Bureau of Indian Education, District of Columbia, and Puerto Rico as authorized under Section 8303 of the Elementary and Secondary Education Act (ESEA), as amended by the Every Student Succeeds Act (ESSA). The CSPR collects data on programs authorized by:

• Title I, Part A;
• Title I, Part C;
• Title I, Part D;
• Title II, Part A;
• Title III, Part A;
• Title V, Part A;
• Title V, Part B, Subparts 1 and 2; and
• The McKinney-Vento Act.

The information in this collection relates to the performance and monitoring activities of the aforementioned programs under ESSA and the McKinney-Vento Act. These data are needed for reporting on GPRA as well as other reporting requirements under ESSA. There are significant changes between this collection and the SY2016–17 collection. The SY2016–17 collection represented the reporting requirements under the No Child Left Behind Act while the SY2017–18 aligns with the reporting requirements of the Every Student Succeeds Act.


Tomakie Washington,
Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2018–03521 Filed 2–20–18; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2018–ICCD–0018]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; 2008/18 Baccalaureate and Beyond (B&B: 08/18) Full-Scale

AGENCY: National Center for Education Statistics (NCES), Department of Education (ED).

ACTION: Notice.
SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing a revision of an existing information collection.

DATES: Interested persons are invited to submit comments on or before March 23, 2018.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use http://www.regulations.gov by searching the Docket ID number ED–2018–ICCD–0018. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at http://www.regulations.gov by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted. Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW, LBJ, Room 216–34, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Kashka Kubzdela, 202–245–7377.

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: 2008/18 Baccalaureate and Beyond (B&B: 08/18) Full-Scale.

OMB Control Number: 1850–0729.

Type of Review: A revision of an existing information collection.

Respondents/Affected Public: Individuals or Households.

Total Estimated Number of Annual Responses: 15,336.

Total Estimated Number of Annual Burden Hours: 7,202.

Abstract: The Baccalaureate and Beyond Longitudinal Study (B&B), conducted by the National Center for Education Statistics (NCES), part of the U.S. Department of Education, examines students’ education and work experiences after they complete a bachelor’s degree, with a special emphasis on the experiences of K–12 school teachers. The B&B-eligible cohort is initially identified in the National Postsecondary Study Aid Study (NPSAS). The first cohort (B&B:93) was identified in NPSAS:93, and consisted of students who received their bachelor’s degree in the 1992–93 academic year. The second cohort (B&B:2000) was selected from the NPSAS:2000, and the third cohort (B&B:08) was selected from NPSAS:2008, which became the base year for follow-up interviews in 2009 and 2012. The B&B:08/18 data collection will be the third and final follow-up for the third cohort of the B&B series (OMB# 1850–0729). The fourth cohort of baccalaureate recipients (B&B:16/17), identified in NPSAS:2016, entered full-scale data collection in 2017 (OMB# 1850–0926). The request to conduct the B&B:08/18 field test in 2017, which collected data from B&B:08 sample members after they were first surveyed 10 years earlier, was approved in May 2017 (OMB# 1850–0729 v.11–12). This request is to conduct the full-scale B&B:08/18 from July 2018 through March 2019.


Stephanie Valentine, Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2018–03519 Filed 2–20–18; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Basic Energy Sciences Advisory Committee

AGENCY: Office of Science, Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Basic Energy Sciences Advisory Committee (BESAC). The Federal Advisory Committee Act requires that public notice of these meetings be announced in the Federal Register.

DATES:

Thursday, March 22, 2018 9:00 a.m. to 5:00 p.m.

Friday, March 23, 2018 8:00 a.m. to 12:00 noon.

ADDRESSES: DoubleTree by Hilton Hotel Bethesda—Washington, DC, 8120 Wisconsin Avenue, Bethesda, MD 20814.

FOR FURTHER INFORMATION CONTACT:

Katie Runkles; Office of Basic Energy Sciences; U.S. Department of Energy; Germantown Building, 1000 Independence Avenue SW, Washington, DC 20585; Telephone: (301) 903–6529.

SUPPLEMENTARY INFORMATION: Purpose of the Board: The purpose of this Board is to make recommendation to DOE–SC with respect to the basic energy sciences research program.

Tentative Agenda:

• Call to Order, Introductions, Review of the Agenda
• News from the Office of Science
• News from the Office of Basic Energy Sciences
• Discussion of the BES 40th Report Preparation
• Materials Sciences and Engineering Division COV meeting announcement
• Public Comments
• Adjourn

Breaks Taken as Appropriate

Public Participation: The meeting is open to the public. If you would like to file a written statement with the Committee, you may do so either before or during the meeting. If you would like to make oral statements regarding any of the items on the agenda, you should contact Katie Runkles at (301) 903–6594 (fax) or katie.runkles@science.doe.gov (email). Reasonable provision will be made to include the scheduled oral statements on the agenda. The Chairperson of the Committee will conduct the meeting to facilitate the orderly conduct of business. Public comment will follow the 10-minute rule.

Minutes: The minutes of this meeting will be available for public review and copying within 30 days at by contacting Ms. Runkles at the address or email above.
DEPARTMENT OF ENERGY

Notice of Intent To Prepare a Supplemental Environmental Impact Statement for Decommissioning and/or Long-Term Stewardship at the West Valley Demonstration Project and Western New York Nuclear Service Center, Notice of Floodplain and Wetlands Involvement, and Draft Scope

AGENCY: New York State Energy Research and Development Authority, Department of Energy.

ACTION: Notice of intent and draft scope.

SUMMARY: The U.S. Department of Energy (DOE) and the New York State Energy Research and Development Authority (NYSERDA) announce their intent to jointly prepare a Supplemental Environmental Impact Statement for Decommissioning and/or Long-Term Stewardship at the West Valley Demonstration Project and Western New York Nuclear Service Center (DOE/EIS–0226–S1), hereinafter referred to as the Supplemental Environmental Impact Statement (SEIS) for the West Valley Site, and to conduct a public scoping process. The West Valley Site, for the purposes of this SEIS and associated documents, includes the DOE West Valley Demonstration Project (WVDP) or Project Premises, and the retained premises, which includes the Western New York Nuclear Service Center (WNYNSC) and the State-Licensed Disposal Area (SDA). In 2010, DOE and NYSERDA decided to implement the Phased Decision-making Alternative, which was the preferred alternative in the Final Environmental Impact Statement for Decommissioning and/or Long-Term Stewardship at the West Valley Demonstration Project and Western New York Nuclear Service Center (DOE/EIS–0226) (2010 Final EIS). The Phased Decision-making Alternative is described in the 2010 Final EIS, DOE’s associated Record of Decision (ROD) (75 FR 20582; April 20, 2010), and NYSERDA’s associated Findings Statement (May 12, 2010). During implementation of Phase 1 of the Phased Decision-making Alternative, which is ongoing, a number of highly contaminated facilities at the West Valley Site are being removed via decontamination and demolition and off-site disposal. The Phased Decision-making Alternative deferred decisions (known as Phase 2 decisions) on several facilities for 10 years (the expected time frame to complete Phase 1 decommissioning activities) while DOE and NYSERDA gather additional information and perform additional analyses (Phase 1 Studies) to foster inter-agency consensus and inform the decisions. DOE and NYSERDA intend to make Phase 2 decisions in 2022 on the disposition of the facilities and areas that would remain after completion of Phase 1 decommissioning. The remaining facilities include the Waste Tank Farm, U.S. Nuclear Regulatory Commission (NRC)-Licensed Disposal Area (NDA), non-source area of the North Plateau Groundwater Plume, Construction and Demolition Debris Landfill, Cesium Prong, contaminated stream sediments, balance of the WNYNSC property, and SDA.

DOE and NYSERDA intend to jointly prepare an SEIS to inform Phase 2 decision-making for the West Valley Site. The SEIS process will be structured to meet DOE and NYSERDA’s respective environmental review responsibilities under the National Environmental Policy Act (NEPA, 42 U.S.C. 4321 et seq.) and the New York...
State Environmental Quality Review Act (SEQRA, N.Y. Env. Conserv. Law § 8–0101 et seq.), the West Valley Demonstration Project Act of 1980 (Pub. L. 96–368) (WVDP Act), the Atomic Energy Act of 1954 (as amended) (AEA), and other applicable Federal and state requirements. The SEIS will be prepared in accordance with regulations of the Council on Environmental Quality for implementing NEPA (40 CFR parts 1500–1508). DOE’s NEPA Implementing Procedures (10 CFR part 1021), and State of New York regulations for implementing SEQRA (6 NYCRR Part 617).

The WNYNSC is a 1,351-hectare (3,338-acre) site located 48 kilometers (30 miles) south of Buffalo, NY, and owned by NYSERDA. In 1962, Nuclear Fuel Services, Inc. (“NFS”) entered into Agreements with the Atomic Energy Commission and New York State to construct the first commercial reprocessing plant of nuclear fuel in the United States. NFS, a private company, built and operated the fuel reprocessing plant and burial grounds, processing 640 metric tons of spent nuclear fuel at the WNYNSC from 1966 to 1972 under an Atomic Energy Commission license. Fuel reprocessing ended in 1972, when the plant was shut down for modifications. In 1976, in view of increased costs and regulatory requirements, NFS decided to exercise its contractual right to yield responsibility for the WNYNSC to the State of New York. NFS withdrew without removing any of the in-process nuclear wastes. NYSERDA now holds title to and manages the WNYNSC.

In 1980, Congress passed the WVDP Act, Public Law 96–368. The WVDP Act requires DOE to demonstrate that the high-level radioactive waste from reprocessing could be safely managed by solidifying it at the WNYNSC and transporting it to a Federal repository for permanent disposal. Specifically, Section 2(a) of the WVDP Act directs DOE to take the following actions:

1. Solidify, in a form suitable for transportation and disposal, the high-level radioactive waste at the WNYNSC.
2. Develop containers suitable for the high-level radioactive waste’s permanent disposal.
3. As soon as feasible, transport the solidified waste to a Federal repository for permanent disposal.
4. Dispose of low-level radioactive waste and transuranic waste produced by the solidification of the high-level radioactive waste; and
5. Decontaminate and decommission the tanks and other facilities used at the WNYNSC in which the high-level radioactive waste was solidified, the facilities used in the waste’s solidification, and any material and hardware used in connection with the West Valley Demonstration Project.

Pursuant to the WVDP Act, on October 1, 1980, DOE and NYSERDA entered into a Cooperative Agreement (amended September 18, 1981) that established a framework for the implementation of the WVDP. Under the agreement, NYSERDA has made available to DOE, without transfer of title, a 68-hectare (167-acre) area known as the Project Premises, which includes the formerly operated spent nuclear fuel reprocessing plant, spent nuclear fuel receiving and storage area, underground liquid high-level waste storage tanks, and a liquid low-level waste treatment facility with associated lagoons, as well as other facilities. Most of the facilities on the Project Premises were radioactively contaminated from reprocessing operations and are located on a geographic area known as the North Plateau. Among the other facilities located within the Project Premises is a radioactive waste disposal area known as the NRC-licensed disposal area (NDA). Adjacent to the Project Premises is a radioactive waste disposal area known as the State-Licensed Disposal Area (SDA), for which NYSERDA has operational responsibility. Both the NDA and SDA are located on a geographic area known as the South Plateau.

In 1982, DOE assumed control, but not ownership, of the Project Premises to conduct the WVDP, as required under the WVDP Act. As part of the WVDP Act, NRC was charged with developing decommissioning criteria. In the “Decommissioning Criteria for the WVDP at the West Valley Site; Final Policy Statement” (NRC Policy Statement) (67 FR 5003; February 1, 2002), NRC prescribed the requirements for decommissioning the WVDP. NRC prescribed its License Termination Rule as the decommissioning goal for the WVDP and all NRC-licensed portions of the WNYNSC. The decommissioning criteria define the conditions that would allow the Project Premises to be used with specified restrictions or without restrictions on future use. If those conditions cannot be met, the NRC Policy Statement also defines the circumstances under which sections of the Project Premises could remain under long-term management or stewardship. NRC intends to use the SEIS to evaluate the environmental impacts of the various alternatives before deciding whether to accept the preferred alternative, and the criteria permitted by the License Termination Rule. NRC has placed the Technical Specifications of NYSERDA’s license under the NRC regulations at Title 10 of the Code of Federal Regulations Part 50 in abeyance during DOE’s fulfillment of its WVDP Act requirements.

A 1987 Stipulation of Compromise between the Coalition on West Valley Nuclear Wastes and DOE specified that a closure environmental impact statement (EIS) be prepared that also addresses the disposal of those Class B and C low-level radioactive wastes generated as a result of DOE’s activities at the WVDP. In 1990, DOE and NYSERDA entered into a supplemental agreement to prepare an EIS to address both the completion of the WVDP and closure or long-term management of the WNYNSC.

After issuance of a draft EIS in 1996, DOE and NYSERDA in 2001 announced a revised EIS strategy. Under the revised strategy, DOE and NYSERDA, as co-lead preparers, issued a draft EIS in 2008 and, in 2010, issued the Final Environmental Impact Statement for Decommissioning and/or Long-Term Stewardship at the West Valley Demonstration Project and Western New York Nuclear Service Center (DOE/EIS-0226) (2010 FEIS). As described in DOE’s 2010 ROD and NYSERDA’s 2010 Findings Statement, DOE and NYSERDA decided to implement the Phased Decision-making Alternative based on information and analyses contained in the 2010 FEIS. During implementation of Phase 1 of the Phased Decision-making Alternative, which is ongoing, a number of highly contaminated facilities at the West Valley Site are being removed via decontamination and demolition and off-site disposal. The Phased Decision-making Alternative deferred decisions (known as Phase 2 decisions) on several facilities for up to 10 years (the expected time frame to complete Phase 1 decommissioning activities) while DOE and NYSERDA gather additional information and perform additional analyses (Phase 1 Studies) to foster interagency consensus and better inform the Phase 2 decisions. DOE and NYSERDA plan to make Phase 2 decisions in 2022 on the disposition of the facilities and areas that would remain after completion of Phase 1 decommissioning. The remaining facilities and areas include the Waste Tank Farm, NDA, non-source area of the North Plateau Groundwater Plume, Construction and Demolition Debris Landfill, Cesium Prong, contaminated stream sediments, balance of the WNYNSC property, and SDA.

DOE and NYSERDA have determined that the preparation of an SEIS would further the purposes of NEPA by...
including new information and changes since issuance of the 2010 Final EIS, and is consistent with the commitment in the 2010 ROD and Findings Statement to providing robust and meaningful opportunities for public participation during decommissioning. Preparation of an SEIS for the West Valley Site would also further the purposes of SEQRA, the WVDP Act, the AEA, and other applicable Federal and state requirements. Phase 2 decisions will be informed by the Phase 1 and other scientific studies being performed at the West Valley Site, a long-term probabilistic performance assessment, and an SEIS that will incorporate the above analyses as part of the evaluation of the potential environmental impacts of the range of reasonable Phase 2 alternatives proposed for the West Valley Site. The SEIS will “tier” (40 CFR 1502.20) from the 2010 FEIS, and, where appropriate, information and analyses from the 2010 Final EIS will be summarized and incorporated by reference in the SEIS. The SEIS will contain new information and analyses to ensure its adequacy for Phase 2 decision-making.

Following the 2010 FEIS, DOE and NYSERDA established a process for conducting scientific studies (the Phase 1 Studies) in order to facilitate interagency consensus to complete decommissioning of the remaining facilities. Subject-matter expert working groups were established and studies conducted on topics such as erosion modeling, the geomorphic history of the site, geologic material properties, site radiological inventory, and precedent waste exhumation projects/technologies. The new information produced by these Phase 1 Studies will inform the Phase 2 decisions.

Additionally, in order to further evaluate and potentially reduce uncertainty in the long-term performance assessment, DOE and NYSERDA decided to perform a long-term probabilistic performance assessment (PPA) for the West Valley Site. The PPA model is currently being developed in the GoldSim probabilistic modeling platform and will be supported by several process-level models, including a surface water/sediment transport model, a three-dimensional groundwater flow model, and an erosion model. The PPA will be used to evaluate the range of alternatives in the SEIS. As such, the new information developed by the PPA and component models will inform the Phase 2 decisions.

The Supplemental Environmental Impact Statement for the West Valley Site (DOE/EIS–0226–S1) (SEIS) will further the purposes of NEPA by incorporating the new information produced by the Phase 1 Studies, other scientific studies being performed at the West Valley Site, and the PPA as part of the evaluation of the potential environmental impacts of the Phase 2 alternatives.

**Purpose and Need for Agency Action**

DOE is required by the WVDP Act to decontaminate and decommission the tanks and facilities used in the solidification of the high-level waste, and any material and hardware used in connection with the WVDP, in accordance with such requirements as NRC may prescribe. NRC has prescribed its License Termination Rule as the decommissioning criteria for the WVDP. Therefore, DOE needs to determine the manner that facilities, materials, and hardware for which the Department is responsible are managed or decommissioned, in accordance with the NRC’s License Termination Rule and applicable Federal and state requirements. To this end, DOE needs to determine what, if any, material or structures for which it is responsible that were not addressed in Phase 1 (i.e., Phase 2 facilities) will remain on site, and what, if any, institutional controls, engineered barriers, or stewardship provisions would be needed. That is, DOE needs to determine what it needs to do to complete the WVDP and return the Project Premises to NYSERDA. NYSERDA needs to determine the manner that Phase 2 facilities and property for which NYSERDA is responsible, including the SDA, will be managed or decommissioned, in accordance with applicable Federal and state requirements. To this end, NYSERDA needs to determine what, if any, material or structures for which it is responsible will remain on site, and what, if any, institutional controls, engineered barriers, or stewardship provisions would be needed. It is NYSERDA’s intent to pursue termination of the existing 10 CFR part 50 license for the WNYNNSC upon DOE’s completion of decommissioning under the WVDP Act in accordance with criteria prescribed by NRC. NYSERDA plans to use the analysis of alternatives in the SEIS for the West Valley Site to support any necessary NRC or New York State Department of Environmental Conservation (NYSDEC) license or permit applications.

**Proposed Action**

The Proposed Action is the WVDP’s completion and the decommissioning and/or long-term management or stewardship of the WNYNNSC and SDA. This includes the decontamination and decommissioning of the facilities remaining at the West Valley Site after completion of Phase 1 decommissioning.

**Alternatives**

The SEIS will examine the range of reasonable Phase 2 alternatives (i.e., the alternatives that meet DOE’s and NYSERDA’s respective purpose and need for action) and their potential environmental impacts. The SEIS will also analyze the No Action Alternative, as required by NEPA and SEQRA.

As specified in NRC’s Final Policy Statement, DOE and NYSERDA intend to use NRC’s License Termination Rule as the framework to evaluate alternatives for decommissioning and/or long-term stewardship actions involving West Valley Site facilities. The range of reasonable alternatives encompasses those involving release of West Valley Site facilities and areas for re-use under unrestricted and restricted conditions as allowed under the License Termination Rule. Accordingly, the SEIS will evaluate whether the alternatives would meet the NRC decommissioning criteria and other applicable requirements. This evaluation will include analysis of the long-term radiological dose impacts of the Phase 2 alternatives for the facilities and areas on the West Valley Site. DOE and NYSERDA will consider this information as it is being developed in determining details of the alternatives to be analyzed in the SEIS. This process for alternatives development will help ensure that the range of alternatives is adequate and provides a sound basis for informed decision-making.

Specific action alternatives proposed for analysis in the SEIS include the Sitewide Close-in-Place Alternative and the Sitewide Removal Alternative (described below). Conceptually, these alternatives represent the ends of the spectrum of action alternatives from the perspective of onsite and offsite management of facilities and contaminants, and the associated amount of area for which unrestricted versus restricted future land use would be appropriate. In developing these primary alternatives, DOE and NYSERDA will explore alternative ways to implement them, which would be presented under the primary alternatives as implementing options. In addition, DOE and NYSERDA will explore mitigation measures to avoid or reduce potential environmental impacts of the alternatives and implementing options. These mitigation measures could include institutional controls,
license and or permit terms/controls and other administrative controls (e.g. deed restrictions), robust engineered closure controls (e.g. multi-layer caps, grouts, etc.), robust erosion control structures, and/or additional removal of radiological inventory.

In addition to these primary alternatives and their associated implementing options, analysis of at least two “hybrid” alternatives is planned. Conceptually, the hybrid alternatives would represent points along the middle of the alternatives spectrum between the Sitewide Close-in-Place Alternative and the Sitewide Removal Alternative, with elements of each. To that end, DOE and NYSERDA will consider preliminary information from the PPA as it is developed to inform the development of these alternatives.

The alternatives and associated environmental analyses will be structured so that decisions based on the SEIS need not be limited only to a specific set of elements that happen to define a particular alternative. Rather, decision-makers could ultimately select an alternative comprised of elements of one or more of the primary (including hybrid) alternatives and their associated implementing options.

DOE and NYSERDA invite comments on this approach. Comments are also invited on the potential scope of the hybrid alternatives, including the specific elements, facilities, and areas that should be included.

Preliminary Description of Alternatives

Sitewide Close-in-Place Alternative

Under this alternative, most Phase 2 facilities would be closed in place. Major facilities and sources of contamination such as the Waste Tank Farm, NDA, and SDA would be managed at their current locations. Residual radioactivity in facilities with larger inventories of long-lived radionuclides would be isolated by specially engineered designed structures and barriers. These structures and barriers would be designed to meet regulatory requirements to retain hazardous and radioactive constituents to ensure they would be resistant to long-term degradation and include features to discourage inadvertent intrusion into the material left on site. Structures that would interfere with the construction of these barriers would be removed (e.g., the Supernatant Treatment System Support Building). Facilities with lesser amounts of contamination (e.g., the North Plateau Groundwater Plume, the Cesium Prong) would be allowed to naturally attenuate.

This approach would allow large areas of the WNYSNC to be released for unrestricted use. Facilities that are closed in place, and any buffer areas around them, as well as facilities that are allowed to naturally attenuate, would require long-term stewardship.

Sitewide Removal Alternative

Under this alternative, site facilities, contaminated soil, sediment, and groundwater would be removed to meet criteria that would allow unrestricted release of the WNYSNC. Radioactive, hazardous, and mixed waste would be characterized, packaged, and shipped off site for disposal. Immediate implementation of this alternative would require the disposition of waste for which there is currently no offsite disposal location (e.g., potential non-defense transuranic waste and Greater-Than-Class C low-level radioactive waste). Any such “orphan waste” would be stored on site until an appropriate offsite facility is available. Completion of these activities would allow unrestricted use of the site (i.e., the site could be made available for any public or private use).

Hybrid Alternatives

Analysis of at least two hybrid alternatives is planned. The hybrid alternatives could contain elements of any or all of the other alternatives. For example, a hybrid alternative might include complete or partial removal of certain facilities and close-in-place for the remaining facilities. Additionally, these actions could occur immediately or after a safe-storage period. The results of the PPA will be used to determine which facilities should be removed and which to close-in-place. For example, if the PPA shows that a particular radionuclide from a particular facility dominates the long-term dose/risk estimate, then one hybrid alternative might be the removal of the material containing that radionuclide from that facility and closure in place of the remaining facilities. Depending on the facility and the amount of material to be removed, the approach for implementing the partial removal of material from a facility under the hybrid alternative may differ from the approach presented for the Sitewide Removal Alternative.

No Action Alternative

Under the No Action Alternative, Phase 1 decommissioning actions would be completed, but no further actions toward decommissioning the West Valley Site would be taken. The No Action Alternative would involve the continued management and oversight of West Valley Site facilities. The site would continue to be monitored and maintained for the foreseeable future, as required by Federal and state regulations, to protect the health and safety of workers, the public, and the environment. Additionally, periodic maintenance activities (e.g., replacing permeable treatment wall media, replacing landfill geomembranes) would continue during an assumed period of active institutional controls until, for purposes of analysis only, controls are assumed to become ineffective. The No Action Alternative would not meet the purpose and need for agency action, but analysis of the No Action Alternative is required under NEPA and SEQRA to provide a baseline against which the environmental impacts from the other analyzed alternatives can be compared.

DOE and NYSERDA plan to identify a preferred alternative in the Draft SEIS.

Potential Environmental Issues for Analysis and Potentially Significant Adverse Impacts

DOE and NYSERDA have tentatively identified the following potential environmental issues and potentially significant adverse impacts that will be analyzed in the SEIS. The list is presented to facilitate early comment on the scope of the SEIS. It is not intended to be all-inclusive nor to predetermine the alternatives to be analyzed or their potential impacts.

Potential Environmental Issues for Analysis

- Issues associated with long-term site stewardship, including duration and costs of stewardship, regulatory and engineering considerations, institutional controls, and land use restrictions, including the need for buffer areas.
- Ability of alternatives to satisfy the NRC LTR decommissioning criteria for the WVDP.
- Ability of alternatives to meet the Comprehensive Environmental Response, Compensation and Liability Act risk range.
- Compliance with applicable Federal, state, and local requirements.
- Identification of Derived Concentration Guideline Limits and other relevant clean-up concentrations, where appropriate.
- The influence of, and potential interactions of, any wastes remaining at the West Valley Site after decommissioning.
- Long-term site stability, including seismicity and erosion, based upon available data on the likelihood of future weather events.
- Issues associated with Waste Incidental to Reprocessing.
• Irretrievable and irreversible commitment of resources.

Potentially Significant Adverse Impacts
• Impacts to the general population and onsite workers from radiological and non-radiological releases from decommissioning and/or long-term stewardship activities. Transportation impacts from shipments of radioactive, hazardous, mixed, and clean waste generated during site decommissioning activities.
• Impacts to the general population and onsite workers from radiological and non-radiological releases at radiological and non-radiological waste disposal sites receiving waste generated during site decommissioning and/or long-term stewardship activities.
• Impacts from postulated accidents.
• Disproportionately high and adverse effects on low-income and minority populations (environmental justice).
• Socioeconomic impacts to local communities.
• Areas of concern to the Seneca Nation of Indians related to culturally-specific considerations.
• Short-term and long-term land use impacts.
• Short-term and long-term environmental impacts, including air and water quality, from decommissioning and/or long-term stewardship activities.
• Impacts to floodplains and wetlands (the SEIS will contain an assessment of potential floodplain and wetland impacts in accordance with DOE requirements (10 CFR part 1022)).
• Impacts to groundwater quality.
• Impacts on threatened and endangered species.

Other Agency Involvement
DOE and NYSERDA invite Federal, state, and local agencies with jurisdiction by law or special expertise to participate in the SEIS as cooperating or involved agencies. At this time, the U.S. Environmental Protection Agency (EPA), NYSDEC, and NYSDOH will participate as cooperating agencies under NEPA. NYSDEC and NYSDOH will also participate as involved agencies under SEQRA with respect to NYSERDA’s proposed actions.

Public Scoping Process
The purpose of scoping is to encourage public involvement and to solicit public comments on the proposed scope of the SEIS. DOE and NYSERDA invite interested parties to participate in the scoping process to help identify the range of reasonable alternatives and the environmental issues to be analyzed. Written comments may be provided by any of the means described under ADDRESSES, or orally at public scoping meetings. Both oral and written comments will be considered and given equal weight by DOE and NYSERDA regardless of how submitted. Comments must be provided by April 23, 2018, to ensure consideration in preparation of the Draft SEIS. DOE and NYSERDA will consider late comments to the extent practicable.

DOE and NYSERDA will hold three public scoping meetings on the West Valley SEIS on the following dates:
• Monday, March 19, 2018, from 6:00 p.m. to 9:30 p.m. at the West Valley Volunteer Hose Company, Inc., Firemen’s Memorial Hall and Training, 9091 Route 240, West Valley, NY 14171, in the Main Hall.
• Tuesday, March 20, 2018, from 6:00 p.m. to 9:30 p.m. at Erie Community College, City Campus, Post Office Building, 121 Ellicott Street, Buffalo, NY 14203, in the Minnie Gillette Auditorium.
• Wednesday, March 21, 2018, from 6:00 p.m. to 9:30 p.m. at the Cattaragus Council Chambers, 12837 Route 438, Irving, NY 14081.

Further information about these meetings is available on the SEIS website at www.SEISWestValleySite.com and will be announced in the local media.

Requests to speak at the public meeting should be made to the DOE Document Manager (see ADDRESSES). Speakers will be scheduled on a first-come, first-served basis. Individuals may sign up at the door to speak and will be accommodated as time permits. Written comments will also be accepted at the meeting. Speakers are encouraged to provide written versions of their oral comments for the record.

The meetings will be facilitated by a moderator. Time will be provided for meeting attendees to ask clarifying questions. Individuals requesting to speak on behalf of an organization must identify the organization. Each speaker will be allowed five minutes to present comments unless more time is requested and available. Comments will be recorded by a court reporter and will become part of the scoping meeting record.

SEIS Process and Schedule
DOE and NYSERDA will consider comments received during the public scoping period in defining the alternatives and issues to be analyzed in detail in the Draft SEIS, which is planned for issuance by April 23, 2018. After the document is distributed to the public, EPA will publish a notice of availability of the Draft SEIS in the Federal Register, and NYSERDA will publish notice of availability in the State Environmental Notice Bulletin, which will begin a 6-month public comment period. DOE and NYSERDA will announce how to comment on the Draft SEIS and will hold at least three public hearings during the public comment period, but no sooner than 15 days after EPA’s notice of availability and NYSERDA’s notice are published.

In preparing the Final SEIS, which is planned for issuance in 2022, DOE and NYSERDA will respond to comments received on the Draft SEIS. DOE may issue its ROD no sooner than 30 days after EPA publishes a notice of availability of the Final SEIS. NYSERDA intends to complete the SEIS process to inform Phase 2 decisions in 2022.

Notice of Floodplain and Wetland Involvement: Because the proposed project may involve actions in floodplains and wetlands, in accordance with DOE’s 10 CFR part 1022, the Draft SEIS will include a floodplain and wetland assessment, and, as appropriate, the Final SEIS or ROD will include a floodplain statement of findings.

Public Reading Room
Documents referenced in this Notice of Intent and Draft Scope and related information are available online at www.SEISWestValleySite.com and at the Ashford Community and Training Center, 9377 NY–240, West Valley, New York 14171, (716) 942–6016.

Signed in Washington, DC, this 14th day of February, 2018.

James M. Owendorff,
Acting Assistant Secretary for Environmental Management, Department of Energy.

[FR Doc. 2018–03493 Filed 2–20–18; 8:45 am]
BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

DOE/NSF Nuclear Science Advisory Committee

AGENCY: Office of Science, Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the DOE/NSF Nuclear Science Advisory Committee (NSAC). The Federal Advisory Committee Act requires that public notice of these meetings be announced in the Federal Register.
The minutes of the meeting will be available for review on the U.S.
Department of Energy’s Office of Nuclear Physics website at: http://
science.gov/np/nsac/meetings/.

Issued in Washington, DC, on February 14, 2018,
LaTanya R. Butler,
Deputy Committee Management Officer.

FOR FURTHER INFORMATION CONTACT:
Brenda L. May, U.S. Department of
Energy; SC–26/Germantown Building,
1000 Independence Avenue SW,
Washington, DC 20585; Telephone:
(301) 903–0536 or email: brenda.may@
science.doe.gov

The most current information
concerning this meeting can be found
on the website: http://science.gov/np/
nsac/meetings/.

SUPPLEMENTARY INFORMATION:
Purpose of the Board: The purpose
of the Board is to provide advice and
guidance on a continuing basis to
the Department of Energy and the National
Science Foundation on scientific
priorities within the field of basic
nuclear science research.

Tentative Agenda: Agenda will
include discussions of the following:
Monday, March 12, 2018

• Perspectives from Department of
  Energy and National Science
  Foundation
• Update from the Department of
  Energy and National Science
  Foundation’s Nuclear Physics
  Offices
• Presentation of the Mo–99
  Subcommittee Report
• Discussion of the Mo–99
  Subcommittee Report

Note: The NSAC Meeting will be broadcast
live on the internet. You may find out how
to access this broadcast by going to the
following site prior to the start of
the meeting. A video record of the meeting,
including the presentations that are made,
will be archived at this site after the meeting
ends: http://www.tvworldwide.com/events/
DOE/180312/.

Public Participation: The meeting is
open to the public. If you would like to
file a written statement with the
Committee, you may do so either before
or after the meeting. If you would like
to make oral statements regarding any of
these items on the agenda, you should
contact Brenda L. May, (301) 903–0536
or Brenda.May@science.doe.gov (email).
You must make your request for an oral
statement at least five business days
before the meeting. Reasonable
provisions will be made to include the
scheduled oral statements on the
agenda. The Chairperson of the
Committee will conduct the meeting to
facilitate the orderly conduct of
business. Public comment will follow
the 10-minute rule.

The Department of Energy
Federal Energy Regulatory
Commission

[DOCKET NO. IC18–1–000]

COMMISSION INFORMATION COLLECT

ACTIVITIES (FERC–598); COMMENT
REQUEST; EXTENSION

AGENCY: Federal Energy Regulatory
Commission, Department of Energy.

ACTION: Notice of information collection
and request for comments.

SUMMARY: In compliance with the
requirements of the Paperwork
Reduction Act of 1995, the Federal
Energy Regulatory Commission
(Commission or FERC) is soliciting
public comment on the currently
approved information collection, FERC–
598 (Self-Certification for Entities
Seeking Exempt Wholesale Generator
Status or Foreign Utility Company
Status) and submitting the information
collection to the Office of Management
and Budget (OMB) for review. Any
interested person may file comments
directly with OMB and should address
a copy of those comments to the
Commission as explained below. The
Commission published a Notice in the
Federal Register in Docket No. IC18–1–
000 on December 11, 2017 requesting
public comments. FERC received no
comments and is indicating that in its submittal to the OMB.

DATES: Comments on the collection of
information are due March 23, 2018.

ADDRESSES: Comments filed with OMB,
identified by OMB Control No. 1902–
0166, should be sent via email to the
Office of Information and Regulatory
Affairs: oira_submission@omb.gov.
Attention: Federal Energy Regulatory
Commission Desk Officer. The Desk
Officer may also be reached via

A copy of the comments should also be
sent to the Commission, in Docket
No. IC18–1, by either of the following
methods:

• eFiling at Commission’s website:
  http://www.ferc.gov/docs-filing/
efiling.asp.

• Mail/Hand Delivery/Courier:
  Federal Energy Regulatory
  Commission, Secretary of the
  Commission, 888 First
  Street NE, Washington, DC 20426.

Instructions: All submissions must be
formatted and filed in accordance with
submission guidelines at: http://
www.ferc.gov/help/submission-
guide.asp. For user assistance, contact
FERC Online Support by email at
ferconlinesupport@ferc.gov, or by phone
at: (866) 208–3676 (toll-free), or (202)
502–8659 for TTY.

Docket: Users interested in receiving
automatic notification of activity in this
docket or in viewing/downloading
comments and issuances in this docket
may do so at http://www.ferc.gov/docs-
filing/docs-filing.asp.

FOR FURTHER INFORMATION CONTACT:
Ellen Brown may be reached by email at
DataClearance@FERC.gov, telephone
at (202) 502–8663, and fax at (202) 273–
0873.

SUPPLEMENTARY INFORMATION:
Title: FERC–598, Self-Certification for
Entities Seeking Exempt Wholesale
Generator Status or Foreign Utility
Company Status.

OMB Control No.: 1902–0166.

Type of Request: Three-year extension
of the FERC–598 information collection
requirements with no changes to the
current reporting requirements.

Abstract: The Commission uses the
data in the FERC–598 information
collection to implement the statutory
provisions of Title XII, subtitle F of the
Energy Policy Act of 2005 (EPAct
2005).1

EPAct 2005 repealed the Public
Utility Holding Company Act of 1935
(PUHCA 1935),2 and adopted in its
place the Public Utility Holding
While providing for the Commission’s
regulation of holding companies,
PUHCA 2005 also provided an
exemption from such regulation for
those holding companies that are
subject to Commission regulation as
holding companies solely due to their
holding exempt wholesale generators
(EWG) and foreign utility companies
(FUCO).4 To carry out this statutory
directive, the Commission amended its

1 Energy Policy Act of 2005, Public Law 109–58,
U.S.C. 16451 et seq.).
2 Id. § 1263, 119 Stat. 594, 974.
3 Id. § 1261, 119 Stat. 594, 972.
4 Id. § 1266(a), 119 Stat. 594, 975 (codified at 42
U.S.C. 16454(a)).
Defense of what is included in the information collection burden, refer to Title 5 Code of Federal Regulations 1220.3.

13 Subject matter experts found that industry employment costs (for salary plus benefits) for the FERC–598 information collection closely resemble the Commission’s. FERC’s 2017 average annual salary plus benefits per FTE (full-time equivalent) is $138,754 (or $76.50 per hour).

Comments: Comments are invited on:
(1) Whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility;
(2) the accuracy of the agency’s estimate of the burden and cost of the collection of information, including the validity of the methodology and assumptions used;
(3) ways to enhance the quality, utility and clarity of the information collection;
and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.


Kimberly D. Bose,
Secretary.

[FR Doc. 2018–03458 Filed 2–20–18; 8:45 am]
BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY
Federal Energy Regulatory Commission
[Project No. 3011–016]
Notice of Intent To File License Application, Filing of Pre-Application Document, and Approving Use of the Traditional Licensing Process; Natco Products Corporation

a. Type of Filing: Notice of Intent to File License Application and Request to Use the Traditional Licensing Process.

b. Project No.: 3011–016.

c. Date Filed: December 29, 2017.
d. Submitted By: Natco Products Corporation (Natco).

e. Name of Project: Arctic Project.

f. Location: On the South Branch Pawtuxet River in West Warwick, Kent County, Rhode Island. No federal lands are occupied by the project works or located within the project boundary.
g. Filed Pursuant to: 18 CFR 5.3 and 5.5 of the Commission’s regulations.
h. Potential Applicant Contact: Steve Burke, Natco Products Corporation, 155 Brookside Avenue, West Warwick, RI 02893; (401) 828–0300; email at sburke@natcohome.com.
i. FERC Contact: John Ramer at (202) 502–8969; or email at john.ramer@ ferc.gov.
j. Natco filed its request to use the Traditional Licensing Process on

of electric energy for sale or the distribution at retail of natural or manufactured gas for heat, light, or power, if such company: (1) Derives no part of its income, directly or indirectly, from the generation, transmission, or distribution of electric energy for sale or the distribution at retail of natural or manufactured gas for heat, light, or power, within the United States; and (2) neither the company nor any of its subsidiary companies is a public-utility company operating in the United States." 8 A FUCO is defined as "any company that owns or operates facilities that are not located in any state and that are used for the generation, transmission, or distribution of electric energy for sale or the distribution at retail of natural or manufactured gas for heat, light, or power, if such company: (1) Derives no part of its income, directly or indirectly, from the generation, transmission, or distribution of electric energy for sale or the distribution at retail of natural or manufactured gas for heat, light, or power, within the United States; and (2) [n]either the company nor any of its subsidiary companies is a public-utility company operating in the United States." 9 An EWG, FUCO, or its representative seeking to self-certify its status as an EWG or FUCO must file with the Commission a notice of self-certification (FERC–598) demonstrating that it satisfies the definition of EWG or FUCO. In the case of EWGs, the person filing a notice of self-certification must also file a copy of the notice of self-certification with the state regulatory authority of the state in which the facility is located and that person must also represent to the Commission in its submission that it has filed a copy of the notice with the appropriate state regulatory authority. 10 Submission of the information collected by FERC–598 is necessary for the Commission to carry out its responsibilities under section 1266(a) of EPAct 2005. 11 The Commission implements its responsibilities through the Code of Federal Regulations (CFR), Title 18, Part 366. These filing requirements are mandatory for entities seeking to self-certify their EWG or FUCO status, in order to, in turn, exempt their holding companies from Commission regulation.

Type of Respondents: EWGs and FUCOs.

Estimate of Annual Burden: 12 The Commission estimates the total annual burden and cost 13 for this information collection as follows.

FERC–598
[Self-certification for entities seeking exempt wholesale generator status or foreign utility company status]

<table>
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<th>Number of respondents (EWGs and FUCOs)</th>
<th>Annual number of responses per respondent</th>
<th>Total number of responses</th>
<th>Average burden hrs. &amp; cost ($) per response</th>
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6 18 CFR 366.1, 366.3(a), 366.4, 366.7.

7 18 CFR 366.1.

8 18 CFR 366.7.

9 42 U.S.C. 16454(a).

10 18 CFR 366.7.

11 42 U.S.C. 16454(a).

12 Burden is the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For further explanation...
December 29, 2017, and provided public notice of the request on the same date. In a letter dated February 13, 2018, the Director of the Division of Hydropower Licensing approved Natco’s request to use the Traditional Licensing Process.

k. With this notice, we are initiating informal consultation with the U.S. Fish and Wildlife Service and NOAA Fisheries under section 7 of the Endangered Species Act and the joint agency regulations thereunder at 50 CFR part 402; and NOAA Fisheries under section 305(b) of the Magnuson-Stevens Fishery Conservation and Management Act and implementing regulations at 50 CFR 600.920. We are also initiating consultation with the Rhode Island State Historic Preservation Officer, as required by section 106 of the National Historic Preservation Act, and the implementing regulations of the Advisory Council on Historic Preservation at 36 CFR 800.2.

l. Natco filed a Pre-Application Document (PAD; including a proposed process plan and schedule) with the Commission, pursuant to 18 CFR 5.6 of the Commission’s regulations.

m. A copy of the PAD is available for review at the Commission in the Public Reference Room or may be viewed on the Commission’s website (http://www.ferc.gov), using the “eLibrary” link. Enter the docket number, excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support at FERCOnlineSupport@ferc.gov, (866) 208–3676 (toll free), or (202) 502–8659 (TTY). A copy is also available for inspection and reproduction at the address in paragraph h.

n. The licensee states its unequivocal intent to submit an application for a subsequent license for Project No. 3011. Pursuant to 18 CFR 16.20, each application for a subsequent license and any competing license applications must be filed with the Commission at least 24 months prior to the expiration of the existing license. All applications for license for this project must be filed by December 31, 2020.

o. Register online at http://www.ferc.gov/docs-filing/esubscription.asp to be notified via email of new filing and issuances related to this or other pending projects. For assistance, contact FERC Online Support.


Kimberly D. Bose,

Secretary.

[FR Doc. 2018–03460 Filed 2–20–18; 8:45 am]

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER18–855–000]

Panoche Valley Solar, LLC: Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding Panoche Valley Solar, LLC’s application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission’s Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant’s request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is March 6, 2018.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at http://www.ferc.gov. To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission’s eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission’s Public Reference Room in Washington, DC. There is an eSubscription link on the website that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email FERCOnlineSupport@ferc.gov, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.


Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2018–03506 Filed 2–20–18; 8:45 am]

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Effectiveness of Exempt Wholesale Generator Status

Panda Hummel Station LLC.

Wildwood Lessee, LLC ...

Red Dirt Wind Project, LLC.

ORNI 39 LLC .................

ORNI 41 LLC .................

Hamakua Energy, LLC ...

Docket Nos.

EG18–14–000

EG18–15–000

EG18–16–000

EG18–17–000

EG18–18–000

EG18–19–000

Take notice that during the month of January 2018, the status of the above-captioned entities as Exempt Wholesale Generators became effective by operation of the Commission’s regulations. 18 CFR 366.7(a) (2017).


Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2018–03506 Filed 2–20–18; 8:45 am]
DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG18–46–000.

Applicants: Panoche Valley Solar, LLC.
Description: Self-Certification of EG of Panoche Valley Solar, LLC.

Nathaniel J. Davis, Sr.,
Deputy Secretary.

[FR Doc. 2018–03505 Filed 2–20–18; 8:45 am]
BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2100–185]

California Department of Water Resources; 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: Request for license amendment.

b. Project No.: 2100–185.


d. Applicant: California Department of Water Resources.

e. Name of Project: Feather River Project.

f. Location: The project is located on the Feather River in Butte County, California, and occupies lands of the United States administered by the U.S. Forest Service and the U.S. Bureau of Land Management.

g. Filed Pursuant to: Federal Power Act, 16 U.S.C. 791a–825r.

h. Applicant Contact: Mr. Ted Craddock, California Department of Water Resources, 1416 Ninth Street, P.O. Box 942836, Sacramento, CA 94236–0001, (916) 502–2067.

i. FERC Contact: Mr. John Aedo, (415) 369–3335, john.aedo@ferc.gov.

j. Deadline for filing comments, motions to intervene, and protests is 30 days from the issuance date of this notice by the Commission (March 15, 2018).

All documents may be filed electronically via the internet. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission’s website 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–2100–185) on any comments, motions, or recommendations filed.

k. Description of Request: California Department of Water Resources

[FR Doc. 2018–03504 Filed 2–20–18; 8:45 am]
BILLING CODE 6717–01–P
(licensee) requests Commission approval for an amendment to its current project license to enhance the existing emergency spillway at Oroville Dam to prevent erosion, and to incorporate these enhancements into its project license. The licensee also requests Commission approval to relocate a portion of a project transmission line connecting the Hyatt Powerplant Switchyard and the Thermalito Diversion Dam Powerhouse. In addition, the licensee proposes to reconstruct the Oroville main spillway to similar dimensions as the original design. Finally, the licensee proposes various protective or mitigative measures to minimize impacts to environmental resources during these activities. The above activities are being proposed as a result of the February 2017 failure of the main spillway and extensive erosion caused by the use of the emergency spillway. The Commission will be analyzing the environmental effects of the above activities, also known as the response and recovery phases of the spillway failure. Consequently, any comments, motions to intervene, or protests should concern only the environmental aspects of the response and recovery efforts. Any comments relating to project relicensing are not within the scope of this public notice and subsequent relicensing are not within the scope of this public notice and subsequent

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: All filings 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 amendment. 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 intervenor 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 18 CFR 385.2010.

Kimberly D. Bose,
Secretary.

FEDERAL DEPOSIT INSURANCE CORPORATION
Notice to All Interested Parties of Intent To Terminate Receiverships

Notice is hereby given that the Federal Deposit Insurance Corporation (FDIC or Receiver), as Receiver for the institutions listed below, intends to terminate its receivership for said institutions.

<table>
<thead>
<tr>
<th>Receivership name</th>
<th>Date of appointment of receiver</th>
</tr>
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</table>

The liquidation of the assets for each receivership has been completed. To the extent permitted by available funds and in accordance with law, the Receiver will be making a final dividend payment to proven creditors.

Based upon the foregoing, the Receiver has determined that the continued existence of the receiverships will serve no useful purpose. Consequently, notice is given that the receiverships shall be terminated, to be effective no sooner than thirty days after the date of this notice. If any person wishes to comment concerning the termination of any of the receiverships, such comment must be made in writing, identify the receivership to which the comment pertains, and be sent within thirty days of the date of this notice to: Federal Deposit Insurance Corporation, Division of Resolutions and Receiverships, Attention: Receivership Oversight Department 34.6, 1601 Bryan Street, Dallas, TX 75201.

No comments concerning the termination of the above-mentioned receiverships will be considered which are not sent within this time frame.

Federal Deposit Insurance Corporation.
Robert E. Feldman,
Executive Secretary.

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Federal Deposit Insurance Corporation.
Robert E. Feldman,
Executive Secretary.
Co., Docket No. PENN 2014–816 (Issues include whether the Judge erred in concluding that the operator violated a reporting requirement that applies when an accident has a “reasonable potential to cause death.”)

Any person attending this meeting who requires special accessibility features and/or auxiliary aids, such as sign language interpreters, must inform the Commission in advance of those needs. Subject to 29 CFR 2706.150(a)(3) and 2706.160(d).

CONTACT PERSON FOR MORE INFO:

PHONE NUMBER FOR LISTENING TO ARGUMENT: 1 (866) 867–4769, Passcode: 678–100.

Sarah L. Stewart, Deputy General Counsel.

[FR Doc. 2016–03641 Filed 2–16–18; 4:15 pm]

BILLING CODE 6735–01–P

FEDERAL RESERVE SYSTEM

Proposed Agency Information Collection Activities; Comment Request

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Notice, request for comment.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) invites comment on a proposal to extend for three years, with revision, the Reports of Deposits (FR 2900; OMB No. 7100–0087).

DATES: Comments must be submitted on or before April 23, 2018.

ADDRESSES: You may submit comments, identified by FR 2900, FR 2910a, FR 2915, or FR 2930, by any of the following methods:

- Email: regs.comments@federalreserve.gov. Include OMB number in the subject line of the message.
- Fax: (202) 452–3819 or (202) 452–3102.
- Mail: Ann E. Misback, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW, Washington, DC 20551.

You may submit comments, including the proposed reporting form and instructions, supporting statement, and other documentation will be placed into the Federal Reserve Board’s public website at: http://www.federalreserve.gov/apps/reportforms/review.aspx or may be requested from the agency clearance officer, whose name appears below. Federal Reserve Board Clearance Officer—Nuha Elmaghrahi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC 20551.

SUPPLEMENTARY INFORMATION: On June 15, 1984, the Office of Management and Budget (OMB) delegated to the Board authority under the Paperwork Reduction Act (PRA) to approve of and assign OMB control numbers to collection of information requests and requirements conducted or sponsored by the Board. In exercising this delegated authority, the Board is directed to take every reasonable step to solicit comment. In determining whether to approve a collection of information, the Board will consider all comments received from the public and other agencies.

The Board invites public comment on the following information collection, which is being reviewed under authority delegated by the OMB under the PRA. Comments are invited on the following:

a. Whether the proposed collection of information is necessary for the proper performance of the Federal Reserve’s functions; including whether the information has practical utility;
b. The accuracy of the Federal Reserve’s estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;
c. Ways to enhance the quality, utility, and clarity of the information to be collected;
d. Ways to minimize the burden of information collection on respondents, including through the use of automated collection techniques or other forms of information technology; and
e. Estimates of capital or startup costs and costs of operation, maintenance, and purchase of services to provide information.

At the end of the comment period, the comments and recommendations received will be analyzed to determine the extent to which the Federal Reserve
should modify the proposal prior to giving final approval.

Proposal To Approve Under OMB Delegated Authority the Extension for Three Years, With Revision, of the Following Report


Agency form number: FR 2900; FR 2910a; FR 2915; and FR 2930.

OMB control number: 7100–0087.

Frequency: Weekly, quarterly, annually, and on occasion.

Respondents: Depository institutions.

Estimated number of respondents: FR 2900 (Weekly), 2.007; FR 2900 (Quarterly), 4.395; FR 2910a, 2.941; FR 2915, 122; and FR 2930, 93.

Estimated average hours per response: FR 2900 (Weekly), 1.25; FR 2900 (Quarterly), 3; FR 2910a, 0.75; FR 2915, 0.5; and FR 2930, 0.25.

Estimated annual burden hours: FR 2900 (Weekly), 130,455; FR 2900 (Quarterly), 52,740; FR 2910a, 2,206; FR 2915, 244; and FR 2930, 23.

General description of reports: Data from these mandatory reports are used by the Board for administering Regulation D (Reserve Requirements of Depository Institutions) and for constructing, analyzing, and monitoring the monetary and reserve aggregates. The FR 2900 is the primary source of data used for the calculation of required reserves and applied vault cash, and for the construction and analysis of the monetary aggregates. Data are also used for indexing the exemption amount and low reserve tranche amount each year, as required by statute and for indexing the nonexempt deposit cutoff and reduced reporting limit each year, as determined by the Board, amounts which determine whether depository institutions file the FR 2900 either weekly or quarterly. The FR 2910a is generally submitted by exempt institutions whose total deposits (as shown on their December Call Report) are greater than the exemption amount.

All FR 2900 respondents, both weekly and quarterly, that offer deposits denominated in foreign currencies at their U.S. offices file the FR 2915 quarterly on the same reporting schedule as quarterly FR 2900 respondents. Foreign currency deposits are subject to reserve requirements and, therefore, are included in the FR 2900 data. However, because foreign currency deposits are not included in the monetary aggregates, the FR 2915 data are used to net foreign currency-denominated deposits from the FR 2900 data to exclude them from measures of the monetary aggregates. The FR 2930 data are collected when the low reserve tranche and reserveable liabilities exemption thresholds are adjusted toward the end of each calendar year or upon the establishment of an office outside the home state or Federal Reserve District.

Proposed revisions: The Board proposes raising the nonexempt deposit cutoff to $1 billion, substantially increasing the cutoff from its indexed amount of $457.5 million that is set to take effect in September 2018. This proposed increase in the nonexempt deposit cutoff would reduce reporting burden on depository institutions while maintaining accurate measurements of the money and reserves aggregates. With this increase, the Board estimates that approximately 1,000 depository institutions would become newly eligible to elect to shift from weekly to quarterly FR 2900 reporting. However, consistent with current policy, newly eligible institutions for quarterly reporting may elect to continue reporting weekly. There are no changes proposed for the FR 2910a, FR 2915, or FR 2930.

Legal authorization and confidentiality: The information collected on these reports is authorized under sections 11, 25(7), and 25A(17) of the Federal Reserve Act (FRA), and section 7 of the International Banking Act (IBA). Section 11 of the FRA (12 U.S.C. 248(a)) authorizes the Board to require reports from each depository bank as it may deem necessary and authorizes the Board to prescribe reports of liabilities and assets from insured depository institutions to enable the Board to discharge its responsibility to monitor and control monetary and credit aggregates. Sections 25(7) and 25A(17) of the FRA (12 U.S.C. 604a and 625) authorize the Board to require Edge and agreement corporations to make reports to the Board. Section 7 of the IBA (12 U.S.C. 3105(c)(2)) authorizes the Board to require reports from U.S. branches and agencies of foreign banks. The FR 2900, FR 2910a, FR 2915, and FR 2930 are all mandatory. The release of data collected on these forms would likely cause substantial harm to the competitive position of the respondent if made publicly available. The data collected on these forms, therefore, may be kept confidential under exemption 4 of the Freedom of Information Act, which protects from disclosure trade secrets and commercial or financial information (5 U.S.C. 552(b)(4)).


Ann E. Misback,
Secretary of the Board.

[FR Doc. 2018–03544 Filed 2–20–18; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Proposed Agency Information Collection Activities; Comment Request

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Notice, request for comment.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) invites comment on a proposal to extend for three years, without revision, the voluntary Quarterly Report of Interest Rates on Selected Direct Consumer Installment Loans and the Quarterly Report of Credit Card Plans (FR 2835; FR 2835a; OMB No. 7100–0085).

DATES: Comments must be submitted on or before April 23, 2018.

ADDRESSES: You may submit comments, identified by FR 2835 or FR 2835a, by any of the following methods:


• Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

• Email: regs.comments@federalreserve.gov. Include OMB number in the subject line of the message.

• FAX: (202) 452–3819 or (202) 452–3102.

• Mail: Ann E. Misback, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW, Washington, DC 20551.

All public comments are available from the Board’s website at http://www.federalreserve.gov/apps/foia/proposedregs.aspx as submitted, unless modified for technical reasons. Accordingly, your comments will not be edited to remove any identifying or
Specialized data collection: The data is collected to provide information to the Federal Reserve Board, the Federal Open Market Committee (FOMC), the System's board of directors, and the System's banks for conducting their operations. The data includes the credit card interest rates, the number of credit card issues, and the number of credit card accounts. The proposed information collection includes the following:

- a. Whether the proposed collection of information is necessary for the proper performance of the Federal Reserve's functions; including whether the information has practical utility;
- b. The accuracy of the Federal Reserve's estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;
- c. Ways to enhance the quality, utility, and clarity of the information to be collected;
- d. Ways to minimize the burden of information collection on respondents, including through the use of automated collection techniques or other forms of information technology;
- e. Estimates of capital or startup costs and costs of operation, maintenance, and purchase of services to provide information.

At the end of the comment period, the comments and recommendations received will be analyzed to determine the extent to which the Federal Reserve should modify the proposal prior to giving final approval.

Proposal To Approve Under OMB Delegated Authority the Extension for Three Years, Without Revision, of the Following Report


Agency form number: FR 2835; FR 2835a.

OMB control number: 7100–0085.

Frequency: Quarterly.

Respondents: Commercial banks.

Number of respondents: FR 2835: 150; FR 2835a: 50.

Estimated average hours per response: FR 2835: 29 hours; FR 2835a: 50 hours.

Estimated annual burden hours: FR 2835: 176 hours; FR 2835a: 100 hours.

General description of report: The FR 2835 collects information from a sample of commercial banks on interest rates charged on loans for new vehicles and loans for other consumer goods and personal expenses. The data are used for the analysis of household financial conditions. The FR 2835a collects information on two measures of credit card interest rates from a sample of commercial banks with $1 billion or more in credit card receivables and a representative group of smaller issuers. The data are used to analyze the credit card market and draw implications for the household sector.

Legal authorization and confidentiality: The Board is authorized to collect the information on the FR 2835 and FR 2835a by sections 2A and 11 of the Federal Reserve Act ("FRA"). Section 2A of the FRA (12 U.S.C. 225a) requires that the Board and the Federal Open Market Committee ("FOMC") maintain long-run growth of the nation's credit aggregates commensurate with the economy's long run potential to increase production, so as to promote effectively the goals of maximum employment, stable prices, and moderate long-term interest rates. Section 11 of the FRA (12 U.S.C. 248(a)) authorizes the Board to require reports from each member bank as it may deem necessary and authorizes the Board to prescribe reports of liabilities and assets from insured depository institutions to enable the Board to discharge its responsibility to monitor and control monetary and credit aggregates. The information collected on the FR 2835 and FR 2835a assist the Board and the FOMC with fulfilling these obligations. Both the 2835 and 2835a are voluntary. With respect to the FR 2835, only the narrative information to explain large fluctuations in reported data is considered confidential. With respect to the 2835a, the individual respondent data is considered confidential. Such treatment is appropriate because the data is not publicly available and the public release of this data is likely to impair the Board's ability to collect necessary information in the future and cause substantial harm to the competitive position of the respondent. Thus, this information may be kept confidential under exemption (b)(4) of the Freedom of Information Act, which exempts from disclosure "trade secrets and commercial or financial information obtained from a person and privileged or confidential." (5 U.S.C. 552(b)(4)).


Ann E. Misback,
Secretary of the Board.

[F.R Doc. 2018–03543 Filed 2–20–18; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Formations, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 et seq.) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below. The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of
the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than March 15, 2018.

A. Federal Reserve Bank of San Francisco (Gerald C. Tsai, Director, Applications and Enforcement) 101 Market Street, San Francisco, California 94105–1579:

1. Allegiant United Holdings, LLC and Nano Financial Holdings, Inc., both of Irvine, California; to become bank holding companies through Nano Financial Holdings, Inc. by acquiring holding companies through Nano Financial Holdings, Inc. by acquiring 100 percent of the outstanding shares of Commerzbank of Temecula Valley, Murrieta, California.


Ann Misback,
Secretary of the Board.

[FR Doc. 2018–03048 Filed 2–20–18; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Proposed Agency Information Collection Activities; Comment Request

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Notice, request for comment.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) invites comment on a proposal to extend for three years, without revision, the Senior Loan Officer Opinion Survey on Bank Lending Practices (FR 2018; OMB No. 7100–0058).

DATES: Comments must be submitted on or before April 23, 2018.

ADDRESSES: You may submit comments, identified by FR 2018, by any of the following methods:


• Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

• Email: regs.comments@federalreserve.gov. Include OMB number in the subject line of the message.

• Fax: (202) 452–3819 or (202) 452–3102.

• Mail: Ann E. Misback, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW, Washington, DC 20551.

All public comments are available from the Board’s website at http://www.federalreserve.gov/apps/foia/proposedregs.aspx as submitted, unless modified for technical reasons.

Accordingly, your comments will not be edited to remove any identifying or contact information. Public comments may also be viewed electronically or in paper form in Room 3515, 1801 K Street (between 18th and 19th Streets NW), Washington, DC 20006 between 9:00 a.m. and 5:00 p.m. on weekdays.

Additionally, commenters may send a copy of their comments to the OMB Desk Officer—Shagufa Ahmed—Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–6974.

FOR FURTHER INFORMATION CONTACT: A copy of the PRA OMB submission, including the proposed reporting form and instructions, supporting statement, and other documentation will be placed into OMB’s public docket files, once approved. These documents will also be made available on the Federal Reserve Board’s public website at: http://www.federalreserve.gov/apps/reportforms/review.aspx or may be requested from the agency clearance officer, whose name appears below.


SUPPLEMENTARY INFORMATION: On June 15, 1984, the Office of Management and Budget (OMB) delegated to the Board authority under the Paperwork Reduction Act (PRA) to approve of and assign OMB control numbers to collection of information requests and requirements conducted or sponsored by the Board. In exercising this delegated authority, the Board is directed to take every reasonable step to solicit comment. In determining whether to approve a collection of information, the Board will consider all comments received from the public and other agencies.

Request for Comment on Information Collection Proposal

The Board invites public comment on the following information collection, which is being reviewed under authority delegated by the OMB under the PRA. Comments are invited on the following:

a. Whether the proposed collection of information is necessary for the proper performance of the Federal Reserve’s functions; including whether the information has practical utility;

b. The accuracy of the Federal Reserve’s estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

c. Ways to enhance the quality, utility, and clarity of the information to be collected;

d. Ways to minimize the burden of information collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

e. Estimates of capital or startup costs and costs of operation, maintenance, and purchase of services to provide information.

At the end of the comment period, the comments and recommendations received will be analyzed to determine the extent to which the Federal Reserve should modify the proposal prior to giving final approval.

Proposal to approve, under OMB delegated authority, the extension for three years, without revision, of the following report(s):

Report title: Senior Loan Officer Opinion Survey on Bank Lending Practices.


OMB control number: 7100–0058.

Frequency: Up to six times a year.

Respondents: Domestically chartered large commercial banks and large U.S. branches and agencies of foreign banks.

Estimated number of respondents: 104.

Estimated average hours per response: 2 hours.

Estimated annual burden hours: 1,248 hours.

General description of report: The FR 2018 is conducted with a senior loan officer at each respondent bank, generally through electronic submission, up to six times a year. The purpose of the survey is to provide qualitative and limited quantitative information on credit availability and demand, as well as evolving developments and lending practices in
the U.S. loan markets. A portion of each survey typically covers special topics of timely interest. There is the option to survey other types of respondents (such as other depository institutions, bank holding companies, or other financial entities) should the need arise. The FR 2018 survey provides crucial information for monitoring and understanding the evolution of lending practices at banks and developments in credit markets.

Legal authority and confidentiality: The Board’s Legal Division has determined that the Senior Loan Officer Opinion Survey on Bank Lending Practices is authorized by Sections 2A, 11, and 12A of the Federal Reserve Act (12 U.S.C. 225a, 248(a), and 263) and Section 7 of the International Banking Act (12 U.S.C. 3105(c)(2)) and is voluntary. Individual survey responses from each respondent can be held confidential under section (b)(4) of the Freedom of Information Act (5 U.S.C. 552(b)(4)). However, certain data from the survey is reported in aggregate form and the information in aggregate form is made publicly available and not considered confidential.


Ann E. Misback,
Secretary of the Board.

[FR Doc. 2018–03532 Filed 2–20–18; 8:45 am]
BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Solicitation of Nominations for Appointment to the Lead Exposure and Prevention Advisory Committee

ACTION: Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC) is soliciting nominations for membership on the LEPAC. The LEPAC consists of 15 Federal and non-Federal experts in fields associated with lead screening, the prevention of lead exposure, and services for individuals and communities affected by lead exposure. Nominations are being sought for individuals who have expertise and qualifications necessary to contribute to the accomplishment of the committee’s objectives. Nominees will be selected based on expertise in the fields of epidemiology, toxicology, mental health, pediatrics, early childhood education, special education, diet and nutrition, and environmental health. Members may be invited to serve for three-year terms. Selection of members is based on candidates’ qualifications to contribute to the accomplishment of LEPAC objectives.

DATES: Nominations for membership on the LEPAC must be received no later than April 15, 2018. Packages received after this time will not be considered for the current membership cycle.

ADDRESSES: All nominations should be mailed to Ms. Perri Ruckart, MPH, Centers for Disease Control and Prevention, 4770 Buford Highway, MS F–58, Atlanta, GA 30341, emailed (recommended) to PRuckart@cdc.gov, or faxed to 770–488–3635.

FOR FURTHER INFORMATION CONTACT: Ms. Perri Ruckart, MPH, Designated Federal Officer, National Center for Environmental Health, Centers for Disease Control and Prevention, 4770 Buford Hwy. NE, Mailstop F–58, Atlanta, GA 30341, 770–488–3808, PRuckart@cdc.gov.

SUPPLEMENTARY INFORMATION: The members of this committee are selected by the Secretary of the U.S. Department of Health and Human Services (HHS). The committee advises the Secretary, HHS and the Director, Centers for Disease Control and Prevention/ Administrator, Agency for Toxic Substances and Disease Registry on a range of activities to include: (1) Review of the Federal programs and services available to individuals and communities exposed to lead; (2) review of the current research on lead exposure to identify additional research needs; (3) review of and identification of best practices, or the need for best practices regarding lead screening and the prevention of lead exposure; (4) identification of effective services, including services relating to healthcare, education, and nutrition for individuals and communities affected by lead exposure and lead poisoning, including in consultation with, as appropriate, the lead exposure registry as established in Public Law 114–322 Section 2203(b) (42 U.S.C. 300j–27); and (5) undertaking of any other review or activities that the Secretary determines to be appropriate.

Annually as determined necessary by the Secretary or as required by Congress, the committee shall submit a report to include: (1) An evaluation of the effectiveness of the Federal programs and services available to individuals and communities exposed to lead; (2) an evaluation of additional lead exposure research needs; (3) an assessment of any effective screening methods or best practices; (4) recommendation to prevent or screen for lead exposure; (4) input and recommendations for improved access to effective services relating to health care, education, or nutrition for individuals and communities impacted by lead exposure; and (5) any other recommendations for communities affected by lead exposure, as appropriate.

At least half of the committee will consist of Federal representatives from a range of agencies that may include the Department of Housing and Urban Development; the Environmental Protection Agency; the Consumer Product Safety Commission; the Centers for Medicare and Medicaid Services; the Health Resources and Services Administration; the Food and Drug Administration; the U.S. Department of Agriculture; the Occupational Safety and Health Administration; the National Institute of Environmental Health Sciences; the U.S. Geological Survey; and such additional federal, state, tribal, and local public and private officials as the Secretary deems necessary for the committee to carry out its function. The rest of the committee will consist of non-Federal members. Only non-Federal members are being solicited with this announcement.

The U.S. Department of Health and Human Services policy stipulates that committee membership be balanced in terms of points of view represented and the committee’s function. Appointments shall be made without discrimination on the basis of age, race, ethnicity, gender, sexual orientation, gender identity, HIV status, disability, and cultural, religious, or socioeconomic status. Nominees must be U.S. citizens and cannot be full-time employees of the U.S. Government. Current participation on federal workgroups or prior experience serving on a federal advisory committee does not disqualify a candidate; however, HHS policy is to avoid excessive individual service on advisory committees and multiple committee memberships. Committee members are Special Government Employees, requiring the filing of financial disclosure reports at the beginning and annually during their terms. CDC reviews potential candidates for LEPAC membership each year, and provides a slate of nominees for consideration to the Secretary of HHS for final selection. HHS notifies selected candidates of their appointment as soon as the HHS selection process is completed. Note that the need for different expertise varies from year to year and a candidate who is not selected in one year may be reconsidered in a subsequent year. Nominees must be U.S. citizens, and cannot be full-time employees of the U.S. Government.
Candidates should submit the following items:

- Current curriculum vitae, including complete contact information (telephone numbers, mailing address, email address).
- A least one letter of recommendation from person(s) not employed by the U.S. Department of Health and Human Services. (Candidates may submit letter(s) from current HHS employees if they wish, but at least one letter must be submitted by a person not employed by an HHS agency (e.g., CDC, NIH, FDA, etc.).
- Nominations may be submitted by the candidate him or herself or by the person/organization recommending the candidate.

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.

FOR FURTHER INFORMATION CONTACT:
William Parham at (410) 786–4669.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to Papework@cms.hhs.gov.
3. Call the Reports Clearance Office at (410) 786–1326.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services
[Document Identifier: CMS–10656 and CMS–10277]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS’ intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency’s functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected; and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by March 23, 2018.

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–8806 OR, Email: OIRA_submission@omb.eop.gov.

The data collected will provide us with valuable information to better understand HIIN influence on their hospitals about HIIN influence on their core processes will be used together with follow-up input from stakeholders including CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. Type of Information Collection Request: New collection of information request; Title of Information Collection: Evaluation of the Partnership for Patients (PfP) 3.0; Use: In the summer of 2015, the Centers for Medicare & Medicaid Services (CMS) Administrator approved the plans for integration of the Partnership for Patients (PfP) Hospital Engagement Network (HEN) model test with the Quality Improvement Network-Quality Improvement Organization (QIN–QIO) program. This is consistent with the Agency’s intention for further integration to maximize the strengths of the QIO program and PfP HENs to sustain and expand current national reductions in in-patient harm and 30-day readmissions. The alignment of the two programs permits the systematic use of innovative patient safety practices at a national scale.

Under this initiative, CMS has awarded multiple contracts to Hospital Improvement Innovation Networks (HIINs), formerly known as HENs, to engage the hospital, provider, and broader caregiver communities to implement well-tested and measured best practices. The end result of the overall initiative is the anticipated reduction in preventable hospital-based harm and readmissions for patients.

The PfP initiative is a public-private partnership dedicated to the improvement of health care quality, safety, and affordability. CMS, working with hospitals, providers, and the broader caregiver community, aims to implement and disseminate best practices on a national scale to reduce hospital acquired conditions (HACs) and all-cause readmissions. Through the PfP model, which was initiated in April 2011, CMS fostered rapid learning among a nationwide community of practice, resulting in major strides in patient safety and engagement by patients and families.

A mixed methods approach to answering the PfP HIIN evaluation questions includes three primary data collection activities, as follows: Hospital Survey on Prevention of Adverse Events and Reduction of Readmissions, HIIN Data Quality Assurance (QA) Survey and Qualitative Discussions with HIIN leaders and Other Support Contractors. The data collected will provide us feedback to focus efforts to improve the effectiveness and efficiency of the HIIN initiative. As we draft future HIIN and QIO contracts, information from hospitals about HIIN influence on their care processes will be used together with follow-up input from stakeholders.
about the survey results. Subsequent to the 60-day Federal Register notice (82 FR 51:360), the collection instrument was revised to include pre-testing results. There has been a slight decrease in the burden hours. Form Number: CMS–10656 (OMB Control Number: 0938–NEW); Frequency: Annually; Affected Public: Private Sector: Business or other for-profits and Not-for-profit institutions; Number of Respondents: 819; Total Annual Responses: 838; Total Annual Hours: 380. (For policy questions regarding this collection contact Israel Cross at 410–786–0619.)

2. Type of Information Collection Request: Reinstatement of a previously approved collection; Title of Information Collection: Hospice Conditions of Participation; Use: The Conditions of Participation and accompanying requirements are used by Federal or State surveyors as a basis for determining whether a hospice qualifies for approval or re-approval under Medicare. The healthcare industry and CMS believe that the availability to the hospice of the type of records and general content of records, which the final rule (72 FR 32088) specifies, is standard medical practice, and is necessary in order to ensure the well-being and safety of patients and professional treatment accountability. Form Number: CMS–10277 (OMB control number: 0938–1067); Frequency: Reporting and Recordkeeping—Yearly; Affected Public: Private sector (Business or other for-profit and Not-for-profit institutions); Number of Respondents: 4,473; Total Annual Responses: 19,769,931; Total Annual Hours: 819; Total Annual Responses: 838; Total Annual Hours: 380. (For policy questions regarding this collection contact Mary Rossi-Coajou at 410–786–0619.)


William N. Parham, III.
Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[BFR Doc. 2016–03518 Filed 2–20–18; 8:45 am]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[OMB NO.: 0970–0151]

Submission for OMB Review; Comment Request; Head Start Child and Family Experiences Survey (FACES)

Description: The Office of Planning, Research and Evaluation (OPRE), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is proposing to collect data for a new round of the Head Start Family and Child Experiences Survey (FACES). Similar to FACES 2014–2018, in 2019, two parallel studies will commence. Each study will provide data on a set of key indicators for Head Start programs. FACES 2019 focuses on Head Start Regions I through X (which are geographically based); AI/AN (American Indian and Alaska Native) FACES 2019 focuses on Region XI (which funds Head Start programs that serve federally recognized American Indian and Alaska Native tribes). In fall 2019 and spring 2020, FACES will assess the school readiness skills of 2,400 Head Start children in Regions I–X (FACES 2019) and 800 children in Region XI (AI/AN FACES 2019), survey their parents, and ask their Head Start teachers to rate children’s social and emotional skills. This sample will be drawn from 60 programs in Regions I–X and 22 programs in Region XI. In spring 2020 classroom observations of sampled programs will occur. In Regions I–X, the number of programs will increase from the 60 that are used to collect data on children’s school readiness outcomes to 180 for the purpose of conducting observations in 720 Head Start classrooms. In Region XI, the program sample will remain at 22, and approximately 80 Head Start classroom observations will take place. Program director, center director, and teacher surveys will also be conducted in spring 2020 in Regions I–XI. In spring 2022, program level data collection will be repeated in Regions I–X only. FACES 2019 also features a “Core Plus” design, with the above activities reflecting the Core data, with the potential of “Plus” studies to inform emerging programmatic questions. If any Plus studies are conducted, they will be conducted within the Core sample.

This notice is specific to the data collection activities needed to recruit Head Start programs and centers into FACES. A future notice will provide information about data collection for the study. A nationally representative sample of Head Start programs and centers from Regions I–X (FACES 2019) and a representative sample of Head Start programs and centers from Region XI (AI/AN FACES 2019) will be selected to participate in FACES 2019. From Regions I–X, the programs participating in the Core child-level data collection will be contacted and recruited for the study in spring 2019. In fall 2019, the remaining programs participating in classroom-level data collection will be contacted. All programs will be contacted a second time in fall 2021 to confirm their continued participation in the Core spring 2022 data collection. The programs from Region XI would be recruited a year before data collection (i.e., fall 2018) given the increased amount of time to recruit programs in tribal communities and to obtain tribal council and/or tribal leadership approval.

The method of data collection for recruitment of all programs will include telephone conversations with program directors and on-site coordinators who serve as liaisons between the FACES study team and the Head Start centers. All of these calls will inform program staff about the purpose of the study and will gather lists of centers in each program in order to compile the center sampling frame. The purpose of this data collection is to support the 2007 reauthorization of the Head Start program (Pub. L. 110–134), which calls for periodic assessments of Head Start’s quality and effectiveness.

Respondents: Head Start Program Directors and Staff.

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Total number of respondents</th>
<th>Annual number of respondents</th>
<th>Number of responses per respondent</th>
<th>Average burden hours per response</th>
<th>Annual burden hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Telephone script and recruitment information collection for program directors, Regions I–X</td>
<td>230</td>
<td>77</td>
<td>2</td>
<td>1</td>
<td>154</td>
</tr>
<tr>
<td>Telephone script and recruitment information collection for program directors, Region XI</td>
<td>30</td>
<td>10</td>
<td>1</td>
<td>1</td>
<td>10</td>
</tr>
<tr>
<td>Telephone script and recruitment information collection for on-site coordinators, Regions I–X</td>
<td>230</td>
<td>77</td>
<td>2</td>
<td>.75</td>
<td>116</td>
</tr>
</tbody>
</table>
Estimated Total Annual Burden Hours: 288.

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, 330 C Street SW, Washington, DC 20201, Attn: OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: OPREinfocollection@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, Email: OIRA_SUBMISSION@OMB.EOP.GOV, Attn: Desk Officer for the Administration for Children and Families.

Mary Jones, ACF/OPRE Certifying Officer.

[FR Doc. 2016–03431 Filed 2–20–18; 8:45 am]

BILLING CODE 4184–22–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request Information Collection Request Title: The Maternal, Infant, and Early Childhood Home Visiting Program Quarterly Data Collection, OMB Number: 0906–0016—Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than April 23, 2018.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail the HRSA Information Collection Clearance Officer, 14N39, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email paperwork@hrsa.gov or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: The Maternal, Infant, and Early Childhood Home Visiting Program Quarterly Data Collection, OMB Number: 0906–0016—Revision.

Abstract: This clearance request is for continued approval of the Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Program Quarterly Data Collection. The MIECHV Program, administered by HRSA in partnership with the Administration for Children and Families (ACF), supports voluntary, evidence-based home visiting services during pregnancy and to parents with young children up to kindergarten entry. States, certain non-profit organizations, and Tribal entities are eligible to receive funding from the MIECHV Program and have the flexibility to tailor the program to serve the specific needs of their communities. HRSA is revising the data collection forms for the MIECHV Program by making the following changes:

- Form 4, Table A.2: Revise the columns to reflect counties served, communities served, and number of families served by zip code.
- Form 4, Table A.4: Expand to include a measure of staff retention.
- Form 4, Section A—Notes: Revise to include page-specific notes.
- Form 4, Definition of Key Terms: Update definitions for Tables A.1, A.2, A.3, and A.4.
- Form 4, Section B: Delete.

HRSA is also requesting an extension of this information collection request through November 30, 2021.

Need and Proposed Use of the Information: HRSA uses quarterly performance information to demonstrate program accountability and continuously monitor and provide oversight to MIECHV Program awardees. The information is also used to provide quality improvement guidance and technical assistance to awardees and help inform the development of early childhood systems at the national, state, and local level. HRSA is seeking to revise service utilization, place-based services, and staffing indicators for home visiting programs. This notice is subject to the appropriation of funds, and is a contingency action taken to ensure that, should funds become available for this purpose, information can be collected in a timely manner.

Likely Respondents: MIECHV Program State/Territory awardees (n = 56) and MIECHV Program Tribal awardees (n = 25).

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 table below.

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Total number of respondents</th>
<th>Annual number of respondents</th>
<th>Number of responses per respondent</th>
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<th>Annual burden hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Telephone script and recruitment information collection for on-site coordinators, Regions XI</td>
<td>30</td>
<td>10</td>
<td>1</td>
<td>.75</td>
<td>8</td>
</tr>
</tbody>
</table>
HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency’s functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Amy McNulty, Acting Director, Division of the Executive Secretariat.

[FR Doc. 2016–03457 Filed 2–20–18; 8:45 am]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Family-to-Family Health Information Center Feedback Surveys, OMB No.: 0906–xxxx—New

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this Information Collection Request must be received no later than April 23, 2018.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail the HRSA Information Collection Clearance Officer, Room 14N39, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email paperwork@hrsa.gov or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference, in compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995.

Information Collection Request Title: Family-to-Family Health Information Center Feedback Surveys, OMB Number: 0906–xxxx—New. (25 comments)

Abstract: The Family-to-Family Health Information Center (F2F HIC) program is authorized by the Social Security Act, Title V, § 501(c) (42 U.S.C. 701(c)), as amended by the Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114–10), § 216. The goal of the F2F HIC program is to promote optimal health for children and youth with special health care needs (CYSHCN) by facilitating their access to an effective health delivery system and by meeting the health information and support needs of families of CYSHCN and the professionals who serve them. HRSA’s Maternal and Child Health Bureau (MCHB) funds 51 F2F HICs in each of the 50 United States and the District of Columbia. On average, these Centers provide information, education, technical assistance, and peer support to approximately 160,000 families of CYSHCN and approximately 68,000 health professionals each year. F2F HICs are staffed by families of CYSHCN who are uniquely positioned to provide such services, and by health professionals. F2F HIC staff also assist in ensuring families and health professionals are partners in decision making at all levels of care and service delivery.

HRSA has developed feedback surveys to determine the extent to which F2F HICs provide service to families of CYSHCN and health professionals who serve such families. Each F2F HIC will administer the surveys and report data back to HRSA. Survey respondents will be asked to answer questions about how useful they found the information, assistance, or resources received from the F2F HICs. The purpose of this notice is to solicit comments regarding the proposed feedback surveys.

Need and Proposed Use of the Information: Data from the feedback surveys will support the HHS Secretary’s priorities of engagement and performance and will provide mechanisms to capture consistent performance data from F2F HIC grant recipients. The data will also allow F2F HICs to evaluate the effectiveness of their interventions and improve services provided to families and the providers who serve CYSHCN families. This notice is subject to the appropriation of funds, and is a contingency action taken to ensure that, should funds become available for this purpose, information collection can be completed in a timely manner.

Likely Respondents: Likely respondents are users of F2F HIC services, which include family members of CYSHCN and health professionals who serve such families.

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; to process and to maintain, information; and to disclose and provide information; to train personnel 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 Information Collection Request are summarized in the table below.

<table>
<thead>
<tr>
<th>Form name</th>
<th>Number of respondents</th>
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<th>Total responses</th>
<th>Average burden per response (in hours)</th>
<th>Total burden hours</th>
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<tr>
<td>Form 4: Quarterly Performance Report—State/Territory Awardees</td>
<td>56</td>
<td>4</td>
<td>224</td>
<td>24</td>
<td>5,376</td>
</tr>
<tr>
<td>Form 4: Quarterly Performance Report—Tribal Awardees</td>
<td>25</td>
<td>4</td>
<td>100</td>
<td>24</td>
<td>2,400</td>
</tr>
<tr>
<td>Total</td>
<td>81</td>
<td></td>
<td>324</td>
<td>24</td>
<td>7,776</td>
</tr>
</tbody>
</table>

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS
HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency’s functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Amy McNulty, Acting Director, Division of the Executive Secretariat.


BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, 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: National Eye Institute Special Emphasis Panel; NEI Clinical, Epidemiological and Secondary Data Analysis Applications.

Date: March 22, 2018.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate cooperative agreement applications.

Place: Hilton Garden Inn Bethesda, 7301 Waverly Street, Bethesda, MD 20814.

Contact Person: Brian Hoshaw, Ph.D., Scientific Review Officer, Division of Extramural Research, National Eye Institute, National Institutes of Health, 5635 Fishers Lane, Suite 1300, Bethesda, MD 20892, 301–451–2020, jeanetteh@mail.nih.gov.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Nursing Research; Notice to Close Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, 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 Institute of Nursing Research Special Emphasis Panel; NINR Centers Meeting.

Date: March 5–6, 2018.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.


Contact Person: Weiqun Li, MD, Scientific Review Officer, National Institute of Nursing Research, National Institutes of Health, 6701 Democracy Blvd., Suite 710, Bethesda, MD 20892, (301) 594–5066, wli@mail.nih.gov. (Catalogue of Federal Domestic Assistance Program Nos. 93.361, Nursing Research, National Institutes of Health, HHS)


Sylvia L. Neal, Program Analyst, Office of Federal Advisory Committee Policy.


BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; CTEP Branch and Support Contracts Forms and Surveys (National Cancer Institute)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI) will publish periodic summaries of propose projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments regarding this information collection are best assured
of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Michael Montello, Pharm. D., Shanda Finnigan, MPH, RN, CCRC, or Jacquelyn Goldberg, JD, Cancer Therapy Evaluation Program (CTEP), 9609 Medical Center Drive, MSC 9742, Rockville, MD 20850 or call non-toll-free number 240–276–6080 or Email your request, including your address to: ctsucontact@westat.com. Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: Written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Proposed Collection Title: CTEP Support Contract Forms and Surveys 0925–0753 Expiration Date 06/30/2020 ICR Type: Revision, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: The National Cancer Institute (NCI) Cancer Therapy Evaluation Program (CTEP) and the Division of Cancer Prevention (DCP) fund an extensive national program of cancer research, sponsoring clinical trials in cancer prevention, symptom management and treatment for qualified clinical investigators. As part of this effort, CTEP implements programs to register clinical site investigators and clinical site staff, and to oversee the conduct of research at the clinical sites. CTEP and DCP also oversee two support programs, the NCI Central Institutional Review Board (CIRB) and the Cancer Trial Support Unit (CTSU). The combined systems and processes for initiating and managing clinical trials is termed the Clinical Oncology Research Enterprise (CORE) and represents an integrated set of information systems and processes which support investigator registration, trial oversight, patient enrollment, and clinical data collection. The information collected is required to ensure compliance with applicable federal regulations governing the conduct of human subjects research (45 CFR 46 and 21 CFR 50), and when CTEP acts as the Investigational New Drug (IND) holder, FDA regulations pertaining to the sponsor of clinical trials and the selection of qualified investigators under 21 CFR 312.53.

Information is also collected through surveys to assess satisfaction, provide feedback to guide improvements with processes and technology, and assess health professional’s interests in clinical trials.

To increase efficiencies, reduce administrative burden and cost, CTEP has requested consolidation of their current OMB submission. Consolidation is justified because although the various branches and contracts are responsible for distinct services, the processes that support the NCI and participating clinical sites efforts are intertwined.

This revision of the previous submission includes changes to the NCI CIRB and CTSU form collections and integrates the Clinical Trials Monitoring Branch (CTMB) and Pharmaceutical Management Branch (PMB) form collections related to site audit and clinical investigator and key clinical site staff registration.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 68,855.

**ESTIMATED ANNUALIZED BURDEN HOURS**

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

A Strategic Roadmap for Establishing New Approaches To Evaluate the Safety of Chemicals and Medical Products in the United States; Availability of Report

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) coordinated the development of a strategic roadmap for establishing new approaches to evaluate the safety of chemicals and medical products in the United States. This document, prepared with support from the National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM), is now available.


FOR FURTHER INFORMATION CONTACT: Dr. Warren Casey, Director, NICEATM; email: warren.casey@nih.gov; telephone: (984) 287–3118.

SUPPLEMENTARY INFORMATION:

Background: Scientific and technological advances in toxicology can significantly improve and protect public health. However, a national strategy is required to ensure the safe, effective, and timely implementation of human-based, predictive approaches in toxicity testing.

The goal of the U.S. Strategic Roadmap is to realize the vision set forth in the seminal National Research Council report “Toxicity Testing in the 21st Century: A Vision and a Strategy.” This 2007 report envisioned using human-based assays and model information to provide a more efficient, predictive, and economic system for assessing the effects of chemicals on human health.

The U.S. Strategic Roadmap was developed with participation from the 16 ICCVAM member agencies and multiple interagency workgroups, as well as input from a broad range of stakeholder groups. It describes a new framework that will enable development, establish confidence in, and ensure use of new approaches to toxicity testing that improve human health relevance and reduce or eliminate the need for testing in animals.

Summary of Report Contents: The successful development and implementation of new approaches to toxicity testing will require coordinated efforts that address three strategic goals:

• Connect end users with developers of new approach methodologies
• Foster the use of efficient, flexible, and robust practices to establish confidence in new methods
• Encourage the adoption and use of new methods and approaches by federal agencies and regulated industries

Implementation of the roadmap goals, already underway in specific testing areas, will include key elements needed for advancement of alternative methods.


Background Information on ICCVAM and NICEATM: ICCVAM is an interagency committee composed of representatives from 16 federal regulatory and research agencies that require, use, generate, or disseminate toxicological and safety testing information. ICCVAM conducts technical evaluations of new, revised, and alternative safety testing methods and integrated testing strategies with regulatory applicability and promotes the scientific validation and regulatory acceptance of testing methods that more accurately assess the safety and hazards of chemicals and products and replace, reduce, or refine (enhance animal well-being and lessen or avoid pain and distress) animal use.

The ICCVAM Authorization Act of 2000 (42 U.S.C. 285f–3) establishes ICCVAM as a permanent interagency committee of the National Institute of Environmental Health Sciences and provides the authority for ICCVAM involvement in activities relevant to the development of alternative test methods. ICCVAM acts to ensure that new and revised test methods are validated to meet the needs of federal agencies, increase the efficiency and effectiveness and federal agency test method review, and optimize utilization of scientific expertise outside the federal government. Additional information about ICCVAM can be found at http://ntp.niehs.nih.gov/go/iccvam.

NICEATM administers ICCVAM, provides scientific and operational support for ICCVAM-related activities, and conducts and publishes analyses and evaluations of data from new, revised, and alternative testing approaches. NICEATM and ICCVAM work collaboratively to evaluate new and improved testing approaches applicable to the needs of U.S. federal agencies. NICEATM and ICCVAM welcome the public nomination of new, revised, and alternative testing approaches for validation studies and technical evaluations.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institute of Health

National Institute of Neurological Disorders and Stroke: Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, 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: National Institute of Neurological Disorders and Stroke Initial Review Group; Neurological Sciences and Disorders K; NSF–K Review Meeting.
Date: March 2, 2018.
Time: 1:00 p.m. to 2:30 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telepho Conference Call).
Contact Person: Shanta Rajaram, Ph.D., Scientific Review Officer, Scientific Review Branch, NINDS/NIH/DBHS, Neuroscience Center, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892–9529, 301–435–6033, rajarams@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.
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, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Epidemiology of Chronic and Infectious Disease.
Date: March 5, 2018.
Time: 11:00 a.m. to 3:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).
Contact Person: Heidi B. Friedman, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1012A, MSC 7770, Bethesda, MD 20892, 301–355–3492, hfriedman@nih.gov.
Name of Committee: Center for Scientific Review Special Emphasis Panel; Enhancing Developmental Biology Research at AREA Eligible Institutions.
Date: March 7, 2018.
Time: 10:30 a.m. to 4:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).
Contact Person: Jonathan Arias, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1012A, MSC 7770, Bethesda, MD 20892, 301–435–2406, arias@csr.nih.gov.


David Clary,
Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–03440 Filed 2–20–18; 8:45 am]
BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Draft NTP Research Report on the CLARITY–BPA Core Study: Availability of Document; Request for Comments; Notice of Peer-Review Meeting

AGENCY: National Institutes of Health, HHS.
ACTION: Notice.

SUMMARY: The National Toxicology Program (NTP) announces a meeting to peer review the Draft NTP Research Report on the CLARITY–BPA Core Study. This report presents the results of the core, guideline-compliant, chronic, extended-dose-range study of bisphenol A (BPA) in rats conducted as part of the CLARITY–BPA Research Program. The U.S. Food and Drug Administration’s National Center for Toxicological Research (NCTR) conducted the study under the auspices of the National Toxicology Program and prepared the draft report in collaboration with the National Institute of Environmental Health Sciences (NIEHS). The peer-review meeting will be held at NIEHS in Research Triangle Park, NC and is open to the public. Registration is requested for attendance at the meeting either in-person or by webcast and to present oral comments. Information about the meeting and registration is available at https://ntp.niehs.nih.gov/go/rprpp.

DATES:
Meeting: Tentatively scheduled for April 26, 2018, 8:30 a.m. to adjournment at approximately 5:00 p.m. Eastern Daylight Time (EDT). The meeting may end earlier or later than 5:00 p.m. EDT.


Sylvia L. Neal,
Program Analyst, Office of Federal Advisory Committee Policy.

Written Public Comment
Submissions: Deadline is April 12, 2018.
Registration for Oral Comments:
Deadline is April 12, 2018.

Registration to Attend Meeting In-person or to View Webcast: Deadline is April 26, 2018.

ADDRESSES:
Meeting Location: Rodbell Auditorium, Rall Building, NIEHS, 111 T.W. Alexander Drive, Research Triangle Park, NC 27709.

Meeting web page: The draft NTP Research Report, preliminary agenda, registration, and other meeting materials will be available at https://ntp.niehs.nih.gov/go/rrprp.

Webcast: The URL for viewing the peer-review meeting webcast will be provided to registrants.

FOR FURTHER INFORMATION CONTACT:
Canden Byrd, ICF, 2635 Meridian Parkway, Suite 200, Durham, NC, USA 27713. Phone: (919) 293–1660. Email: NTP-Meetings@icf.com.

SUPPLEMENTARY INFORMATION:
Background: Bisphenol A (BPA) is a chemical produced in large quantities for use primarily in the production of polycarbonate plastics and epoxy resins. BPA also is used in the production of certain flame retardants and as a color developer in some thermal paper. BPA has been detected in air, soil, water, landfill leachate, and the human body. The primary source of human exposure to BPA is thought to be through the diet. More than 800 studies were published on the health effects of BPA between the mid-1990s and the mid-2000s. Although BPA is a well-studied chemical, few existing, chronic toxicity studies have included exposure during the perinatal period. There is also inconsistency among BPA toxicological studies with regard to findings and their interpretation for human health. Given the uncertainty regarding the potential health effects from BPA exposure, NTP, NIEHS, and U.S. Food and Drug Administration (FDA) established the Consortium Linking Academic and Regulatory Insights on Toxicity of BPA (CLARITY–BPA).

The aim of the CLARITY–BPA program was to attempt to bridge guideline-compliant research conducted at the FDA with hypothesis-based research investigations conducted by academia on the toxicity of BPA. A detailed description of the CLARITY–BPA program has been published (https://www.ncbi.nlm.nih.gov/pubmed/26232603). The CLARITY–BPA research program has two components: (1) A “core,” guideline-compliant, chronic study conducted at NCTR according to FDA Good Laboratory Practice (GLP) regulations (2-year perinatal only or chronic BPA exposure, including perinatal), and (2) CLARITY–BPA grantee studies of various health endpoints, conducted by NIEHS-funded researchers at academic institutions using animals born to the same exposed pregnant rats as the core GLP study.

The draft NTP Research Report presents the results of the core GLP chronic study. The interpretation of biological and toxicological responses described in the draft NTP Research Report is based only on the results of the core GLP study. Integration of these data with other data from the grantee-studies conducted as part of the CLARITY–BPA research program or extrapolation of the results to other species, including characterization of hazards and risks to humans, is outside of the scope of the draft NTP Research Report.

Meeting Attendance Registration:
The meeting is open to the public with time set aside for oral public comment; in-person attendance at NIEHS is limited by the space available (~100 attendees). Registration for in-person attendance is on a first-come, first-served basis. After the first 100 registrants, persons will be placed on a wait list and notified should an opening become available.

Registration to attend the meeting in-person or view the webcast is by April 26, 2018, at https://ntp.niehs.nih.gov/go/rrprp. The URL for the webcast will be provided in the email confirming registration. Visitor and security information for those attending in person is available at https://www.niehs.nih.gov/about/visiting/index.cfm. Individuals with disabilities who need accommodation to view the webcast should contact Canden Byrd by phone: (919) 293–1660 or email: NTP-Meetings@icf.com. TTY users should contact the Federal TTY Relay Service at (800) 877–8339. Requests should be made at least five business days in advance of the event.


The deadline for submission of written comments is April 12, 2018. Written public comments should be submitted through the meeting website. Persons submitting written comments should include name, affiliation, mailing address, phone, email, and sponsoring organization (if any). Written comments or a response to this notice will be posted on the NTP website, and the submitter will be identified by name, affiliation, and sponsoring organization (if any). Comments that address scientific or technical issues will be forwarded to the peer-review panel and NTP staff prior to the meeting.

The agenda allows for one oral public comment period (12 commenters, up to 5 minutes per speaker). Registration to provide oral comments is on or before April 12, 2018, at https://ntp.niehs.nih.gov/go/rrprp. Registration is on a first-come, first-served basis. Each organization is allowed one time slot. Oral comments may be presented in person at NIEHS or by teleconference line. The access number for the teleconference line will be provided to registrants by email prior to the meeting.

After the maximum number of speakers is exceeded, individuals registered to provide oral comment will be placed on a wait list (6 slots on wait list) and notified should an opening become available. Commenters will be notified after April 12, 2018, the deadline to register for oral public comments, about the actual time allotted per speaker.

If possible, oral public commenters should send a copy of their slides and/or statement to Canden Byrd by email: NTP-Meetings@icf.com by April 12, 2018.

Meeting Materials: The draft NTP Research Report and preliminary agenda will be available on the NTP website at https://ntp.niehs.nih.gov/go/rrprp. The draft NTP Research Report should be available by February 23, 2018. Additional information will be posted when available or may be requested in hardcopy; contact Canden Byrd by phone: (919) 293–1660 or email: NTP-Meetings@icf.com. The preliminary meeting agenda is available on the meeting web page and will be updated one week before the meeting.

Individuals are encouraged to access the meeting web page to stay abreast of the most current information regarding the meeting.

Following the meeting, a report of the peer review will be prepared and made available on the NTP website.

Background Information on NTP Peer-Review Panels: NTP panels are technical, scientific advisory bodies established on an “as needed” basis to provide independent scientific peer review and advise NTP on agents of public health concern, new/revised toxicological test methods, or other issues. These panels help ensure transparent, unbiased, and scientifically rigorous input to the program for its use in making credible decisions about human health hazards, setting research and testing priorities, and providing information to regulatory agencies about

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alternative methods for toxicity screening. NTP welcomes nominations of scientific experts for upcoming panels. Scientists interested in serving on an NTP panel should provide their current curriculum vitae to Canden Byrd by email: NTP-Meetings@icf.com. The authority for NTP panels is provided by 42 U.S.C. 217a; section 222 of the Public Health Service Act, as amended. The panel is governed by the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.


Brian R. Berridge, Associate Director, National Toxicology Program.

[FR Doc. 2018–03472 Filed 2–20–18; 8:45 am] BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health

National Heart, Lung, and Blood Institute; 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Jackson Heart Study Coordinating Center (CEC).

Date: March 14, 2018.

Time: 9:00 a.m. to 9:30 a.m.

Agenda: To review and evaluate contract proposals.

Place: Holiday Inn National Airport Hotel, 2650 Jefferson Davis Highway, Arlington, VA 22202.

Contact Person: William J. Johnson, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7178, Bethesda, MD 20892–7924, 301–827–7938, johnsonw@nhlbi.nih.gov.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Jackson Heart Study Training and Education Center (TEC).

Date: March 14, 2018.

Time: 9:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: Holiday Inn National Airport Hotel, 2650 Jefferson Davis Highway, Arlington, VA 22202.

Contact Person: William J. Johnson, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7178, Bethesda, MD 20892–7924, 301–827–7938, johnsonw@nhlbi.nih.gov.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Jackson Heart Study Coordinating Center (CC).

Date: March 14, 2018.

Time: 9:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: Holiday Inn National Airport Hotel, 2650 Jefferson Davis Highway, Arlington, VA 22202.

Contact Person: William J. Johnson, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7178, Bethesda, MD 20892–7924, 301–827–7938, johnsonw@nhlbi.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)


Michelle Trout, Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–03441 Filed 2–20–18; 8:45 am] BILLING CODE 4140–01–P

DEPARTMENT OF THE INTERIOR
National Park Service

[NPS–WASO–NRNH–24925; PPWOCRADIO, PCU00RP14.R50000]

National Register of Historic Places; Notification of Pending Nominations and Related Actions

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The National Park Service is soliciting comments on the significance of properties nominated before January 20, 2018, for listing or related actions in the National Register of Historic Places. DATES: Comments should be submitted by March 8, 2018.

ADDRESSES: Comments may be sent via U.S. Postal Service and all other carriers to the National Register of Historic Places, National Park Service, 1849 C St. NW, MS 7228, Washington, DC 20240.

SUPPLEMENTARY INFORMATION: The properties listed in this notice are being considered for listing or related actions in the National Register of Historic Places. Nominations for their consideration were received by the National Park Service before January 20, 2018. Pursuant to section 60.13 of 36 CFR part 60, written comments are being accepted concerning the significance of the nominated properties under the National Register criteria for evaluation.

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 your 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.

Nominations submitted by State Historic Preservation Officers:

ARIZONA

Maricopa County

Ponderosa II, 602 S. Edgewater Dr., Mesa, SG100002146

ILLINOIS

Coles County

Burgess–Osborne Memorial Auditorium, 1701 Wabash Ave., Mattoon, SG100002149

Kankakee County

Kankakee Downtown Historic District, Roughly bounded by West Ave., Oak, Indiana & Station Sts., Kankakee, SG100002150

KENTUCKY

Allen County

Halcomb, Dr. Francis Joseph (F.J.) Jr., House, 253 Franklin Rd., Scottsville, SG100002152

Campbell County

Bonnie Leslie Historic District, Bounded by Memorial Pkwy., Taylor, Wilson, Berry & Anspaugh Aves., Bellevue, SG100002153

Edmonson County

Chalybeate Springs Hotel Springhouse, 2327 Chalybeate Rd., Smiths Grove vicinity, SG100002154
Jefferson County
LeCompte Saloon, 3200 Rudd Ave.,
Louisville, SG100002155
Queen Products Company, Inc. Complex,
1226–1234 Rowan St., Louisville,
SG100002157

Mason County
Durrett, Richard, House, 804 Clarks Run Rd.,
Maysville, SG100002158
GAR Monument, Maysville-Mason County
Cemetery, 1521 Forest Ave., Maysville,
MP100002159
May’s Lick Negro School, 5003 Raymond Rd.,
May’s Lick, SG100002160

MASSACHUSETTS
Worcester County
Osgood Bradley Building, 18 Grafton St.,
Worcester, SG100002161

MINNESOTA
Fillmore County
Chicago, Milwaukee, St. Paul and Pacific
Railroad Depot, NW corner of intersection
of W Prairie Ave. & Main St. N, Fillmore,
MP100002162

NEBRASKA
Burt County
Tekamah Auditorium, 1315 K St., Tekamah,
SG100002164

WISCONSIN
Dixon County
Emerson City Park, Square block between
4th, 5th, Main & Logan Sts., Emerson,
SG100002165

Perkins County
Venango Public School, 201 E Washington
St., Venango, MP100002170

NEW JERSEY
Salem County
Mecum, William and Margaret, House, 168
Lighthouse Rd., Pennsville Township,
MP100002172

NEBRASKA
Douglas County
Barton, Guy C., House, 3522 Farnam St.,
Omaha, OT73001060
Monmouth Park School, 4508 N. 33rd St.,
Omaha, OT3003988
Main Street Bridge, (Highway Bridges in
Nebraska MPS), Main St. over W. Papillion
Cr., Elkhorn, OT92000746
Fillmore County
Elberhardt, Philip and Addie Ellis, Farmstead,
3 mi. N of US 8, Exeter vicinity,
OT91000299
Additional documentation has been received
for the following resources:

OREGON
Multnomah County
Public Service Building and Garage, 920 6th
Ave., SW, Portland, AD6000998

WEST VIRGINIA
Wood County
Avery Street Historic District, Roughly
bounded by Nineteenth, Spring and
Quiny, Eighth, and Market Sts.,
Parkersburg, AD6000849
Nominations submitted by Federal
Preservation Officers:
The State Historic Preservation Officer
reviewed the following nominations and
responded to the Federal Preservation Officer
within 45 days of receipt of the nominations
and supports listing the properties in the
National Register of Historic Places.

CALIFORNIA
Marin County
Point Reyes Peninsula Dairy Ranches
Historic District, Point Reyes NS, Inverness
vicinity, SG100002147

COLORADO
Larimer County
Fall River Entrance Historic District
(Boundary Increase and Additional
Document), (Rocky Mountain
National Park MRA), Rocky Mountain NP,
Estes Park vicinity, BC100002148
Authority: 60.13 of 36 CFR part 60.
Julie H. Ernstlein,
Acting Chief, National Register of Historic
Places/National Historic Landmarks Program.
[FR Doc. 2018–03539 Filed 2–20–18; 8:45 am]
BILLING CODE 4312–52–P

INTERNATIONAL TRADE COMMISSION
Investigation No. 337–TA–1100]
Certain Microfluidic Systems and Components Thereof and Products
Containing Same Institution of Investigation
AGENCY: U.S. International Trade
Commission.
ACTION: Notice.

SUMMARY: Notice is hereby given that a
complaint was filed with the U.S.
International Trade Commission on
January 11, 2018, under section 337 of the
Tariff Act of 1930, as amended, on
behalf of 10X Genomics, Inc. of
Pleasanton, California. A supplement to
the complaint was filed on January 29,
2018. The complaint alleges violations of
section 337 based upon the
importation into the United States, the
sale for importation, and the sale within
the United States after importation of
certain microfluidic systems and
components thereof and products
containing same by reason of
infringement of U.S. Patent No.
9,644,204 ("the '204 Patent"); U.S.
Patent No. 9,689,024 ("the '024 Patent");
U.S. Patent No. 9,695,468 ("the '468
Patent"); and U.S. Patent No. 9,856,530
("the '530 Patent"). The complaint
further alleges that an industry in the
United States exists as required by the
applicable Federal Statute.

The complainant requests that the
Commission institute an investigation
and, after the investigation, issue a
limited exclusion order and a cease and
desist order.

ADDRESSES: The complaint, except for
any confidential information contained
therein, is 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, Room
112, Washington, DC 20436, telephone
(202) 205–2000. Hearing impaired
individuals are advised that information
on this matter can be obtained by
contacting the Commission’s TDD
terminal on (202) 205–1810. Persons
with mobility impairments who will
need special assistance in gaining access
to the Commission should contact the
Office of the Secretary at (202) 205–
2000. General information concerning
the Commission may also be obtained
by accessing its internet server at
https://www.usitc.gov. The public
record for this investigation may be
viewed on the Commission’s electronic
docket (EDIS) at https://edis.usitc.gov.

FOR FURTHER INFORMATION CONTACT:
Pathenia M. Proctor, The Office of
Unfair Import Investigations, U.S.
International Trade Commission,
telephone (202) 205–2560.

SUPPLEMENTARY INFORMATION:
Authority: The authority for
institution of this investigation is
contained in section 337 of the Tariff
Act of 1930, as amended, 19 U.S.C. 1337
and in section 210.10 of the
Commission’s Rules of Practice and

Scope of Investigation: Having
considered the complaint, the U.S.
International Trade Commission, on
February 12, 2018, Ordered that—

1) Pursuant to subsection (b) of
section 337 of the Tariff Act of 1930, as
amended, an investigation be instituted
to determine whether there is a
violation of subsection (a)(1)(B) of
section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain microfluidic systems and components thereof and products containing same by reason of infringement of one or more of claims 1–4, 6–9, 17, 20, 21, 23, 25, 27, 29, 31, and 33 of the ’204 Patent; claims 1, 2, 5, 8, 10, 11, 13, 15–17, 19, 21, and 22 of the ’024 Patent; claims 1–4, 6–9, 11, 12, 21, and 22 of the ’468 Patent; and claims 1–6, 8–11, 14–20, and 24–30 of the ’530 Patent; and whether an industry in the United States exists as required by subsection (a)(2) of section 337;

(2) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainant is: 10X Genomics, Inc., 7068 Koll Center Parkway, Suite 401, Pleasanton, CA 94566.

(b) The respondent is the following entity alleged to be in violation of section 337, and is the party upon which the complaint is to be served: Bio-Rad Laboratories, Inc., 1000 Alfred Nobel Drive, Hercules, CA 94547.

(c) The Office of Unfair Import Investigations, U.S. International Trade Commission, 500 E Street SW, Suite 401, Washington, DC 20436; and

(3) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

Responses to the complaint and the notice of investigation must be submitted by the named respondent in accordance with section 210.13 of the Commission’s Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(e) and 210.13(a), such responses will be considered by the Commission if received not later than 20 days after the date of service by the Commission of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of the respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.


Lisa R. Barton, Secretary to the Commission.

DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms and Explosives

[OMB Number 1140–0087]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Revision of a Currently Approved Collection; eForm Access Request

AGENCY: Bureau of Alcohol, Tobacco, Firearms and Explosives, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Department of Justice (DOJ), Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), will submit the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 60 days until April 23, 2018.

FOR FURTHER INFORMATION CONTACT: If you have additional comments, particularly with respect to the estimated public burden or associated response time, have suggestions, need a copy of the proposed information collection instrument with instructions, or desire any additional information, please contact Desiree Dickinson either by mail at 244 Needy Road, Martinsburg, WV 25405, by email at Desiree.Dickinson@atf.gov or by telephone at (304) 616–4584.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agency’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of this information collection:

1. Type of Information Collection (check justification or form 83): Revision of a currently approved collection.

2. The Title of the Form/Collection: eForm Access Request.

3. The agency form number, if any, and the applicable component of the Department sponsoring the collection: Form number (if applicable): None. Component: Bureau of Alcohol, Tobacco, Firearms and Explosives, U.S. Department of Justice.

4. Affected public who will be asked or required to respond, as well as a brief abstract: Primary: Business or other for-profit. Other (if applicable): None. Abstract: Respondents must complete the eForm Access Request form in order to receive a user ID and password to obtain access to ATF’s eForm System.

The information is used by the Government to verify the identity of the end users, prior to issuing passwords.

5. An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond: An estimated 76,000 respondents will utilize the form, and it will take each respondent approximately 2.24 minutes to complete the form.

6. An estimate of the total public burden (in hours) associated with the collection: The estimated annual public burden associated with this collection is 2,387 hours which is equal to 76,000 (# of respondents) * 134 seconds (2.24 minutes).

7. An Explanation of the Change in Estimates: The adjustments associated with this collection are an increase in both the number of respondents and burden hours by 52,000 and 1,941 respectively.

If additional information is required contact: Melody Braswell, Department...
DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the
Comprehensive Environmental Response, Compensation and Liability Act

On February 12, 2018, the Department of Justice lodged a proposed Consent Decree with the United States District Court for the District of Idaho in the lawsuit entitled United States v. Potlatch Corporation and Potlatch Land and Lumber, LLC, Civil Action No. 1:18–cv–0069–CWD.

The proposed settlement resolves the United States’ claims under Section 107 of the Comprehensive Environmental Response, Compensation and Liability Act, 42 U.S.C. Section 9607 against the Potlatch Corporation (“Potlatch”) and Potlatch Land and Lumber, LLC (“PLL”) (collectively “Potlatch/PLL”) for recovery of past response costs incurred at the Avery Landing Site in Shoshone County, Idaho. The Site is approximately ten acres in size and is located along the St. Joe River about one mile west of the town of Avery in northern Idaho. Potlatch was the owner and operator of a portion of the Site at the time of disposal of hazardous substances. PLL, a Potlatch subsidiary, is the current owner of that portion of the Site. Potlatch/PLL will pay $6 million in past response costs to resolve the United States’ claims.

The publication of this notice opens a period for public comment on the proposed Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to United States v. Potlatch Corporation and Potlatch Land and Lumber, LLC, D.J. Ref. No. 90–11–3–1116/DJ Ref. No. 90–11–3–11294.

All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:

- By email: pubcomment-ees.enrd@usdoj.gov
- By mail: Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

During the public comment period, the proposed Consent Decree may be examined and downloaded at this Justice Department website: https://www.justice.gov/enrd/consent-decree. We will provide a paper copy of the proposed Consent Decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $6.25 (25 cents per page reproduction cost) payable to the United States Treasury.

Susan M. Akers,
Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

Agency Information Collection Activities; Proposed eCollection, eComments Requested; Extension Without Change of a Previously Approved Collection; Application for Registration, Application for Registration Renewal, Affidavit for Chain; Renewal DEA Forms 225, 225a and 225b

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Department of Justice (DOJ), Drug Enforcement Administration (DEA), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 60 days until April 23, 2018.

FOR FURTHER INFORMATION CONTACT: If you have comments on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Michael J. Lewis, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

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. Evaluate whether and if so how the quality, utility, and clarity of the information proposed to be collected can be enhanced; 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 forms of information technology, e.g., permitting electronic submission of responses.

Overview of This Information Collection

1. Type of Information Collection: Extension of a currently approved collection.
2. Title of the Form/Collection: Application for Registration, Application for Registration Renewal, Affidavit for Chain Renewal.
3. The agency form number, if any, and the applicable component of the Department sponsoring the collection: The form numbers are DEA Forms 225, 225a, and 225b. The applicable component within the Department of Justice is the Drug Enforcement Administration, Diversion Control Division.
4. Affected public who will be asked or required to respond, as well as a brief abstract:
   - Affected public: Business or other for-profit.
   - Affected public (Other): Not-for-profit institutions, Federal, State, local, and tribal governments.

Abstract: The Controlled Substances Act requires all businesses and individuals who manufacture, distribute, import, export, and conduct research and laboratory analysis with controlled substances to register with
DEA. 21 U.S.C. 822, 21 CFR 1301.11 and 1301.13. Registration is a necessary control measure and helps to prevent diversion by ensuring the closed system of distribution of controlled substances can be monitored by DEA and the businesses and individuals handling controlled substances are qualified to do so and are accountable.

5. An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond: The below table presents information regarding the number of respondents, responses and associated burden hours.

<table>
<thead>
<tr>
<th>Number of annual respondents</th>
<th>Average time per response</th>
<th>Total annual hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEA–225 (paper)</td>
<td>308</td>
<td>0.33 hours (20 minutes)</td>
</tr>
<tr>
<td>DEA–225 (online)</td>
<td>1,993</td>
<td>0.17 hours (10 minutes)</td>
</tr>
<tr>
<td>DEA–225a (paper)</td>
<td>366</td>
<td>0.25 hours (15 minutes)</td>
</tr>
<tr>
<td>DEA–225a (online)</td>
<td>13,246</td>
<td>0.12 hours (7 minutes)</td>
</tr>
<tr>
<td>DEA–225b (chain renewal)*</td>
<td>4</td>
<td>1 hour</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>15,919</strong></td>
<td><strong>2,076</strong></td>
</tr>
</tbody>
</table>

*In total, 4 chains represent 82 individual registrant locations. Figures are rounded.

6. An estimate of the total public burden (in hours) associated with the proposed collection: The DEA estimates that this collection takes 2,076 annual burden hours.

If additional information is required please contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, Suite 3E.405B, Washington, DC 20530.


Melody Braswell,
Department Clearance Officer for PRA, U.S. Department of Justice.
[FR Doc. 2018–03514 Filed 2–20–18; 8:45 am]
BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE
[OMB Number 1117–0015]

Agency Information Collection Activities; Proposed eCollection, eComments Requested; Extension Without Change of a Previously Approved Collection; Application for Registration, Application for Registration Renewal; DEA Forms 363, 363a

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Department of Justice (DOJ), Drug Enforcement Administration (DEA), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 60 days until April 23, 2018.

FOR FURTHER INFORMATION CONTACT: If you have comments on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Michael J. Lewis, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agency’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Evaluate whether and if so how the quality, utility, and clarity of the information proposed to be collected can be enhanced; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of This Information Collection

1. Type of Information Collection: Extension of a currently approved collection.

2. Title of the Form/Collection: Application for Registration, Application for Registration Renewal.

3. The agency form number, if any, and the applicable component of the Department sponsoring the collection: The form numbers are DEA Forms 363, 363a. The applicable component within the Department of Justice is the Drug Enforcement Administration, Diversion Control Division.

4. Affected public who will be asked or required to respond, as well as a brief abstract:

Affected public: Business or other for-profit.

Affected public (Other): Not-for-profit institutions, Federal, State, local, and tribal governments.

Abstract: The Controlled Substances Act requires practitioners who dispense narcotic drugs to individuals for maintenance or detoxification treatment to register annually with DEA.2 21 U.S.C. 822, 823; 21 CFR 1301.11 and 1301.13. Registration is a necessary control measure and helps to prevent diversion by ensuring the closed system of distribution of controlled substances can be monitored by DEA and the businesses and individuals handling controlled substances are qualified to do so and are accountable.

5. An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond: DEA Form 363 is submitted on an as needed basis by persons seeking to become registered; DEA Form 363a is submitted on an annual basis thereafter.

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1 This registration requirement is waived for certain practitioners under specified circumstances. See 21 U.S.C. 823(i)(2).
to renew existing registrations. The below table presents information regarding the number of respondents, responses and associated burden hours.

<table>
<thead>
<tr>
<th>DEA Form 363 (paper)</th>
<th>Number of annual respondents</th>
<th>Average time per response</th>
<th>Total annual hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEA Form 363 (paper)</td>
<td>15</td>
<td>0.30 hours (18 minutes)</td>
<td>5</td>
</tr>
<tr>
<td>DEA Form 363 (online)</td>
<td>223</td>
<td>0.13 hours (8 minutes)</td>
<td>30</td>
</tr>
<tr>
<td>DEA Form 363a (paper)</td>
<td>51</td>
<td>0.22 hours (13 minutes)</td>
<td>11</td>
</tr>
<tr>
<td>DEA Form 363a (online)</td>
<td>1,437</td>
<td>0.10 hours (6 minutes)</td>
<td>144</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>1,726</strong></td>
<td></td>
<td><strong>189</strong></td>
</tr>
</tbody>
</table>

Figures are rounded.

6. An estimate of the total public burden (in hours) associated with the proposed collection: The DEA estimates that this collection takes 189 annual burden hours.

If additional information is required please contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, Suite 3E-405B, Washington, DC 20530.


Melody Braswell,
Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2018–05153 Filed 2–20–18; 8:45 am]
BILLING CODE 4410–09–P

DEPARTMENT OF LABOR
Employment and Training Administration

Notice of a Public Meeting of the Task Force on Apprenticeship Expansion

AGENCY: Employment and Training Administration (ETA), Labor.

ACTION: Notice.

SUMMARY: Pursuant to the Federal Advisory Committee Act (FACA) and its implementing regulations, notice is hereby given to announce the third public meeting of the Task Force on Apprenticeship Expansion on Thursday, March 15, 2018. The Task Force is a FACAC committee established by Presidential Executive Order that is charged with identifying strategies and proposals to promote and expand apprenticeships, especially in sectors where apprenticeship programs are insufficient. The Task Force is solely advisory in nature, and will consider reports, comments, research, evidence, and existing practices as appropriate to develop recommendations for inclusion in its final report to the President. To achieve its mission, the Task Force will convene two additional meetings between April and May 2018; one meeting will convene virtually and one meeting will convene in person.

DATES: The meeting will begin at approximately 1:00 p.m. Eastern Daylight Time on Thursday, March 15, 2018, and adjourn at approximately 3:00 p.m. Eastern Daylight Time.

ADDRESSES: The meeting will be held at the U.S. Department of Labor, Frances Perkins Building, 200 Constitution Avenue NW, Washington, DC 20210. The Department will post any updates regarding the agenda and meeting logistics to the Task Force website: https://www.dol.gov/apprenticeship/task-force.htm.

FOR FURTHER INFORMATION CONTACT: Ms. Laurie Rowe, Senior Policy Advisor to the Secretary, U.S. Department of Labor, 200 Constitution Avenue NW, Washington, DC 20210, Telephone: (202) 693–2772 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Public Viewing Accommodations

In order to promote openness, and increase public participation, in person or web based viewing accommodations will be made available for members of the public to observe the meeting proceedings. Additional information will be provided on https://www.dol.gov/apprenticeship/task-force.htm. Members of the public interested in the viewing accommodations, must register via the registration link below, space is limited and in person participants are encouraged to arrive 30 minutes early to allow for security clearance into the U.S. Department of Labor, Frances Perkins Building.

Security and Transportation Instructions for Frances Perkins Building

Meeting participants should use the visitor’s entrance to access the Frances Perkins Building, one block north of Constitution Avenue on 3rd and C Streets NW. For security purposes:

1. Visitors must present valid photo identification (ID) to receive a visitor badge.

2. Visitors must know the name of the event you are attending: The meeting event is the Task Force on Apprenticeship Expansion meeting.

3. Visitor badges are issued by the security officer at the Visitor Entrance located at 3rd and C Streets NW, as described above.

4. Laptops and other electronic devices may be inspected and logged for identification purposes.

5. Due to limited parking options, Metrorail is the easiest way to travel to the Frances Perkins Building. For individuals wishing to take Metrorail, the closest metro stop to the building is Judiciary Square on the Red Line.

Notice of Intent To Attend the Meeting and Submission of a Written Statement

Interested members of the public must register for the Task Force meeting by Thursday, March 12, 2018, via the public registration website using the following link: https://www.apprenticeshiptaskforce.com/reg/. Additionally, individuals with special needs and/or disabilities that will require special accommodations should send an email to Apprenticeshiptaskforce@dol.gov with the subject line “Special Accommodations for the March 2018 Task Force Meeting” no later than Tuesday, March 6, 2018.

The tentative agenda for this meeting includes the following:

- Updates Since February 2018 Meeting
- Updates from the Subcommittees
- Next Meeting and Next Steps

Also in the interest of increasing public participation, any member of the public who wishes to provide a written statement should send it via electronic mail to Apprenticeshiptaskforce@dol.gov, subject line “Public Comment March 2018 Task Force Meeting.” The agenda and meeting logistics may be updated between the time of this publication and the scheduled date of the Task Force meeting. All meeting
I. Notice of the Application for Expansion

The Occupational Safety and Health Administration is providing notice that MET Laboratories, Inc. (MET), is applying for expansion of its current recognition as a NRTL. MET requests the addition of two test standards to its NRTL scope of recognition.

OSHA recognition of a NRTL signifies that the organization meets the requirements specified in 29 CFR 1910.7. Recognition is an acknowledgment that the organization can perform independent safety testing and certification of the specific products covered within its scope of recognition. Each NRTL’s scope of recognition includes (1) the type of products the NRTL may test, with each type specified by its applicable test standard; and (2) the recognized site(s) that has/have the technical capability to perform the product-testing and product-certification activities for test standards within the NRTL’s scope.

The Agency processes applications by a NRTL for initial recognition and for an expansion or renewal of this recognition, following requirements in Appendix A to 29 CFR 1910.7. This appendix requires that the Agency publish two notices in the Federal Register in processing an application. In the first notice, OSHA announces the application and provides its preliminary finding. In the second notice, the Agency provides its final decision on the application. These notices set forth the NRTL’s scope of recognition or modifications of that scope. OSHA maintains an informational web page for each NRTL, including MET, which details the NRTL’s scope of recognition. These pages are available from the OSHA website at http://www.osha.gov/dts/otpca/nrtl/index.html.

II. General Background on the Application

MET submitted an application, dated July 27, 2016 (OSHA–2006–0028–0042), to expand its recognition to include two additional test standards.
performed a detailed analysis of the application packet and reviewed other pertinent information. OSHA did not perform any on-site reviews in relation to this application. Table 1, below, lists the appropriate test standards found in MET’s application for expansion for testing and certification of products under the NRTL Program.

<table>
<thead>
<tr>
<th>Test standard</th>
<th>Test standard title</th>
</tr>
</thead>
</table>

*Represents the standard that OSHA proposes to add to the NRTL Program’s List of Appropriate Test Standards.

III. Proposal To Add New Test Standard to the NRTL Program’s List of Appropriate Test Standards

Periodically, OSHA will propose to add new test standards to the NRTL list of appropriate test standards following an evaluation of the test standard document. To qualify as an appropriate test standard, the Agency evaluates the document to (1) verify it represents a product category for which OSHA requires certification by a NRTL, (2) verify the document represents an end product and not a component, and (3) verify the document defines safety test specifications (not installation or operational performance specifications). OSHA becomes aware of new test standards through various avenues. For example, OSHA may become aware of new test standards by: (1) Monitoring notifications issued by certain Standards Development Organizations; (2) reviewing applications by NRTLs or applicants seeking recognition to include new test standard in their scopes of recognition; and (3) obtaining notification from manufacturers, manufacturing organizations, government agencies, or other parties. OSHA may determine to include a new test standard in the list, for example, if the test standard is for a particular type of product that another test standard also covers or it covers a type of product that no standard previously covered.

In this notice, OSHA proposes to add a new test standard to the NRTL Program’s List of Appropriate Test Standards. Table 2, below, lists the test standard that is new to the NRTL Program. OSHA preliminarily determined that this test standard is an appropriate test standard and proposes to include it in the NRTL Program’s List of Appropriate Test Standards. OSHA seeks public comment on this preliminary determination.

<table>
<thead>
<tr>
<th>Test standard</th>
<th>Test standard title</th>
</tr>
</thead>
</table>

IV. Preliminary Findings on the Application

MET submitted an acceptable application for expansion of its scope of recognition. OSHA’s review of the application file, and pertinent documentation, indicate that MET can meet the requirements prescribed by 29 CFR 1910.7 for expanding its recognition to include the addition of these two test standards for NRTL testing and certification listed above. This preliminary finding does not constitute an interim or temporary approval of MET’s application.

OSHA welcomes public comment as to whether MET meets the requirements of 29 CFR 1910.7 for expansion of its recognition as a NRTL. Comments should consist of pertinent written documents and exhibits. Commenters needing more time to comment must submit a request in writing, stating the reasons for the request. Commenters must submit the written request for an extension by the due date for comments. OSHA will limit any extension to 10 days unless the requester justifies a longer period. OSHA may deny a request for an extension if the request is not adequately justified. To obtain or review copies of the exhibits identified in this notice, as well as comments submitted to the docket, contact the Docket Office, at the above address. These materials also are available online at http://www.regulations.gov under Docket No. OSHA–2006–0028. OSHA staff will review all comments to the docket submitted in a timely manner and, after addressing the issues raised by these comments, will recommend to the Assistant Secretary for Occupational Safety and Health whether to grant MET’s application for expansion of its scope of recognition. The Assistant Secretary will make the final decision on granting the application. In making this decision, the Assistant Secretary may undertake other proceedings prescribed in Appendix A to 29 CFR 1910.7. OSHA will publish a public notice of its final decision in the Federal Register.

IV. Authority and Signature

Loren Sweatt, Deputy Assistant Secretary of Labor for Occupational Safety and Health, authorized the preparation of this notice. Accordingly, the Agency is issuing this notice pursuant to 29 U.S.C. 657(g)(2), Secretary of Labor’s Order No. 1–2012 (77 FR 3912, Jan. 25, 2012), and 29 CFR 1910.7.

Signed at Washington, DC, on February 14, 2018.

Loren Sweatt.
Deputy Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2018–03529 Filed 2–20–18; 8:45 am]

BILLING CODE 4510–26–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[NOTICE: (18–008)]

Notice of Information Collection

AGENCY: National Aeronautics and Space Administration (NASA),
ACTION: Notice of information collection.

SUMMARY: The National Aeronautics and Space Administration, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections.

DATES: All comments should be submitted within 60 calendar days from the date of this publication.

ADDRESSES: All comments should be addressed to Lori Parker, National Aeronautics and Space Administration, 300 E Street SW, Washington, DC 20546–0001.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to Lori Parker, NASA Clearance Officer, NASA Headquarters, 300 E Street SW, JF0000, Washington, DC 20546, (202) 358–1351.

SUPPLEMENTARY INFORMATION:

I. Abstract

Federal agencies are required by statute not to engage in discrimination on the bases of race, color, religion, sex, national origin, age, disability, genetic information, or retaliation. A federal employee, former employee, or job applicant who believes s/he was discriminated against has a right to file a complaint with the agency’s office responsible for its Equal Employment Opportunity (EEO) programs. Federal agencies must offer pre-complaint counseling or EEO alternative dispute resolution (EEO ADR) to individuals who allege that they were discriminated against by the agency. If pre-complaint counseling or EEO ADR does not resolve the dispute(s), the individual can file a formal discrimination complaint with the agency’s EEO office.

II. Methods of Collection

Title 29 of the Code of Federal Regulations (CFR) Part 1614 Section 104 requires agencies to establish procedures for processing individual and class complaints of discrimination that include the provisions contained in 29 CFR 1614.105 through 1614.110 and in § 1614.204, which are consistent with all other applicable Federal EEO regulations and complaint processing requirements contained in the Equal Employment Opportunity Commission (EEOC) Management Directives (MD).

When an individual decides to pursue the formal discrimination complaint process, EEOC MD 110 requires that the formal complaint must be:

- In writing;
- Specific with regard to the claim(s) that the individual raised in pre-complaint counseling and that the person wishes to pursue;
- Must be signed by the individual and/or his or her representative; and
- Must be filed within fifteen (15) calendar days from the date s/he receives the Notice of Right to File a Discrimination Complaint.

Consequently, NASA established NF–1355P form to ensure the individual who wishes to utilize the EEO process complies with the requirements listed above.

III. Data

Title: Formal Discrimination Complaint Form.

OMB Number: 2700–0163.

Type of Review: Extension of Existing Form.

Affected Public: Individuals who wish to file a formal discrimination complaint against NASA.

Estimated Number of Respondents: 60.

Estimated Time per Response: 30 minutes.

Estimated Total Annual Public Burden Hours: 30 hours.

Estimated Total Annual Government Cost: $500.

IV. Request for Comments

Comments are invited on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of NASA, including whether the information collected has practical utility; (2) the accuracy of NASA’s estimate of the burden (including hours and cost) of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including automated collection techniques or the use of other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the request for OMB approval of this information collection. They will also become a matter of public record.

Lori Parker,

NASA PRA Clearance Officer.

[FR Doc. 2018–03466 Filed 2–20–18; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL SCIENCE FOUNDATION

Notice of Intent To Seek Approval To Establish an Information Collection

AGENCY: National Science Foundation.

ACTION: Notice and request for comments.

SUMMARY: The National Science Foundation (NSF) is announcing plans to request establishment and clearance of this collection. In accordance with the requirements of the Paperwork Reduction Act of 1995, we are providing opportunity for public comment on this action. After obtaining and considering public comment, NSF will prepare the submission requesting that OMB approve clearance of this collection for no longer than three years.

DATES: Written comments on this notice must be received by April 23, 2018 to be assured of consideration. Comments received after that date will be considered to the extent practicable.

For Additional Information, Contact: Suzanne H. Plimpton, Reports Clearance Officer, National Science Foundation, 2415 Eisenhower Avenue, Room W 18000, Alexandria, Virginia 22314; or send email to splimpto@nsf.gov.

Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339, which is accessible 24 hours a day, 7 days a week, 365 days a year (including federal holidays).

Instructions: Please submit one copy of your comments by only one method. All submissions received must include the agency name and collection name identified above for this information collection. Commenters are strongly encouraged to transmit their comments electronically via email. Comments, including any personal information provided become a matter of public record. They will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request.

SUPPLEMENTARY INFORMATION:

Comments: Comments are invited on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information shall have practical utility; (b) the accuracy of the Agency’s estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information on respondents, including through the use of automated collection techniques or other forms of information technology; (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, or other technological collection techniques or other forms of information technology.

**Title of Collection:** Developing an Evaluation Framework and Pilot-Testing a Longitudinal Tracking System for REU Site Students.

**OMB Number:** 3145–NEW.

**Expiration Date of Approval:** Not applicable.

**Abstract**

The National Science Foundation (NSF) seeks to develop and pilot test different approaches to collecting data electronically from one cohort of applicants to the Research Experiences for Undergraduates (REU) Program and track their program and career outcomes over time. The intent is for the pilot tests to provide information for NSF to select the most effective and least burdensome approach to collect data needed to monitor the Program, report to NSF leadership, and comply with a Congressional requirement.

The REU program was created in 1987 to strengthen the science, technology, engineering, and mathematics (STEM) workforce. Building on research experiences as “one of the most effective avenues for attracting students to and retaining them in science and engineering, and for preparing them for careers in these fields,” the program is designed to foster student research and careers in these fields,” the program is designed to foster student research and promote diversity.

The main goal of the current study is to pilot test alternative approaches to collecting data required by Congress in the America COMPETES Reauthorization Act of 2010, which states that students in the REU program must “be tracked, for employment and continued matriculation in STEM fields, through receipt of the undergraduate degree and for at least three years thereafter” (Section 514[a][6] of Pub. L. 111–358). The legislation also mentions specific demographic characteristics of participants that need to be reported, such as gender, ethnicity, and enrollment in a two-year college. In addition to needing these data to report to Congress, NSF program officers and leadership need a more robust data system to enhance their efforts to monitor participation in the program and eventually to assess its effectiveness.

In addition to designing the system, the present study will pilot test different approaches to collecting data from a sample of REU Sites that volunteer to participate. By participating in this study, these Sites will have the opportunity to experience the data collections first hand and provide feedback that will be used to determine which approach will be the most effective, most efficient, and least burdensome for possible future implementation across all REU Sites. The pilot includes:

1. **Testing a web-based system that includes two approaches to obtain basic student background and participation information:**
   - **Registration.** The registration will be designed to collect the basic demographic and contact information needed for analysis and tracking purposes. Students will be asked to register at a website through which they will obtain a unique ID. With this unique ID, they will then apply directly to the REU Sites using the existing Site application processes.
   - **Common Application.** The common application will replace existing REU Site applications among participating Sites for the 2019 cycle. It will enable students to apply to multiple Sites through one application. Students will first complete the REU Registration desorbed above, and then proceed to the common application through which they will submit additional information commonly required by Sites as part of their applications, such as transcripts. Staff at REU Sites will use the system to provide information needed by potential applicants, retrieve applicant information, record application decisions and participation status of admitted applicants.

2. **Obtaining and integrating educational and employment information.** The study will follow the subset of rising seniors who participate in the REU program in 2019 (as seniors are the large majority of participants) to:
   - **Obtain educational outcomes information from the National Student Clearinghouse (NSC).**
   - **Administer a survey to obtain information on employment outcomes (among those not enrolled in graduate school at the time of the survey).**

3. **Conducting site visits to a few REU Sites participating in the pilot to interview principal investigators and program administrators, and to conduct focus groups with REU students.** The site visits will be used to elicit in-depth feedback with the registration and common application systems as well as the tools available for PIs to obtain data and reports through the REU data system.

**Estimate of Burden:** At present, applications to the REU program are submitted yearly directly to each Site. For those participating in the registration pilot, it is estimated that applicants will spend 2 hours submitting basic information through the REU Data System and then complete the rest of their applications through the individual REU sites. For those participating in the common application pilot, it is estimated that each submission will take, on average, 12 hours. Reference writers are expected to take 0.5 hours to draft a letter in support of students’ application to the program.

It is estimated that REU Principal Investigators will spend 8.9 hours using the system to track applications.

**Respondents:** Individuals.

**Estimated Number of Respondents:** 30,455.

**Estimated Total Annual Burden on Respondents:** 96,130 hours.

**Frequency of Responses:** One round of pilot data collection.

**Dated:** February 9, 2018.

**Suzanne H. Plimpton,**

**Reports Clearance Officer, National Science Foundation.**

[FR Doc. 2018–03469 Filed 2–20–18; 8:45 am]

**BILLING CODE 7555–01–P**

**NATIONAL TRANSPORTATION SAFETY BOARD**

Sunshine Act Meeting

**AGENDA**

**TIME AND DATE:** 9:30 a.m., Tuesday, March 13, 2018

**PLACE:** NTSB Conference Center, 429 L’Enfant Plaza SW, Washington, DC 20594.

**STATUS:** The one item is open to the public.

**MATTERS TO BE CONSIDERED:**

56526 Railroad Accident Brief—Collision of Two Southwestern Railroad Freight Trains, Roswell, New Mexico, April 28, 2015.

**NEWS MEDIA CONTACT:** Telephone: (202) 314–6100.

The press and public may enter the NTSB Conference Center one hour prior to the meeting for set up and seating.

Individuals requesting specific accommodations should contact Rochelle McCallister at (202) 314–6305 or by email at Rochelle.McCallister@ntsb.gov by Wednesday, March 7, 2018.

The public may view the meeting via a live or archived webcast by accessing a link under “News & Events” on the NTSB home page at www.ntsb.gov.
NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–390 and 50–391; NRC–2018–0029]

Tennessee Valley Authority; Watts Bar Nuclear Plant, Units 1 and 2

AGENCY: Nuclear Regulatory Commission.

ACTION: License amendment request; opportunity to comment, request a hearing and petition for leave to intervene.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is considering issuance of amendments to Facility Operating License Nos. NPF–90, issued on February 7, 1996, and NPF–96, issued on October 22, 2015, and held by Tennessee Valley Authority (TVN or the licensee) for the operation of Watts Bar Nuclear Plant, Units 1 and 2 (Watts Bar or WBN), located in Rhea County, Tennessee.

The proposed amendments would revise the Technical Specifications (TSs) related to control and shutdown rods, and rod and bank position indication. The proposed amendments adopt the changes contained in Technical Specification Task Force (TSTF) Change Traveler TSTF–547, Revision 1, “Clarification of Rod Position Requirements,” with variations as described in the application.

DATES: Submit comments by March 23, 2018. Request for a hearing or petition for leave to intervene must be filed by April 23, 2018.

ADDRESSES: Please refer to Docket ID NRC–2018–0029 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

• Federal Rulemaking Website: Go to http://www.regulations.gov and search for Docket ID NRC–2018–0029. Address questions about NRC dockets to Jennifer Borges; telephone: 301–415–9127; email: Jennifer.Borges@nrc.gov. For technical questions, contact the individual listed in the FOR FURTHER INFORMATION CONTACT section of this document.

• NRC’s Agencywide Documents Access and Management System (ADAMS): You may obtain publicly-available documents online in the NRC Public Documents collection at http://www.nrc.gov/reading-rm/adams.html. To begin the search, select “ADAMS Public Documents” and then select “Begin Web-based ADAMS Search.” For problems with ADAMS, please contact the NRC’s Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to pdr.resource@nrc.gov. The ADAMS accession number for each document referenced in this notice (if that document is available in ADAMS) is provided the first time that a document is referenced.

• NRC’s PDR: You may examine and purchase copies of public documents at the NRC’s PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT:


SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2018–0029 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

• Federal Rulemaking Website: Go to http://www.regulations.gov and search for Docket ID NRC–2018–0029. Address questions about NRC dockets to Jennifer Borges; telephone: 301–415–9127; email: Jennifer.Borges@nrc.gov. For technical questions, contact the individual listed in the FOR FURTHER INFORMATION CONTACT section of this document.

• NRC’s Agencywide Documents Access and Management System (ADAMS): You may obtain publicly-available documents online in the NRC Public Documents collection at http://www.nrc.gov/reading-rm/adams.html. To begin the search, select “ADAMS Public Documents” and then select “Begin Web-based ADAMS Search.” For problems with ADAMS, please contact the NRC’s Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to pdr.resource@nrc.gov. The ADAMS accession number for each document referenced in this notice (if that document is available in ADAMS) is provided the first time that a document is referenced.

• NRC’s PDR: You may examine and purchase copies of public documents at the NRC’s PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

II. Introduction

The NRC is considering issuance of amendments to Facility Operating License Nos. NPF–90 and NPF–96, issued to TVA for operation of the Watts Bar Nuclear Plant, Units 1 and 2, located in Rhea County, Tennessee.

The proposed amendments would revise the TSs related to control and shutdown rods, and rod and bank position indication. The proposed amendments adopt the changes contained in TSTF–547, Revision 1, with variations as described in the application. The variations include several changes to make the TSs consistent with NUREG–1431, Revision 4, “Standard Technical Specifications—Westinghouse Plants,” that are not identified as changes in TSTF–547, Revision 1. Before issuance of the proposed license amendments, the NRC will make the findings required by the Atomic Energy Act of 1954, as amended (the Act) and the NRC’s regulations.

The NRC has made a proposed determination that the license

B. Submitting Comments

Please include Docket ID NRC–2018–0029 in your comment submission. The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at http://www.regulations.gov as well as enter the comment submissions into ADAMS. The NRC does not edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submissions. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comments into ADAMS.

The NRC has made a proposed determination that the license...
amendment request involves no significant hazards consideration. Under the NRC’s regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendments would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?
   
   Response: No.
   
   Control and shutdown rods are assumed to insert into the core to shut down the reactor in evaluated accidents. Rod insertion limits ensure that adequate negative reactivity is available to provide the assumed shutdown margin (SDM). Rod alignment and overlap limits maintain an appropriate power distribution and reactivity insertion profile.
   
   Control and shutdown rods are initiators to several accidents previously evaluated, such as rod ejection. The proposed change does not change the limiting conditions for operation for the rods and makes technical changes to the Surveillance Requirements (SRs) governing the rods. However, the proposed change has no significant effect on the probability of any accident previously evaluated.
   
   Revising the TS Actions to provide a limited time to repair rod movement control has no effect on the SDM assumed in the accident analysis as the proposed Action[s] require verification that SDM is maintained. The effects on power distribution will not cause a significant increase in the consequences of any accident previously evaluated as all TS requirements on power distribution continue to be applicable.
   
   Revising the TS Actions to provide an alternative to frequent use of the moveable incore detector system to verify the position of rods with inoperable rod position indicator does not change the requirement for the rods to be aligned and within the insertion limits.
   
   Therefore, the assumptions used in any accidents previously evaluated are unchanged and there is no significant increase in the consequences.
   
   The consequences of an accident that might occur during the 1-hour period provided for the analog rod position indication to stabilize after rod movement are no different than the consequences of the accident under the existing actions with the rod declared inoperable.
   
   The proposed change to resolve the conflicts in the TS ensure that the intended Actions are followed when equipment is inoperable. Actions taken with inoperable equipment are not assumptions in the accidents previously evaluated and have no significant effect on the consequences.

2. Does the proposed amendment create the possibility of a new or different kind of accident from any previously evaluated?
   
   Response: No.
   
   The proposed change does not involve a physical alteration of the plant (i.e., no new or different type of equipment will be installed). The change does not alter assumptions made in the safety analyses. The proposed change does alter the limiting conditions for operation for the rods and makes technical changes to the SRs governing the rods. However, the proposed change to actions maintains or improves safety when equipment is inoperable and does not introduce new failure modes.
   
   Therefore, the proposed change does not create the possibility of a new or different kind of accident from any previously evaluated.

3. Does the proposed amendment involve a significant reduction in a margin of safety?
   
   Response: No.
   
   The proposed change to allow time for rod position indication to stabilize after rod movement and to allow an alternative method of verifying rod position has no effect on the safety margin as actual rod position is not affected. The proposed change to provide time to repair rods that are Operable but inmovable does not result in a significant reduction in the margin of safety because all rods must be verified to be Operable, and thus the rod must be within the insertion limits. The remaining proposed changes to make the requirements internally consistent and to eliminate unnecessary actions do not affect the margin of safety as the changes do not affect the ability of the rods to perform their specified safety function.
   
   Therefore, the proposed change does not involve a significant reduction in a margin of safety.
   
   The NRC staff has reviewed the licensee’s analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the license amendment request involves no significant hazards consideration.
   
   The NRC is seeking public comments on this proposed determination that the license amendment request involves no significant hazards consideration. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendments until the expiration of 60 days after the date of publication of this notice. The Commission may issue the license amendments before expiration of the 60-day notice period if the Commission concludes the amendments involve no significant hazards consideration. In addition, the Commission may issue the amendments prior to the expiration of the 30-day comment period if circumstances change during the 30-day comment period such that failure to act in a timely way would result, for example, in prevention of either resumption of operation or of increase in power output up to the plant’s licensed power level. If the Commission takes action prior to the expiration of either the comment period or the notice period, it will publish in the Federal Register a notice of issuance. If the Commission make a final no significant hazards consideration determination, any hearing will take place after issuance. The Commission expects that the need to take this action will occur very infrequently.

III. Opportunity To Request a Hearing and Petition for Leave To Intervene

Within 60 days after the date of publication of this notice, any person (petitioner) whose interest may be affected by this action may file a request for a hearing and petition for leave to intervene (petition) with respect to the action. Petitions shall be filed in accordance with the Commission’s “Agency Rules of Practice and Procedure” in 10 CFR part 2. Interested persons should consult a current copy of 10 CFR 2.309. The NRC’s regulations are accessible electronically from the NRC Library on the NRC’s website at http://www.nrc.gov/reading-rm/doc-collections/cfr/. Alternatively, a copy of the regulations is available at the NRC’s Public Document Room, located at One White Flint North, Room O1–F21, 11555 Rockville Pike (first floor), Rockville, Maryland 20852. If a petition is filed, the Commission or a presiding officer will rule on the petition and, if appropriate, a notice of a hearing will be issued.

As required by 10 CFR 2.309(d) the petition should specifically explain the reasons why intervention should be permitted with particular reference to the following general requirements for standing: (1) The name, address, and number of the petitioner; (2) the nature of the petitioner’s right under the Act to be made a party to the
proceeding; (3) the nature and extent of the petitioner’s property, financial, or other interest in the proceeding; and (4) the possible effect of any decision or order which may be entered in the proceeding on the petitioner’s interest.

In accordance with 10 CFR 2.309(f), the petition must also set forth the specific contentions which the petitioner seeks to have litigated in the proceeding. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner must provide a brief explanation of the bases for the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to the specific sources and documents on which the petitioner intends to rely to support its position on the issue. The petition must include sufficient information to show that a genuine dispute exists with the applicant or licensee on a material issue of law or fact. Contentions must be limited to matters within the scope of the proceeding. The contention must be one which, if proven, would entitle the petitioner to relief. A petitioner who fails to satisfy the requirements at 10 CFR 2.309(f) with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene. Parties have the opportunity to participate fully in the conduct of the hearing with respect to resolution of that party’s admitted contentions, including the opportunity to present evidence, consistent with the NRC’s regulations, policies, and procedures.

Petitions must be filed no later than 60 days from the date of publication of this notice. Petitions and motions for leave to file new or amended contentions that are filed after the deadline will not be entertained absent a determination by the presiding officer that the filing demonstrates good cause by satisfying the three factors in 10 CFR 2.309(c)(1)(i) through (iii). The petition must be filed in accordance with the filing instructions in the “Electronic Submissions (E-Filing)” section of this document.

If a hearing is requested, and the Commission has not made a final determination on the issue of no significant hazards consideration, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to establish when the hearing is held. If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing would take place after issuance of the amendment. If the final determination is that the amendment request involves a significant hazards consideration, then any hearing held would take place before the issuance of the amendment unless the Commission finds an imminent danger to the health or safety of the public, in which case it will issue an appropriate order or rule under 10 CFR part 2.

A State, local governmental body, Federally-recognized Indian Tribe, or agency thereof, may submit a petition to the Commission to participate as a party under 10 CFR 2.309(h)(1). The petition should state the nature and extent of the petitioner’s interest in the proceeding. The petition should be submitted to the Commission by July 31, 2017. The petition must be filed in accordance with the filing instructions in the “Electronic Submissions (E-Filing)” section of this document, and should meet the requirements for petitions set forth in this section, except that under 10 CFR 2.309(h)(2) a State, local governmental body, or federally-recognized Indian Tribe, or agency thereof does not need to address the standing requirements in 10 CFR 2.309(d) if the facility is located within its boundaries. Alternatively, a State, local governmental body, Federally-recognized Indian Tribe, or agency thereof may participate as a non-party under 10 CFR 2.315(c).

If a hearing is granted, any person who is not a party to the proceeding and is not affiliated with or represented by a party may, at the discretion of the presiding officer, be permitted to make a limited appearance pursuant to the provisions of 10 CFR 2.315(a). A person making a limited appearance may make an oral or written statement of his or her position on the matter in question and may not otherwise participate in the proceeding. A limited appearance may be made at any session of the hearing or at any prehearing conference, subject to the limits and conditions as may be imposed by the presiding officer. Details regarding the opportunity to make a limited appearance will be provided by the presiding officer if such sessions are scheduled.

IV. Electronic Submissions (E-Filing)

All documents filed in NRC adjudicatory proceedings, including a request for hearing and petition for leave to intervene (petition), any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities that request to participate under 10 CFR 2.315(c), must be filed in accordance with the NRC’s E-Filing rule (72 FR 49139; August 28, 2007, as amended at 77 FR 46562, August 3, 2012). The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases to mail copies on electronic storage media. Detailed guidance on making electronic submissions may be found in the Guidance for Electronic Submissions to the NRC and on the NRC website at http://www.nrc.gov/Regulatory-Info/RegGuide/eg-49139.html. Participants may not submit paper copies of their filings unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at hearing.docket@nrc.gov, or by telephone at 301–415–1677, to (1) request a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign submissions and access the E-Filing system for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a petition or other adjudicatory document (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the hearing in this proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC’s public website at http://www.nrc.gov/site-help/e-submittals/getting-started.html. Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit adjudicatory documents. Submissions must be in Portable Document Format (PDF). Additional guidance on PDF submissions is available on the NRC’s public website at http://www.nrc.gov/site-help/e-submittals-ref-mat.html. A filing is considered complete at the time the document is submitted through the NRC’s E-Filing system. If the filing is timely, an electronic filing must be submitted to the E-Filing system no later than 11:59
p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email notice confirming receipt of the document. The E-Filing system also distributes an email notice that provides access to the document to the NRC’s Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the document on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before adjudicatory documents are filed so that they can obtain access to the documents via the E-Filing system.

A person filing electronically using the NRC’s adjudicatory E-Filing system may seek assistance by contacting the NRC’s Electronic Filing Help Desk through the “Contact Us” link located on the NRC’s public website at http://www.nrc.gov/site-help/e-submittals.html by email to MSHD.Resource@nrc.gov, or by a toll-free call at 1–866–672–7640. The NRC Electronic Filing Help Desk is available between 9 a.m. and 6 p.m., Eastern Time, Monday through Friday, excluding government holidays.

Participants who believe that they have a good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing stating the good cause for not filing electronically and requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, 11555 Rockville Pike, Rockville, Maryland 20852. Attention: Rulemaking and Adjudications Staff. Participants filing adjudicatory documents in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service. A presiding officer, having granted an exemption request from using E-Filing may require a participant or party to use E-Filing if the presiding officer subsequently determines that the reason for granting the exemption from use of E-Filing no longer exists.

Documents submitted in adjudicatory proceedings will appear in the NRC’s electronic hearing docket which is available to the public at https://adams.nrc.gov/ehd, unless excluded pursuant to an order of the Commission or the presiding officer. If you do not have an NRC-issued digital ID certificate as described above, click cancel when the link requests certificates and you will be automatically directed to the NRC’s electronic hearing dockets where you will be able to access any publicly available documents in a particular hearing docket. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or personal phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. For example, in some instances, individuals provide home addresses in order to demonstrate proximity to a facility or site. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submission.

For further details with respect to this action, see the application for amendment dated November 23, 2016, as supplemented by letters dated September 29, November 16, and December 27, 2017. Attorney for licensee: General Counsel, Tennessee Valley Authority, 400 West Summit Hill Drive, 6A West Tower, Knoxville, TN 37902.

Dated at Rockville, Maryland, this 14th day of February, 2018.

For the Nuclear Regulatory Commission.

Andrew Hon,
Acting Chief, Plant Licensing Branch II–2, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2018–03456 Filed 2–20–18; 8:45 am]
BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards (ACRS); Meeting of the ACRS Subcommittee on Future Plant Designs; Notice of Meeting

The ACRS Subcommittee on Future Plant Designs will hold a meeting on February 22, 2018 at 11:45 Rockville Pike, Room T–2B1, Rockville, Maryland 20852.

The entire meeting will be open to public attendance.

The agenda for the subject meeting shall be as follows:

Thursday, February 22, 2018—8:30 a.m. until 12:00 p.m.

The Subcommittee will review the draft SECY Paper, “Functional Containment Performance Criteria for Non-Light Water Reactor Designs.” The Subcommittee will hear presentations by and hold discussions with NRC staff and other interested persons regarding this matter. The Subcommittee will gather information, analyze relevant issues and facts, and formulate proposed positions and actions, as appropriate, for deliberation by the Full Committee.

Members of the public desiring to provide oral statements and/or written comments should notify the Designated Federal Official (DFO), Derek Widmayer (Telephone 301–221–1448 or Email: Derek.Widmayer@nrc.gov) five days prior to the meeting, if possible, so that appropriate arrangements can be made. Thirty-five hard copies of each presentation or handout should be provided to the DFO thirty minutes before the meeting. In addition, one electronic copy of each presentation should be emailed to the DFO one day before the meeting. If an electronic copy cannot be provided within this timeframe, presenters should provide the DFO with a CD containing each presentation at least thirty minutes before the meeting. Electronic recordings will be permitted only during those portions of the meeting that are open to the public. Detailed procedures for the conduct of and participation in ACRS meetings were published in the Federal Register on October 4, 2017 (82 FR 46312).

Detailed meeting agendas and meeting transcripts are available on the NRC website at http://www.nrc.gov/reading-rm/doc-collections/acrs. Information regarding topics to be discussed, changes to the agenda, whether the meeting has been canceled or rescheduled, and the time allotted to present oral statements can be obtained from the website cited above or by contacting the identified DFO.

Moreover, in view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with these references if such rescheduling would result in a major inconvenience.

If attending this meeting, please enter through the One White Flint North building, 11555 Rockville Pike,

Nuclear Regulatory Commission

Advisory Committee on Reactor Safeguards (ACRS); Meeting of the ACRS Subcommittee on APR1400; Notice of Meeting

The ACRS Subcommittee on APR1400 will hold meetings on February 21, 2018, at 11:545 Rockville Pike, Room T–2B1, Rockville, Maryland 20852. The meeting will be open to public attendance with the exception of portions that may be closed to protect information that is proprietary pursuant to 5 U.S.C. 552b(c)[4]. The agenda for the subject meeting shall be as follows:

Wednesday, February 21, 2018, 8:30 a.m. Until 5:00 p.m.

The Subcommittee will review the APR1400 Design Control Document and Safety Evaluation Report with No Open Items, Chapter 9, “Auxiliary Systems,” and Chapter 19.3–19.5, “Severe Accident Evaluation.” The Subcommittee will hear presentations by and hold discussions with the NRC staff and Korea Hydro & Nuclear Power Company regarding this matter. The Subcommittee will gather information, analyze relevant issues and facts, and formulate proposed positions and actions, as appropriate, for deliberation by the Full Committee.

Members of the public desiring to provide oral statements and/or written comments should notify the Designated Federal Official (DFO), Christopher Brown (Telephone 301–415–7111 or Email: Christopher.Brown@nrc.gov) five days prior to the meeting, if possible, so that appropriate arrangements can be made. Thirty-five hard copies of each presentation or handout should be provided to the DFO thirty minutes before the meeting. In addition, one electronic copy of each presentation should be emailed to the DFO one day before the meeting. If an electronic copy cannot be provided within this timeframe, presenters should provide the DFO with a CD containing each presentation at least thirty minutes before the meeting. Electronic recordings will be permitted only during those portions of the meeting that are open to the public. Detailed procedures for the conduct of and participation in ACRS meetings were published in the Federal Register on October 4, 2017 (82 FR 46312).

Detailed meeting agendas and meeting transcripts are available on the NRC website at http://www.nrc.gov/reading-rm/doc-collections/acrs. Information regarding topics to be discussed, changes to the agenda, whether the meeting has been canceled or rescheduled, and the time allotted to present oral statements can be obtained from the website cited above or by contacting the identified DFO. Moreover, in view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with these references if such rescheduling would result in a major inconvenience.

If attending this meeting, please enter through the One White Flint North building, 11555 Rockville Pike, Rockville, Maryland 20852. After registering with Security, please contact Ms. Kendra Freeland (Telephone 301–415–4207) to be escorted to the meeting room.


OVERSEAS PRIVATE INVESTMENT CORPORATION

Sunshine Act Meeting Notice

TIME AND DATE: Thursday, March 8, 2017, 10 a.m. (OPEN Portion); 10:15 a.m. (CLOSED Portion).

PLACE: Offices of the Corporation, Twelfth Floor Board Room, 1100 New York Avenue NW, Washington, DC.

STATUS: Meeting OPEN to the Public from 10 a.m. to 10:15 a.m. Closed portion will commence at 10:15 a.m. (approx.).

MATTERS TO BE CONSIDERED:
1. President’s Report
2. Tribute—Maxwell Taylor Kennedy
3. Minutes of the Open Session of the December 14, 2017, Board of Directors Meeting

FURTHER MATTERS TO BE CONSIDERED (Closed to the Public 2:15 p.m.):
1. Finance Project—Colombia

For Further Information Contact: A copy of this ICR, with applicable supporting documentation, may be obtained from Catherine F. I. Andrade at (202) 336–8768, or via email at Catherine.Andrade@opic.gov.


Catherine Andrade, Corporate Secretary, Overseas Private Investment Corporation.

FURTHER MATTERS TO BE CONSIDERED

1. Minutes of the Closed Session of the December 14, 2017, Board of Directors Meeting
2. Reports
4. Pending Projects

Submit for Review: Reinstatement of a Previously Approved Information Collection Without Change, Standard Form 2812, 2812–A, and OPM Form 1523

AGENCY: Office of Personnel Management.

ACTION: 60-day notice and request for reinstatement.

SUMMARY: The Office of Personnel Management (OPM) offers the general public and other Federal agencies the opportunity to comment on a revised information collection request (ICR) for Standard Form 2812, 2812–A and OPM Form 1523. Reinstatement will allow continued use of the collection and an additional 180 days to complete the full Paperwork Reduction Act approval process.

DATES: Comments are encouraged and will be accepted until April 23, 2018.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the U.S. Office of Personnel Management, Funds Management, 1900 E Street NW, Washington, DC 20415–3500, Attention: Antoinette Cunningham or sent by email to Antoinette.Cunningham@opm.gov.

For Further Information: A copy of this ICR, with applicable supporting documentation, may be obtained by mail at the U.S. Office of Personnel Management, Chief Financial Office, Financial Services, 1900 E Street NW, Room 5478, Washington, DC 20415, Attention: Antoinette Cunningham, by email at Antoinette.Cunningham@opm.gov, or by phone at (202) 606–7119.

Supplementary Information: As required by the Paperwork Reduction Act...

Federal Register / Vol. 83, No. 35 / Wednesday, February 21, 2018 / Notices
Act of 1995, (Pub. L. 104–13, 44 U.S.C. chapter 35) as amended by the Clinger-Cohen Act (Pub. L. 104–106), OPM is soliciting comments for this collection (OMB No. 3206–0262). The Middle Class Tax Relief and Job Creation Act of 2012 (Pub. L. 112–96, Section 5001), made two significant changes to the Federal Employees’ Retirement System (FERS). First, beginning in 2013, new employees (as designated in the statute) will have to pay significantly higher employee contributions, an increase of 2.3 percent of salary. Second, new Members of Congress and Congressional employees, in addition to paying higher retirement contributions, will accrue retirement benefits at the same rate as regular employees. New employees affected by this law will be classified in a new retirement category; the Federal Employees’ Retirement System—Revised Annuity Employees (FERS-RAE). The current Standard Form 2812, Standard Form 2812–A, and OPM Form 1523, have been changed to reflect this additional category.

Reinstatement will allow continued use of the collection and an additional 180 days to complete the full Paperwork Reduction Act approval process. The Office of Personnel Management is particularly interested in comments that:

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 submissions of responses.

Analysis


Title: (1) Report of Withholdings and Contributions for Health Benefits, Life Insurance and Retirement (Standard Form 2812); (2) Report of Withholdings and Contributions for Health Benefits by Enrollment Code (Standard Form 2812–A); (3) Supplemental Semiannual Headcount Report (OPM Form 1523).

OMB Number: 3206–0262.

Frequency: Semiannually for OPM Form 1523 and once-per-pay-period for Standard Form 2812 and Standard Form 2812–A.

Affected Public: Public Entities with Federal Employees and Retirees.

Number of Respondents: 100.

Estimated Time per Respondent: 30 Minutes.

Total Burden Hours: 2700.

Kathleen M. McGettigan,
Acting Director, U.S. Office of Personnel Management.

[FR Doc. 2018–03439 Filed 2–20–18; 8:45 am]

BILLING CODE 6325–23–P

OFFICE OF PERSONNEL MANAGEMENT

Excepted Service; August 2017

AGENCY: Office of Personnel Management (OPM).

ACTION: Notice.

SUMMARY: This notice identifies Schedule A, B, and C appointing authorities applicable to a single agency that were established or revoked from August 1, 2017 to August 31, 2017.

FOR FURTHER INFORMATION CONTACT: Senior Executive Resources Services, Senior Executive Service and Performance Management, Employee Services, 202–606–2246.

SUPPLEMENTARY INFORMATION: In accordance with 5 CFR 213.103, Schedule A, B, and C appointing authorities available for use by all agencies are codified in the Code of Federal Regulations (CFR). Schedule A, B, and C appointing authorities applicable to a single agency are not codified in the CFR, but the Office of Personnel Management publishes a notice of agency-specific authorities established or revoked each month in the Federal Register at www.gpo.gov/fdsys/. OPM also publishes an annual notice of the consolidated listing of all Schedule A, B, and C appointing authorities, current as of June 30, in the Federal Register.

Schedule A

No schedule A authorities to report during August 2017.

Schedule B

No schedule B authorities to report during August 2017.

The following Schedule C appointing authorities were approved during August 2017.

<table>
<thead>
<tr>
<th>Agency name</th>
<th>Organization name</th>
<th>Position title</th>
<th>Authorization No.</th>
<th>Effective date</th>
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<td>Deputy Director for Intergovernmental Affairs. White House Liaison Speechwriter Press Assistant State Director—Idaho Confidential Assistant.</td>
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Kathleen M. McGettigan, Acting Director.

[FR Doc. 2018–03511 Filed 2–20–18; 8:45 am]  
BILLING CODE 6325–39–P

OFFICE OF PERSONNEL MANAGEMENT

Excepted Service; September 2017

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The following Schedule C appointing authorities were revoked during September 2017.
**RAILROAD RETIREMENT BOARD**

**Proposed Collection; Comment Request**

**Summary:** In accordance with the requirement of Section 3506 (c)(2)(A) of the Paperwork Reduction Act of 1995 which provides opportunity for public comment on new or revised data collections, the Railroad Retirement Board (RRB) will publish periodic summaries of proposed data collections.

**Comments are invited on:** (a) Whether the proposed information collection is necessary for the proper performance of the functions of the agency, including whether the information has practical utility; (b) the accuracy of the RRB’s estimate of the burden of the collection of the information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden related to the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

1. **Title and purpose of information collection:** Appeal Under the Railroad Retirement and Railroad Unemployment Insurance Act; OMB 3220–0007. Under Section 7(b)(3) of the Railroad Retirement Act (RRA), and Section 5(c) of the Railroad Unemployment Insurance Act (RUIA) any person aggrieved by a decision made by an office of the RRB on his or her application for an annuity or benefit under those Acts has the right to appeal to the RRB. This right is prescribed in 20 CFR 260 and 20 CFR 320. The notification letter, which is provided at the time of filing the original application, informs the applicant of such right. When an applicant protests a decision, the concerned RRB office reviews the entire file and any additional evidence submitted and sends the applicant a letter explaining the basis of the determination. The applicant is then notified that to protest further, they can appeal to the RRB’s Bureau of Hearings and Appeals. The appeal process is prescribed in 20 CFR 260.5 and 260.9 and 20 CFR 320.12 and 320.38.

To file a request for an appeal the applicant must complete Form HA–1, *Appeal Under the Railroad Retirement Act or Railroad Unemployment Insurance Act*. The form asks the applicant to explain the basis for their request for an appeal and, if necessary, to describe any additional evidence they wish to submit in support of the appeal. Completion is voluntary, however, if the information is not provided the RRB cannot process the appeal. The RRB proposes no changes to Form HA–1.

**ESTIMATE OF ANNUAL RESPONDENT BURDEN**

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2. **Title and purpose of information collection:** Annual Earnings Questionnaire; OMB 3220–0179. Under section 2(e)(3) of the Railroad Retirement Act (RRA), an annuity is not payable for any month in which a beneficiary works for a railroad. In addition, an annuity is reduced for any month in which the beneficiary works for an employer other than a railroad employer and earns more than a prescribed amount. Under the 1988 amendments to the RRA, the Tier II portion of the regular annuity and any supplemental annuity must be reduced by one dollar for each two dollars of Last Pre-Retirement Non-Railroad Employment (LPE) earnings for each month of such service. However, the reduction cannot exceed 50 percent of the Tier II and supplemental annuity amount for the month to which such deductions apply. The LPE generally refers to an annuitant’s last employment with a non-railroad person, company, or institution prior to retirement, which was performed at the same time as railroad employment or after the annuitant stopped railroad employment. The collection obtains earnings information needed by the RRB to determine if possible reductions in annuities are in order due to LPE.

The RRB utilizes Form G–19L, *Annual Earnings Questionnaire*, to obtain LPE earnings information from annuitants. One response is requested of each respondent. Completion is required to retain a benefit. The RRB proposes no changes to Form G–19L.

**ESTIMATE OF ANNUAL RESPONDENT BURDEN**

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**Additional Information or Comments:** To request more information or to obtain a copy of the information collection justification, forms, and/or supporting material, contact Dana Hickman at (312) 751–4981 or
SECURITIES AND EXCHANGE COMMISSION


Self-Regulatory Organizations; Nasdaq ISE, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Exchange’sINET Port Fees To Indicate Immediate Effectiveness of Proposed ISE, LLC; Notice of Filing and

February 14, 2018.


Pursuant to Section 19(b)(1) of the Act,3 and Rule 19b–4 thereunder,2 notice is hereby given that on February 9, 2018, Nasdaq ISE, LLC (“ISE” or “Exchange”) 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 INET Port Fees at Section V, D, entitled “INET Port Fees” to clarify that the port fees in this section are not subject to proration. Today, the Exchange does not prorate the pricing for these ports.

Background

The Exchange previously filed3 to: (1) Establish ports and gateways that members use to connect to the Exchange with the migration of the Exchange’s trading system to the Nasdaq INET architecture, and (2) amend the Schedule of Fees to adopt fees for those ports and gateways. The Exchange established fees for the following connectivity options that are available in connection with the Exchange’s trading system: Specialized Quote Feed ("SQF")4, SQF Purge,5 Dedicated SQF Host,6 Ouch to Trade Options (“OTTO”),7

1. Purpose

The purpose of the proposed rule change is to include language within the Schedule of Fees at Section V, D, entitled “INET Port Fees” to clarify that the port fees in this section are not subject to proration. Today, the Exchange does not prorate the pricing for these ports.

A. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to include language within the Schedule of Fees at Section V, D, entitled “INET Port Fees” to clarify that the port fees in this section are not subject to proration. Today, the Exchange does not prorate the pricing for these ports.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,13 in general, and furthers the

9. Clearing Trade Interface (“CTI”).8 Financial Information eXchange (“FIX”).9 FIX Drop,10 Disaster Recovery,11 and Market Data Port.12 The Exchange proposes to add a clarifying sentence to make clear that port fees are assessed in full month increments and are not prorated, to avoid any confusion.

1. Purpose

The purpose of the proposed rule change is to include language within the Schedule of Fees at Section V, D, entitled “INET Port Fees” to clarify that the port fees in this section are not subject to proration. Today, the Exchange does not prorate the pricing for these ports.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,13 in general, and furthers the


5. SQF Purge is a specific port for the SQF interface that only receives and notifies of purge requests from the market maker. Dedicated SQF Purge Ports enable market makers to centrally manage their ability to remove their quotes in a swift manner.

6. A Dedicated SQF Host is an optional offering available to Market Makers—i.e., Primary Market Makers (“PMMs”) and Competitive Market Makers (“CMMs”—only for their SQF Port & SQF Purge Port connectivity. A Dedicated SQF Host provides the PMM or CMM with assurance that their SQF data will be delivered orders; (v) liquidity indicators and transaction type for billing purposes; (vi) capacity.

8. FIX is an interface that allows market participants to connect and send orders and auction orders into the Exchange. Data includes the following: (1) Options Symbol Directory Messages; (2) System Event Messages (e.g., start of messages, start of system hours, start of quoting, start of opening); (3) Option Trading Action Messages (e.g., halts, resumes); (4) Execution Messages; (5) Order Messages (order messages, risk protection triggers or purge notifications).

10. FIX Drop is a real-time order and execution update message that is sent to a member after an order has been received/modified or an execution has occurred and contains trade details. The information includes, among other things, the following: (1) Executions; (2) cancellations; (3) modifications to an existing order (4) busts or post-trade corrections.

11. Disaster Recovery ports provide connectivity to the exchange’s disaster recovery data center in Chicago to be utilized in the event the exchange has to fail over during the trading day. DR Ports are available for SQF, SQF Purge, Dedicated SQF, CTI, OTTO, FIX and FIX Drop.

12. Market Data ports provide connectivity to the Exchange’s proprietary market data feeds, including the Nasdaq ISE Real-time Depth of Market Raw Data Feed (“Depth of Market Feed”), the Nasdaq ISE Order Feed (“Order Feed”), the Nasdaq ISE Top Quote Feed (“Top Quote Feed”), the Nasdaq ISE Trades Feed (“Trades Feed”), and the Nasdaq ISE Speed Feed (“Speed Feed”). Each of the feeds described above, with the exception of the Trades Feed, have previously been established as market data offerings of the Exchange, and market participants are charged for subscriptions to these products. The Trades Feed is a free market data product provided to subscribers at least once of the fee liable market data products described above. In connection with the adoption of Market Data ports described above, the Exchange further proposes to establish the Trades Feed. Market Data ports are available via multicast, TCP, or as an intra-day snapshot, except that the intra-day snapshot option is available solely for the Depth of Market Feed, Top Quote Feed, and Spread Feed.


4. 17 CFR 240.3a–1(d)(1).
the date of the filing. However, Rule 19b–4(f)(6)(iii)18 permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the Exchange may clarify that the INET Port Fees in Chapter V, D will not be prorated to avoid any misunderstanding. The Exchange notes that adding language to clarify that the Exchange will not prorate the INET Port Fees in Section V, D does not significantly affect the protection of investors or the public interest because there is no substantive change to the manner in which the Exchange bills these services. The Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the operative delay and designates the proposed rule change as operative upon filing.19

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. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule 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);
• Send an email to rule-comments@sec.gov. Please include File Number SR–ISE–2018–14 on the subject line.

Paper Comments

• Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–ISE–2018–14. 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 website (http://www.sec.gov/rules/sro.shtml). Copies of the submission, all subsequent amendments, 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 website 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. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–ISE–2018–14 and should be submitted on or before March 14, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.20

Eduardo A. Aleman,
Assistant Secretary.

[FR Doc. 2018–03450 Filed 2–20–18; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION


Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Expand the Short Term Option Series Program

February 14, 2018.

16 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.
19 For purposes of waiving the 30-day operative delay, the Commission has also considered the proposed rule’s impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).
Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"), and Rule 19b–4 thereunder, notice is hereby given that on February 8, 2018, The Nasdaq Stock Market LLC ("Nasdaq" or "Exchange") 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 expand the Short Term Option Series Program to allow Monday expirations for options listed pursuant to the Short Term Option Series program ("Program"), including options on the SPDR S&P 500 ETF Trust.

The text of the proposed rule change is available on the Exchange’s website at http://nasdaq.cchwallstreet.com, at the principal office of the Exchange, and at the Commission’s Public Reference Room.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the rules of the Nasdaq Options Market LLC ("NOM") at Chapter I, Section 1 and Chapter IV, Section 6 at Commentary .07 to expand the Short Term Option Series Program ("Program") to permit the listing and trading of options series with Monday expirations that are listed pursuant to the Program, including options on the SPDR S&P 500 ETF Trust ("SPY").

The Exchange notes that having Monday expirations is not a novel proposal. Specifically, Nasdaq PHLX LLC ("Phlx") recently received approval to list Monday expirations for SPY options pursuant to its Short Terms Options Series program. As set forth in Chapter I, Section 1(a)(59), a Short Term Option Series is a series in an option class that is approved for listing and trading on the Exchange in which the series is opened for trading on any Tuesday, Wednesday, Thursday or Friday that is a business day and that expires on the Wednesday or Friday of the next business week. The Exchange is now proposing to amend Chapter I, Section 1(a)(59) to permit the listing of options series that expire on Mondays. Specifically, the Exchange is proposing that it may open for trading series of options on any Monday that is a business day and that expires on the Monday of the next business week. The Exchange is also proposing to list Monday expirations series on Fridays that precede the expiration Monday by one business week plus one business day. Since Chapter I, Section 1(a)(59) already provides for the listing of short term option series on Fridays, the Exchange is not modifying this provision to allow for Friday listing of Monday expiration series. However, the Exchange is amending Chapter I, Section 1(a)(59) to clarify that, in the case of a series that is listed on a Friday and expires on a Monday, that series must be listed one business week and one business day prior to that expiration (i.e., two Fridays prior to expiration).

As part of this proposal, the Exchange is also amending Chapter I, Section 1(a)(59) to address the expiration of Monday option series when the Monday is not a business day. In that case, the rule will provide that the series shall expire on the first business day immediately following that Monday. This procedure differs from the expiration date of Wednesday expiration series that are scheduled to expire on a holiday. In that case, the Wednesday expiration series shall expire on the first business day immediately prior to that Wednesday, e.g., Tuesday of that week. However, the Exchange believes that it is preferable to require Monday expiration series in this scenario to expire on the Tuesday of that week rather than the previous business day, e.g., the previous Friday, since the Tuesday is closer in time to the scheduled expiration date of the series than the previous Friday, and therefore may be more representative of anticipated market conditions. The Exchange notes that this provision is identical to the corresponding provision recently adopted by Phlx in its proposal to list options series with Monday expirations pursuant to its Short Term Option Series program. The Exchange also notes that Cboe Exchange, Inc. ("Cboe") uses the same procedure for options on the S&P 500 index ("SPX") with Monday expirations that listed pursuant to its Nonstandard Expirations Pilot Program and that are scheduled to expire on a holiday.

The Exchange also proposes to make corresponding changes to Commentary .07 to Chapter IV, Section 6, which sets forth the requirements for SPY options that are listed pursuant to the Short Term Options Series Program, to permit Monday SPY expirations ("Monday SPY Expirations"). Accordingly, the Exchange proposes to amend Commentary .07 to state that, with respect to Monday SPY Expirations, the Exchange may open for trading on any Monday or Friday that is a business day day series of options on the SPY to expire on any Monday of the month that is a business day and is not a Monday in which Quarterly Options Series expire, provided that Monday SPY Expirations that are listed on a Friday must be listed at least one business week and one business day prior to the expiration. As with the current rules for Wednesday SPY Expirations, the Exchange will also amend Commentary .07 to state that it may list up to five consecutive Monday SPY Expirations at one time, and may have no more than a total of five Monday SPY Expirations (in addition to a maximum of five Short Term Option Series expirations for SPY expiring on Friday and five Wednesday SPY Expirations). The Exchange will also clarify that, as with Wednesday SPY Expirations, Monday SPY Expirations will be subject to the provisions of this Rule.

The interval between strike prices for the proposed Monday SPY Expirations will be the same as those for the current Short Term Option Series for Wednesday and Friday SPY Expirations. Specifically, the Monday SPY Expirations will have a $0.50 strike interval minimum. As is the case with other options series listed pursuant to

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4 See Chapter I, Section 1(a)(59).
5 See Cboe Rule 24.9(e)(1) ("If the Exchange is not open for business on a respective Monday, the normally Monday expiring Weekly Expirations will expire on the following business day. If the Exchange is not open for business on a respective Wednesday or Friday, the normally Wednesday or Friday expiring Weekly Expirations will expire on the previous business day.")
the Short Term Option Series, the Monday SPY Expiration series will be P.M.-settled.

Currently, for each option class eligible for participation in the Program, the Exchange is limited to opening thirty (30) series for each expiration date for the specific class. The thirty (30) series restriction does not include series that are open by other securities exchanges under their respective short term option rules; the Exchange may list these additional series that are listed by other exchanges. This thirty (30) series restriction shall apply to Monday SPY Expiration series as well. In addition, the Exchange will be able to list series that are listed by other exchanges, assuming they file similar rules with the Commission to list SPY options expiring on Mondays.

Finally, the Exchange is amending Commentary .07(b) to Chapter IV, Section 6, which addresses the listing of Short Term Options Series that expire in the same week as monthly or quarterly option series. Currently, that rule states that no Short Term Option Series may expire in the same week in which monthly option series on the same class expire (with the exception of Wednesday SPY Expirations) or, in the case of Quarterly Options Series, on an expiration that coincides with an expiration of Quarterly Option Series on the same class. The Exchange is proposing to extend this exemption to Monday SPY Expirations. As with Wednesday SPY Expirations, the Exchange believes that it is reasonable to extend the exemption to Monday SPY Expirations because Monday SPY Expirations and standard monthly options will not expire on the same trading day, as standard monthly options expire on Fridays. Additionally, the Exchange believes that listing Monday SPY Expirations for one week every month because there was a monthly SPY expiration on the Friday of that week would create investor confusion. As part of this proposal, the Exchange is amending Commentary .07(b) to Chapter IV, Section 6 to clarify that Monday and Wednesday SPY Expirations may expire in the same week as monthly option series in the same class expire, but that no Short Term Option Series may expire on the same day as an expiration of Quarterly Option Series on the same class.

The Exchange does not believe that any market disruptions will be encountered with the introduction of P.M.-settled Monday expirations. The Exchange has the necessary capacity and surveillance programs in place to support and properly monitor trading in the proposed Monday expiration series, including Monday SPY Expirations. The Exchange currently trades P.M.-settled Short Term Option Series that expire almost every Wednesday and Friday, which provide market participants a tool to hedge special events and to reduce the premium cost of buying protection. The Exchange notes that it has been listing Wednesday expirations pursuant to Chapter I, Section 1 and Chapter IV, Section 6 since 2016. With the exception of Monday expiration series that are scheduled to expire on a holiday, the Exchange does not believe that there are any material differences between Monday expirations and Wednesday or Friday expirations for Short Term Option Series.

The Exchange seeks to introduce Monday expirations to, among other things, expand hedging tools available to market participants and to continue the reduction of the premium cost of buying protection. The Exchange believes that Monday expirations will be of benefit to market participants, particularly to Wednesday and Friday expirations, will allow market participants to purchase an option based on their timing as needed and allow them to tailor their investment and hedging needs more effectively. As noted above, Phlx recently received approval to list Monday expirations for SPY options pursuant to its Nonstandard Expirations Program.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act, in general, and furthers the objectives of Section 6(b)(5) of the Act, in particular, that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest.

In particular, the Exchange believes the Short Term Option Series Program has been successful to date and that Monday expirations, including Monday SPY Expirations, simply expand the ability of investors to hedge risk against market movements stemming from economic releases or market events that occur throughout the month in the same way that the Short Term Option Series Program has expanded the landscape of hedging. Similarly, the Exchange believes Monday expirations, including Monday SPY Expirations, should create greater trading and hedging opportunities and flexibility, and will provide customers with the ability to tailor their investment objectives more effectively. As noted above, Phlx recently received approval to list Monday expirations for SPY options pursuant to its Short Term Options program. In addition, Cboe currently permits Monday expirations for other options with a weekly expiration, such as options on the SPX.

With the exception of Monday expiration series that are scheduled to expire on a holiday, the Exchange does not believe that there are any material differences between Monday expirations, including Monday SPY expirations, and Wednesday or Friday expirations, including Wednesday and Friday SPY Expirations, for Short Term Option Series. The Exchange notes that it has been listing Wednesday expirations pursuant to Chapter I, Section 1 and Chapter IV, Section 6 since 2016. The Exchange believes that it is consistent with the Act to treat Monday expiration series that expire on a holiday differently than Wednesday or Friday expiration series, since the proposed treatment for Monday expiration series will result in an expiration date that is closer in time to the scheduled expiration date of the series, and therefore may be more representative of anticipated market conditions. The Exchange also notes that Cboe uses the same procedure for SPX options with Monday expirations that are listed pursuant to its Nonstandard Expirations Pilot Program and that are scheduled to expire on a holiday.

Given the similarities between Monday SPY Expiration series and Wednesday and Friday SPY Expiration series, the Exchange believes that applying the provisions in Commentary .07 to Chapter IV, Section 6 that currently apply to Wednesday SPY Expirations to Monday SPY Expirations is justified. For example, the Exchange believes that allowing Monday SPY Expirations and monthly SPY expirations in the same week will benefit investors and minimize investor confusion by providing Monday SPY Expirations in a continuous and
uniform manner. The Exchange also believes that is appropriate to amend Comment .07(b) to Chapter IV, Section 6 to clarify that no Short Term Option Series may expire on the same day as an expiration of Quarterly Option Series on the same class. This change will make that provision more consistent with the existing language in Comment .07 that prohibits Wednesday SPY Expirations from expiring on a Wednesday in which Quarterly Options Series expire.

Finally, the Exchange represents that it has an adequate surveillance program in place to detect manipulative trading in Monday expirations, including Monday SPY Expirations, in the same way that it monitors trading in the current Short Term Option Series. The Exchange also represents that it has the necessary systems capacity to support the new options series.

B. Self-Regulatory Organization’s Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The Exchange notes that having Monday expirations is not a novel proposal, as Phlx has received approval to list Monday expirations for SPY options, and Cboe currently lists and trades short-term SPX options with a Monday expiration. The Exchange does not believe the proposal will impose any burden on intra-market competition, as all market participants will be treated in the same manner under this proposal. Additionally, the Exchange does not believe the proposal will impose any burden on inter-market competition, as nothing prevents the other options exchanges from proposing similar rules to list and trade short-term options series with Monday expirations.

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

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative 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)(iii) of the Act and Rule 19b–4(f)(6) thereunder.12

A proposed rule change filed under Rule 19b–4(f)(6) normally does not become operative for 30 days from the date of filing. However, Rule 19b–4(f)(6)(iii)13 permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Commission notes that it recently approved Phlx’s substantially similar proposal to list and trade Monday SPY Expirations.14 The Exchange has stated that waiver of the operative delay will allow the Exchange to list and trade Monday SPY Expirations as soon as possible, and therefore, promote competition among the option exchanges. For these reasons, the Commission believes that the proposed rule change presents no novel issues and that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest, and will allow the Exchange to remain competitive with other exchanges. Therefore, the Commission hereby waives the 30-day operative delay and designates the proposal effective upon filing.15

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 to determine whether the proposed rule 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–NASDAQ–2018–011 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2018–011. 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 website (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 website 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. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2018–011 and should be submitted on or before March 14, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.16

Eduardo A. Aleman, Assistant Secretary.

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BILLING CODE 8011–01–P

14 In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intention to file 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.
15 See supra note 3.
16 For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule’s impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).
SECURITIES AND EXCHANGE COMMISSION


Self-Regulatory Organizations; NYSE Arca, Inc.: Notice of Filing and Immediate Effectiveness of Proposed Rule Change to Temporarily Amend Rule 7.35–E(a)(8) Relating to the Auction Reference Price for the Trading Halt Auction for ProShares Short VIX Short-Term Futures ETF

February 14, 2018.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the “Act”) and Rule 19b–4 thereunder, notice is hereby given that, on February 6, 2018, NYSE Arca, Inc. (the “Exchange”) filed with the Commission (the “Commission”) the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. 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 temporarily amend Rule 7.35–E(a)(8) relating to the Auction Reference Price for the Trading Halt Auction for ProShares Short VIX Short-Term Futures ETF (SVXY), which would be operative for February 6, 2018 only. The proposed rule change is available on the Exchange’s website at www.nyse.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 self-regulatory organization 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 those 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 parts of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to temporarily amend Rule 7.35–E(a)(8) relating to the Auction Reference Price for the Trading Halt Auction for ProShares Short VIX Short-Term Futures ETF (SVXY), which would be operative for February 6, 2018 only.

On February 5, 2018, both the U.S. and global markets experienced increased selling pressure and the Dow Jones Industrial Average (“DJIA”) closed 4.6% down over the prior closing day. In addition, on February 5, 2018, the Cboe Volatility Index (“VIX”), which is a common measure of volatility, more than doubled from its prior close of 17.16 to 37.32. On the morning of February 6, 2018, the level of VIX continued to fluctuate significantly, reaching both a high of 50.30 and a low of 22.42 before noon.

SVXY, which is listed on the Exchange, seeks daily investment results that correspond to the inverse (−1x) of the daily performance of the S&P 500 VIX Short-Term Futures Index. On February 5, 2018, the Official Closing Price for SVXY was $71.82. The price of SVXY declined in after-market trading on February 5, 2018, and the last reported extended-hours trade price on that day was $14.90. Because of the volatility in pricing for SVXY and because the NAV for February 5, 2018 was not yet publicly available, on February 6, 2018, NYSE Arca halted trading in SVXY before the Early Trading Session began at 4:00 a.m. Eastern Time. The NAV was published at $3.96. While the security was halted, an Intraday Indicative Value (“IIV”) was published under the ticker SVXY.IV and as of 11:00 a.m. Eastern Time on February 6, 2018, the IIV was $11.4111.

As set forth in Rule 7.35–E(a)(8)(A), the Auction Reference Price for a Trading Halt Auction is either the last consolidated round-lot price of that trading day and, if none, the prior day’s Official Closing Price. Pursuant to Rule 7.35–E(a)(7), for a Trading Halt Auction, the Price Collar Threshold for Auction Collars is the Auction Reference Price multiplied by 5 percent. Accordingly, consistent with these rules, for the Trading Halt Auction for SVXY, which would also be the first trade on February 6, 2018, the Auction Reference Price would be $71.82 and the Price Collar Thresholds would be $68.23 and $75.41.

However, because of market events unique to the circumstances of February 5, 2018 and February 6, 2018, and the impact on pricing of SVXY, the Exchange does not believe that SVXY’s Official Closing Price would be an appropriate Auction Reference Price for the Trading Halt Auction for that security. The Exchange believes that the significant difference between the Official Closing Price on the one hand, and the last reported extended-hours sale price, NAV, and IIV for that security on the other hand indicates that the Official Closing Price does not reflect the value of the security and would not be an appropriate Auction Reference Price.

The Exchange believes that it would be consistent with fair and orderly markets and the protection of investors and the public to temporarily amend Rule 7.35–E(a)(8) and set a different Auction Reference Price for SVXY. The Exchange believes that given the unique circumstances for SVXY, including the selling pressure on February 5, 2018 and the fluctuating prices relating to SVXY overnight, an IIV identified shortly before the Trading Halt Auction would more closely correlate to the value of SVXY as of the time of the Trading Halt Auction. More specifically, the Exchange believes that using an Auction Reference Price based on an IIV for SVXY that is identified prior to the Trading Halt Auction would reduce the potential for volatility in trading after the security resumes trading.

Accordingly, the Exchange proposes to temporarily amend Rule 7.35–E(a)(8) so that the Auction Reference Price for SVXY would be $11.4111. Because this proposed amendment would be operative for only one trading day and for only one symbol, the Exchange does not believe it is necessary to amend the rule text to effect this change. The Exchange proposes to provide notice of the amended Auction Reference Price and related Auction Collars via a Trader Update, to be published before the Trading Halt Auction in SVXY.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,5 in general, and furthers the objectives of Section 6(b)(5) of the Act,6 in particular, in that it is 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, and 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 Exchange believes that it would promote the protection of investors and the public interest to temporarily amend Rule 7.35–E(a)(8) to set a different Auction Reference Price for SVXY for the Trading Halt Auction that would resume trading in that security on February 6, 2018. In particular, the Exchange believes that the unique circumstances of the market-wide trading volatility on February 5 and 6, 2018, and related impact on the various prices relating to SVXY, using the Official Closing Price as the Auction Reference Price could result in extreme market volatility for that security after the security resumes trading on February 6, 2018. Specifically, the difference between the Official Closing Price on the one hand, and the NAV, last reported extended-hours sale price, and IV on the morning of February 6, 2018 on the other hand, indicate that the Official Closing Price no longer reflects the value of SVXY.

By contrast, the Exchange believes that for this unique circumstance, using an IV identified shortly before the Trading Halt Auction would more closely reflect the value of SVXY and would reduce the potential for volatile trading after the security resumes trading. Accordingly, the Exchange believes that it would remove impediments 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, to temporarily amend Rule 7.35–E(a)(8) to provide that the Auction Reference Price for SVXY on February 6, 2018 only would be based on an IV as of 11:00 a.m. Eastern Time.

B. Self-Regulatory Organization’s Statement on Burden on Competition

The Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is not designed to address any competitive issues but rather is designed to ensure a fair and orderly market by temporarily amending the Auction Reference Price that would be used for the Trading Halt Auction to resume trading in SVXY on February 6, 2018 only.

C. Self-Regulatory Organization’s Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the proposed rule change does not (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative 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 7 and Rule 19b–4(f)(6) thereunder. 8 A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act 9 normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iiii) 10 permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the five-day pre-filing requirement, as well the 30-day operative delay, so that the proposal may become operative on February 6, 2018. According to the Exchange, waiver of the operative delay would allow it to use an Auction Reference Price for the Trading Halt Auction to resume trading on SVXY on February 6, 2018, that more closely correlates to the value of that security, thereby reducing the potential of volatility after the security resumes trading. The Commission waives the pre-filing requirement and finds that the 30-day operative delay is consistent with the protection of investors and the public interest because the proposed rule change is designed to facilitate the orderly reopening of trading in SVXY.

Therefore, the Commission hereby waives the operative delay and designates the proposal operative upon filing.11 At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) 12 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–NYSEARCA–2018–12 on the subject line.

Paper Comments

• Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090. All submissions should refer to File Number SR–NYSEARCA–2018–12. 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 website (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

11 For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule’s impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

8 17 CFR 240.19b–4(f)(6). Rule 19b–4(f)(6)(iiii) requires the Exchange to provide the Commission with written notice of its intent to file the proposed rule change, along with a brief description and the text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has requested that the Commission waive this requirement.
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 website 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. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEARCA–2018–12 and should be submitted on or before March 14, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.13

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–03454 Filed 2–20–18; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION


Self-Regulatory Organizations; Nasdaq GEMX, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Port Fees

February 14, 2018.

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 February 9, 2018, Nasdaq GEMX, LLC ("GEMX" or "Exchange") 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 Port Fees at Section IV, E to indicate those fees are not prorated.

The text of the proposed rule change is available on the Exchange’s website at http://nasdagexm.chicagostreet.com/, at the principal office of the Exchange, and at the Commission’s Public Reference Room.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to include language within the Schedule of Fees at Section IV, E, entitled “Port Fees” to clarify that the port fees in this section are not subject to proration. Today, the Exchange does not prorate the pricing for these ports.

Background

The Exchange previously filed3 to: (1) Establish ports and gateways that members use to connect to the Exchange with the migration of the Exchange’s trading system to the Nasdaq INET architecture, and (2) amend the Schedule of Fees to adopt fees for those ports and gateways. The Exchange established fees for the following connectivity options that are available in connection with the Exchange’s trading system: Specialized Quote Feed ("SQF"),4 SQF Purge,5 Ouch to Trade Options ("OTTO"),6 Clearing Trade Interface ("CTI"),7 Financial Information eXchange ("FIX"),8 FIX Drop,9 Disaster Recovery,10 and Market Data Port.11 The Exchange proposes to


1 SQF is an interface that allows market makers to connect and send quotes, sweeps and auction responses into the Exchange. Data includes the following: (1) Options Auction Notifications (e.g., opening imbalance, Flash, PIM, Solicitation and Facilitation or other information); (2) Options Symbol Directory Messages; (3) System Event Messages (e.g., start of messages, start of system hours, start of quoting, start of opening); (4) Option Trading Action Messages (e.g., halts, resumes); (5) Execution Messages (e.g., quote messages, quote/ sweep messages, risk protection triggers or purge notifications).

2 SQF Purge is a specific port for the SQF interface that only receives and notifies of purge requests from the market maker. Dedicated SQF Purge Ports enable market makers to seamlessly manage their ability to remove their quotes in a swift manner.

3 OTTO is an interface that allows market participants to connect and send orders, auction orders and auction responses into the Exchange. Data includes the following: (1) Options Auction Notifications (e.g., Flash, PIM, Solicitation and Facilitation or other information); (2) Options Symbol Directory Messages; (3) System Event Messages (e.g., start of messages, start of system hours, start of quoting, start of opening); (5) Option Trading Action Messages (e.g., halts, resumes); (6) Execution Messages; (7) Order Messages (e.g., order messages, risk protection triggers or purge notifications).

4 CTI is a real-time clearing trade update message that is sent to a member after an execution has occurred and contains trade details. The message containing the trade details is also simultaneously sent to The Options Clearing Corporation ("OCC."); the information includes, among other things, the following: (i) The Clearing Member Trade Agreement or "CMTA" or "OCC" number; (ii) Exchange badge or house number; (iii) The exchange internal firm identifier; and (iv) an indicator which will distinguish electronic and non-electronically delivered orders; (v) liquidity indicators and transaction type for billing purposes; (vi) capacity.

5 FIX is an interface that allows market participants to connect and send orders and auction orders into the Exchange. Data includes the following: (1) Options Symbol Directory Messages; (2) System Event Messages (e.g., start of messages, start of system hours, start of quoting, start of opening); (2) Option Trading Action Messages (e.g., halts, resumes); (4) Execution Messages; (5) Order Messages (e.g., order messages, risk protection triggers or purge notifications).

6 FIX Drop is a real-time order and execution update message that is sent to a member after an order has been received/modified or an execution has occurred and contains trade details. The message containing the trade details is also simultaneously sent to The Options Clearing Corporation ("OCC."); the information includes, among other things, the following: (1) Executions; (2) cancellations; (3) modifications to an existing order (4) busters or post-trade corrections.

7 Disaster Recovery ports provide connectivity to the Exchange’s disaster recovery data center in Chicago to be utilized in the event the exchange has to fail over during the trading day. DR Ports are available for SQF, SQF Purge, Dedicated SQF, CTI, OTTO, FIX and FIX Drop.

8 Market Data ports provide connectivity to the Exchange’s proprietary market data feeds, including the Nasdaq GEMX Real-time Depth of Market Raw Data Feed (“Depth of Market Feed”), the Nasdaq GEMX Order Feed (“Order Feed”), the Nasdaq GEMX Top Quote Feed (“Top Quote Feed”), the
add a clarifying sentence to make clear that port fees are assessed in full month increments and are not prorated, to avoid any confusion.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act, in general, and furthers the objectives of Section 6(b)(5) of the Act, in particular, that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest, by clearly specifying in Section IV, E that the Exchange’s pricing regarding ports is not prorated. The Exchange believes that its decision to not prorate these ports is consistent with the Act because prorating billing results in complexity and increased costs associated with the billing process. The Exchange notes that this proposal does not amend the Exchange’s current billing practice.

B. Self-Regulatory Organization’s Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The Exchange will uniformly assess the fees in Section IV, E to all GEMX Members in a uniform manner.

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

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative 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)(iii) of the Act and subparagraph (f)(6) of Rule 19b–4 thereunder.

A proposed rule change filed under Rule 19b–4(f)(6) normally does not become operative prior to 30 days after the date of the filing. However, Rule 19b–4(f)(6)(iii) permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the Exchange may clarify that the INET Port Fees in Chapter V, D will not be prorated to avoid any misunderstanding. The Exchange notes that adding language to clarify that the Exchange will not prorate the INET Port Fees in Chapter V, D does not significantly affect the protection of investors or the public interest because there is no substantive change to the manner in which the Exchange bills these services. The Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the operative delay and designates the proposed rule change as operative upon filing.

At any time within 60 days of the filing of the proposed rule change, the Commission 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. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule 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);

• Send an email to rule-comments@sec.gov. Please include File Number SR–GEMX–2018–06 on the subject line.

Paper Comments

• Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–GEMX–2018–06. 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 website (http://www.sec.gov/rules/sro.shtml). Copies of the submission, all subsequent amendments, all written statements in support of 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 website 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. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly.

All submissions should refer to File Number SR–GEMX–2018–06 and should be submitted on or before March 14, 2018.

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15 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.
18 For purposes of waiving the 30-day operative delay, the Commission has also considered the proposed rule’s impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).
For the Commission, by the Division of Trading and Markets, pursuant to delegated authority. 19
Eduardo A. Alemán,
Assistant Secretary.

SECURITIES AND EXCHANGE COMMISSION


Self-Regulatory Organizations; Nasdaq MRX, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend INET Port Fees at Section II, C To Indicate Those Fees Are Not Prorated

February 14, 2018.

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 February 9, 2018, Nasdaq MRX, LLC ("MRX" or "Exchange") 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 INET Port Fees at Section II, C to indicate those fees are not prorated. The text of the proposed rule change is available on the Exchange’s website at http://nasdaqmrx.cchwallstreet.com/, at the principal office of the Exchange, and at the Commission’s Public Reference Room.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to include language within the Schedule of Fees at Section II, C, entitled “INET Port Fees” to clarify that the port fees in this section are not subject to proration. Today, the Exchange does not prorate the pricing for these ports.

Background

The Exchange previously filed 3 to: (1) Establish ports and gateways that members use to connect to the Exchange with the migration of the Exchange’s trading system to the Nasdaq INET architecture, and (2) amend the Schedule of Fees to adopt fees for those ports and gateways. The Exchange established fees for the following connectivity options that are available in connection with the Exchange’s trading system: Specialized Quote Feed ("SQF"), 4 SQF Purge, 5 Ouch to Trade Options ("OTTO"), 6 Clearing Trade Interface ("CTI"), 7 Financial Information eXchange ("FIX"), 8 FIX Drop, 9 and Disaster Recovery. 10 The Exchange proposes to add a clarifying sentence to make clear that port fees are assessed in full month increments and are not prorated, to avoid any confusion.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act, 11 in general, and furtheres the objectives of Section 6(b)(5) of the Act, 12 in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest, by clearly specifying in Section II, C that the Exchange’s pricing regarding ports is not prorated. The Exchange believes that its decision to not prorate these ports is consistent with the Act because preventing billing results in complexity and increased costs associated with the billing process. The Exchange notes that this proposal does not amend the Exchange’s current billing practice.

B. Self-Regulatory Organization’s Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The Exchange will uniformly assess the fees in Section II, C to all MRX Members in a uniform manner.

Agreement or or “CMTA” or “OCC” number; (ii) exchange, broker, or house number; (iii) the Exchange’s internal firm identifier; and (iv) an indicator which will distinguish electronic and non-electronically delivered orders; (v) liquidity indicators and transaction type for billing purposes; (vi) capacity.

8 FIX is an interface that allows market participants to connect and send orders and auction orders into the Exchange. Data includes the following: (1) Options Symbol Directory Messages; (2) System Event Messages (e.g., start of messages, start of system hours, start of quoting, start of opening); (3) Option Trading Action Messages (e.g., halts, resumes); Execution Messages (6) Quote Messages (quote/ sweep messages, risk protection triggers or purge notifications).

9 FIX Purge is a specific port for the SQF interface that only receives and notifies of purge requests from the market maker. Dedicated SQF Purge Ports enable market makers to seamlessly manage their ability to remove their quotes in a swift manner.

10 OTTO is an interface that allows market participants to connect and send orders, auction orders and auction responses into the Exchange. Data includes the following: (1) Options Auction Notifications (e.g., opening imbalance, Flash, PIM, Solicitation and Facilitation or other information); (2) Options Symbol Directory Messages; (3) System Event Messages (e.g., start of messages, start of system hours, start of quoting, start of opening); (4) Option Trading Action Messages (e.g., halts, resumes); Execution Messages (6) Quote Messages (quote/ sweep messages, risk protection triggers or purge notifications).

11 FIX Drop is a real-time order and execution update message that is sent to a member after an order has been received/modified or an execution has occurred and contains trade details. The information includes, among other things, the following: (1) Executions; (2) cancellations; (3) modifications to an existing order (4) huts or post-trade corrections.

12 Disaster Recovery ports provide connectivity to the exchange’s disaster recovery data center in Chicago to be utilized in the event the exchange has to fail over during the trading day. DR Ports are available for SQF, SQF Purge, Dedicated SQF, CTI, OTTO, FIX and FIX Drop.


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

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative 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)(iii) of the Act and subparagraph (f)(6) of Rule 19b–4 thereunder.14

A proposed rule change filed under Rule 19b–4(f)(6)15 normally does not become operative prior to 30 days after the date of the filing. However, Rule 19b–4(f)(6)(iii)16 permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the Exchange may clarify that the INET Port Fees in Chapter V, D will not be prorated to avoid any misunderstanding. The Exchange notes that adding language to clarify that the Exchange will not prorate the INET Port Fees in Section V, D does not significantly affect the protection of investors or the public interest because there is no substantive change to the manner in which the Exchange bills these services. The Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the operative delay and designates the proposed rule change as operative upon filing.17

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. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule 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–MRX–2018–05 on the subject line.

Paper Comments

• Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090. All submissions should refer to File Number SR–MRX–2018–05. 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 website (http://www.sec.gov/rules/sro.shtml). Copies of the submission, all subsequent amendments, 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 website 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. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–MRX–2018–05 and should be submitted on or before March 14, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.18

Eduardo A. Aleman,
Assistant Secretary.

[PR Doc. 2018–03452 Filed 2–20–18; 8:45 am]

SECURITIES AND EXCHANGE COMMISSION


Self-Regulatory Organizations; Nasdaq GEMX, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Exchange’s Schedule of Fees

February 14, 2018.

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 February 1, 2018, Nasdaq GEMX, LLC (“GEMX” or “Exchange”) 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 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 the Exchange’s Schedule of Fees to eliminate obsolete text related to Gateway Fees.

The text of the proposed rule change is available on the Exchange’s website at http://nasdagemx.cchwallstreet.com/, at the principal office of the Exchange, and at the Commission’s Public Reference Room.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for

the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to remove the current pricing related to gateways at IV, D of the Schedule of Fees and reserve “D.” The Exchange’s gateway pricing at IV, D applied to connections to the legacy T7 system and are no longer relevant. In 2017, GEMX migrated its technology to INET. Prior to the technology migration, GEMX assessed a Shared Gateway fee for DTI Ports and a paired Dedicated Gateway offering. The Shared Gateway was assessed at $750 per gateway, per month for DTI ports. The paired Dedicated Gateway fee was assessed at $2,250 per gateway pair, per month. These gateways provided connectivity to both Nasdaq GEMX, LLC and Nasdaq SSE, LLC. The Exchange decommissioned the legacy gateways in July 2017. The gateway pricing is obsolete. As of the decommissioning of the legacy T7 connections, no GEMX Member has been billed for use of a gateway. Today, the Exchange does not assess a shared gateway fee for its order entry ports and does not offer a dedicated option.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act, in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act, in particular, in that it provides for the equitable allocation of reasonable dues, fees, and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that removing the current pricing related to gateways is reasonable because the pricing applied to connections to legacy T7 and the pricing is no longer applicable. As of the decommissioning of the legacy T7 connections, no GEMX Member has been billed for use of a gateway. Today, the Exchange does not assess a shared gateway fee for its order entry ports and does not offer a dedicated option.

The Exchange believes that removing the current pricing related to gateways is equitable and not unfairly discriminatory because, today, the Exchange does not bill any Member for use of a shared gateway and GEMX does not offer a dedicated option to any Member.

B. Self-Regulatory Organization’s Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. In terms of inter-market competition, 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, or rebate opportunities available at other venues to be more favorable. In such an environment, the Exchange 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, the Exchange believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited. In terms of intra-market competition the Exchange does not bill any Member for use of a shared gateway and GEMX does not offer a dedicated option to any Member.

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. 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. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule 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–GEMX–2018–04 on the subject line.

Paper Comments

• Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–GEMX–2018–04. 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 website (http://www.sec.gov/rules/sro.shtml). Copies of the submission, all subsequent amendments, 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 website 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. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–GEMX–2018–04 and
must be submitted on or before March 14, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.2

Eduardo A. Alemán,
Assistant Secretary.

[FR Doc. 2018–03582 Filed 2–16–18; 11:15 am]
BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meetings

TIME AND DATE: 2:00 p.m. on Thursday, February 22, 2018.

PLACE: Closed Commission Hearing Room 10800.

STATUS: This meeting will be closed to the public.

MATTERS TO BE CONSIDERED:
Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the closed meeting. Certain staff members who have an interest in the matters also may be present.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(3), (5), (6), (7), (8), 9(b) and (10) and 17 CFR 200.402(a)(3), (a)(5), (a)(6), (a)(7), (a)(8), (a)(9)(ii) and (a)(10), permit consideration of the scheduled matters at the closed meeting.

Commissioner Piwowar, as duty officer, voted to consider the items listed for the closed meeting in closed session.

The subject matters of the closed meeting will be:

Institution and settlement of injunctive actions;

Institution and settlement of administrative proceedings;

Adjudicatory matters; and

Other matters relating to enforcement proceedings.

At times, changes in Commission priorities require alterations in the scheduling of meeting items.

CONTACT PERSON FOR MORE INFORMATION:
For further information and to ascertain what, if any, matters have been added, deleted or postponed; please contact Brent J. Fields from the Office of the Secretary at (202) 551–5400.


Brent J. Fields,
Secretary.

[FR Doc. 2018–03582 Filed 2–16–18; 11:15 am]
BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION


Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Temporarily Amend Rule 11.23(d)(2)(E) Relating to the Halt Auction Collar for a Halt Auction for REX VolMAXX Short Weekly Futures Strategy ETF

February 14, 2018.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the “Act”),1 and Rule 19b–4 thereunder,2 notice is hereby given that on February 7, 2018, Cboe BZX Exchange, Inc. (the “Exchange” or “BZX”) 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 Exchange has designated this proposal as a “non-controversial” proposed rule change pursuant to Section 19(b)(3)(A) of the Act3 and Rule 19b–4(b)(6)(iii) thereunder,4 which renders it effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

1. Purpose

The Exchange proposes to temporarily amend Rule 11.23(d)(2)(E) relating to the Halt Auction Collar for a Halt Auction for REX VolMAXX Short Weekly Futures Strategy ETF (VMIN), which would be operative for February 6, 2018 only. On February 5, 2018, both the U.S. and global markets experienced increased selling pressure and the Dow Jones Industrial Average (“DJI”) closed 4.6% down over the prior closing day. In addition, on February 5, 2018, volatility was significantly higher across all measures of U.S. markets and continued to fluctuate significantly through the morning of February 6, 2018.

VMIN, which is listed on the Exchange, seeks to provide investors with inverse exposure to the implied volatility of the broad-based, large-cap U.S. equity market by obtaining investment exposure to an actively managed portfolio of exchange-traded Cboe Volatility Index (“VIX”) Futures Contracts with weekly and monthly expirations. On February 5, 2018, the Official Closing Price for VMIN was $16.57. The price of VMIN declined in after-market trading on February 5, 2018, and the last reported extended-hours trade price on that day was $7.50. The reported NAV for February 5, 2018 was $3.37. Because of the volatility in the pricing for VMIN and based on information from the issuer that there was a news event forthcoming, the Exchange halted trading in VMIN during the Pre-Opening Session. While the security was halted, an Intraday Indicative Value (“IVV”) was published under the ticker VMIN.IV, and as of 3:00 p.m. Eastern Time on February 6, 2018, the IVV was $3.19. As such, the Halt Auction Reference Price for a Halt Auction would be the prior day’s Official Closing Price, $16.57, and the Halt Auction Collar would be $14.91 and $18.23.

However, because of market events unique to the circumstances of February 5, 2018 and February 6, 2018, and the impact on pricing of VMIN, the Exchange does not believe that VMIN’s Official Closing Price would be an appropriate Halt Auction Reference Price and the basis for calculating the


Halt Auction Collar for the Halt Auction for that security. The Exchange believes that the significant difference between the Official Closing Price on the one hand, and the last reported extended-hours sale price, the NAV, and the IIV on the other hand indicates that the Official Closing Price does not reflect the value of the security and would not be an appropriate Halt Auction Reference Price.

The Exchange believes that it would be consistent with fair and orderly markets and the protection of investors and the public interest to temporarily amend 11.23(d)(2)(E) and set a different Halt Auction Collar for VMIN based on a different Halt Auction Reference Price. The Exchange believes that the unique circumstances for VMIN, including the selling pressure on February 5, 2018 and the fluctuating prices relating to VMIN overnight, an IIV identified shortly before the Trading Halt Auction would more closely correlate to the value of VMIN as of the time of the Trading Halt Auction. More specifically, the Exchange believes that using a Halt Auction Reference Price based on an IIV for VMIN as the basis for forming the Halt Auction Collars that is identified prior to the Halt Auction would reduce the potential for volatility in trading after the security resumes trading.

Accordingly, the Exchange proposes to temporarily amend Rule 11.23(d)(2)(E) so that the Halt Auction Reference Price for VMIN used to calculate the Halt Auction Collars would be $3.19. Because this proposed amendment would be operative for only one trading day and for only one symbol, the Exchange does not believe it is necessary to amend the rule text to effect this change. The Exchange proposes to provide notice of the amended Halt Auction Reference Price via a Trade Desk Notice, to be published before the Trading Halt Auction in VMIN.

2. Statutory Basis

The Exchange believes that the proposal is consistent with Section 6(b) of the Act in general and Section 6(b)(5) of the Act in particular in that it is 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, and 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 Exchange believes that it would promote the protection of investors and the public interest to temporarily amend Rule 11.23(d)(2)(E) to set a different Halt Auction Reference Price for VMIN for the Halt Auction that would resume trading in that security on February 6, 2018. In particular, the Exchange believes that the unique circumstances of the market-wide trading volatility on February 5 and 6, 2018, and related impact on the various prices relating to VMIN, using the Official Closing Price as the Halt Auction Reference Price could result in extreme market volatility for that security after the security resumes trading on February 6, 2018. Specifically, the difference between the Official Closing Price on the one hand, and the NAV, last reported extended-hours sale price, and IIV on the morning of February 6, 2018 on the other hand, indicate that the Official Closing Price no longer reflects the value of VMIN.

By contrast, the Exchange believes that for this unique circumstance, using an IIV identified shortly before the Halt Auction would more closely reflect the value of VMIN and would reduce the potential for volatile trading after the security resumes trading. Accordingly, the Exchange believes that it would remove impediments 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, to temporarily amend Rule 11.23(d)(2)(E) to provide that the Halt Auction Reference Price that is used for the basis of calculating the Halt Auction Collars on February 6, 2018 only would be based on an IIV as of 3:00 p.m. Eastern Time.

For the above reasons, the Exchange believes that the proposed rule change is consistent with the requirements of Section 6(b)(5) of the Act.

(B) Self-Regulatory Organization’s Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purpose of the Act. The proposed rule change is not designed to address any competitive issues but rather is designed to ensure a fair and orderly market by temporarily amending the Auction Reference Price that would be used for the Trading Halt Auction to resume trading in VMIN on February 6, 2018 only.

(C) Self-Regulatory Organization’s Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the proposed rule change does not (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative 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 Act7 and Rule 19b–4(f)(6) thereunder.8

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii)10 permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the five-day prefile requirement, as well as the 30-day operative delay, so that the proposal may become operative immediately. The Commission waives the prefile requirement and finds that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest because the proposed rule change is designed to facilitate the orderly reopening of trading in VMIN, and raises no new or novel issues. Therefore, the Commission hereby waives the operative delay and designates the proposal operative upon filing.11

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such
action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) \(^{12} \) 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 proposal 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–CboeBZX–2018–011 on the subject line.

Paper Comments
- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

(a) All submissions should refer to File No. SR–CboeBZX–2018–011. 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 website (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 website viewing and printing in the Commission’s Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing will also be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File No. SR–CboeBZX–2018–011 and should be submitted on or before March 14, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.\(^{13} \)

Eduardo A. Aleman, Assistant Secretary.

[FR Doc. 2018–03453 Filed 2–20–18; 8:45 am]

BILLING CODE 8011–01–P

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**SMALL BUSINESS ADMINISTRATION**

**[Disaster Declaration #15442 and #15443; New York Disaster Number NY–00176]**

**Administrative Declaration of a Disaster for the State of New York**

**AGENCY:** U.S. Small Business Administration.

**ACTION:** Notice.

**SUMMARY:** This is a notice of an Administrative declaration of a disaster for the State of New York dated 02/13/2018.

**Incident:** Severe Storms and Flooding.

**Incident Period:** 07/01/2017 through 07/24/2017.

**DATES:** Issued on 02/13/2018.

**Physical Loan Application Deadline Date:** 04/16/2018.

**Economic Injury (EIDL) Loan Application Deadline Date:** 11/13/2018.

**ADDRESSES:** Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

**FOR FURTHER INFORMATION CONTACT:** A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

**SUPPLEMENTARY INFORMATION:** Notice is hereby given that as a result of the Administrator’s disaster declaration, applications for disaster loans may be filed at the address listed above or other locally announced locations. The following areas have been determined to be adversely affected by the disaster:

**Primary Counties:** Cayuga, Oneida, Rensselaer, Wyoming

**Contiguous Counties:** New York: Albany, Allegany, Cattaraugus, Columbia, Cortland, Erie, Genesee, Greene, Herkimer, Lewis, Livingston, Madison, Onondaga, Oswego, Otsego, Saratoga, Seneca, Tompkins,

Washington, Wayne
Massachusetts: Berkshire
Vermont: Bennington

The Interest Rates are:

<table>
<thead>
<tr>
<th>For Physical Damage:</th>
<th>Percent</th>
</tr>
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<tbody>
<tr>
<td>Homeowners With Credit Available Elsewhere</td>
<td>3.875</td>
</tr>
<tr>
<td>Homeowners Without Credit Available Elsewhere</td>
<td>1.938</td>
</tr>
<tr>
<td>Businesses With Credit Available Elsewhere</td>
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<tr>
<td>Businesses Without Credit Available Elsewhere</td>
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<tr>
<td>Non-Profit Organizations With Credit Available Elsewhere</td>
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</tr>
<tr>
<td>Non-Profit Organizations Without Credit Available Elsewhere</td>
<td>2.500</td>
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</tbody>
</table>

The number assigned to this disaster for physical damage is 154426 and for economic injury is 154430.

The States which received an EIDL Declaration # are New York, Massachusetts, Vermont. (Catalog of Federal Domestic Assistance Number 59008)


Linda E. McMahon, Administrator.

[FR Doc. 2018–03489 Filed 2–20–18; 8:45 am]

BILLING CODE 8025–01–P

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**DEPARTMENT OF STATE**

**[Public Notice: 10319]**

**Notice of Determinations; Culturally Significant Objects Imported for Exhibition Determinations: “King Tut: Treasures of the Golden Pharaoh” Exhibition**

**SUMMARY:** Notice is hereby given of the following determinations: I hereby determine that certain objects to be included in the exhibition “King Tut: Treasures of the Golden Pharaoh,” imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to a loan agreement with the foreign owner or custodian. I also determine that the exhibition or display of the exhibit objects at the California Science Center, Los Angeles, California, from on or about March 24, 2018, until on or about January 6, 2019, and at possible additional exhibitions or

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\(^{13} 17\) CFR 200.30–3(a)(12).
DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Agency Information Collection Activities: Notice of Request for Reinstatement of a Previously Approved Information Collection

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of request for extension of currently approved information collection.

SUMMARY: The FHWA invites public comments about our intention to request the Office of Management and Budget’s (OMB) approval for renewal of an existing information collection that is summarized below under SUPPLEMENTARY INFORMATION. We are required to publish this notice in the Federal Register by the Paperwork Reduction Act of 1995.

DATES: Please submit comments by April 23, 2018.

ADDRESSES: You may submit comments identified by DOT Docket ID Number 2018–0012 by any of the following methods:

Website: For access to the docket to read background documents or comments received go to the Federal eRulemaking Portal: Go to http://www.regulations.gov. Follow the online instructions for submitting comments.


Mail: Docket Management Facility, U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Hand Delivery or Courier: U.S. Department of Transportation, 1200 New Jersey Avenue SE, between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Mark Glaze, 202 366–4053, Office of Natural Environment, Federal Highway Administration, Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590, Monday through Friday, except Federal holidays.

DEPARTMENT OF STATE

[Public Notice: 10316]

Determination Under Section 620(q) of the Foreign Assistance Act of 1961, Relating to Assistance to Antigua and Barbuda

Pursuant to the authority vested in me by section 620(q) of the Foreign Assistance Act of 1961 (FAA) and Executive Order 12163, I hereby determine that assistance to Antigua and Barbuda is in the national interest of the United States and waive the application of section 620(q) of the FAA with respect to such assistance.

This Determination shall be published in the Federal Register and, with the accompanying Memorandum of Justification, shall be transmitted to the Congress.

Rex W. Tillerson,
Secretary of State.

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Agency Information Collection Activities: Notice of Request for Extension of Currently Approved Information Collection

AGENCY: Federal Highway Administration (FHWA), DOT.
ACTION: Notice of request for extension of currently approved information collection.

SUMMARY: The FHWA invites public comments about our intention to request the Office of Management and Budget’s (OMB) approval for renewal of an existing information collection that is summarized below under SUPPLEMENTARY INFORMATION. We are required to publish this notice in the Federal Register by the Paperwork Reduction Act of 1995.

DATES: Please submit comments by April 23, 2018.

ADDRESSES: You may submit comments identified by DOT Docket ID Number 2018–0010 by any of the following methods:

   Website: For access to the docket to read background documents or comments received go to the Federal eRulemaking Portal: Go to http://www.regulations.gov. Follow the online instructions for submitting comments.
   Hand Delivery or Courier: U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Michael Howell, 202–366–5707, Office of Information and Management Service, Federal Highway Administration, Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590–0001. Hand Delivery or Courier: U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Title: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.

Background: The information collection activity will garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Administration’s commitment to improving service delivery. By qualitative feedback we mean information that provides useful insights on perceptions and opinions, but are not statistical surveys that yield quantitative results that can be generalized to the population of study. This feedback will provide insights into customer and stakeholder perceptions, experiences and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative and actionable communications between the Agency and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management.

Feedback collected under this generic clearance will provide useful information, but it will not yield data that can be generalized to the overall population. This type of generic clearance for qualitative information will not be used for quantitative information collections that are designed to yield reliably actionable results, such as monitoring trends over time or documenting program performance. Such data uses require more rigorous designs that address: The target population to which generalizations will be made, the sampling frame, the sample design (including stratification and clustering), the precision requirements or power calculations that justify the proposed sample size, the expected response rate, methods for assessing potential non-response bias, the protocols for data collection, and any testing procedures that were or will be undertaken prior to fielding the study. Depending on the degree of influence the results are likely to have, such collections may still be eligible for submission for other more rigorous designs that address: The sampling frame, the sample design (including stratification and clustering), the precision requirements or power calculations that justify the proposed sample size, the expected response rate, methods for assessing potential non-response bias, the protocols for data collection, and any testing procedures that were or will be undergone prior to fielding the study. Depending on the degree of influence the results are likely to have, such collections may still be eligible for submission for other generic mechanisms that are designed to yield quantitative results. Below we provide FHWA’s projected average estimates for the next three years:

   Respondents: State and local governments, highway industry organizations, and the general public.

   Estimated Average Annual Burden:

   The burden hours per response will vary with each survey; however, we estimate an average burden of 15 minutes for each survey.

   Estimated Total Annual Burden Hours: We estimate that FHWA will survey approximately 21,000 respondents annually during the next 3 years. Therefore, the estimated total annual burden is 5,200 hours.


   Issued on: February 13, 2018.

   Michael Howell, Information Collection Officer.

   [FR Doc. 2018–03501 Filed 2–20–18; 8:45 am]
information in this notice, please contact Ms. Frances Bourne, Office of Policy and Planning, Federal Railroad Administration, 1200 New Jersey Avenue SE, Room W38–207, Washington, DC 20590; email: frances.bourne@dot.gov; phone: 202–493–6366. Grant application submission and processing questions should be addressed to Ms. Amy Houser, Office of Program Delivery, Federal Railroad Administration, 1200 New Jersey Avenue SE, Room W36–412, Washington, DC 20590; email: amy.houser@dot.gov; phone: 202–493–0303.

SUPPLEMENTARY INFORMATION:

Notice to applicants: FRA recommends that applicants read this notice in its entirety prior to preparing application materials. A list providing the definitions of key terms used throughout the NOFO is in Section A(2) below. These key terms are capitalized throughout the NOFO. There are several administrative prerequisites and specific eligibility requirements described herein that applicants must comply with to submit an application. Additionally, applicants should note that the required Project Narrative component of the application package may not exceed 25 pages in length.

Table of Contents:

A. Program Description
B. Federal Award Information
C. Eligibility Information
D. Application and Submission Information
E. Application Review Information
F. Federal Award Administration Information
G. Federal Awarding Agency Contacts

A. Program Description

1. Overview

The U.S. rail network is central to the success of the American economy, carrying over 31.3 million passengers on Amtrak services and more than 1.6 billion tons of freight valued at nearly $600 billion. This program provides a comprehensive solution to fund Capital Project development and implementation to support infrastructure safety and improvements for both intercity passenger and freight railroads. Congress authorized this grant program for the Secretary to invest in a wide range of projects to improve railroad safety, efficiency, and reliability; mitigate congestion at both intercity passenger and freight rail chokepoints; enhance multi-modal connections; and lead to new or substantially improved Intercity Passenger Rail corridors. Additionally, the program includes rail safety projects, such as grade crossing enhancements, rail line Relocations and Improvements, and positive train control (PTC) deployment. Funds are also available to support rail regional and corridor Planning and environmental analyses. The purpose of this notice is to solicit applications for competitive CRISI Program funding authorized under Section 11301 of the Fixing America’s Surface Transportation (FAST) Act, Public Law 114–94 (2015); 49 U.S.C. 24407 and funded in the Appropriations Act. The Appropriations Act did not include funding for projects described in 49 U.S.C. 24407 (c)(11) or (12).

2. Definitions of Key Terms

a. “Benefit-Cost Analysis” (or “Cost-Benefit Analysis”) is a systematic, data driven, and transparent analysis comparing monetized project benefits and costs, using a no-build baseline and properly discounted present values, including concise documentation of the assumptions and methodology used to produce the analysis; a description of the baseline, data sources used to project outcomes, and values of key input parameters; basis of modeling including spreadsheets, technical memos, etc.; and presentation of the calculations in sufficient detail and transparency to allow the analysis to be reproduced and sensitivity of results evaluated by FRA. Please refer to the Benefit-Cost Analysis Guidance for TIGER and INFRA Applications to preparing a BCA at https://www.transportation.gov/office-policy/transportation-policy/benefit-cost-analysis-guidance. In addition, please also refer to the BCA FAQs on FRA’s website for some rail specific examples of how to apply the BCA Guidance for TIGER and INFRA Applications to CRISI applications.

b. “Capital Project” means a project for: Acquiring, constructing, improving, or inspecting rail equipment, track and track structures, or a rail facility; expenses incidental to the acquisition or Construction including pre-construction activities (such as designing, engineering, location surveying, mapping, acquiring rights-of-way) and related relocation costs, environmental studies, and all work necessary for FRA to approve the project under the National Environmental Policy Act (NEPA) and related environmental laws and regulations; highway-rail grade crossing improvements; communication and signalization improvements; and rehabilitating, remanufacturing or overhauling rail rolling stock and facilities.

c. “Construction” means the production of fixed works and structures or substantial alterations to such structures or land and associated costs.

d. “Final Design (FD)” means design activities following Preliminary Engineering, and at a minimum, includes the preparation of final Construction plans, detailed specifications, and estimates sufficiently detailed to inform project stakeholders (designers, reviewers, contractors, suppliers, etc.) of the actions required to advance the project from design through completion of Construction.

e. “Improvement” means repair or enhancement to existing Rail Infrastructure, or Construction of new Rail Infrastructure, that results in efficiency of the rail system and the safety of those affected by the system.

f. “Initiation” or “Initiate” means commencing service on a route that did not previously operate Intercity Rail Passenger Transportation.

g. “Intercity Rail Passenger Transportation” means rail passenger transportation, except commuter rail passenger transportation. See 49 U.S.C. 24401(3). In this notice, “Intercity Passenger Rail Service” and “Intercity Passenger Rail Transportation” are equivalent terms to “Intercity Rail Passenger Transportation.”

h. “NEPA” is a Federal law that requires Federal agencies to assess the environmental impacts of a proposed action in consultation with appropriate federal, state, and local authorities, and with the public. The NEPA class of action depends on the nature of the proposed action, its complexity, and the potential impacts. For purposes of this NOFO, NEPA also includes all related Federal laws and regulations including Section 4(f) of the Department of Transportation Act, Section 7 of the Endangered Species Act, and Section 106 of the National Historic Preservation Act. (See FRA’s Environmental Procedures at: https://www.fra.dot.gov/eLib/details/L025601.)

i. “Planning” means activities that support the development of a state or regional rail plan or a corridor service development plan.

j. “Positive Train Control (PTC) system” is defined by 49 CFR 270.5 to mean a system designed to prevent train-to-train collisions, overspeed derailments, incursions into established work zone limits, and the movement of a train through a switch left in the wrong position, as described in 49 CFR part 236, subpart I.

k. “Preliminary Engineering (PE)” means engineering design to: (1) Define a project, including a number of all environmental impacts, design of all critical project elements at a level
sufficient to assure reliable cost estimates and schedules, (2) complete project management and financial plans, and (3) identify procurement requirements and strategies. The PE development process starts with specific project design alternatives that allow for the assessment of a range of rail improvements, specific alignments, and project designs—to be used concurrent with project or service level NEPA and related analyses. PE occurs prior to FD and Construction.

1. “Rail Carrier” means a person providing common carrier railroad transportation for compensation, but does not include street, suburban, or interurban electric railways not operated as part of the general system of rail transportation. See 49 U.S.C. 10102(5).

m. “Railroad Infrastructure” means intermodal or rail facilities, including track, bridges, tunnels, rail yards, buildings, passenger stations, and maintenance and repair shops. In this NOFO, “Railroad Infrastructure” is an equivalent term to “Railroad Infrastructure.”

n. “Relocation” is defined by 49 CFR 262.3 to mean moving a rail line vertically or laterally to a new location. Vertical Relocation refers to raising above the current ground level or sinking below the current ground level of a rail line. Lateral Relocation refers to moving a rail line horizontally to a new location.

o. “Restoration” means reinstating service to a route that formerly operated Intercity Rail Passenger Transportation.

p. “Rural Project” means a project in which all or the majority of the project (determined by the geographic location or locations where the majority of the project funds will be spent) is located in a Rural Area.

q. “Rural Area” is defined in 49 U.S.C. 24407(g)(2) to mean any area not in an urbanized area as defined by the Census Bureau. The Census Bureau defines Urbanized Area (UA) as an area with a population of 50,000 or more people.2 Updated lists of UAs as defined by the Census Bureau are available on the Census Bureau website at http://www2.census.gov/geo/maps/dc10map/UAUC_RefMap/ua/.

r. “Tier 1 NEPA” includes the analysis and evaluation of the potential environmental impacts of an action at a broad level, such as a program concept for an entire corridor, and typically does not lead directly to project construction. It identifies the potential environmental impacts of the alternatives being considered for the program, as well as the mitigations that may be needed to address the impacts. The potential environmental impacts and mitigations must be incorporated into each alternative that is evaluated. These are generally Environmental Impact Statements (EIS) that result in the identification of a preferred alternative.

s. “Tier 2 NEPA” includes the required analysis and evaluation of the potential environmental impacts of an action at a project-specific level of detail. Tier 2 NEPA should be sufficient to support final design and construction activities and may include an EIS, an environmental assessment (EA), or a categorical exclusion (CE).

B. Federal Award Information

1. Available Award Amount

The total funding available for awards under this NOFO is $65,232,400 after $680,000 is set aside for FRA program oversight and $2,087,600 is set aside for Special Transportation Circumstances grants that are announced under a separate NOFO at www.GrantSolutions.gov. Under 49 U.S.C. 24407(g) at least $17 million must be made available for Rural Projects. The Appropriations Act directed FRA to award at least $10 million for projects under 49 U.S.C. 24407(c)(2) that contribute to the Initiation or Restoration of Intercity Passenger Rail Service.

2. Award Size

There are no predetermined minimum or maximum dollar thresholds for awards. FRA anticipates making multiple awards with the available funding. FRA may not be able to award grants to all eligible applicants, nor even to all applications that meet or exceed the stated evaluation criteria (see Section E, Application Review Information). Projects may require more funding than is available. FRA encourages applicants to propose projects or components of projects that have operational independence that can be completed and implemented with the level of CRISI funding available together with other sources.

FRA strongly encourages applicants to identify and include other state, local, public, or private funding or financing to support the proposed project.

3. Award Type

FRA will make awards for projects selected under this notice through grant agreements and/or cooperative agreements. Grant agreements are used when FRA does not expect to have substantial Federal involvement in carrying out the funded activity. Cooperative agreements allow for substantial Federal involvement in carrying out the agreed upon investment, including technical assistance, review of interim work products, and increased program oversight. The funding provided under these cooperative agreements will be made available to grantees on a reimbursable basis. Applicants must certify that their expenditures are allowable, allocable, reasonable, and necessary to the approved project before seeking reimbursement from FRA. Additionally, the grantee is expected to expend matching funds at the required percentage alongside Federal funds throughout the life of the project. See an example of standard terms and conditions for FRA grant awards at: https://www.fra.dot.gov/eLib/Details/L19057.

4. Concurrent Applications

As DOT and FRA are concurrently soliciting applications for transportation infrastructure projects for several financial assistance programs, applicants may submit applications requesting funding for a particular project to one or more of these programs. In the application for CRISI Program funding, applicants must indicate the other programs to which they submitted or plan to submit an application for funding the entire project or certain project components, as well as highlight new or revised information in the CRISI Program application that differs from the application(s) for other federal financial assistance programs.

C. Eligibility Information

This section of the notice explains applicant eligibility, cost sharing and matching requirements, project eligibility, and project component operational independence. Applications that do not meet the requirements in this section will be ineligible for funding. Instructions for submitting eligibility information to FRA are detailed in Section D of this NOFO.

1. Eligible Applicants

The following entities are eligible applicants for all project types permitted under this notice:

a. A State;

b. A group of States;

c. An Interstate Compact;

d. A Metropolitan Planning Organization;

e. A public or private transit agency;

f. A Regional Transit Authority;

g. A Metropolitan or Regional Transit Authority;

h. A Transit Joint Venture;

i. A State-approved planning organization;

j. An intermunicipal transit agency;

k. A governing body or instrumentality of a State or political subdivision of a State;

l. An interstate, intermunicipal, or intergovernmental entity, association, or organization;

m. A group of States, a regional organization, or any combination of public or private transit agencies or their special purpose entities;

n. A Federal or State agency or instrumentality responsible for transportation or planning;

o. An association of governments.

2. Matching and Cost Sharing

Instructions for submitting applications are detailed in Section D of this NOFO.
d. A public agency or publicly chartered authority established by one or more States;  
   e. A political subdivision of a State;  
   f. Amtrak or another Rail Carrier that provides Intercity Rail Passenger Transportation (as defined in 49 U.S.C. 24102);  
   g. A Class II railroad or Class III railroad (as those terms are defined in 49 U.S.C. 20102);  
   h. Any Rail Carrier or rail equipment manufacturer in partnership with at least one of the entities described in paragraph (a) through (e);  
   i. The Transportation Research Board together with any entity with which it contracts in the development of rail-related research, including cooperative research programs;  
   j. A University transportation center engaged in rail-related research; or  
   k. A non-profit labor organization representing a class or craft of employees of Rail Carriers or Rail Carrier contractors.

Joint applications must identify an eligible applicant as the lead applicant. The lead applicant serves as the primary point of contact for the application, and if selected, as the recipient of the CRISI Program grant award. Entities that are not eligible applicants may be included in an application as a project partner with one or more eligible applicants.

2. Cost Sharing or Matching

The Federal share of total costs for projects funded under this notice will not exceed 80 percent, though FRA will provide selection preference to applications where the proposed Federal project costs is 50 percent or less. The estimated total cost of a project must be based on the best available information, including engineering studies, studies of economic feasibility, environmental analyses, and information on the expected use of equipment and/or facilities. Additionally, in preparing estimates of total project costs, applicants should refer to FRA’s cost estimate guidance documentation, “Capital Cost Estimating: Guidance for Project Sponsors,” which is available at: https://www.fra.dot.gov/Page/P0926. The minimum 20 percent non-Federal match may be comprised of public sector (e.g., state or local) and/or private sector funding. FRA will not consider any Federal financial assistance, nor any non-Federal funds already expended (or otherwise encumbered) that do not comply with 2 CFR 200.458 toward the matching requirement. FRA is limiting the first 20 percent of the non-Federal match to cash contributions only. FRA will not accept “in-kind” contributions for the first 20 percent in matching funds. Eligible in-kind contributions may be accepted for any non-Federal matching beyond the first 20 percent. In-kind contributions, including the donation of services, materials, and equipment, may be credited as a project cost, in a uniform manner consistent with 2 CFR 200.306.

If Amtrak or another Rail Carrier is an applicant, whether acting on its own behalf or as part of a joint application, Amtrak or another Rail Carrier may use ticket and other non-Federal revenues generated from its operations and other sources as matching funds. Applicants must identify the source(s) of its matching and other funds, and must clearly and distinctly reflect these funds as part of the total project cost.

Before applying, applicants should carefully review the principles for cost sharing or matching in 2 CFR 200.306. See Section D(2)(a)(iii) for required application information on non-Federal match and Section E for further discussion of FRA’s consideration of matching funds in the review and selection process.

3. Other

a. Project Eligibility

The following rail projects that improve the safety, efficiency, and/or reliability of passenger and/or freight rail transportation systems are eligible for funding under this NOFO:

i. Deployment of railroad safety technology, including PTC and rail integrity inspection systems. Examples include: PTC components; integration of PTC with highway grade crossing systems; broken rail detection and warning systems; track intrusion systems; and electronically controlled pneumatic (ECP) braking systems.4

ii. A capital project as defined in 49 U.S.C. 24401(2) relating to Intercity Passenger Rail Service, except that such projects under this NOFO are not required to be in a State rail plan. Examples include: Acquisition improvement, or rehabilitation of railroad equipment (locomotives and rolling stock); Railroad Infrastructure (grade crossings, catenary, signals, and PTC equipment); and rail facilities (yards, passenger stations, or maintenance and repair shops).

iii. A Capital Project necessary to address congestion challenges affecting rail service. Examples include: Projects addressing congestion that increase rail capacity; add or upgrade the condition, clearances, and capacity of rail mainlines; enhance capacity and service with less conflict between freight and intercity passenger rail; reduce delays and risks associated with highway-rail grade crossings; and provide more effective rail equipment.

iv. A Capital Project necessary to reduce congestion and facilitate ridership growth in Intercity Passenger Rail Transportation along heavily traveled rail corridors. Examples include: Projects addressing congestion that improve stations; increase rail capacity; reduce conflict between freight and intercity passenger rail; reduce delays and risks associated with highway-rail grade crossings; and provide more effective rail equipment.

v. A highway-rail grade crossing improvement project, including installation, repair, or improvement of grade separations, railroad crossing signals, gates, and related technologies; highway traffic synchronization; highway lighting and crossing approach signage; roadway improvements such as medians or other barriers; railroad crossing panels and surfaces; and safety engineering improvements to reduce risk in quiet zones or potential quiet zones.

vi. A rail line Relocation and Improvement project. Examples include projects that: Improve the route or structure of a rail line by replacing degraded track; enhance/relocate railroad switching operations; add or lengthen passing tracks to increase capacity; improve interlockings; and relocate rail lines to alleviate congestion, and eliminate frequent rail service interruptions.

vii. A Capital Project to improve short-line or regional Railroad Infrastructure.

viii. The preparation of regional rail and corridor service development plans and corresponding environmental analyses. (See the examples under Track 1 and 2 below in Subsections C(3)(b)(i)–(ii) as they apply to regional and corridor rail Planning.)

ix. A project necessary to enhance multimodal connections or facilitate service integration between rail service and other modes, including between Intercity Rail Passenger Transportation and intercity bus service or commercial air service. Examples include: Intermodal transportation facilities projects that encourage joint scheduling, ticketing, and/or baggage handling; freight rail intermodal connections; and rail projects improving access to ports.

x. The development or implementation of a safety program or
institute designed to improve rail safety. Examples include: Employee training; and public safety outreach and education.

b. Project Tracks for Eligible Projects

An applicant must submit an eligible project under one of the following four tracks: Track 1—Planning; Track 2—PE/NEPA; Track 3—FD/Construction; or Track 4—Safety Programs and Institutes. Applicants are not limited in the number of projects for which they seek funding. However, under this NOFO, applicants must submit only one application per project, and must designate only one track for that project. For example, an applicant cannot seek funding in the same application or multiple applications for both PE/NEPA and FD/Construction elements of the same project. FRA will only accept one project per application, with one exception: FRA will accept an application that proposes a combination of project elements such as track enhancement and grade crossing improvements if, and only if, (1) those project elements are contiguous or (2) those project elements result in greater improvement to rail safety, efficiency, and/or reliability if jointly implemented.

i. Track 1—Planning

Track 1 consists of eligible rail Planning Projects. Examples include the technical analyses and associated environmental analyses that support the development of state rail plans, regional rail plans, and corridor service development plans, including: Identification of alternatives, rail network Planning, market analysis, travel demand forecasting, revenue forecasting, railroad system design, railroad operations analysis and simulation, equipment fleet Planning, station and access analysis, conceptual engineering and capital programming, operating and maintenance cost forecasting, capital replacement and renewal analysis, railroad industry governance and organization, and economic analysis.

ii. Track 2—PE/NEPA

Track 2 consists of eligible PE/NEPA projects. PE examples include: PE drawings and specifications (scale drawings at the 30% design level, including track geometry as appropriate); design criteria, schematics and/or track charts that support the development of PE; and work that can be funded in conjunction with development of PE, such as operations modeling, surveying, project work/management plans, preliminary cost estimates, and preliminary project schedules. NEPA examples include analysis and documentation related to a Tier 2 NEPA EIS, EA or CE. PE/NEPA projects funded under this track must result in sufficiently developed product(s) to support FD or Construction activities.

iii. Track 3—FD/Construction

Track 3 consists of eligible projects consisting of FD, Construction, and project implementation and deployment activities. Applicants must complete all necessary Planning, PE and NEPA requirements for projects submitted under this track. FD funded under this track must: Resolve remaining uncertainties or risks associated with changes to design scope; address procurement processes; and update and refine plans for financing the project or program to reflect accurately the expected year-of-expenditure costs and cash flow projections. Applicants selected for funding under the FD/Construction track must demonstrate the following to FRA’s satisfaction prior to FRA’s obligation of such funding: (A) PE is completed for the proposed project, resulting in project designs that are reasonably expected to conform to all regulatory, safety, security, and other design requirements, including those under the Americans with Disabilities Act (ADA); (B) NEPA is completed for the proposed project; (C) Signed agreements with key project partners, including infrastructure-owning entities; and (D) A project management plan is in-place for managing the implementation of the proposed project, including the management and mitigation of project risks.

FD examples include: Drawings at the 100% Design Level, interim design drawings that support development (e.g., drawings at the 60% Design Level), project work/project management plan, cost estimates, project schedules, and right-of-way acquisition and relocation plans. Construction examples include: Additions, improvements, replacements, renovations and/or repairs to track, bridge, station, rail yard, signal, and communication system infrastructure, and deployment of PTC or other railroad safety technology.

iv. Track 4—Safety Programs and Institutes (Non-Railroad Infrastructure)

Track 4 consists of projects for the development and implementation of safety programs or institutes designed to improve rail safety that clearly demonstrate the expected positive impact on rail safety. Sufficient detail must be provided on what the program or institute will accomplish, as well as the applicant’s capability to achieve the proposed safety outcomes. Examples include: Initiatives for improving rail safety, such as training, public outreach, and education. Safety projects that involve eligible Planning, PE/NEPA, or FD/Construction should be submitted under Tracks 1–3, as appropriate.

c. Project Component Operational Independence

If an applicant requests funding for a project that is a component or set of components of a larger project, the project component(s) must be attainable with the award amount, together with other funds as necessary, obtain operational independence, and must comply with all eligibility requirements described in Section C.

In addition, the component(s) must be capable of independent analysis and decision making, as determined by FRA, under NEPA (i.e., have independent utility, connect logical termini, if applicable, and not restrict the consideration of alternatives for other reasonably foreseeable rail projects.)

d. Rural Project

FRA will consider a project to be in a Rural Area if all or the majority of the project (determined by geographic location(s) where the majority of the project funds will be spent) is located in a Rural Area. However, in the event FRA elects to fund a component of the project, then FRA will reexamine whether the project is in a Rural Area.

D. Application and Submission Information

Required documents for the application are outlined in the following paragraphs. Applicants must complete and submit all components of the application. See Section D(2) for the application checklist. FRA welcomes the submission of additional relevant supporting documentation, such as planning, engineering and design documentation, and letters of support from partnering organizations that will not count against the Project Narrative 25-page limit.

1. Address To Request Application Package

Applicants must submit all application materials in their entirety through www.Grants.gov no later than 5:00 p.m. EDT, on June 21, 2018. FRA reserves the right to modify this deadline. General information for submitting applications through Grants.gov can be found at: https://www.fra.dot.gov/Page/P0270.
For any supporting application materials that an applicant cannot submit via Grants.gov, such as oversized engineering drawings, an applicant may submit an original and two (2) copies to Ms. Amy Houser, Office of Program Delivery, Federal Railroad Administration, 1200 New Jersey Avenue SE, Room W36–412, Washington, DC 20590. However, due to delays caused by enhanced screening of mail delivered via the U.S. Postal Service, FRA advises applicants to use other means of conveyance (such as courier service) to assure timely receipt of materials before the application deadline. Additionally, if documents can be obtained online, explaining to FRA how to access files on a referenced website may also be sufficient.

2. Content and Form of Application Submission

FRA strongly advises applicants to read this section carefully. Applicants must submit all required information and components of the application package to be considered for funding. Additionally, applicants selected to receive funding must generally satisfy the grant readiness checklist requirements on https://www.fra.dot.gov/Page/P0268 as a precondition to FRA issuing a grant award, as well as the requirements in 49 U.S.C. 24405 explained in part at https://www.fra.dot.gov/page/P0185.

Required documents for an application package are outlined in the checklist below.

i. Project Narrative (see D.2.a)
ii. Statement of Work (see D.2.b.i)
iii. Benefit-Cost Analysis (see D.2.b.ii)
iv. SF 424—Application for Federal Assistance
v. Either: SF 424A—Budget Information for Non-Construction projects (required for Tracks 1, 2 and 4) or SF 424C—Budget Information for Construction (required for Track 3)
vi. Either: SF 424B—Assurances for Non-Construction projects (required for Tracks 1, 2 and 4) or SF 424D—Assurances for Construction (required for Track 3)

vii. FRA’s Additional Assurances and Certifications
viii. SF LLL—Disclosure of Lobbying Activities

a. Project Narrative

This section describes the minimum content required in the Project Narrative of the grant application. The Project Narrative must follow the basic outline below to address the program requirements and assist evaluators in locating relevant information.

I. Cover Page See D.2.a.i.

The above content must be provided in a narrative statement submitted by the applicant. The Project Narrative may not exceed 25 pages in length (excluding cover pages, table of contents, and supporting documentation). FRA will not review or consider for award applications with Project Narratives exceeding the 25-page limitation. If possible, applicants should submit supporting documents via website links rather than hard copies. If supporting documents are submitted, applicants must clearly identify the page number(s) of the relevant portion in the Project Narrative supporting documentation. The Project Narrative must adhere to the following outline.

i. Cover Page: Include a cover page that lists the following elements in a table:

<table>
<thead>
<tr>
<th>Project Title.</th>
<th>Lead applicant and co-applicant(s).</th>
</tr>
</thead>
<tbody>
<tr>
<td>Will this project contribute to the Restoration or Initiation of Intercity Passenger Rail Service?</td>
<td>Was a Federal grant application previously submitted for this project?</td>
</tr>
<tr>
<td>If yes, state the name of the Federal grant program and title of the project in the previous application</td>
<td>If applicable, what stage of NEPA is the project in (e.g., EA, Tier 1 NEPA, Tier 2 NEPA, or CE)?</td>
</tr>
<tr>
<td>Is this a Rural Project? What percentage of the project cost is based in a Rural Area?</td>
<td>City(ies), State(s) where the project is located.</td>
</tr>
<tr>
<td>Urbanized Area where the project is located.</td>
<td>Population of Urbanized Area.</td>
</tr>
<tr>
<td>Is the project currently programmed in the: State rail plan, State Freight Plan, TIP, STIP, MPO Long Range Transportation Plan, State Long Range Transportation Plan?</td>
<td>Yes/no. (If yes, please specify in which plans the project is currently programmed).</td>
</tr>
</tbody>
</table>

ii. Project Summary: Provide a brief 4–6 sentence summary of the proposed project and what the project will entail. Include challenges the proposed project aims to address, and summarize the intended outcomes and anticipated benefits that will result from the proposed project.

iii. Project Funding: Indicate in table format the amount of Federal funding requested, the proposed non-Federal match, identifying contributions from the private sector if applicable, and total project cost. Describe the non-Federal funding arrangement. Include funding commitment letters outlining funding agreements, as attachments or in an appendix. Identify any specific project components that the applicant proposes for partial project funding. If all or a majority of a project is located in a Rural Area, identify the Rural Area(s) and estimated percentage of project costs that will be spent in the Rural Area. Identify any previously incurred costs, as well as other sources of Federal funds committed to the project and any pending Federal requests. Also, note if the requested Federal funding under this NOFO or other programs must be obligated or spent by a certain date due to dependencies or relationships with other Federal or non-Federal funding sources, related projects, law, or other factors. If applicable, provide the type and estimated value of any proposed in-kind contributions, and demonstrate the in-kind contributions meet the requirements in 2 CFR 200.306.

Example Project Funding Table:
iv. ** Applicant Eligibility:** Explain how the applicant meets the applicant eligibility criteria outlined in Section C of this notice, including references to creation or enabling legislation for public agencies and publicly chartered authorities established by one or more States. Joint applications must be signed by an authorized representative of each applicant and must include a description of the roles and responsibilities of each applicant, including budget and sub-recipient information showing how the applicants will share project costs.

v. **Project Eligibility:** Identify which project eligibility category the project is eligible under in Section C(3) of this notice, and explain how the project meets the project eligibility criteria.

vi. **Detailed Project Description:** Include a detailed project description that expands upon the brief project summary. This detailed description should provide, at a minimum, background on the challenges the project aims to address; the expected users and beneficiaries of the project, including all railroad operators; the specific components and elements of the project; and any other information the applicant deems necessary to justify the proposed project. If applicable, explain how the project will benefit communities in Rural Areas.

For all projects, applicants must provide information about proposed performance measures, as discussed in Section F(3)(c) and required in 2 CFR 200.301 and 49 U.S.C. 24407(f).

(A) **Grade crossing information, if applicable:** For any project that includes crossing inventory number, and the primary railroad operator, the DOT crossing inventory number, and the roadway at the crossing. Applicants can search for data to meet this requirement at the following link: http://safetydata.fra.dot.gov/OfficeofSafety/default.aspx.

(B) **Heavily traveled rail corridor information, if applicable:** For any project eligible under the eligibility category in Subsection C(3)(a)(iv), that reduces congestion and facilitates ridership growth in Intercity Passenger Rail Transportation, describe how the project is located on a heavily traveled rail corridor.

(C) **PTC information, if applicable:** For any project that includes deploying PTC, applicants must:

1. Document submission of a revised Positive Train Control Implementation Plan (PTCIP) to FRA as required by 49 U.S.C. 20157(a);
2. Be tenants on one or more host railroads whose host railroad(s) document submission of a revised PTCIP as required by 49 U.S.C. 20157(a); or
3. Document why the applicant is not required to submit a revised PTCIP as required by 49 U.S.C. 20157(a), and how the proposed project will assist in the deployment (i.e., installation and/or full implementation) of a PTC system required under 49 U.S.C. 20157.

vii. **Project Location:** Include geospatial data for the project, as well as a map of the project’s location. On the map, include the Congressional districts and Rural Area boundaries, if applicable, in which the project will take place.

viii. **Evaluation and Selection Criteria:** Include a thorough discussion of how the proposed project meets all the evaluation criteria and selection criteria, as outlined in Section E of this notice. If an application does not sufficiently address the evaluation and selection criteria, it is unlikely to be a competitive application.

ix. **Project Implementation and Management:** Describe proposed project implementation and project management arrangements. Include descriptions of the expected arrangements for project contracting, contract oversight, change-order management, risk management, and conformance to Federal requirements for project progress reporting (see https://www.fra.dot.gov/Page/P0274).

Describe past experience in managing and overseeing similar projects.

x. **Planning Readiness for Tracks 2 and 3 (PE/NEPA and FD/Construction) Projects:** Provide information about the planning process that analyzed the investment needs and service objectives of the project. If applicable, cite sources of this information from a Service Development Plan, State or regional rail plan, or similar planning document where the project has been identified for solving a specific existing transportation problem, and makes the case for investing in the proposed solution.

xi. **Environmental Readiness for Track 3 FD/Construction Projects:** If the NEPA process is complete, an applicant should indicate the date of completion, and provide a website link or other reference to the documents demonstrating compliance with NEPA, which might include a final CE, Finding of No Significant Impact, or Record of Decision. If the NEPA process is not yet underway or is underway, but is not complete, the application should detail the type of NEPA review underway, where the project is in the process, and indicate the anticipated date of completion of all NEPA and related milestones. If the last agency action with respect to NEPA documents occurred more than three years before the application date, the applicant should describe why the project has been delayed and include a proposed approach for verifying, and if necessary, updating this information in accordance with applicable NEPA requirements. Additional information regarding FRA’s environmental processes and requirements are located at https://www.fra.dot.gov/eLib/Details/L05286.

b. Additional Application Elements

Applicants must submit:

i. A Statement of Work (SOW) addressing the scope, schedule, and budget for the proposed project if it were selected for award. The SOW must contain sufficient detail so FRA, and the applicant, can understand the expected outcomes of the proposed work to be performed and monitor progress toward
benefits should be presented in subjective estimates. Estimates of possible, and applicants should provide costs should be quantified whenever

ii. A Benefit-Cost Analysis (BCA), as an appendix to the Project Narrative for each project submitted by an applicant. The BCA must demonstrate in economic terms the merits of investing in the proposed project. The BCA for Track 2—PE/NEPA projects should be for the underlying project, not the PE/NEPA work itself. The project narrative should summarize the project’s benefits. Benefits may be to existing and new rail users, as well as users of other modes of transportation. In some cases, benefits may be applied to populations in the general vicinity of the project area. Improvements to multimodal connections and shared-use rail corridors may benefit all users involved. Benefits may be quantified for savings in safety costs, reduced costs from disruption of service, maintenance costs, reduced travel time, emissions reductions, and increases in capacity or ability to offer new types of freight or passenger services. Applicants may also describe other categories of benefits that are difficult to quantify such as noise reduction, environmental impact mitigation, improved quality of life, or reliability of travel times. All benefits claimed for the project must be clearly tied to the expected outcomes of the project. Please refer to the Benefit-Cost Analysis Guidance for TIGER and INFRA Applications prior to preparing a BCA at https://www.transportation.gov/office-policy/transportation-policy/benefit-cost-analysis-guidance. In addition, please also refer to the BCA FAQs on FRA’s website for some rail specific examples of how to apply the BCA Guidance for TIGER and INFRA Applications to CRISI applications.

For Tracks 1 and 4—Applicants are required to document project benefits. Any subjective estimates of benefits and costs should be quantified whenever possible, and applicants should provide appropriate evidence to support their subjective estimates. Estimates of benefits should be presented in monetary terms whenever possible; if a monetary estimate is not possible, then a quantitative estimate (in physical, non-monetary terms, such as crash or employee casualty rates, ridership estimates, emissions levels, energy efficiency improvements, etc.) should be provided. At a minimum, qualitatively describe the project benefits.

iii. SF 424—Application for Federal Assistance;

iv. SF 424A—Budget Information for Non-Construction or SF 424C—Budget Information for Construction;

v. SF 424B—Assurances for Non-Construction or SF 424D—Assurances for Construction;

vi. FRA’s Additional Assurances and Certifications; and

vii. SF 3L1—Disclosure of Lobbying Activities.

Forms needed for the electronic application process are at www.Grants.gov.

c. Post-Selection Requirements See subsection F(2) of this notice for post-selection requirements.

3. Unique Entity Identifier, System for Award Management (SAM), and Submission Instructions

To apply for funding through Grants.gov, applicants must be properly registered. Complete instructions on how to register and submit an application can be found at www.Grants.gov. Registering with Grants.gov is a one-time process; however, it can take up to several weeks for first-time registrants to receive confirmation and a user password. FRA recommends that applicants start the registration process as early as possible to prevent delays that may preclude submitting an application package by the application deadline. Applications will not be accepted after the due date. Delayed registration is not an acceptable justification for an application extension.

FRA may not make a grant award to an applicant until the applicant has complied with all applicable Data Universal Numbering System (DUNS) and SAM requirements. (Please note that if a Dun & Bradstreet DUNS number must be obtained or renewed, this may take a significant amount of time to complete.) Late applications that are the result of a failure to register or comply with Grants.gov applicant requirements in a timely manner will not be considered. If an applicant has not fully complied with the requirements by the submission deadline, the application will not be considered. To submit an application through Grants.gov, applicants must:

a. Obtain a DUNS Number

A DUNS number is required for Grants.gov registration. The Office of Management and Budget requires that all businesses and nonprofit applicants for Federal funds include a DUNS number in their applications for a new award or renewal of an existing award. A DUNS number is a unique nine-digit sequence recognized as the universal standard for the government in identifying and keeping track of entities receiving Federal funds. The identifier is used for tracking purposes and to validate address and point of contact information for Federal assistance applicants, recipients, and sub-recipients. The DUNS number will be used throughout the grant life cycle. Obtaining a DUNS number is a free, one-time activity. Applicants may obtain a DUNS number by calling 1–866–705–5711 or by applying online at http://www.dnb.com/us.

b. Register With the SAM at www.SAM.gov

All applicants for Federal financial assistance must maintain current registrations in the SAM database. An applicant must be registered in SAM to successfully register in Grants.gov. The SAM database is the repository for standard information about Federal financial assistance applicants, recipients, and sub-recipients. Organizations that have previously submitted applications via Grants.gov are already registered with SAM, as it is a requirement for Grants.gov registration. Please note, however, that applicants must update or renew their SAM registration at least once per year to maintain an active status. Therefore, it is critical to check registration status well in advance of the application deadline. If an applicant is selected for an award, the applicant must maintain an active SAM registration with current information throughout the period of the award. Information about SAM registration procedures is available at www.sam.gov.

c. Create a Grants.gov Username and Password

Applicants must complete an Authorized Organization Representative (AOR) profile on www.Grants.gov and create a username and password. Applicants must use the organization’s DUNS number to complete this step. Additional information about the registration process is available at: http://www.grants.gov/web/grants/applicants/organization-registration.html.
d. Acquire Authorization for Your AOR From the E-Business Point of Contact (E-Biz POC)

The E-Biz POC at the applicant’s organization must respond to the registration email from Grants.gov and login at www.Grants.gov to authorize the applicant as the AOR. Please note there can be more than one AOR for an organization.

e. Submit an Application Addressing All Requirements Outlined in This NOFO

If an applicant experiences difficulties at any time during this process, please call the Grants.gov Customer Center Hotline at 1–800–518–4726, 24 hours a day, 7 days a week (closed on Federal holidays). For information and instructions on each of these processes, please see instructions at: http://www.grants.gov/web/grants/applicants/apply-for-grants.html.

Note: Please use generally accepted formats such as .pdf, .doc, .docx, .xls, .xlsx, and .ppt, when uploading attachments. While applicants may embed picture files, such as .jpg, .gif, and .bmp, in document files, applicants should not submit attachments in these formats. Additionally, the following formats will not be accepted: .com, .bat, .exe, .vsb, .cfg, .dat, .db, .dbf, .dll, .ini, .log, .ora, .sys, and .zip.

4. Submission Dates and Times

Applicants must submit complete applications to www.Grants.gov no later than 5:00 p.m. EDT, June 21, 2018. FRA reviews www.Grants.gov information on dates/times of applications submitted to determine timeliness of submissions. Late applications will be neither reviewed nor considered. Delayed registration is not an acceptable reason for late submission. In order to apply for funding under this announcement, all applicants are expected to be registered as an organization with Grants.gov. Applicants are strongly encouraged to apply early to ensure all materials are received before this deadline.

To ensure a fair competition of limited discretionary funds, the following conditions are not valid reasons to permit late submissions: (1) Failure to complete the Grants.gov registration process before the deadline; (2) failure to follow Grants.gov instructions on how to register and apply as posted on its website; (3) failure to follow all instructions in this NOFO; and (4) technical issues experienced with the applicant’s computer or information technology environment.

5. Intergovernmental Review

Executive Order 12372 requires applicants from State and local units of government or other organizations providing services within a State to submit a copy of the application to the State Single Point of Contact (SPOC), if one exists, and if this program has been selected for review by the State. Applicants must contact their State SPOC to determine if the program has been selected for State review.

6. Funding Restrictions

FRA is prohibited in 49 U.S.C. 24405(f) from providing CRISI grants for commuter rail passenger transportation (as defined in 49 U.S.C. 24102(3)). FRA’s interpretation of this restriction is informed by the language in 49 U.S.C. 24407. FRA’s primary intent in funding passenger rail projects will be to make reasonable investments in intercity passenger rail transportation. Such projects may be located on shared corridors where commuter rail passenger transportation and/or freight rail also benefit from the project.

FRA will only approve pre-award costs consistent with 2 CFR 200.458. Under 2 CFR 200.458, grant recipients must seek written approval from FRA for pre-award activities to be eligible for reimbursement under the cooperative agreement. Activities initiated prior to the execution of a cooperative agreement or without FRA’s written approval may not be eligible for reimbursement or included as a grantee’s matching contribution.

FRA will also consider the applicant’s past performance in developing and delivering similar projects and previous financial contributions, and previous competitive grant technical evaluation ratings that the proposed project received under previous competitive grant programs administered by the DOT if applicable.

b. Evaluation Criteria

FRA subject-matter experts will evaluate all eligible and complete applications by Track using the evaluation criteria outlined in this section to determine project benefits and technical merit.

i. Project Benefits:

FRA will evaluate the Benefit-Cost Analysis of the proposed project for the anticipated private and public benefits relative to the costs of the proposed project and the summary of benefits provided in response to subsection D(2)(a)(iii) including—

(A) Effects on system and service performance;

(B) Effects on safety, competitiveness, reliability, trip or transit time, and resilience;

(C) Efficiencies from improved integration with other modes; and

(D) Ability to meet existing or anticipated demand.

ii. Technical Merit:

FRA will evaluate application information for the degree to which—

(A) The tasks and subtasks outlined in the SOW are appropriate to achieve the expected outcomes of the proposed project.

(B) Applications indicate strong project readiness and meet requirements under the project track designated by the applicant.

(C) The technical qualifications and experience of key personnel proposed to lead and perform the technical efforts, and the qualifications of the primary and supporting organizations to fully and successfully execute the proposed project within the proposed timeframe and budget are demonstrated.

(D) The proposed project’s business plan considers potential private sector participation in the financing, construction, or operation of the proposed project.

(E) The applicant has, or will have the legal, financial, and technical capacity to carry out the proposed project; satisfactory continuing control over the use of the equipment or facilities; and the capability and willingness to maintain the equipment or facilities.

(F) The proposed project is consistent with planning guidance and documents set forth by DOT, including those required by law or State rail plans developed under Title 49, United States Code, Chapter 227.

c. Selection Criteria

In addition to the eligibility and completeness review and the evaluation criteria outlined in this subsection, the FRA Administrator will select projects applying the following selection criteria:
1. FRA will give preference to projects for which the:
   (A) Proposed Federal share of total project costs is 50 percent or less; and
   (B) Net benefits of the grant funds will be maximized considering the Benefit-Cost Analysis, including anticipated private and public benefits relative to the costs of the proposed project, and factoring in the other considerations in 49 U.S.C. 24407(e).

   ii. After applying the above preferences, the FRA Administrator will take into account the following key Departmental objectives:
   (A) Supporting economic vitality at the national and regional level;
   (B) Leveraging Federal funding to attract other, non-Federal sources of infrastructure investment, as well as accounting for the life-cycle costs of the project;
   (C) Using innovative approaches to improve safety and expedite project delivery; and,
   (D) Holding grant recipients accountable for their performance and achieving specific, measurable outcomes identified by grant applicants.

2. Review and Selection Process
   FRA will conduct a three-part application review process, as follows:
   a. Screen applications for completeness and eligibility;
   b. Evaluate eligible applications (completed by technical panels applying the evaluation criteria); and
   c. Select projects for funding (completed by the FRA Administrator applying the selection criteria).

F. Federal Award Administration Information

1. Federal Award Notice
   FRA will announce applications selected for funding in a press release and on the FRA website after the application review period. FRA will contact applicants with successful applications after announcement with information and instructions about the award process. This notification is not an authorization to begin proposed project activities. A formal cooperative agreement or grant agreement signed by both the grantee and the FRA, including an approved scope, schedule, and budget, is required before the award is considered complete.

   For all projects, obligation occurs when a selected applicant and FRA enter a written project specific cooperative agreement or grant agreement and is after the applicant has satisfied applicable requirements. For Track 2 PE/NEPA projects, these requirements may include transportation planning. For Track 3 FD/Construction projects, these requirements may include transportation planning, PE and environmental reviews.

2. Administrative and National Policy Requirements
   Due to funding limitations, projects that are selected for funding may receive less than the amount originally requested. In those cases, applicants must be able to demonstrate the proposed projects are still viable and can be completed with the amount awarded.

   Grantees and entities receiving funding from the grantee, must comply with all applicable laws and regulations. Examples of administrative and national policy requirements that grantees must follow include: 2 CFR part 200; procurement standards; compliance with Federal civil rights laws and regulations; requirements for disadvantaged business enterprises, debarment and suspension requirements; FRA’s and OMB’s Assurances and Certifications; Americans with Disabilities Act; safety requirements including those applicable to PTC projects; NEPA, environmental justice requirements, performance measures under 49 U.S.C. 24407(f), and the requirements in 49 U.S.C. 24405 including the Buy America requirements.

   See an example of standard terms and conditions for FRA grant awards at https://www.fra.dot.gov/Elib/Document/14426.

3. Reporting
   a. Reporting Matters Related to Integrity and Performance
      Before making a Federal award with a total amount of Federal share greater than the simplified acquisition threshold of $150,000 (see 2 CFR 200.88 Simplified Acquisition Threshold), FRA will review and consider any information about the applicant that is in the designated integrity and performance system accessible through SAM (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). See 41 U.S.C. 2313.

      An applicant, at its option, may review information in the designated integrity and performance systems accessible through SAM and comment on any information about itself that a Federal awarding agency previously entered and is currently in the designated integrity and performance system accessible through SAM.

      FRA will consider any comments by the applicant, in addition to the other information in the designated integrity and performance system, in making a judgment about the applicant’s integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants as described in 2 CFR 200.205.

b. Progress Reporting on Grant Activity
   Each applicant selected for a grant will be required to comply with all standard FRA reporting requirements, including quarterly progress reports, quarterly Federal financial reports, and interim and final performance reports, as well as all applicable auditing, monitoring and close out requirements. Reports may be submitted electronically.

c. Performance Reporting
   Each applicant selected for funding must collect information and report on the project’s performance using measures mutually agreed upon by FRA and the grantee to assess progress in achieving strategic goals and objectives. Examples of some rail performance measures are listed in the table below. The applicable measure(s) will depend upon the type of project. Applicants requesting funding for the acquisition of rolling stock must integrate at least one equipment/rolling stock performance measure, consistent with the grantee’s application materials and program goals.
<table>
<thead>
<tr>
<th>Rail measures</th>
<th>Unit measured</th>
<th>Temporal</th>
<th>Primary strategic goal</th>
<th>Secondary strategic goal</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Slow Order Miles</td>
<td>Miles</td>
<td>Annual</td>
<td>State of Good Repair</td>
<td>Safety</td>
<td>The number of miles per year within the project area that have temporary speed restrictions (“slow orders”) imposed due to track condition. This is an indicator of the overall condition of track. This measure can be used for projects to rehabilitate sections of a rail line since the rehabilitation should eliminate, or at least reduce the slow orders upon project completion. The annual gross tonnage of freight shipped in the project area. Gross tons include freight cargo minus tare weight of the rail cars. This measure the volume of freight a railroad ships in a year. This measure can be useful for projects that are anticipated to increase freight shipments. The number of annual automobile crossings that are eliminated at an at-grade crossing as a result of a new grade separation.</td>
</tr>
<tr>
<td>Gross Ton</td>
<td>Gross Tons</td>
<td>Annual</td>
<td>Economic Competitiveness</td>
<td>State of Good Repair</td>
<td>Count of the annual passenger boardings and alignments at stations within the project area. Point-to-point travel times between pre-determined station stops within the project area. This measure demonstrates how track improvements and other upgrades improve operations on a rail line. It also helps make sure the railroad is maintaining the line after project completion. If a project is upgrading a line to accommodate heavier rail cars (typically an increase from 263,000 lb. rail cars to 286,000 lb. rail cars.) The number of track miles that exist within the project area. This measure can be beneficial for projects building sidings or sections of additional main line track on a railroad.</td>
</tr>
<tr>
<td>Rail Track Grade</td>
<td>Count</td>
<td>Annual</td>
<td>Economic Competitiveness</td>
<td>Safety</td>
<td>passenger</td>
</tr>
<tr>
<td>Separation.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Safety</td>
</tr>
<tr>
<td>Passenger Counts.</td>
<td>Count</td>
<td>Annual</td>
<td>Economic Competitiveness</td>
<td>State of Good Repair</td>
<td>Count of the annual passenger boardings and alignments at stations within the project area.</td>
</tr>
<tr>
<td>Travel Time</td>
<td>Time/Trip</td>
<td>Annual</td>
<td>Economic Competitiveness</td>
<td>Economic Competitiveness</td>
<td>Quality of Life ...</td>
</tr>
<tr>
<td>Track Weight Capacity.</td>
<td>Yes/No</td>
<td>One Time</td>
<td>State of Good Repair</td>
<td>Economic Competitiveness</td>
<td>Economic Competitiveness.</td>
</tr>
<tr>
<td>Track Miles</td>
<td>Miles</td>
<td>One Time</td>
<td>State of Good Repair</td>
<td>Economic Competitiveness</td>
<td>Economic Competitiveness.</td>
</tr>
</tbody>
</table>

G. Federal Awarding Agency Contacts

For further information regarding this notice and the grants program, please contact Ms. Amy Houser, Office of Program Delivery, Federal Railroad Administration, 1200 New Jersey Avenue SE, Room W36–412, Washington, DC 20590; email: amy.houser@dot.gov; phone: 202–493–0303, or Ms. Frances Bourne, Office of Policy and Planning, Federal Railroad Administration, 1200 New Jersey Avenue SE, Room W38–207, Washington, DC 20590; email: frances.bourne@dot.gov; phone: 202–493–6366.

DEPARTMENT OF TRANSPORTATION
Federal Railroad Administration
Notice of Funding Opportunity for the Restoration and Enhancement Grants Program

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Notice of Funding Opportunity (NOFO or notice).

SUMMARY: This notice details the application requirements and procedures to obtain grant funding for eligible projects under the Restoration and Enhancement (R&E) Grants Program. This notice makes available R&E Grants Program funding provided by the Consolidated Appropriations Act, 2017, Div. K, Tit. I, Public Law 115–31 (Appropriations Act). The opportunities described in this notice are available under Catalog of Federal Domestic Assistance (CFDA) number 20.324, “Restoration and Enhancement.”

DATES: Applications for funding under this solicitation are due no later than 5:00 p.m. EDT May 22, 2018.

APPLICATIONS: Only applicants who comply with all submission requirements described in this notice and submit applications through www.Grants.gov will be eligible for award. For any supporting application materials that an applicant is unable to submit via www.Grants.gov, an applicant may submit an original and two (2) copies to Amy Houser, Office of Program Delivery, Federal Railroad Administration, 1200 New Jersey Avenue SE, Room W36–412, Washington, DC 20590. However, due to delays caused by enhanced screening of mail delivered via the U.S. Postal Service, applicants are advised to use other means of conveyance (such as
courier service) to assure timely receipt of materials before the application deadline.

FOR FURTHER INFORMATION CONTACT: For further information regarding this notice, please contact Ruthie Americus, Office of Policy and Planning, Federal Railroad Administration, 1200 New Jersey Avenue SE, Room W36–403, Washington, DC 20590; email: ruthie.americus@dot.gov; phone: 202–493–0431. Grant application submission and processing questions should be addressed to Amy Houser, Office of Program Delivery, Federal Railroad Administration, 1200 New Jersey Avenue SE, Room W36–412, Washington, DC 20590; email: amy.houser@dot.gov; phone: 202–493–0303.

SUPPLEMENTARY INFORMATION:

Notice to applicants: FRA recommends that applicants read this notice in its entirety prior to preparing application materials. A list providing the definitions of key terms used throughout the NOFO is in Section A(2) below. These key terms are capitalized throughout the NOFO. There are several administrative prerequisites and eligibility requirements described herein that applicants must comply with to submit an application. Additionally, applicants should note that the required Project Narrative component of the application package may not exceed 25 pages in length.

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A. Program Description
B. Federal Award Information
C. Eligibility Information
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A. Program Description

1. Overview

The purpose of this notice is to solicit applications for Operating Assistance grants for Initiating, Restoring, or Enhancing Intercity Rail Passenger Transportation authorized in Section 1303 of the Fixing America’s Surface Transportation (FAST) Act, Public Law 114–94 (2015); 49 U.S.C. 24408 and funded in the Appropriations Act. FRA will consider applications consistent with the priorities in 49 U.S.C. § 24408(d).

2. Definitions of Key Terms

a. “Enhancing” or “Enhance” means upgrading or modifying the service currently offered on a route or train. Examples may include operating costs associated with, but are not limited to, adding a station stop, increasing frequency of a train (e.g., bi-weekly to daily train service or increasing daily train service frequencies), or modifying on-board services offered on the train (e.g., food or sleeping accommodations).

b. “Initiating” or “Initiate” means commencing service on a route that did not previously operate Intercity Rail Passenger Transportation.

c. “Intercity Rail Passenger Transportation” is defined by 49 U.S.C. 24102(4) to mean rail passenger transportation, except commuter rail passenger transportation. “Intercity Rail Passenger Service” is used interchangeably with “Intercity Rail Passenger Transportation” in this NOFO and is intended to have the same meaning.

d. “Net Operating Costs” are defined as operating expenses incurred minus operating revenue. Operating costs are described below in the definition for Operating Assistance.

e. “Operating Assistance” refers to financial assistance covering expenses associated with the operation of Intercity Rail Passenger Transportation. Examples of such expenses may include: Staffing costs for train engineers, conductors, and on-board service crew; diesel fuel or electricity costs associated with train propulsion power; station costs such as ticket sales, customer information, and train dispatching services; station building utility and maintenance costs; lease payments on rolling stock; routine planned maintenance costs of equipment and train cleaning; host railroad costs; train yard operation costs; general and administrative costs; and management, marketing, sales and reservations costs.

f. “Rail Carrier” or “Railroad Carrier” is defined by 49 U.S.C. 10102(5) to mean a person providing common carrier railroad transportation for compensation, but does not include street, suburban, or interurban electric railways not operated as part of the general system of rail transportation.

g. “Restoring” or “Restore” means reinitiating service to a route that formerly operated Intercity Rail Passenger Transportation.

B. Federal Award Information

1. Available Award Amount

The total funding available for awards under this NOFO is $4,796,500 after $50,000 is set aside for R&E project management oversight as provided in the Appropriations Act and $153,500 is set aside for Special Transportation Circumstances grants that will be announced under a separate NOFO.

2. Award Limits

The R&E grants may not provide funding for more than three years for any individual Intercity Rail Passenger Transportation route and may not be renewed. Applicants may apply for R&E funding for: (a) Multiple (up to the first three) years of service or (b) only the first year of service. Grantees receiving funding for only the first year of service may apply for R&E Operating Assistance for the second and third year of service in response to future NOFOs, if funds are available. In addition, no more than six R&E grants may be active simultaneously, but an applicant may be awarded more than one grant.

3. Award Size

While there are no predetermined minimum or maximum dollar thresholds for awards, FRA will only make a maximum of six simultaneous awards with the available funding. Projects may require more funding than is available. Given the limited amount of funding currently available, applicants are also encouraged to identify scalable elements, because FRA may select a project for funding that is less than the total amount requested in the application.

FRA may not be able to award grants to all eligible applications, or even those applications that meet or exceed the stated evaluation criteria (see Section E, Application Review Information). A recipient of an R&E grant may use the grant funding in combination with other Federal grants that would benefit the applicable rail service.

4. Award Type

FRA will make awards for projects selected under this notice through cooperative agreements. Cooperative agreements allow for substantial Federal involvement in carrying out the agreed upon investment, including technical assistance, and increased program oversight under 2 CFR 200.24. The funding provided under these cooperative agreements will be made available to grantees on a reimbursable basis. Applicants must certify that their expenditures are allowable, allocable, reasonable, and necessary to the approved project before seeking reimbursement from FRA. Additionally, the grantee must expend matching funds at the required percentage alongside Federal funds throughout the life of the project. FRA may award grants in installments, and may terminate any cooperative agreement upon the cessation of service or the violation of any other term of the cooperative agreement.
C. Eligibility Information

This section of the notice explains applicant eligibility, cost sharing and matching requirements, and project eligibility. Applications that do not meet the requirements in this section will be ineligible for funding.

Instructions for submitting eligibility information to FRA are detailed in Section D of this NOFO.

1. Eligible Applicants

The following entities are eligible applicants for all project types permitted under this notice:

(1) A State (including the District of Columbia);
(2) A group of States;
(3) An Interstate Compact;
(4) A public agency or publicly chartered authority established by one or more States; 
(5) A political subdivision of a State;
(6) Amtrak or another Rail Carrier that provides Intercity Rail Passenger Transportation;
(7) Any Rail Carrier in partnership with at least one of the entities described in paragraphs (1) through (5); and
(8) Any combination of the entities described in paragraph (1) through (7).

Joint applicants must identify an eligible applicant as the lead applicant. The lead applicant serves as the primary point of contact for the application, and if selected, as the recipient of the R&E Program grant award. Joint applicants must include a description of the roles and responsibilities of each applicant, including budget and sub-recipient information showing how the applicants will share project costs, and must be signed by an authorized representative of each entity. Entities that are not eligible applicants may be included in an application with one or more eligible applicants.

2. Cost Sharing or Matching

Grants for a project funded under the R&E program shall not exceed 80 percent of the projected Net Operating Costs for the first year of service; 60 percent of the Net Operating Costs for the second year of service; and 40 percent of the projected Net Operating Costs for the third year of service. FRA will give priority to applications proposing a lower R&E grant share of projected Net Operating Costs than stated above, as further discussed in Section E(1). The required matching funds for the projected Net Operating Costs not covered by the R&E grant may be comprised of eligible public sector funding (state, local, or other federal funding) or private sector funding. However, FRA will not consider funds already expended (or otherwise encumbered) that do not comply with 2 CFR 200.458 toward the matching funds requirement. Additionally, only cash contributions will be counted toward the matching funds requirements. FRA strongly encourages applicants to identify and include state, local, Amtrak, public agency or authority, or private funding or financing to support the proposed project. Applicants must identify the source(s) of their matching funds for the R&E grant associated with the service, and must clearly and distinctly reflect these funds in the application budget.

Before submitting an application, applicants should carefully review the principles for cost sharing or matching in 2 CFR 200.306.

3. Project Eligibility

Projects eligible for funding under this NOFO must be projects for Operating Assistance to Initiate, Restore, or Enhance Intercity Rail Passenger Transportation. FRA will give priority to proposed projects in applications that:

a. Show completed or nearly completed planning, design, environmental reviews, negotiation of agreements, acquisition of equipment, construction, and other actions necessary for Initiation, Restoration, or Enhancement of service;

b. Restore service over routes formerly operated by Amtrak, including routes in the Gulf Coast region between New Orleans, Louisiana, and Orlando, Florida as described in section 11304 of the Passenger Rail Reform and Investment Act of 2015;

c. Provide daily or daytime service over routes where such service did not previously exist;

d. Include funding or other significant participation by State, local, and regional governmental and private entities;

e. Include a funding plan that demonstrates the Intercity Rail Passenger Service will be financially sustainable beyond the three-year grant period;

f. Provide service to regions and communities that are underserved or not served by other intercity public transportation;

g. Foster economic development, particularly in rural communities and for disadvantaged populations;

h. Provide other non-transportation benefits, such as livability benefits; and

1. Enhance connectivity and geographic coverage of the existing national network of Intercity Rail Passenger Service.

D. Application and Submission Information

Required documents for the application are outlined in the following paragraphs. Applicants must complete and submit all components of the application. See Section D(2) for the application checklist. FRA welcomes the submission of additional relevant supporting documentation, such as host railroad agreements, Amtrak/operator agreements, and funding commitment documentation. The additional relevant supporting documentation will not count against the Project Narrative page limit.

1. Address To Request Application Package

Applicants must submit all application materials in their entirety through http://www.Grants.gov no later than 5:00 p.m. EDT, on May 22, 2018. FRA reserves the right to modify this deadline. General information for submitting applications through Grants.gov can be found at: https://www.fra.dot.gov/Page/P0270.

For any supporting application materials that an applicant cannot submit via Grants.gov, an applicant may submit an original and two (2) copies to Amy Houser, Office of Program Delivery, Federal Railroad Administration, 1200 New Jersey Avenue SE, Room W36–412, Washington, DC 20590. However, due to delays caused by enhanced screening of mail delivered via the U.S. Postal Service, FRA advises applicants to use other means of conveyance (such as courier service) to assure timely receipt of materials before the application deadline. Additionally, if documents can be obtained online, explaining to FRA how to access files on a referenced website may also be sufficient.

2. Content and Form of Application Submission

FRA strongly advises applicants to read this section carefully. Applicants must submit all required information and components of the application package to be considered for funding. Additionally, applicants selected to receive funding must generally satisfy the grant readiness checklist requirements on https://www.fra.dot.gov/Page/P0268 as a precondition to FRA issuing a grant award, as well as the requirements in 49 U.S.C. 24405 explained in part at https://www.fra.dot.gov/page/P0185.
Required documents for an application package are outlined in the checklist below:

- **Project Narrative (see D.2.a)**
- **Statement of Work (see D.2.b.i)**
- **Capital and mobilization plan (see D.2.b.ii)**
- **Operating plan (see D.2.b.iii)**
- **Funding plan (see D.2.b.iv)**
- **Status of negotiations and agreements (see D.2.b.v)**
- **SF 424—Application for Federal Assistance**
- **SF 424A—Budget Information for Non-Construction**
- **SF 424B—Assurances for Non-Construction**
- **FRA’s Additional Assurances and Certifications**
- **SF LLL—Disclosure of Lobbying Activities**

These requirements must be satisfied through a narrative statement submitted by the applicant. The Project Narrative may not exceed 25 pages in length (excluding cover pages, table of contents, and supporting documentation). FRA will not review or consider for award applications with narrative statements exceeding the page limitation. If possible, applicants should submit supporting documents via website links rather than hard copies. If supporting documents are submitted, applicants must clearly identify the page number of the relevant portion of the supporting documentation in the Project Narrative. The Project Narrative must adhere to the following outline.

1. **Cover Page:** Include a cover page that lists the following elements in either a table or formatted list: Project title; location (e.g., city, State, Congressional district); lead applicant organization name; name of any co-applicants; projected Net Operating Costs; the annual amount of R&E funding requested up to the first three years of operation; and match for the remaining operating costs not provided by R&E funding.

2. **Project Narrative:** Provide a brief 4–6 sentence summary of the proposed project and what the project will entail. Include challenges the proposed project aims to address, and summarize the intended outcomes and anticipated benefits that will result from the proposed project.

3. **Project Summary:** Provide a brief 4–6 sentence summary of the proposed project and what the project will entail. Include challenges the proposed project aims to address, and summarize the intended outcomes and anticipated benefits that will result from the proposed project.

4. **Project Funding Summary:** Indicate the annual amount of R&E funding requested, the match for the remaining operating costs not provided by R&E funding, and the total annual projected Net Operating Costs for the first three years of operation. Identify the source(s) of matching funds, and clearly and distinctly reflect these funds as part of the total projected Net Operating Cost in the application budget. Additionally, identify any other sources of Federal funds committed to the project and any pending Federal requests. Also, note if the requested Federal funding must be obligated or spent by a certain date due to dependencies or relationships with other Federal or non-Federal funding sources, related projects, law, or other factors. Additionally, specify whether Federal funding for the project has previously been sought, and identify the Federal program and fiscal year of the funding request(s). Rail Carriers other than Amtrak should state whether they will require access to Amtrak’s reservation system, stations, or facilities because they are directly related to the Rail Carrier’s operations, and whether they expect the FRA to award a portion of the requested R&E grant to Amtrak for such access (and in what amount).

5. **Project Readiness:** Include a thorough discussion of how the proposed project meets all of the evaluation and selection criteria, as outlined in Section E of this notice. If an application does not sufficiently address the evaluation and selection criteria, it is unlikely to be a competitive application.

6. **Project Implementation and Management:** Describe proposed project implementation and project management arrangements. Include descriptions of the expected arrangements for project contracting, contract oversight, change-order management, risk management, and conformance to Federal requirements for project progress reporting.

7. **Project Location:** Include geospatial data for the project, as well as a map of the project’s location. Include the Congressional districts in which the project will take place.

8. **Evaluation and Selection Criteria:** Include a thorough discussion of how the proposed project meets all of the evaluation and selection criteria, as outlined in Section E of this notice. If an application does not sufficiently address the evaluation and selection criteria, it is unlikely to be a competitive application.

The Secretary, acting through the FRA, is permitted in 49 U.S.C. 24408(h) to award an appropriate portion of R&E grants under this NOFO to Amtrak as compensation for permitting certain access.
timelines for undertaking and completing each of the investments. Describe the appropriate planning, design, any environmental reviews, negotiation of agreements, acquisition of equipment, construction, and other actions necessary for initiation of service that have been completed or nearly completed. Provide the date when the first year of rail service will commence or when enhancements to existing service will be placed into service.

b. Additional Application Elements Applicants must submit:

i. A Statement of Work (SOW) addressing the scope, schedule, and budget for the proposed project if it were selected for award. The SOW must contain sufficient detail so FRA and the applicant, can understand the expected outcomes of the proposed work to be performed and can monitor progress toward completing project tasks and deliverables during a prospective grant's period of performance. Applicants must use the standard SOW template to be considered for award. The SOW template is located at [https://www.fra.dot.gov/eLib/Details/L18661](https://www.fra.dot.gov/eLib/Details/L18661). When preparing the budget, the total cost of a project must be based on the best available information as indicated in cited references. The project schedule should be sufficiently detailed to include the date when the first year of service will commence (or when the proposed Enhancement will be placed into service), as well as reasonable due dates for expenses associated with the operation of the Intercity Rail Passenger Transportation.

ii. Capital and mobilization plan that includes:

(A) A description of any capital investments, service planning actions (such as environmental reviews), and mobilization actions (such as qualifications of train crews) required for initiation of the Intercity Rail Passenger Transportation; and

(B) A timeline for undertaking and completing each of the investments and actions referred to in subparagraph (A).

iii. Operating plan describing:

(A) Planned service operation;

(B) Identity and qualifications of the train operator;

(C) Identity and qualifications of any other service providers (e.g. on-board service, equipment maintenance, station staff);

(D) Service frequency;

(E) Planned routes and schedules;

(F) Station facilities that will be utilized;

(G) Projected ridership, revenues, and costs;

(H) Descriptions of how the operations under subparagraph (G) were developed;

(I) Equipment that will be utilized, how such equipment will be acquired or refurbished (if necessary), and where such equipment will be maintained; and

(J) A plan for ensuring safe operations and compliance with applicable safety regulations;

iv. Funding plan that:

(A) Describes the funding of initial capital costs and operating costs for the first three years of operation;

(B) Includes commitment by the applicant to provide the funds described in subparagraph (A) to the extent not covered by Federal grants and revenues; and

(C) Describes the funding of operating costs and capital costs, to the extent necessary, after the first three years of operation.

v. Status of negotiations and agreements with:

(A) Each of the railroads or regional transportation authorities whose tracks or facilities would be utilized by the service;

(B) The anticipated Railroad Carrier, if such entity is not part of the applicant group; and

(C) Any other service providers or entities expected to provide services or facilities that will be used by the service, including any required access to Amtrak systems, stations, and facilities if Amtrak is not part of the applicant group.

vi. SF424—Application for Federal Assistance

vii. SF 424A—Budget Information for Non-Construction

viii. SF 424B—Assurances for Non-Construction

ix. FRA's Additional Assurances and Certifications; and

x. SF LLL—Disclosure of Lobbying Activities.


c. Post-Selection Requirements

See Section F(2) for post-selection requirements.

1. Unique Entity Identifier, System for Award Management (SAM), and Submission Instructions

All applicants must be registered as an organization with [Grants.gov](http://www.Grants.gov). To apply for funding through [Grants.gov](http://www.Grants.gov), applicants must be properly registered. Complete instructions on how to register and submit an application can be found at [www.Grants.gov](http://www.Grants.gov). Registering with [Grants.gov](http://www.Grants.gov) is a one-time process; however, it can take up to several weeks for first-time registrants to receive confirmation and a user password. FRA recommends that applicants start the registration process as early as possible to prevent delays that may preclude submitting an application package by the application deadline. Applications will not be accepted after the due date. Delayed registration is not an acceptable justification for an application extension.

FRA may not make a discretionary grant award to an applicant until the applicant has complied with all applicable Data Universal Numbering System (DUNS) and SAM requirements. (Please note that if a Dun & Bradstreet DUNS number must be obtained or renewed, this may take a significant amount of time to complete.) Late applications that are the result of failure to register or comply with [Grants.gov](http://www.Grants.gov) applicant requirements in a timely manner will not be considered. If an applicant has not fully complied with the requirements by the submission deadline, the application will not be considered. To submit an application through [Grants.gov](http://www.Grants.gov), applicants must:

a. Obtain a DUNS Number

A DUNS number is required for [Grants.gov](http://www.Grants.gov) registration. The Office of Management and Budget requires that all businesses and nonprofit applicants for Federal funds include a DUNS number in their applications for a new award and renewal of an existing award. A DUNS number is a unique nine-digit sequence recognized as the universal standard for the government in identifying and keeping track of entities receiving Federal funds. The identifier is used for tracking purposes and to validate address and point of contact information for Federal assistance applicants, recipients, and sub-recipients. The DUNS number will be used throughout the grant life cycle. Obtaining a DUNS number is a free, one-time activity. Applicants may obtain a DUNS number by calling 1–866–705–5711 or by applying online at [http://www.dnb.com/us](http://www.dnb.com/us).

b. Register With the SAM at [www.SAM.gov](http://www.SAM.gov)

All applicants for Federal financial assistance must maintain current registrations in the SAM database. An applicant must be registered in SAM to successfully register in [Grants.gov](http://www.Grants.gov). The SAM database is the repository for standard information about Federal financial assistance applicants, recipients, and sub-recipients. Organizations that have previously submitted applications via [Grants.gov](http://www.Grants.gov) are already registered with SAM, as it is
a requirement for Grants.gov registration. Please note, however, that applicants must update or renew their SAM registration at least once per year to maintain an active status. Therefore, it is critical to check registration status well in advance of the application deadline. If an applicant is selected for an award, the applicant must maintain an active SAM registration with current information throughout the period of the award. Information about SAM registration procedures is available at www.sam.gov.

c. Create a Grants.gov Username and Password

Applicants must complete an Authorized Organization Representative (AOR) profile on www.Grants.gov and create a username and password. Applicants must use the organization’s DUNS number to complete this step. Additional information about the registration process is available at: https://www.grants.gov/web/grants/applicants/organization-registration.html.

d. Acquire Authorization for Your AOR From the E-Business Point of Contact (E-Biz POC)

The E-Biz POC at the applicant’s organization must respond to the registration email from Grants.gov and login at www.Grants.gov to authorize the applicant as the AOR. Please note there can be more than one AOR for an organization.

e. Submit an Application Addressing All Requirements Outlined in this NOFO

If an applicant experiences difficulties at any point during this process, please call the Grants.gov Customer Center Hotline at 1–800–518–4726, 24 hours a day, 7 days a week (closed on Federal holidays). For information and instructions on each of these processes, please see instructions at: http://www.grants.gov/web/grants/applicants/apply-for-grants.html

Note: Please use generally accepted formats such as .pdf, .doc, .docx, .xls, .xlsx and .ppt when uploading attachments. While applicants may embed picture files, such as .jpg, .gif and .bmp in document files, applicants should not submit attachments in these formats. Additionally, the following formats will not be accepted: .com, .bat, .exe, .vbs, .cfg, .dat, .db, .dbf, .dll, .ini, .log, .ora, .sys, and .zip.

2. Submission Dates and Times

Applicants must submit complete applications in their entirety to www.Grants.gov no later than 5:00 p.m. EDT, May 22, 2018. FRA reviews www.Grants.gov information on dates/times of applications submitted to determine timeliness of submissions. Late applications will be neither reviewed nor considered. Delayed registration is not an acceptable reason for late submission. Applicants are strongly encouraged to apply early to ensure that all materials are received before this deadline.

To ensure a fair competition of limited discretionary funds, the following conditions are not valid reasons to permit late submissions: (1) Failure to complete the registration process before the deadline; (2) failure to follow Grants.gov instructions on how to register and apply as posted on its website; (3) failure to follow all instructions in this NOFO; and (4) technical issues experienced with the applicant’s computer or information technology environment.

3. Intergovernmental Review

Executive Order 12372 requires applicants from State and local units of government or other organizations providing services within a State to submit a copy of the application to the State Single Point of Contact (SPOC), if one exists, and if this program has been selected for review by the State. Applicants must contact their State SPOC to determine if the program has been selected for State review.

4. Funding Restrictions

R&E grants awarded for any individual Intercity Rail Passenger Transportation route will not receive funding for more than three years and may not be renewed. No more than six Operating Assistance grant awards will be simultaneously active. FRA will only approve pre-award costs consistent with 2 CFR 200.458. Under 2 CFR 200.458, grant recipients must seek written approval from FRA for pre-award activities to be eligible for reimbursement under the cooperative agreement. Activities initiated prior to the execution of a cooperative agreement without FRA’s written approval may not be eligible for reimbursement or included as a grantee’s matching contribution. For Enhancement projects, FRA will only fund the portion of the operating costs associated with the Enhancement, and not the entire project or service.

5. Application Review Information

1. Criteria

FRA will first screen each application for eligibility (eligibility requirements are outlined in Section C of this notice) and completeness (application documentation and submission requirements are outlined in Section D of this notice). The matching requirement is considered in determining whether the application is eligible. FRA will also provide selection preference to applications where the proposed matching funds exceed the annual minimum required amounts specified in Section C(2).

b. Evaluation Criteria

FRA subject-matter experts will evaluate all eligible and complete applications using the evaluation criteria outlined in this section to determine technical merit and public benefits consistent with the priorities in 49 U.S.C. § 24408(d).

i. Technical Merit: FRA will evaluate application information for the degree to which—

(A) The tasks and subtasks outlined in the SOW are appropriate to achieve the expected outcomes of the proposed project;

(B) The appropriate planning, design, any environmental reviews, negotiation of agreements, acquisition of equipment, construction, and other actions necessary for Initiation of service have been completed or nearly completed.

(C) Service is restored over routes formerly operated by Amtrak, including routes in the Gulf Coast region between New Orleans, Louisiana, and Orlando, Florida as described in section 11304 of the Passenger Rail Reform and Investment Act of 2015.

(D) The appropriate funding or other significant participation by State, local, and regional governmental and private entities are in-place.

(E) The application is thorough and responsive to all the requirements outlined in this notice, including the strength and comprehensiveness of the capital and mobilization plan, operating plan, funding plan, and status of negotiations and agreements described in Section D(2)(b).

The funding plan demonstrates the Intercity Rail Passenger Service will be financially sustainable beyond the 3-year grant period.

ii. Benefits:

FRA will evaluate the proposed rail service on:

(A) Providing daily or daytime service over routes where such service did not previously exist;

(B) Providing service to regions and communities that are underserved or not served by other intercity public transportation;

(C) Fostering economic development, particularly in rural communities and for disadvantaged populations; and
(D) Enhancing connectivity and geographic coverage of the existing national network of Intercity Rail Passenger Service, and
(E) Providing other non-transportation benefits.

3. Reporting Matters Related to Integrity and Performance

Before making a Federal award with a total amount of Federal share greater than the simplified acquisition threshold (see 2 CFR 200.88 Simplified Acquisition Threshold), FRA will review and consider any information about the applicant that is in the designated integrity and performance system accessible through SAM. The grant recipient must provide similar information regarding the route performance, financial, and ridership projections, and capital and business plans that Amtrak is required to provide to FRA, as well as other implementation information that includes the status of the investments and funded operations, the plans for continued operation and funding of routes, and any legislative recommendations.

Grant recipients must also collect information and report on the project’s performance using measures established by the FRA to assess progress in achieving strategic goals and objectives. Examples of some rail measures are listed in the below table.

<table>
<thead>
<tr>
<th>Rail measures</th>
<th>Unit measured</th>
<th>Temporal</th>
<th>Primary strategic goal</th>
<th>Secondary strategic goal</th>
<th>Description</th>
</tr>
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</table>

2. Administrative and National Policy Requirements

Due to funding limitations, projects that are selected for funding may receive less than the amount originally requested. In those cases, applicants must be able to demonstrate the proposed projects are still viable and can be completed with the amount awarded.

For projects on a State-Supported route (as defined in 49 U.S.C. 24102(13), grant recipients must be in compliance with the cost allocation methodology required under Section 209 of the Passenger Rail Investment and Improvement Act of 2008 (Pub. L. 110–432) with respect to that route. Selected grantees must maintain compliance with the cost allocation methodology for the duration of the service.

Grantees and entities receiving funding from the grantee must comply with all applicable laws and regulations. A non-exclusive list of administrative and national policy requirements that grantees must follow includes: 2 CFR part 200; procurement standards; compliance with Federal civil rights laws and regulations; disadvantaged business enterprises; debarment and suspension; drug-free workplace; FRA’s and OMB’s Assurances and Certifications; Americans with Disabilities Act; safety requirements; NEPA; environmental justice; and the requirements in 49 U.S.C. 24405 including the Buy America requirements.

See an example of standard terms and conditions for FRA grant awards at https://www.fra.dot.gov/Elib/Document/14426.

3. Reporting

a. Reporting Matters Related to Integrity and Performance

Before making a Federal award with a total amount of Federal share greater than the simplified acquisition threshold (see 2 CFR 200.88 Simplified Acquisition Threshold), FRA will review and consider any information about the applicant that is in the designated integrity and performance system accessible through SAM (currently the Federal Awardee Performance and Integrity Information System [FAPIIS]) (see 41 U.S.C. 2313).

An applicant, at its option, may review information in the designated integrity and performance systems accessible through SAM and comment on any information about itself that a Federal awarding agency previously entered and is currently in the designated integrity and performance system accessible through SAM.

FRA will consider any comments by the applicant, in addition to the other information in the designated integrity and performance system, in making a judgment about the applicant’s integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants as described in 2 CFR 200.205.

b. Progress Reporting on Grant Activity

Each applicant selected for a grant will be required to comply with all standard FRA reporting requirements, including quarterly progress reports, quarterly Federal financial reports, and interim and final performance reports, as well as all applicable auditing, monitoring and close out requirements. Reports may be submitted electronically.

c. Performance Reporting

As a part of the grant agreement, the grant recipient must provide similar information regarding the route performance, financial, and ridership projections, and capital and business plans that Amtrak is required to provide to FRA, as well as other implementation information that includes the status of the investments and funded operations, the plans for continued operation and funding of routes, and any legislative recommendations.
G. Federal Awarding Agency Contacts

For further information regarding this notice and the grants program, please contact Amy Houser, Office of Program Delivery, Federal Railroad Administration, 1200 New Jersey Avenue SE, Room W36–412, Washington, DC 20509; email: amy.houser@dot.gov, or Ruthie Americus, Office of Policy and Planning, Federal Railroad Administration, 1200 New Jersey Avenue SE, Room W36–403, Washington, DC 20509; email: ruthie.americus@dot.gov.

Issued in Washington, DC, on February 15, 2018.

Jamie Rennert,
Director, Office of Program Delivery, Federal Railroad Administration.

[FR Doc. 2018–03536 Filed 2–20–18; 8:45 am]
BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration
[Docket Number FRA–2007–28097]

Petition for Waiver of Compliance

Under part 211 of Title 49 of the Code of Federal Regulations (CFR), this provides the public notice that on January 16, 2018, the Boone & Scenic Valley Railroad (BSV) petitioned the Federal Railroad Administration (FRA) for a renewal of a waiver of compliance from certain provisions of the Federal railroad safety regulations contained at 49 CFR part 223. Safety glazing standards—Locomotives, passenger cars and cabooses. FRA assigned the petition docket number FRA–2007–28097.

BSV is an 11-mile-long tourist railroad that is owned and operated by the Iowa Railroad Historical Society. BSV operates steam locomotive Number JS8419, a 2–8–2 "Mikado" type locomotive which was built in October 1988 at the Datong Locomotive Works in Shanxi, China. This locomotive was purchased new by BSV in 1989, and delivered with automotive-type safety glazing. It is typically operated on Saturdays from Memorial Day weekend until the end of October. BSV is specifically requesting a waiver renewal with respect to 49 CFR 223.11—

Requirements for existing locomotives.

A copy of the petition, as well as any written communications concerning the petition, is available for review online at www.regulations.gov and in person at the U.S. Department of Transportation’s (DOT) Docket Operations Facility, 1200 New Jersey Avenue SE, W12–140, Washington, DC 20590. The Docket Operations Facility is open from 9 a.m. to 5 p.m., Monday through Friday, except Federal Holidays.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested parties desire an opportunity for oral comment and a public hearing, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number and may be submitted by any of the following methods:

• Website: http://www.regulations.gov. Follow the online instructions for submitting comments.
• Fax: 202–493–2251.
• Hand Delivery: 1200 New Jersey Avenue SE, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

Communications received by April 9, 2018 will be considered by FRA before final action is taken. Comments received after that date will be considered if practicable.

Anyone can search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). Under 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its processes. DOT posts these comments, without edit, including any personal information the commenter provides, to www.regulations.gov, as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at https://www.transportation.gov/privacy. See also https://www.regulations.gov/privacyNotice for the privacy notice of regulations.gov.

Robert C. Lauby,
Associate Administrator for Railroad Safety, Chief Safety Officer.

[FR Doc. 2018–03444 Filed 2–20–18; 8:45 am]
BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration
[Docket No. NHTSA–2017–0096]

Request for Approval of a New Information Collection

ACTION: Notice and request for comments.

SUMMARY: Before a Federal agency can collect certain information from the public, it must receive approval from the Office of Management and Budget (OMB). In compliance with the Paperwork Reduction Act of 1995, this notice announces that the Information Collection Request (ICR) abstracted below is being forwarded to the OMB for review and comment. A Federal Register Notice with a 60-day comment period soliciting comments on the following information collection was published on November 27, 2017.

DATES: Written comments should be submitted by March 23, 2018.

ADDRESSES: Send comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503, Attention: NHTSA Desk Officer.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995, before an agency submits a proposed collection of information to OMB for approval, it must first publish a document in the Federal Register providing a 60-day comment period and otherwise consult with members of the public and affected agencies concerning each proposed collection of information. OMB has promulgated regulations describing what must be included in such a document. Under OMB’s regulation (at 5 CFR 1320.8(d)), an agency must ask for public comment on the following:

(i) 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;
(ii) 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;
(iii) How to enhance the quality, utility, and clarity of the information to be collected;
(iv) How to minimize the burden of the collection of information on those who are to respond, including 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.

In compliance with these requirements, NHTSA sought public comment on the following proposed collection of information for which the agency is seeking approval from OMB:

OMB Control Number: Not assigned.

Title: State Highway Safety Grant Programs.

Form Numbers: N/A (Highway Safety Plan, Annual Report, Assessment).

Type of Review: New Collection.

Requested Expiration Date of Approval: Three years from the approval date.

Abstract: In response to the 60-day notice, the following groups submitted comments to the public docket on www.regulations.gov; Governors Highway Safety Association (GHSA) and a joint submission by the Departments of Transportation of Idaho, Montana, North Dakota, South Dakota and Wyoming (5-State DOTs). Both groups offered comments on State obligations related to the grant application and assessment requirements under the collection of information. These comments included examples of burden hours and costs associated with meeting the requirements. These comments are addressed in the agency’s response below.

The Fixing America’s Surface Transportation Act (FAST), Public Law 114–94, authorizes the National Highway Traffic Safety Administration (NHTSA) to issue highway safety grants to States under Chapter 4 of Title 23, U.S.C. Specifically, these grant programs include the Highway Safety Program grants (23 U.S.C. 402 or Section 402), the National Priority Safety Program grants (23 U.S.C. 405 or Section 405) and a separate grant on racial profiling data collection contained in a previous authorization that was revised and restored under the FAST Act (Pub. L. 109–59, Sec. 1906 or Section 1906, as amended by Sec. 4011, Pub. L. 114–94).

For all of these grants, as directed in statute, NHTSA uses a consolidated application process that relies on the Highway Safety Plan (HSP) States submit under the Section 402 program as a single application. The information required to be submitted for these grants includes the HSP, consisting of information on the highway safety planning process, performance report, performance plan, problem identification, highway safety countermeasure strategies, planned activities and funding amounts, certifications and assurances, and application materials that cover Section 405 grants and the reauthorized Section 1906 grants. States also must submit an annual report evaluating their progress in achieving performance targets. In addition, as part of the statutory criteria for Section 405 grants covering the areas of occupant protection, traffic safety information system improvements and impaired driving countermeasures, States may be required to receive assessments of their State programs in order to receive a grant. States must provide information and respond to questions as part of the assessment process.

Consistent with the statute, NHTSA recently issued a Final Rule (83 FR 3466, Jan. 25, 2018) that creates uniform procedures for States to apply for grant funds. These procedures specify the information that is required to be submitted to receive a grant and the type of information required to verify performance under the grants. Under these efforts, NHTSA has taken actions to streamline the required application procedures, including the expanded use of an electronic submission process identified as the Grants Management Solutions Suite (GMSS). This system will replace the current grant management tracking system and allow States to apply for and receive grants electronically. Implementation is scheduled to occur after several participating States have completed system usability testing, and NHTSA has reviewed and considered any feedback provided. With the application requirements set as part of the issuance of the Final Rule, this process addresses the burden estimates covering hours and costs associated with meeting the established application requirements. Separately, it addresses the burden estimates covering the assessment process required under three of the individual grant programs.

Description of the Need for the Information and Proposed Use of the Information: As noted above, the statute provides that the HSP is the application basis for grants each fiscal year. The information is necessary to determine whether a State satisfies the Federal criteria for grant awards. The annual report tracks progress in achieving the aims of the grant program. The information is necessary to verify performance under the grants and to provide a basis for improvement. As specified in statute, States may be

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1 Section 405 grants cover the following: Occupant Protection Grants; State Traffic Safety Information System Improvements Grants; Impaired Driving Countermeasures Grants (including Alcohol-Ignition Interlock Grants and 24–7 Sobriety Program Grants); Distressed Driving Grants; Motorcyclist Safety Grants; State Graduated Driver Licensing Incentive Grants; and Nonmotorized Safety Grants. Section 1906 is a separate racial profiling data collection grant.

2 Under occupant protection grants, one criterion that a State with a lower belt use rate may use to get a grant is to complete an asset grant of State occupied protection program once every three years (23 U.S.C. § 405(b)(3)(B)(ii)(VI)(aa)) and another criterion is a comprehensive occupant protection program that includes a program assessment conducted every five years as one of its elements (23 U.S.C. 405(b)(3)(B)(ii)(VI)(aa), 23 CFR 1300.21(e)(3)(E)). Under traffic safety information system assessment, a State must have an assessment of its highway safety data and traffic records system once every 5 years in order to receive a grant (23 U.S.C. 405(c)(3)(E)). Under impaired driving counter grants, a State with high average impaired driving fatality rates must have an assessment of its impaired driving program once every 3 years in order to receive a grant (23 U.S.C. 405(d)(3)(E)(ii)(I)).
required to receive an assessment of certain covered programs. The information provided by a State allows subject matter experts to provide recommendations for the purpose of improving the covered grant area.

In general, both commenters indicated support for the agency’s collection of information. GHSA stated that it “strongly supports the role of a single, unified annual Highway Safety Plan,” and further supported “the use of Annual Reports to document progress on performance” and the “assessment process as a mechanism to help States improve programs.” The 5-State DOTs noted separately that “NHTSA must have an application process and that States must provide periodic reports.” However, both commenters requested simplification of the application requirements contained in the Interim Final Rule published on May 23, 2016 (81 FR 32554). NHTSA addressed substantially similar comments from both commenters about the Interim Final Rule through a separate process that established the Final Rule for these requirements published on January 25, 2018 (83 FR 3466). In the Final Rule, NHTSA explained that it adopted some of the commenter’s recommendations, clarified NHTSA expectations about requirements where the actual burdens were potentially misunderstood, and further explained the importance of a requirement where a commenter’s request was not adopted. As with the prior effort, NHTSA sought to achieve a balance between the minimum need to ensure proper stewardship of Federal funds and the States’ need for flexibility and efficiency in the use of their funds.

Similarly, for the statutorily-mandated assessments that also are part of the Final Rule and about which the commentators raise issues, NHTSA developed the assessment tools through a separate public comment process. For occupant protection and impaired driving grants, the assessment tools are identified in the Final Rule as the Highway Safety Uniform Guidelines that have been in place for many years and are familiar to all States under the grant program. States use the guidelines as a basis to develop the Section 402 portion of their HSPs. For traffic records assessments, NHTSA developed the current approach based on comments provided by several States and other interested parties in 2012. Currently, NHTSA is reviewing the traffic records assessment tool under a separate public comment process that recently closed. (82 FR 49473, Oct. 25, 2017) We note that both commenters provided comments to that process as well and their comments are being considered as part of the agency’s overall effort to refine the traffic records assessment process.

Estimated Burden: Under the grant application and annual report requirements for Section 402 grants, with 57 potential respondents, we estimated that it will take each respondent approximately 240 hours to collect, review and submit the required information to NHTSA. For Section 405 grants, with 56 potential respondents, we estimated that it will take each respondent approximately 180 hours to collect, review and submit the required information to NHTSA.

In response to these estimates, both commenters provided anecdotal examples of time and cost spent by States to meet application requirements, concluding that the agency underestimated the time burdens involved. According to GHSA, the examples suggest that NHTSA’s burden estimates “fall far short of actual time commitments in many States.” Separately, the 5-State DOTs commented that “the burden of complying with these processes is significantly underestimated by NHTSA.” GHSA also acknowledged the difficulty of developing an estimate across States with “different size grant programs and staff.” We agree that an average may be not reflective of the experience of some States. However, our view is that the estimates properly reflect what should be the average time spent on the required application. As GHSA notes, the estimates suggest that States spend 52.5 days to provide the required HSP and annual report under this program. In most cases, HSP applications are between 100 and 200 pages in length and consist of revising or updating a previously produced document. The agency’s estimate is in line with updating and revising a document of this size over a 50-day period. Recognizing that variability exists among States, we believe that this is a reasonable estimate of the average burden. Regardless, we plan to reach out to GHSA to gain more specific information about the examples provided and will work with those States that may be spending an excessive amount of time (and cost) on application activities.

We note further that, while we appreciate the anecdotal examples provided, the information provided by the commenters is based on meeting the prior IFR requirements. States have not yet submitted an application based on the Final Rule just released, which sought to reduce burdens where possible. In addition, these comments do not take into account the more automated application process NHTSA intends to use this year under GMSS. Although the 5-State DOTs provide their view that the system will not achieve time savings, we do not agree with the assessment. As an improvement over the current paperwork-intensive process, GMSS will align directly with the applicable program requirements, tying discrete fields within GMSS to the specific regulatory component. Such an approach should reduce uncertainty about what level of information must be provided to meet the application requirements, resulting in increased efficiency in State applications. Understandably, there may be some additional time spent providing the necessary application information the first year GMSS operates, but the system will save the information each year and only require that a State revise and update information in a succeeding year to apply for a grant. As stated in the Final Rule, we believe that GMSS will streamline and simplify the application process, decrease the overall size of HSPs by eliminating content unnecessary to satisfy statutory requirements, and reduce duplicative entries related to grants.

The estimate totals covering hours and costs also are based on the universe of potential applicants submitting the required information for every available grant, and in this regard overestimate the burden, as not all States apply for and receive a grant each year under each of these programs. In addition, under Section 405 grants, some requirements permit States to submit a single application covering multiple years, allowing States to simply recertify in subsequent years. Considering the agency’s steps to streamline the current submission process, including increased use of prepopulated information fields in GMSS and greater reliance on electronic submission in general, we believe that the approach represents the highest possible burden hours and costs for States submitting the required information.

NHTSA plans to deploy GMSS as soon as possible. NHTSA recently worked with GHSA and States on user acceptance testing, making system enhancements based on the feedback provided as part of the process. In the future, NHTSA will complete a second round of user acceptance testing based on States using the enhanced system.

GHSA included within its comments some “high-level concerns” about the...
system, including that NHTSA provide opportunity for training and additional technical support during deployment; that the system offer a template that States can use to organize their application content and upload data; and that system functionality allow States to produce a formatted HSP document. In response to these comments, in line with prior information provided to GHSA, NHTSA plans regular contact with GHSA and the States throughout GMSS implementation. These activities include several planned training sessions with States and the development of an extensive user manual. NHTSA also will provide help desk services and additional support through its regional offices with dedicated system experts available in each office. GMSS also will include system capabilities that cover the ability to accept State submissions via a template-based system, with capability for bulk uploads of certain information found in many State e-grant systems. Finally, the system will be capable of exporting information in a printed format. We believe these steps will be responsive to the noted concerns. We plan to have GMSS available to accept application submissions in late March and will continue to work with States throughout the system’s deployment and use.

In addition to the application process, this collection also covers the assessment process that is a requirement of three separate grant areas under Section 405—occupant protection, impaired driving countermeasures and traffic safety system improvement grants. For occupant protection and impaired driving countermeasures grants, we estimated that it takes 80 hours to respond to questions under an assessment. For traffic safety information system improvement grants, we estimated that it takes 165 hours of time needed for State respondents to questions under the assessment. In response to these estimates, the commenters provided anecdotal examples of time and cost for States responding to assessments. On this basis, GHSA concluded that the estimates “do not reflect the time needed to carry out the assessment.” Although not specific to the estimates, the 5-State DOTs added that “the assessment process for the programs has become costly and very wide-ranging.”

More specifically, both commenters shared concerns about the time and cost necessary for a State to respond to a traffic records assessment. On the basis of these comments, however, with one exception explained below, we do not believe that our estimates need to be revised.

Assessments serve as a critical evaluation of a State’s traffic safety programs, resulting in recommendations from a panel of experts. Congress has recognized the value of the assessment process as well, making these statutorily-mandated components of the grant requirements. Federal grant funds are available to States to defray the costs of these assessments. While we understand that some grant funds may be diverted from program uses to support the assessment process (as the 5-State DOTs assert), a State that continues its same approach without review may spend funds in inefficient ways or focus on areas that do not improve traffic safety. Assessments are not carried out on an annual basis, but rather occur on a 3- or 5-year basis depending on the statutory requirement. Some anecdotal examples of assessment costs cited by the commenters may not have taken this into account. For example, for FY19 grants, NHTSA estimates that only 6 States will need occupant protection assessments and only 2 States will need traffic records assessments to qualify for grants. (These States will not need another assessment for several years.) This is far smaller than the total number of jurisdictions that are eligible for grants (and smaller than the average number of assessments per year the agency used to develop the burden estimates). In addition, the period between assessments may be even longer if a State improves its performance in certain grant areas, as the statute identifies the need for assessment relating to programs such as occupant protection and impaired driving on the basis of performance in key safety metrics (e.g., seat belt use rate or average impaired driving fatality rate).

Separately, both commenters expressed concern about the number of questions that might be raised during an assessment. Assessments are intended to be comprehensive and by their nature can entail an extensive review. Occupant protection and impaired driving countermeasures assessments do not limit the number of questions that may be asked but instead set a time limit on the actual process. States provide background materials in advance, which are reviewed by a team of experts prior to the assessment, with the actual assessment process taking place over a single week. States participate in an interview process (based on the review of background materials) during the first half of the work (2.5 days), with the remaining period spent by the team of experts producing and presenting recommendations. For these types of assessments, the agency estimated 80 hours of time needed for State participation. This covers the background material collection, responding to questions and participating in interviews during the assessment week. For traffic records assessments, NHTSA estimated 165 hours of time needed to respond to questions through a web-based interface. These responses are reviewed by a team of experts separately, and a final report is provided to the State. NHTSA developed this estimate based on system usage time by States (i.e., records of time logged in to the system). It also presumes that States have access to a Traffic Records Coordinating Committee—a requirement of the Section 405 grant statute—that represents each of the traffic records disciplines in a State. With this mechanism in place, the State should be able to draw readily on the required expertise to answer the questions, limiting the amount of time needed to respond. In general, we expect States to be familiar with their own programs and to be able to identify the expertise and decision-making authority required for a response.

Our estimates do not take into account the possibility that coordination issues within a State may exist that delay responses. However, with regard to traffic record assessments, we recognize that our burden estimates are more than double that of other assessments. The agency is reviewing this assessment tool under a separate process, in light of comments received from GHSA, the 5-State DOTs, and other stakeholders. We will pay careful attention to issues of burden as we work to refine that process.

Based on GHSA’s comment regarding the costs of on-site assessment teams used for occupant protection and impaired driving assessments, we are revising the cost estimates to include the travel, per diem, and honoraria paid to assessment team members. Although States are allowed to use Section 402 grant funds to cover these costs, we agree with GHSA that they should be included in the estimate of overall cost under this collection of information. Although GHSA’s anecdotal examples indicate that these costs are lower, our estimate is that States spend on average $25,000 per assessment to cover the costs of the on-site team members and related expenses. Using thirteen (13) as

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*The notice seeking public comment on the traffic records assessment advisory appears at 82 FR 49473, Oct. 25, 2017.*
the average number of assessments for impaired driving and occupant protection grants per year, the overall increase in cost would be $325,000. We have added this amount to the total estimated costs for the collection.

Estimate of the Total Annual Reporting and Recordkeeping Burden Resulting from the Collection of Information:

(1) Estimated Number of Respondents

The estimated burden hours for the grant application and annual report part of the collection of information are based on all eligible respondents each year for each of the grants:
- Section 402 grants: 57 (fifty States, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, and the Bureau of Indian Affairs);
- Section 405 Grants (except Impaired Driving Countermeasures, Motorcyclist Safety and Nonmotorized Grants) and Section 1906 Grant: 56 (fifty States, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands); and
- Section 405, Impaired Driving Countermeasures, Motorcyclist Safety and Nonmotorized Grants: 52 (fifty States, the District of Columbia, and Puerto Rico).

The estimated burden hours for the assessment part of the collection of information are based on the average number of State assessments that are carried out each year in each of the covered grant areas:
- Section 405, Occupant protection grants: 9 assessments;
- Section 405, Traffic safety information system improvement grants: 11 assessments; and
- Section 405, Impaired driving countermeasure grants: 4 assessments.

(2) Estimated Hours per Respondent

- Section 402 and 405 Grant Applications/Annual Report: 420
- Occupant Protection Grant Assessments: 80
- Traffic Safety Information System Improvement Grant Assessments: 165
- Impaired Driving Countermeasures Grant Assessments: 80

(3) Estimated Annual Burden Hours: 26,615

Under the grant application and annual report requirements for Sections 402 and 405, we estimate that it will take each respondent approximately 420 hours to collect, review and submit the required information to NHTSA. For traffic safety information system improvement grants, we estimate that it will take 165 hours to respond to questions under the assessment. For occupant protection and impaired driving countermeasures grants, we estimate that it will take 80 hours to provide the required information and respond to questions under an assessment. Based on the above information, the estimated annual burden hours for all respondents are 26,615 hours.

Assuming the average salary of the individuals preparing the application materials or assessment responses is $50.00 per hour, the estimated cost for each respondent to respond is $23,350. If all eligible States applied for and received grants for all programs (and including the annual number of assessment responses required from States), the total labor costs for all respondents would be $1,330,750.

In addition to these labor costs, NHTSA is revising the total costs to include the assessment team costs paid for by States under occupant protection and impaired driving assessments. Annually, these additional costs are $25,000 per assessment, totaling $325,000 based on the average estimated number of assessments conducted each year for these programs. Based on these additional costs, the overall total cost is revised to be $1,655,750.


Issued in Washington, DC, on: February 14, 2018.

Mary D. Gunnels,
Associate Administrator for Regional Operations and Program Delivery.

BILLING CODE 4910–59–P
II. Public Participation and Request for Public Comments

On November 27, 2017, the DOT published a 30-day comment period notice in the Federal Register (82 FR 56116) seeking comment to reinstate previously approved information collection entitled “Barrier Failure Reporting in Oil and Gas Operations on the Outer Continental Shelf.” On March 30, 2017, BTS published a notice (82 FR 15787) encouraging interested parties to submit comments to docket number DOT–OST–2017-0043 and allowing for a 60-day comment period. DOT published both the 30 and 60-day notices using the wrong OMB Number, 2139–0046. The correct OMB Number is 2138–0046. Therefore, BTS is reissuing the 30-day notice and extending the comment period accordingly. Comments submitted during the first notice will be considered. To view comments, go to http://www.regulations.gov and insert the docket number, “DOT–OST–2017–0043” in the “Search” box and click “Search.” Next, click “Open Docket Folder” button and choose document listed to review. If you do not have access to the internet, you may view the docket by visiting the Docket Management Facility in Room W12–140 on the ground floor of the U.S. DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m. Monday through Friday, except Federal holidays.

Privacy Act

All comments the BTS received were posted without change to http://www.regulations.gov. Anyone may search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or of the person signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT’s complete Privacy Act Statement in the Federal Register published on January 17, 2008 (73 FR 3316), or you may visit https://www.gpo.gov/fdsys/pkg/FR-2017-03-30/pdf/2017-06272.pdf;

III. Discussion of Public Comments and BTS Responses

BTS announced on March 30, 2017 in a Federal Register Notice (82 FR 15788) its intention to request that OMB approve the following continuation of information collection: Barrier Failure Reporting in Oil and Gas Operations on the Outer Continental Shelf. BTS received no comments during the 60-day public comment period. The March 30th notice stated that the BTS was seeking to renew the previously approved collection. The 60-day notice referenced the wrong OMB Number, the correct number is 2138–0046. On November 27, 2017, the DOT published a 30-day comment period notice in the Federal Register (82 FR 56116) seeking comment to reinstate previously approved information collection entitled “Barrier Failure Reporting in Oil and Gas Operations on the Outer Continental Shelf,” also referencing the wrong OMB Number. Comments submitted in response to the November 27, 2017 notice will be considered along with comments to this notice.

The 30-day notice clarifies that BTS is seeking reinstatement of the expired collection and is requesting OMB to authorize the collection for three years. DOT is issuing a revised notice with the correct OMB Number and extending the comment period 30 days from the publication of the corrected notice.

Issued on: February 14, 2018.

Patricia Hu,
Director, Bureau of Transportation Statistics, Office of the Assistant Secretary for Research and Technology.
Electronic Availability

The list of Specially Designated Nationals and Blocked Persons (SDN List) and additional information concerning OFAC sanctions programs are available on OFAC’s website (http://www.treasury.gov/ofac).

Notice of OFAC Actions

On February 14, 2018, OFAC determined that the property and interests in property of the following persons are unblocked and removed from the SDN List under the relevant sanctions authority listed below.

Individuals

1. JIMENEZ URREGO, Jorge Enrique, Bogota, Colombia; DOB 13 Jan 1957; citizen Colombia; Cedula No. 7307324 (Colombia); Passport AK353217 (Colombia); alt. Passport AJ096613 (Colombia) [SDNTK].
2. YOUSSEF, Ziad Mohamad, Lebanon; DOB 22 Sep 1976; POB West Bekaa, Baaloul, Lebanon; nationality Lebanon; citizen Lebanon (individual) [SDNT].
3. YOUSSEF, Ismael Mohammed (a.k.a. YOUSSEF ABDALLAH, Ismael; a.k.a. YOUSSEF, Ismael Mohammad), Lebanon; DOB 12 Sep 1979; POB Santa Marta, Colombia; alt. POB Lebanon; nationality Lebanon; citizen Lebanon (individual) [SDNT].
4. BALLEN SOLANO, Manuel Humberto, Tulua, Valle, Colombia; DOB 22 Sep 1956; citizen Colombia; Cedula No. 19295921 (Colombia) [SDNT].
5. JIMENEZ URREGO, Carmen Rosa, c/o FINMESA DE COLOMBIA S.A., Bogota, Colombia; c/o C.I. STONES AND MARKET S.A., Colon, Panama; R.F.C. CGI0501197ST (Mexico) [SDNT].
6. CASA V, Av. Vallarta 3216, Col. Vallarta San Jorge, Guadalajara, Jalisco, Mexico; DOB 13 Mar 1964; POB Tepatitlan de Morelos, Jalisco, Mexico; R.F.C. SAGR640714–882 (Mexico); C.U.R.P. SAGR640714HCCNNB02 (Mexico) [individual] [SDNTK] (Linked To: GRUPO FRACSA, S.A. DE C.V.; Linked To: DBARDI, S.A. DE C.V.; Linked To: PISCILANEA, S.A. DE C.V.; Linked To: CARITATDE GRUPO INMOBILIARIO, S.A. DE C.V.).
7. PISCILANEA, S.A. DE C.V. (a.k.a. ALBERCAS Y TINAS BARCELONA), Tepatitlan de Morelos, Jalisco, Mexico; R.F.C. 44690, Mexico; C.U.R.P. PAPA751109HNEDSL04 (Mexico) [individual] [SDNTK] (Linked To: CASA V; Linked To: PAPA751109870 (Mexico); C.U.R.P. PAPA751109HNEZIDST04 (Mexico) [individual] [SDNTK] (Linked To: WAKED MONEY LAUNDERING [SDNT]).
8. BEDOYA VELEZ, Jose Roberto, c/o TECNICAR DIAGNOSTICENTRO S.A., Envigado, Colombia; Carrera 28 No. 16–85, Medellin, Antioquia, Colombia; nationality Colombia; citizen Colombia; Cedula No. 15256905 (Colombia); Passport AI406455 (Colombia) [individual] [SDNT].
9. PADRO PASTOR, Alvaro, DOB 09 Nov 1975; nationality Spain; R.F.C. PAPA751109HNEZIDST04 (Mexico) [individual] [SDNTK] (Linked To: CASA V; Linked To: PISCILANEA, S.A. DE C.V.).
10. SANCHEZ GONZALEZ, Ruben, Av. Arcos 960, Colonia Jardines del Bosque, Guadalajara, Jalisco, Mexico; DOB 14 Jul 1964; POB Tepatitlan de Morelos, Jalisco, Mexico; R.F.C. SAGR640714–882 (Mexico); C.U.R.P. SAGR640714HCCNNB02 (Mexico) [individual] [SDNTK] (Linked To: GRUPO FRACSA, S.A. DE C.V.; Linked To: DBARDI, S.A. DE C.V.; Linked To: PISCILANEA, S.A. DE C.V.; Linked To: CARITATDE GRUPO INMOBILIARIO, S.A. DE C.V.).

Entities

1. ZONA LIBRE INTERNATIONAL MARKET S.A., Colon, Panama; RUC # 66161–20–363386 (Panama) [individual] [SDNTK] (Linked To: CASA V; Linked To: PAPA751109HNEDSL04 (Mexico) [individual] [SDNTK].
2. C.I. STONES AND BYPRODUCTS TRADING S.A., Transversal 14 No. 119–67 Interior 4, Bogota, Colombia; NIT # 830003485–3 (Colombia) [SDNTK].
3. FINMESA DE COLOMBIA S.A., Transversal 14 No. 119–67 Interior 4, Oficina 203, Bogota, Colombia; NIT # 830129115–15 (Colombia) [SDNTK].
4. PROMOTORA DE MATERIAS PRIMAS ORGANICAS DEL TOLIMA LTDA, Bogota, Colombia; DOB 23 Aug 1965; citizen Colombia; Cedula No. 51788462 (Colombia); Passport A1822940 (Colombia) [individual] [SDNT].
5. GARALES LONDONO, Lina Maria, c/o AGRONILO S.A., Toro, Valle, Colombia; c/o HEBRON S.A., Tulua, Valle, Colombia; c/o HOTEL LOS VINEDOS, La Union, Valle, Colombia; c/o JOSAPAT S.A., Tulu, Valle, Colombia; c/o SALMA S.A., La Union, Valle, Colombia; c/o CITCAR LTDA., La Union, Valle, Colombia; c/o CONFECCIONES LINA MARIA LTDA., La Union, Valle, Colombia; c/o DOX A S.A., La Union, Valle, Colombia; c/o GBS TRADING S.A., Cali, Colombia; c/o L.G.R. E.U., Cali, Colombia; DOB 13 Mar 1979; POB Bogota, Colombia; Cedula No. 29567575 (Colombia) [individual] [SDNT].
6. CASTRO MONOTO, Norman Douglas; DOB 06 Jul 1962; citizen Panama; Passport 1871296 (Panama) [individual] [SDNTK] (Linked To: MAKED MONEY LAUNDERING ORGANIZATION).
7. BENZAYO VELEZ, Jose Roberto, c/o TECNICAR DIAGNOSTICENTRO S.A., Envigado, Colombia; Carrera 28 No. 16–85, Casas 12, Medellin, Antioquia, Colombia; DOB 10 Oct 1960; POB Medellin, Antioquia, Colombia; nationality Colombia; citizen Colombia; Cedula No. 15256905 (Colombia); Passport AI406455 (Colombia) [individual] [SDNT].

SUMMARY: The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning Form 982, Reduction of Tax Attributes Due to Discharge of Indebtedness.

DATES: Written comments should be received on or before April 23, 2018 to be assured of consideration.

ADDRESSES: Direct all written comments to L. Brimmer, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Lanita Van Dyke, at (202) 317–6009, or at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet at Lanita.VanDyke@irs.gov.

SUPPLEMENTARY INFORMATION: Title: Reduction of Tax Attributes Due to Discharge of Indebtedness.

OMB Number: 1545–0046. Form Number: 982. Abstract: Reduction of Tax Attributes Due to Discharge of Indebtedness. Internal Revenue Code (IRC) section 108 allows taxpayers to exclude from gross income amounts attributable to discharge of indebtedness in title 11 cases, insolvency or a qualified farm indebtedness. Section 108(b) allows corporations to exclude from gross income amounts attributable to certain transfers of property. The data is used to verify adjustments to basis of property and reduction of tax attributes. Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension without change of a currently approved collection.

AFFECTED PUBLIC: Individuals or households, Businesses or other for profit, Small businesses or organizations

Estimated Number of Respondents: 667.

Estimated Time per Respondent: 11.23 hrs.

Estimated Total Annual Burden Hours: 7491.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number.
Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency’s estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: February 14, 2018.

L. Brimmer,
Senior Tax Analyst.

[FR Doc. 2016–03488 Filed 2–20–18; 8:45 am]
BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY
Internal Revenue Service

Proposed Information Collection; Comment Request

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments should be received on or before April 23, 2018 to be assured of consideration.

ADDRESSES: Direct all written comments to L. Brimmer, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224. Please send separate comments for each specific information collection listed below. You must reference the information collection’s title, form number, reporting or record-keeping requirement number, and OMB number (if any) in your comment.

FOR FURTHER INFORMATION CONTACT: Requests for additional information, or copies of the information collection and instructions, or copies of any comments received, contact Elaine Christophe, at (202) 317–5745, or at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet, at Elaine.H.Christophe@irs.gov.

SUPPLEMENTARY INFORMATION:

1. Title: Procedural Rules for Excise Taxes Currently Reportable on Form 720.

OMB Number: 1545–1296.

Regulation Project Number: PS–27–91 and PS–8–96 (Final (T.D. 8442)).

Abstract: Internal Revenue Code section 6302(c) authorizes the use of Government depositaries for the receipt of taxes imposed under the internal revenue laws. These final regulations provide reporting and recordkeeping requirements related to return, payments, and deposits of tax for excise taxes currently reportable on Form 720, including special rules for use of Government depositaries under chapter 33 of the Internal Revenue Code.

Existing procedural regulations under 26 CFR parts 43, 46, 48, 49, and 52 are amended and consolidated in a new part 40. These regulations also reflect changes to the law made by the Omnibus Budget Reconciliation Acts of 1989 and 1990. The regulations affect persons required to report liability for excise taxes currently reportable on Form 720.

Current Actions: There are no changes being made to these existing regulations.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 10,500.

Estimated Time per Respondent: 23 hours, 5 minutes.

Estimated Total Annual Burden: 242,350.

2. Title: Limitation on Passive Activity Losses and Credits-Treatment of Self-Charged Items of Income and Expense.

OMB Number: 1545–1244.

Regulation Project Number: (T.D. 9013)

Abstract: Section 1.469–7(f)(1) of this regulation permits entities to elect to avoid application of the regulation in the event the pass-through entity chooses to not have the income from leading transactions with owners of interests in the entity re-characterized as passive activity gross income. The IRS will use this information to determine whether the entity has made a proper timely election and to determine that taxpayers are complying with the election in the taxable year of the election and subsequent taxable years.

Current Actions: There is no change to this existing regulation.

Type of Review: Extension of currently approved collection.

Affected Public: Individuals and business or other for-profit organizations.

Estimated Number of Respondents: 1,000.

Estimated Time per Respondent: 6 minutes.

Estimated Total Annual Burden Hours: 100.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in our request for Office of Management and Budget (OMB) approval of the relevant information collection. All comments will become a matter of public record. Please do not include any confidential or inappropriate material in your comments.

We invite comments on: (a) Whether the collection of information is necessary for the proper performance of the agency’s functions, including whether the information has practical utility; (b) the accuracy of the agency’s estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

The IRS is seeking comments concerning the following forms, and reporting and record-keeping requirements:
DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel's Toll-Free Phone Line Project Committee; Change

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting; change.

SUMMARY: In the Federal Register notice that was originally published on January 18, 2018, the meeting date has changed.

DATES: The meeting will be held Thursday, March 22, 2018 and Friday, March 23, 2018.


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 Thursday, March 22, 2018, from 8:00 a.m. to 5:00 p.m. Eastern Time and Friday, March 23, 2018, from 8:00 a.m. until 12:00 p.m. Eastern Time at the IRS Office, Jacksonville, Florida. The public is invited to make oral comments or submit written statements for consideration. Due to limited time and structure of meeting, notification of intent to participate must be made with Rosalind Matherne. For more information please contact Rosalind Matherne at 1–888–912–1227 or 202–317–4115.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel’s Notices and Correspondence Project Committee; Change

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting; change.

SUMMARY: In the Federal Register notice that was originally published on January 18, 2018, the meeting date has changed.

DATES: The meeting will be held Monday, March 19, 2018 and Friday, March 20, 2018.


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 Monday, March 19, 2018, from 1:00 p.m. to 5:00 p.m. Eastern Time and Tuesday, March 20, 2018, from 8:00 a.m. until 5:00 p.m. Eastern Time at the IRS Office, Jacksonvile, Florida. The public is invited to make oral comments or submit written statements for consideration. Due to limited time and structure of meeting, notification of intent to participate must be made with Otis Simpson. For more information please contact Otis Simpson at 1–888–912–1227 or 202–317–3332 or write TAP Office, 1111 Constitution Ave. NW, Room 1509, Washington, DC 20224 or contact us at the website: http://www.improveirs.org. The agenda will include various IRS issues.


Antoinette Ross,
Acting Director, Taxpayer Advocacy Panel.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel's Toll-Free Phone Line Project Committee; Change

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting; change.

SUMMARY: In the Federal Register notice that was originally published on January 18, 2018, the meeting date has changed. The date of the meeting is: Monday, March 19, 2018 and Friday March 20, 2018.

DATES: The meeting will be held Monday, March 19, 2018 and Tuesday, March 20, 2018.


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 Toll-Free Phone Line Project Committee will be held Thursday, March 22, 2018, from 8:00 a.m. to 5:00 p.m. Mountain Time and Friday, March 23, 2018, from 8:00 a.m. until 12:00 p.m. Mountain Time at the IRS Office, Albuquerque, New Mexico. The public is invited to make oral comments or submit written statements for consideration. Due to limited time and structure of meeting, notification of intent to participate must be made with Robert Rosalia. For more information please contact Robert Rosalia 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 a meeting of the Taxpayer Advocacy Panel's Tax Forms and Publications Project Committee will be held Thursday, March 22, 2018 and Friday, March 23, 2018.


DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel’s Notices and Correspondence Project Committee; Change

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting; change.

SUMMARY: In the Federal Register notice that was originally published on January 18, 2018, the meeting date has changed. The date of the meeting is: Monday, March 19, 2018 and Friday March 20, 2018.

DATES: The meeting will be held Monday, March 19, 2018 and Tuesday, March 20, 2018.


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’s Taxpayer Communications Project Committee will be held Monday, March 19, 2018, from 1:00 p.m. to 5:00 p.m. Mountain Time and Tuesday, March 20, 2018, from 8:00 a.m. until 5:00 p.m. Mountain Time at the IRS Office in Albuquerque, New Mexico. The public is invited to make oral comments or submit written statements for consideration. Due to limited time and structure of meeting, notification of intent to participate must be made with Antoinette Ross. For more information please contact Antoinette Ross at 1–888–912–1227 or 202–317–4110, or write TAP Office, 1111 Constitution Ave. NW, Room 1509, Washington, DC 20224.


Antoinette Ross,
Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2018–03478 Filed 2–20–18; 8:45 am]
BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel’s Special Projects Committee; Change

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting; change.

SUMMARY: In the Federal Register notice that was originally published on January 18, 2018, (83 FR 2725) the meeting date has changed. The date of the meeting is: Monday, March 19, 2018 and Friday, March 20, 2018.

DATES: The meeting will be held Monday, March 19, 2018 and Tuesday, March 20, 2018.

FOR FURTHER INFORMATION CONTACT: Matthew O’Sullivan at 1–888–912–1227 or (510) 907–5274.

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’s Special Projects Committee will be held Monday, March 19, 2018, from 1:00 p.m. to 5:00 p.m. Central Time and Tuesday, March 20, 2018, from 8:00 a.m. until 5:00 p.m. Central Time at the IRS Office in Dallas, Texas. The public is invited to make oral comments or submit written statements for consideration. Due to limited time and structure of meeting, notification of intent to participate must be made with Matthew O’Sullivan. For more information please contact Matthew O’Sullivan at 1–888–912–1227 or (510) 907–5274, or write TAP Office, 1301 Clay Street, Oakland, CA 94612–5217 or contact us at the website: http://www.improveirs.org. The agenda will include various IRS issues.


Antoinette Ross,
Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2018–03481 Filed 2–20–18; 8:45 am]
BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel’s Notices and Correspondence Project Committee; Change

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting; change.

SUMMARY: In the Federal Register notice that was originally published on January 18, 2018, the meeting date has changed.

DATES: The meeting will be held Monday, March 19, 2018 and Tuesday, March 20, 2018.


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 Monday, March 19, 2018, from 1:00 p.m. to 5:00 p.m. Eastern Time and Tuesday, March 20, 2018, from 8:00 a.m. until 5:00 p.m. Eastern Time at the IRS Office, Jacksonville, Florida. The public is invited to make oral comments or submit written statements for consideration. Due to limited time and structure of meeting, notification of intent to participate must be made with Otis Simpson. For more information please contact Otis Simpson at 1–888–912–1227 or 202–317–3332, or write TAP Office, 1111 Constitution Ave. NW, Room 1509, Washington, DC 20224 or contact us at the website: http://www.improveirs.org. The agenda will include various IRS issues.


Antoinette Ross,
Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2018–03480 Filed 2–20–18; 8:45 am]
BILLING CODE 4830–01–P
Environmental Protection Agency

40 CFR Part 320
Financial Responsibility Requirements Under CERCLA Section 108(b) for Classes of Facilities in the Hardrock Mining Industry; Final Rule
ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 320

[40 CFR Part 320]

SUPPLEMENTARY INFORMATION:

FOR FURTHER INFORMATION CONTACT:

K. Executive Order 12898: Federal Actions

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D. Regulatory Flexibility Act

C. Paperwork Reduction Act

B. Executive Order 13771: Reducing

A. Executive Order 12866: Regulatory

III. Background Information

II. Authority

I. Executive Summary

A. Overview

EPA is announcing its decision on its proposed regulations for financial responsibility requirements applicable to hardrock mining facilities that were published on January 11, 2017. This decision is based on the record for this rulemaking. This final rulemaking is the Agency’s final action on the proposed rule.

DATES: This final action is effective on March 23, 2018.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–HQ–SFUND–2015–0781. All documents in the docket are listed on the https://www.regulations.gov website. Although listed in the index, some information is not publicly available, e.g., 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 electronically through https://www.regulations.gov.

FOR FURTHER INFORMATION CONTACT:

Office of Resource Conservation and Recovery, Mail Code 5303P, Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; Barbara Foster, (703) 308–7057, Foster.Barbara@epa.gov; or Michael Pease, (703) 308–0008, Pease.Michael@epa.gov.

SUPPLEMENTARY INFORMATION:

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1. Overall Concerns Regarding Cost and Economic Impact

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A. Overview

EPA is announcing its decision on its proposed regulations for financial responsibility requirements applicable to hardrock mining facilities that were published on January 11, 2017. EPA has decided not to issue final regulations because the Agency has determined that final regulations are not appropriate. This decision is based on EPA’s interpretation of the statute and analysis of its record developed for this rulemaking. EPA has analyzed the need for financial responsibility based on risk of taxpayer funded cleanups at hardrock mining facilities operating under modern management practices and modern environmental regulations, i.e., the type of facilities to which financial responsibility regulations would apply. That risk is identified by examining the management of hazardous substances at such facilities, as well as by examining federal and state regulatory controls on that management and federal and state financial responsibility requirements.

With that focus, the record demonstrates that, in the context of CERCLA section 108(b), the degree and duration of risk associated with the modern production, transportation, treatment, storage or disposal of hazardous substances by the hardrock mining industry does not present a level of risk of taxpayer funded response actions that warrant imposition of financial responsibility requirements for this sector. This determination reflects EPA’s interpretation of the statute, EPA’s evaluation of the record for the proposed rule, and the public comment received by EPA.
The decision not to issue final regulations will address the concerns of those federal and state regulators and members of the regulated community who commented that the proposed requirements were unnecessary and would, therefore, impose an undue burden on the regulated community. This decision will provide assurance to state regulators who were concerned that the proposed requirements would be disruptive of state mining programs. This decision also will address the information provided by the insurance industry regarding the lack of availability of financial instruments that meet the requirements of section 108(c)(2). This decision is based on the record for this rulemaking, and does not affect the process for site-specific risk determinations, or determinations of the need for a particular CERCLA response, at individual sites, nor does this decision affect EPA’s authority to take appropriate CERCLA response actions. Decisions on risk under other environmental statutes would continue under those statutes. This final rulemaking is the Agency’s final action on the proposed rule.

B. Purpose of the Regulatory Action

Section 108(b) of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), also known as Superfund, directs EPA to develop regulations that require classes of facilities to establish and maintain evidence of financial responsibility consistent with the degree and duration of risk associated with the production, transportation, treatment, storage, or disposal of hazardous substances. The statute further requires that the level of financial responsibility be established to protect against the level of risk that the President, in his discretion, believes is appropriate, based on factors including the payment experience of the Fund. The President’s authority under this section for non-transportation-related facilities has been delegated to the EPA Administrator.1

In a Federal Register notice dated July 28, 2009,2 EPA identified the classes of facilities within hardrock mining as those for which it would first develop financial responsibility requirements based on consideration of many factors, including factors unrelated to modern facilities, such as legacy contamination, and factors not demonstrating risk, in and of themselves, such as Toxic Release Inventory (TRI) reports under Superfund Amendments and Reauthorization Act of 1986 (SARA) section 313.

On January 11, 2017, the Agency published proposed financial responsibility requirements applicable to hardrock mining facilities.3 The proposal identified two goals for section 108(b) regulations—the goal of providing funds to address CERCLA liabilities at sites, and the goal of creating incentives for sound practices that will minimize the likelihood of need for a future CERCLA response. As discussed below, EPA now believes that these goals have been met for the hardrock mining classes of facilities. The proposal identified for public comment a range of options and supporting information, as described in the proposed rule preamble.4 The proposed rule set forth, in proposed 40 CFR part 320, subparts A through C, requirements for a comprehensive financial responsibility program under section 108(b) that would be applicable to hardrock mining facilities as well as to future industry sectors for which requirements under section 108(b) are later developed. In addition, the proposed rule set forth, in proposed part 320, subpart H, requirements specifically applicable to hardrock mining facilities.

EPA provided information and analysis demonstrating releases and potential releases of hazardous substances at hardrock mining facilities. EPA also discussed the relationship of section 108(b) to other federal law and to state law.5 EPA, however, despite making a commitment to do so in the notice entitled “Identification of Priority Classes of Facilities for Development of CERCLA Section 108(b) Financial Responsibility Requirements” (2009 Priority Notice), published on July 28, 2009, in the development of the proposed rule the Agency did not consider other federal and state programs when determining the need for section 108(b) regulations.6 Instead, the proposed rule would have considered other programs only after financial responsibility requirements are imposed, as a means to reduce such requirements. EPA now believes that it is appropriate to consider such programs at the outset, when evaluating both the degree and duration of risk associated with the production, transportation, treatment, storage, or disposal of hazardous substances as well as when evaluating the risk of taxpayer financed response costs. EPA’s final action on the proposed rule is a decision not to promulgate it.7

As explained below, EPA has reconsidered whether the rulemaking record supports the proposed rule in light of the Agency’s interpretation of the statute, the Agency’s evaluation of the record, and the information and data received through public comment. As a result of this reconsideration, EPA has determined that the rulemaking record it assembled does not support imposing financial responsibility requirements under section 108(b) on current hardrock mining operations. This determination is based on information in the record on the degree and duration of risk posed by modern production, transportation, treatment, storage or disposal of hazardous substances at mining sites operating under modern regulations that demonstrates that financial responsibility requirements are not necessary to address the risk of taxpayer financed response actions at hardrock mines. EPA has reconsidered its assessment of the risks posed by hardrock mining operations presented in the proposed rule, and determined that that assessment did not adequately consider the degree to which existing federal and state regulatory programs and improved mining practices at modern mines reduce the risk that there would be unfunded response liabilities at currently operating mines.

Furthermore, EPA notes that even under the analysis in the proposed rule, the

1 See E.O. 12580, 52 FR 2923 (January 23, 1987).
3 For purposes of this final rulemaking, EPA includes within the term “hardrock mining” the facilities included in the definition of that term developed for purposes of the Priority Notice, that is, facilities that extract, beneficiate, or process metals (e.g., copper, gold, iron, lead, magnesium, molybdenum, silver, uranium, and zinc), and non-metallic non-fuel minerals (e.g., asbestos, gypsum, phosphate rock, and sulfur).
5 See 82 FR 3388, January 11, 2017.
6 82 FR 3402–03 (concluding that section 108(b) applies even when a facility is subject to financial responsibility requirements under federal law).
7 74 FR 37219 and n. 50.
8 EPA has made editorial changes to this document from the prepublication version, including replacing various references to the action being a “final rule,” in accordance with the Office of the Federal Register’s (OFR) interpretations of its implementing regulations (1 CFR 5.9 and parts 21 and 22), the Federal Register Act (44 U.S.C. chapter 15) and Document Drafting Handbook. OFR regulations, however, expressly disclaim a legal effect from these publication requirements. “In prescribing regulations governing headings, preambles, effective dates, authority citations, and similar matters of form, the Administrative Committee does not intend to affect the validity of any document that is filed and published under law.” 1 CFR 5.1(c). Accordingly, these editorial changes do not affect the legal status of the action as a final regulation under CERCLA.
projected level of risk of EPA-funded response actions was relatively low ($15 to $15.5 million per year), and was significantly less than the projected cost to industry of providing the additional financial responsibility that would have been required by the proposed rule ($111–$171 million per year).

The Agency’s decision that a section 108(b) rule for the hardrock mining industry is not appropriate relies on the record developed for this rulemaking as well as information submitted by commenters on three key points, which in combination demonstrate significantly reduced risk at current hardrock mining operations: (1) The reduction in risks due to the requirements of existing federal and state mining programs and voluntary protective practices of current hardrock mining owners and operators, (2) the reduced costs to the taxpayer resulting from effective hardrock mining programs, enforcement actions, and owner or operator responses, including financial assurance requirements pursuant to these other programs, and (3) the resulting reduction in the risk of the need for federally financed response actions at hardrock mines. The record thus evaluated also supports EPA’s determination that federal and state regulation and practices at modern facilities reduce the risks posed by operating facilities and, therefore, the imposition of section 108(b) financial responsibility requirements is not appropriate. This determination also addresses concerns regarding disruption and duplication of state and federal financial responsibility requirements, the difficulty in tailoring financial responsibility to a specific level of risk, as well as concerns raised by the financial industry regarding challenges in providing financial instruments that meet the requirements of the statute and the proposed rule. As discussed below, the proposed rule created the potential for the preemption of state financial responsibility requirements. In addition, EPA acknowledges that the formula through which EPA had proposed to determine the level of financial assurance relied on information unrelated to risks of taxpayer financed costs posed by the current facilities to which the proposed rule would apply. Finally, as discussed below, members of the financial industry commented that section 108(c)(2), which allows direct claims against a guarantor providing evidence of financial responsibility, is at odds with relevant commercial law and practice and would significantly deter the financial industry from providing such instruments and services.

This final rulemaking does not affect, limit, or restrict EPA’s authority to take a response action or enforcement action under CERCLA at any individual hardrock mining facility, including the currently operating facilities described elsewhere in this final rulemaking and in the Technical Support Document for this final rulemaking, and to include requirements for financial responsibility as part of such response action. The set of facts in the rulemaking record related to the individual facilities discussed in this final rulemaking support the Agency’s decision not to issue financial responsibility requirements under section 108(b) for currently operating hardrock mining facilities as a class, but a different set of facts could demonstrate a need for a CERCLA response at those sites. This final rulemaking also does not affect the Agency’s authority under other authorities that may apply at hardrock mining facilities, such as the Clean Water Act (CWA), the Resource Conservation and Recovery Act (RCRA), the Clean Air Act (CAA), and the National Environmental Policy Act (NEPA).

C. Summary of the Major Provisions of the Regulatory Action

EPA is not requiring evidence of financial responsibility under section 108(b) at hardrock mining facilities in this action. Thus, there are no regulatory provisions associated with this final action.

D. Costs and Benefits of the Regulatory Action

The Regulatory Impact Analysis for the proposed rule demonstrated that the projected level of taxpayer liability that would have been avoided by the proposed rule was relatively small, and that the costs of meeting the proposed financial responsibility requirements were an order of magnitude greater than the costs avoided by the federal government as a result of such requirements. EPA is not requiring evidence of financial responsibility under section 108(b) at hardrock mining facilities in this action. EPA therefore has not conducted a Regulatory Impact Analysis for this action.

II. Authority


III. Background Information

A. Overview of Section 108(b) and Other CERCLA Provisions

CERCLA, as amended by the Superfund Amendments and Reauthorization Act of 1986 (SARA), establishes a comprehensive environmental response and cleanup program. Generally, CERCLA authorizes EPA to undertake removal or remedial actions in response to any release or threatened release into the environment of “hazardous substances” or, in some circumstances, any other “pollutant or contaminant.” As defined in CERCLA section 101, remedial actions include actions to “prevent, minimize, or mitigate damage to the public health or welfare or to the environment,” and remedial actions are “actions consistent with [a] permanent remedy[,]” Remedial and removal actions are jointly referred to as “response actions.” CERCLA section 111 authorizes the use of the Superfund Trust Fund (the Fund) established under title 26, United States Code, including financing response actions undertaken by EPA. In addition, CERCLA section 108(c) gives EPA authority to compel action by liable parties in response to a release or threatened release of a hazardous substance that may pose an “imminent and substantial endangerment” to public health or welfare or the environment.

CERCLA section 107 imposes liability for response costs on a variety of parties, including certain past owners and operators, current owners and operators, and certain transporters of hazardous substances. Such parties are liable for any costs of removal or remedial action incurred by the federal government, so long as the costs incurred are “not inconsistent with the national contingency plan.” (NCP). Section 107 also imposes liability for natural resource damages and health assessment costs. As has been the case since

10 Although Congress conferred the authority for administering CERCLA on the President, most of that authority has since been delegated to EPA. See Exec. Order No. 12580, 52 FR 2923 (Jan. 23, 1987). The executive order also delegates to other federal agencies specified CERCLA response authorities at certain facilities under their jurisdiction, custody or control.” This can include CERCLA authorities at mines located on federal lands under the jurisdiction of BLM and the Forest Service.

11 CERCLA sections 100 and 122 authority is also delegated to other federal agencies in certain circumstances. See Exec. Order No. 13016, 61 FR 45871 (Aug. 28, 1996).

12 See CERCLA section 107 (a)(4)(A).

13 See CERCLA section 107 (a)(4)(C)(i)(D).

CERCLA’s enactment, these provisions of CERCLA are available according to their terms, to the federal government and other parties, regardless of whether an owner or operator has provided evidence of financial responsibility under section 108(b).

In accordance with CERCLA, in 1990 EPA issued the current version of the NCP. These regulations provide the organizational structure and procedures for preparing for, and responding to, discharges of oil and releases of hazardous substances, pollutants, and contaminants. The NCP is codified at 40 CFR part 300. Among other provisions, the NCP provides procedures for hazardous substance response including site evaluation, removal actions, remedial investigation/feasibility studies (RI/FS), remedy selection, remedial design/remedial action (RD/RA), and operation and maintenance. The NCP also designates federal, state, and tribal trustees for natural resource damages, and identifies their responsibilities under the NCP. Under the NCP, EPA undertakes response actions that address or prevent risk to human health and the environment from the release of hazardous substances, pollutants or contaminants. A determination whether a release of hazardous substances, pollutants or contaminants presents a risk to be addressed under other sections of CERCLA or under other law is a separate determination from whether under section 108(b) risk associated with the management of hazardous substances at current hardrock mining operations warrants imposition of financial responsibility requirements. Nothing in this final action restricts EPA’s other authorities. The Agency’s decision not to issue final regulations under section 108(b) applicable to hardrock mining facilities does not change or substitute for EPA’s procedures for site-specific evaluations of risk, and for determining the need for response, in accordance with the NCP.

Section 108(b) establishes an authority to require owners and operators of facilities to establish and maintain evidence of financial responsibility. Section 108(b)(1) directs EPA to develop regulations requiring owners and operators of facilities (in addition to those under Subtitle C of the Solid Waste Disposal Act and other federal law) to establish evidence of financial responsibility “consistent with the degree and duration of risk associated with the production, transportation, treatment, storage, or disposal of hazardous substances.” In turn, section 108(b)(2) directs that the level of financial responsibility shall be initially established, and, when necessary, adjusted to protect against the level of risk that EPA in its discretion believes is appropriate based on the payment experience of the Fund, commercial insurers, courts settlements and judgments, and voluntary claims satisfaction. Section 108(b)(2) does not, however, preclude EPA from considering other factors in addition. The statute prohibited promulgation of such regulations before December 1985.

In addition, section 108(b)(1) provides for publication within three years of the date of enactment of CERCLA of a “priority notice” identifying the classes of facilities for which EPA would first develop financial responsibility requirements. It also directs that priority in the development of requirements shall be accorded to those classes of facilities, owners, and operators that present the highest level of risk of injury.

B. History of This Rulemaking

In November 2003, EPA initiated a study of the Superfund program, commonly referred to as the “120 Day Study.” This “120 Day Study” resulted in more than 100 recommendations. In 2005, EPA initiated an Action Plan for implementing the recommendations of the 120-Day Study of the Superfund Program. Under that plan, EPA conducted an analysis to determine whether action 108(b) was appropriate (Recommendation 12). This analysis resulted in two detailed studies specifically designed to help identify classes of facilities for priority consideration under section 108(b), carried out from 2006 through 2008. The report of these studies, labeled “draft” and dated February 2009, are titled: “CERCLA 108(b) Financial Responsibility, Phase 1: Preliminary Analysis” (hereinafter Phase 1 Report) and “CERCLA 108(b) Financial Responsibility, Phase 2 Preliminary Analysis” (hereinafter Phase 2 Report). Another analysis, referred to as the 40 TSD Study, also recommended by the 120-Day Study (Recommendations 10 and 11), on the sufficiency of financial assurance requirements imposed on hazardous waste treatment, storage, and disposal (TSD) facilities regulated under RCRA also provides relevant information.

In the Phase 1 and Phase 2 analyses, EPA interpreted the financial responsibility requirements of section 108(b) to apply to currently operating facilities and current or future risks. Accordingly, in the analyses performed from 2006 through 2008, the Agency attempted to exclude historic practices and legacy contamination resulting from such practices by using 1990 as a date to distinguish between modern and legacy practices. The Agency stated that it used 1990 because by that date most of the regulations under RCRA relating to management of hazardous waste had been promulgated. This approach was consistent with the 40 TSD study, which excluded facilities proposed to the National Priorities List (NPL) before 1990 to exclude facilities with legacy contamination that predated the RCRA hazardous waste regulatory program. However, because EPA determined in 1986 under section 3001(b)(3)(C) of RCRA that solid waste from the extraction and beneficiation of ores and minerals do not present sufficient risk to warrant regulation under subtitle C of RCRA, 1990 is not a precise date for the advent of modern regulation of mining. As discussed below, commenters noted that state and federal mining regulations developed over a period of time. For mining regulated under state law, commenters suggest the mid-1990s represent the advent of modern mining regulation.

In 2009, the Agency changed its interpretation of the statute. A July 2, 2009, memorandum attached to the Phase 1 and Phase 2 reports states that EPA decided that the reports were deficient because they excluded sites listed on the NPL before 1990. Accordingly, EPA did not finalize the reports and did not proceed to an analysis of the federal and state regulatory requirements and the modern practices of any specific industry sector. Instead, in a Federal Register notice dated July 28, 2009, EPA identified certain classes of facilities within the hardrock mining sector as the classes for which it would first develop financial responsibility requirements.

14 See 55 FR 8666, March 8, 1990.
15 See 40 CFR part 300, subpart E.
16 See 40 CFR part 300, subpart G.
20 See 51 FR 24,496 (July 3, 1986).
21 State mining laws are discussed below.
EPA based that identification on consideration of many factors, including factors unrelated to risk posed by the production, transportation, treatment, storage, and disposal of hazardous substances at facilities that would be regulated under the proposed rule, such as legacy contamination, and non-risk based information, such as Toxic Release Inventory reports under SARA section 313. This notice represented a substantial departure from previous EPA interpretation of the statute to exclude legacy activities when determining the need for financial responsibility requirements under section 108(b).24

In the 2009 Priority Notice, EPA identified hardrock mining facilities as a priority without considering the impacts of modern federal and state regulations. Instead, EPA stated: “EPA will carefully examine specific activities, processes, and/or metals and minerals in order to determine what proposed financial responsibility requirements may be appropriate. As part of this process, EPA will conduct a close examination and review of existing Federal and State authorities, policies, and practices that currently focus on hardrock mining activities.” 25

On January 11, 2017, the Agency published proposed financial responsibility requirements applicable to hardrock mining facilities.26 The proposed rule adopted two goals for section 108(b) regulations—to provide funds to address CERCLA liabilities at sites, and to create incentives for sound practices that will minimize the likelihood of need for a future CERCLA response. The proposal identified for public comment a range of options and supporting analysis, as described in the proposed rule preamble. The proposed rule set forth, in proposed part 320, subparts A through C, requirements for a comprehensive financial responsibility program under section 108(b) that would be applicable to hardrock mining facilities, as well as to future industry sectors for which requirements under section 108(b) are later developed. In addition, the proposed rule set forth, in proposed part 320, subpart H, requirements specifically applicable to hardrock mining facilities.

The proposed rule provided information and analyses on releases and potential releases of hazardous substances at hardrock mining facilities. The proposed rule identified several classes of hardrock mining facilities that were excluded from the financial responsibility requirements because they involved a lower risk, and sought comment on whether additional classes should be excluded from the scope of a final rule.27 The proposed rule also discussed the relationship of section 108(b) to other federal law and to state law.28 However, contrary to the commitment made in the 2009 Priority Notice, the proposed rule did not consider reductions in risk as a result of such laws when determining the need for financial responsibility requirements. Instead, the proposed rule would have established such requirements at a level based on the activities already covered by reclamation bonds as well as the cost of cleaning up historic mining sites and then, based on information provided by the facility, would have allowed reductions in the amount of financial responsibility.29 or release from the requirement for financial responsibility entirely.30

EPA received over 11,000 public comment submissions on the proposed rule. Other federal agencies, state agencies, and industry representatives overwhelmingly opposed financial responsibility requirements under section 108(b) for the hardrock mining industry. Environmental groups urged adoption of the proposed rule. EPA also received a large number of identical comments from individuals through multiple letter-writing campaigns, advocating both for and against adoption of the rule. Among other concerns, commenters objecting to the proposed rule expressed the view that the Agency’s assessment of the information relating to risks posed by hardrock mining operations as presented in the proposed rule was deficient because the Agency: (1) Rely on inappropriate evidence, such as data that did not demonstrate risk, and evidence not relevant to the facilities to be regulated under the rule; and (2) failed to consider relevant evidence, such as the role of federal and state mining programs and voluntary protective mining practices in reducing risks at current32 hardrock mining operations, and the reduced costs to the taxpayer resulting from effective hardrock mining programs, including existing financial responsibility requirements, and owner or operator responses.

EPA has considerable discretion under the statute and, as explained below, has reconsidered whether the making rule supports the proposed rule in light of EPA’s interpretation of the statute, review of the record, and the information and data received through public comment. As a result, EPA has determined that the assessment of the information relating to risks posed by hardrock mining operations as presented in the proposed rule was not supported by the record. This reassessment relies on the information in the record on three key points: (1) The reduction in risks due to the requirements of existing federal and state mining programs and protective practices of current hardrock mining owners and operators, (2) the reduced costs to the taxpayer resulting from effective hardrock mining programs, including existing financial responsibility requirements, and owner or operator responses, and (3) the resulting reduction in the risk of the need for federally financed response actions at hardrock mines.

C. Recent Litigation Under Section 108(b)

On March 11, 2008, Sierra Club, Great Basin Resource Watch, Amigos Bravos, and Idaho Conservation League filed a suit against then EPA Administrator Steven Johnson and then Secretary of the U.S. Department of Transportation Mary E. Peters, in the U.S. District Court for the Northern District of California. Sierra Club, et al. v. Johnson, No. 08–01409 (N.D. Cal.). On February 25, 2009, that court ordered EPA to publish the Priority Notice required by section 108(b)(1) later that year. The court later dismissed the remaining claims.32 EPA continued to work on a proposed rule for the next several years. However, developing a regulation that meets the statutory requirements presented a significant challenge.33 Dissatisfied with the pace of EPA’s progress, in August 2014, the Idaho Conservation League, Earthworks, Sierra Club, Amigos Bravos,

25 74 FR 37219.
26 82 FR 3388 (January 11, 2017).
27 82 FR 3456–59; Hoffman Memo, “Mining Classes Not Included in Identified Classes of Hardrock Mining,” June 2009. See 82 FR 3455 n. 145. See exclusions from the rule at proposed 40 CFR 320.60(a)(2). EPA solicited comments on whether to identify additional exclusions based on a finding of minimal risk, citing iron ore phosphates and uranium mines as examples. 82 FR 3456.
28 82 FR 3402–03.
30 Proposed 40 CFR 320.27.
Great Basin Resource Watch, and Communities for a Better Environment filed a new lawsuit in the U.S. Court of Appeals for the District of Columbia Circuit, seeking a writ of mandamus requiring issuance of section 108(b) financial responsibility rules for the hardrock mining industry and for three other industries—chemical manufacturing; petroleum and coal products manufacturing; and electric power generation, transmission, and distribution. Companies and organizations representing business interests in the hardrock mining and other sectors also sought to intervene in the case.

Following oral argument, the court issued an Order in May 2015 requiring the parties to submit, among other things, supplemental submissions addressing a schedule for further administrative proceedings under section 108(b). The Court’s May 19, 2015 Order encouraged the parties to confer regarding a schedule and, if possible, to submit a jointly agreed upon proposal. Petitioners and EPA agreed to a schedule calling for the Agency to sign for publication in the Federal Register a proposed rule for the hardrock mining industry by December 1, 2016, and a notice of its final action on the proposal by December 1, 2017. The parties submitted this schedule to the court, and on January 29, 2016, the court granted the parties’ joint motion and issued an order that mirrored the submitted schedule in substance. With this action the Agency has now satisfied both of these obligations.

D. Hardrock Mining Priority Notice

As described above, section 108(b)(1) requires the President to identify those classes of facilities for which requirements will be first developed and to publish notice of such identification in the Federal Register. On July 28, 2009, EPA issued a “Priority Notice” entitled “Identification of Priority Classes of Facilities for Development of Section 108(b) Financial Responsibility Requirements.” In the 2009 Priority Notice, EPA explained how it then allowed adjustments to the level of financial responsibility as specified in the proposed rule.

The proposed rule identified two goals for section 108(b) regulations—the goal of providing funds to address CERCLA liabilities at sites, and the goal of creating incentives for sound practices that will minimize the costs of such response action, action, are likely to be higher where protective management practices were not utilized during facility operations.

The proposed rule discussed information assembled by EPA in the record for the action, which, as discussed below, included information on legacy practices and legacy contamination, as well as information not related to risk. Based on that record, EPA had proposed to presume that hardrock mining facilities as a class present the type of risks that section 108(b) addresses. The proposed rule then proceeded to establish a methodology to determine a level of financial responsibility in accordance with a proposed formula. The formula then allowed adjustments to the level of those requirements if a facility could demonstrate site specific conditions that rebut the presumption that the hardrock mining facilities that would be regulated under the rule pose a risk.

E. Hardrock Mining Proposed Rule

On January 11, 2017, EPA proposed requirements in a new 40 CFR part 320 that owners and operators of hardrock mining facilities subject to the rule demonstrate and maintain financial responsibility as specified in the proposed rule. The proposed rule identified two goals for section 108(b) regulations—the goal of providing funds to address CERCLA liabilities at sites, and the goal of creating incentives for sound practices that will minimize the costs of such response action. The proposed rule explained that first, when releases of hazardous substances occur, or when a threat of release of hazardous substances must be averted, a Superfund response action may be necessary. Therefore, the costs of such response actions can fall to the taxpayer if parties responsible for the release or potential release of hazardous substances are unable to assume the costs. Second, the likelihood of a CERCLA response action being needed, as well as the costs of such a response action, are likely to be higher where protective management practices were not utilized during facility operations.

The proposed rule discussed information assembled by EPA in the record for the action, which, as discussed below, included information on legacy practices and legacy contamination, as well as information not related to risk. Based on that record, EPA had proposed to presume that hardrock mining facilities as a class present the type of risks that section 108(b) addresses. The proposed rule then proceeded to establish a methodology to determine a level of financial responsibility in accordance with a proposed formula. The formula then allowed adjustments to the level of those requirements if a facility could demonstrate site specific conditions that rebut the presumption that the hardrock mining facilities that would be regulated under the rule pose a risk.

The proposed rule also relied, in part, on the grounds that these owners and operators are more likely to further the regulatory goals of section 108(b) requirements than are owners and operators of facilities that are closed or abandoned. EPA also proposed limiting the applicability of the rule to current hardrock mining operations because those facilities are readily identifiable and, since they are ongoing concerns, they are more likely to be able to obtain the kind of financial responsibility necessary under the regulation. EPA continues to believe that this focus upon current hardrock mining operations is appropriate.

IV. Statutory and Record Support for This Final Rulemaking

A. Statutory Interpretation

Section 108(b) provides EPA only general instructions in paragraphs (b)(1) and (b)(2), on how to determine what financial responsibility requirements to impose for a particular class of facility. Section 108(b)(1) directs EPA to develop regulations requiring owners and operators of facilities to establish evidence of financial responsibility “consistent with the degree and duration of risk associated with the production, transportation, treatment, storage, or disposal of hazardous substances. Section 108(b)(2) directs that the level of financial responsibility shall be initially established, and, when necessary, adjusted to protect against the level of risk that EPA in its discretion believes is appropriate based on the payment experience of the Fund, commercial insurers, courts settlements
and judgments, and voluntary claims claims satisfaction. Section 108(b)(2) does not indicate that this list of factors is exclusive. Read together, it is clear that the statutory language on determining the degree and duration of risk presented by a class, and in setting the level of financial responsibility as it determines is appropriate, confers a significant amount of discretion upon the Agency. EPA discusses these key phrases in turn below.

Section 108(b)(1) directs EPA to develop regulations requiring owners and operators of classes of facilities that EPA identifies, to establish evidence of financial responsibility “consistent with the degree and duration of risk associated with the production, transportation, treatment, storage, or disposal of hazardous substances.” Thus, the statute indicates that EPA is to evaluate risk from a selected class. However, EPA does not interpret this direction to require a precise calculation of risk associated with the selected classes of facilities. Standard dictionary definitions of the term “consistent” include merely “being in agreement” or “compatible.” Moreover, section 108(b) requirements are necessarily imposed in the absence of any response action, although it is through such response actions that the precise level of risk associated with a particular site is ascertained. The statute thus confers upon EPA wide latitude to determine, for purposes of a section 108(b) rulemaking proceeding, what the degree and duration of risk presented by the identified class is. Section 108(b)(2) in turn directs that the level of financial responsibility shall be initially established, and, when necessary, adjusted to protect against the level of risk that EPA in its discretion believes is appropriate based on the payment experience of the Fund, commercial insurers, courts settlements and judgments, and voluntary claims satisfaction. This statutory direction does not specify a particular methodology for the evaluation, indicating simply that the level of financial responsibility be established to protect against the level of risk that EPA “in its discretion believes is appropriate.” Thus, this decision is committed to the discretion of the Administrator. While the statute does provide a list of information sources in section 108(b)(2) on which EPA is to base its decision—the payment experience of the Superfund, courts settlements and judgments, and voluntary claims satisfaction—that list is not exclusive, nor does the statute specify how the information from these sources is to be used, for example, by indicating how the categories are to be weighted relative to one another. As discussed elsewhere in this final rulemaking and in the Technical Support Document, the record and comments received by EPA, provide details about the payment history of the Fund, experience with enforcement actions and court settlements resulting in operational changes, and voluntary actions by companies to reduce risks at specific sites that were used by the Administrator in his judgement to evaluate the risks from current hardrock mining operations. EPA has, therefore, taken multiple considerations into account, including information in these categories which, taken together, inform the exercise of its statutory discretion.

Among the types of information the statute authorizes EPA to consider are the existence of federal and state regulations and financial responsibility requirements. Section 108(b)(1) directs EPA to promulgate financial responsibility requirements “for facilities in addition to those under subtitle C of the Solid Waste Disposal Act and other Federal law.” According to the 1980 Senate Report on legislation that was later enacted as CERCLA, Congress felt it was appropriate for EPA to examine those additional requirements when evaluating the degree and duration of risk:

The bill requires also that facilities maintain evidence of financial responsibility consistent with the degree and duration of risks associated with the production, transportation, treatment, storage, and disposal of hazardous substances. These requirements are in addition to the financial responsibility requirements promulgated under the authority of section 3004(6) of the Solid Waste Disposal Act. It is not the intention of the Committee that operators of facilities covered by section 3004(6) of that Act be subject to two financial responsibility requirements for the same dangers.47

While the report language addresses section 3004(6) of RCRA specifically, EPA believes that it is consistent with Congressional intent for EPA to consider other potentially duplicative Federal financial responsibility requirements when examining the “degree and duration of risk” or the “level of risk” when determining whether and what financial responsibility requirements are appropriate. EPA also believes that it is consistent with Congressional intent for EPA to consider state laws before imposing federal financial responsibility requirements on facilities.

Consideration of state laws before

46 301 Webster’s II New Riverside University Dictionary (1988).

47 S. Rept. 96–948 (2d Sess, 96th Cong.), at 92.
the record does not document significant risks associated with such facilities. Further, this final rulemaking does not rely on the cost of responding to historic mining activities and instead reflects the reduction in the risk of federally financed response actions at modern hardrock mining facilities that result from modern practices and modern regulation. With a few exceptions, discussed below, EPA has made minimal expenditures for modern hardrock mining operations. In addition, EPA engaged in significant discussions with, and received significant comments from, commercial insurers and other financial instrument providers. These providers have submitted information indicating that the availability of financial responsibility instruments would likely be limited for regulated entities, should EPA require companies to obtain them. Thus, to the extent that risks remain at current hardrock mining operations, the information provided by commenters has further convinced EPA that it is not appropriate to establish financial responsibility requirements on this class of facilities.

Nor does EPA believe that issuing final financial responsibility requirements is necessary to achieve the stated goals of the proposed section 108(b) rules for hardrock mining, namely, the goal to increase the likelihood that regulated entities will provide funds necessary to address CERCLA liabilities if and when they arise, and the goal to create an incentive for sound practices. EPA’s economic analysis showing that the proposed rule would avoid governmental costs of only $15–$15.5 million a year supports this conclusion. Based on these estimates, commenters objected that the projected annualized costs to industry ($111–$171 million) are an order of magnitude higher than the avoided costs to the government ($15–15.5 million) sought by the rule. Further, given the fact that federal and state laws, including potential liability under CERCLA, have already created an incentive for sound practices, promulgating financial responsibility regulations for hardrock mining facilities under section 108(b) also is not necessary to advance that goal.

This final rulemaking is based on the record assembled for this action. This decision does not substitute for any site-specific determinations of risk made in the context of individual CERCLA site responses. Those decisions will continue to be made in accordance with preexisting procedures. EPA has reached these conclusions on the record for this rulemaking, including public comments.

The major concerns raised by commenters are described below in Sections C and D. Section E below, and the Technical Support Document for this final rulemaking, discuss case examples in EPA’s record that correspond to these major concerns. It should be noted that much of the public comment received on the proposed rule addressed specific provisions of the proposal. Because EPA has decided not to issue regulatory text under section 108(b) for hardrock mining facilities, or the general provisions in proposed subparts A through C, comments on specific regulatory provisions are outside the scope of this final rulemaking.

B. Evaluation of the Administrative Record

EPA has reevaluated the administrative record for this rulemaking regarding risk at current hardrock mining operations in light of its interpretation of the statute discussed above, and has determined that that record does not support the proposed rule and supports, instead, a final Agency action of no rule. This determination is based on an evaluation of the three primary reports that the proposed rule relied on to identify risk to be addressed by section 108(b):

Evidence of CERCLA Hazardous Substances and Potential Exposures at Section 108(b) Mining and Mineral Processing Sites (hereinafter referred to as the “Evidence Report”); Releases from Hardrock Mining Facilities (hereinafter referred to as the “Releases Report”); and Comprehensive Report: An Overview of Practices at Hardrock Mining and Mineral Processing Facilities and Related Releases of CERCLA Hazardous Substances (hereinafter referred to as the “Practices Report”). This determination also is based on EPA’s consideration of the reduction of risk as a result of federal and state regulatory and financial assurance requirements. Finally, this determination is based on the record of payments from the Superfund Trust Fund to address hazardous substance releases from modern mining facilities.

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50 See proposed 40 CFR 320.2 and 82 FR 3404–05.

51 See 82 FR 3470–80.

52 See exclusions from the rule at proposed 40 CFR 320.60(a)(2), as well as the opportunity to obtain a release from financial responsibility requirements at proposed 40 CFR 320.27. Both were proposed based on an evaluation of the level of risk posed by the facilities. 82 FR 3455–59.

53 See 82 FR 3456.

54 See 82 FR 3460–61.

55 See, for example, Clean Water Act effluent limitations applicable to mining, discussed below.

1. Reports on Risks Posed by Hardrock Mining Facilities

Evidence Report

As described in the preamble to the proposed rule, the Evidence Report documents EPA’s preliminary efforts from 2009–2012 to examine CERCLA site-specific documents for estimated exposures of human and ecological receptors to CERCLA hazardous substances from mining and mineral processing sites cleaned up under Superfund in the past. This report also collected available information on potential exposures of human and ecological receptors to CERCLA hazardous substances from mining and mineral processing sites that were operational in 2009 (the most current available data at the time the evaluation took place). The proposed rule relied on the following conclusions from the Evidence Report:

Overall, the compiled information demonstrates that sites requiring cleanup under Superfund in the past, and sites operational in 2009 share characteristics related to the potential release of CERCLA hazardous substances and the exposure of human and ecological receptors, and illustrated the applicability of EPA’s CERCLA experience to evaluating currently operating mines and processors.

Upon review, EPA has now determined that those conclusions are not supported by the information provided in the Evidence Report. Further, these conclusions are not a primary factor in determining the “degree and duration of risk” presented by currently operating mines under modern environmental regulations. As a result, the Evidence Report does not support a rulemaking under section 108(b).

First, the Evidence Report compares releases of hazardous substances at 24 facilities on the NPL that continued to operate after 1980 (called post-1980 historical sites) to facilities operating in 2009. It does not specify whether or not 1980 can be considered a date by which mining facilities could be considered modern facilities subject to modern regulations. The report does not identify or consider whether the releases from the historical sites were due to pre-1980 activities and practices or whether the releases were caused by practices that are no longer typical of current mines. Instead, the report conflates risks posed by the historical facilities to risks posed by the 2009 facilities by comparing mining practices and contaminants of concern released at the facilities.

When comparing mining practices, the report does not take into account the fact that by 2009, practices at mining facilities were already heavily regulated. For example, the effluent limitation for processes that use cyanide to extract gold or silver is zero discharge.

When comparing contaminants of concern, the Evidence Report identifies contaminants of concern at the historic sites through CERCLA response action documentation. In contrast, at the 2009 operating sites, contaminants of concern are identified through reports of TRI releases and through discharge monitoring reports submitted pursuant to Clean Water Act permits. The report fails to acknowledge that the evidence presented regarding releases of hazardous substances from facilities operating in 2009 is not evidence of risk. “TRI data do not reveal whether or to what degree the public is exposed to listed chemicals.” Further, releases reported under Clean Water Act permits are regulated releases. The fact that the same hazardous substances may be present at historic modern hardrock mining facilities is simply a consequence of the type of ores and processes used at hardrock mines. The mere presence of hazardous substances is not equivalent to risk. Similarly, the existence of common environmental receptors at historic and modern mines is not determinative of risk. Rather, the primary determinant of risk is how current operations at the mine are conducted, including the current regulatory regime under which they operate. As documented in this final action, it is in this respect that most of the historic examples discussed in the proposed rule differ from the modern mines that would actually be subject to its requirements.

Finally, the Evidence Report admits that the releases identified as a cause of past fund expenditures are now regulated under the Clean Air Act and RCRA. As a result of these limitations, the Evidence Report fails to identify substantial risks associated with modern hardrock mining facilities and therefore does not support a rule that would impose financial responsibility requirements on the current hardrock mining sector.

Releases Report and Practices Report

Implicitly recognizing the limitations of the Evidence Report, as well as the inability to rely on reports that are decades old, EPA developed two additional reports to attempt to provide record support for a rule under section 108(b), the Releases Report and the Practices Report.

The Releases Report was intended to substantiate the ongoing existence of environmental risk from releases to the environment from hardrock mining and mineral processing operations in spite of improved regulation of and practices instituted by the hardrock mining and mineral processing industry.” It purports to document releases from facilities “that had no previous significant legacy mining issues.”

The report lists sites that required CERCLA, CERCLA-like, and potential CERCLA actions, and describes the releases and response narratively. However, the limitations of this report prevent it from supporting a determination that requirements under section 108(b) for hardrock mining facilities are appropriate. As discussed in section E, below, and in the Technical Support Document for this final rulemaking, the Releases Report included facilities with significant mining activity that pre-dated modern regulation, creating legacy contamination. The report also fails to address whether or not the releases resulted in the expenditure of federal dollars or appropriately distinguish releases that predate modern regulation and are now prohibited by law or otherwise regulated.

The Practices Report purports to present information on the potential for future releases at operating hardrock mining facilities. However, the Practices Report acknowledges that it cannot be used to draw conclusions about future releases, stating that: “Many sites and facilities within the non-operating and currently operating samples have been active for a century or longer. When a post-1980 release occurred at these facilities, it was difficult to determine if the equipment or practice responsible for the release was newly constructed or part of the site’s past operations.”

The Practices Report acknowledges that “a number of

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57 82 FR 3475.
58 See 40 CFR 440.100(d).
60 Evidence Report, at 17.
63 See the 1992 and 1997 reports cited at 82 FR 3475.
64 Releases Report, at 1.
65 82 FR 3471.
68 Id., at 5.
factors limited the inferences that can be drawn from data about releases at currently operating facilities.”

Both reports also lack important information on whether or not the releases resulted in the expenditure of federal dollars or whether the releases identified are now prohibited by law or otherwise regulated. As noted in section E, below, and the Technical Support Document for this final rulemaking, many of the releases discussed in those reports are being addressed by the responsible parties.

Despite the limitations of the Releases Report and the Practices Report, the proposed rule claimed that they validated the conclusions of earlier reports stating that: “EPA believes the results of this relatively recent effort to further document the state of current mining practices substantiates the findings from the other documents described herein [the Evidence Report and the reports from 1992 and 1997] and further reinforces the Agency’s belief that currently operating hardrock mining and mineral processing facilities subject to this proposal continue to present risks of release of hazardous substances.”

As discussed above, upon reexamination, EPA now believes that none of these reports provide an appropriate basis for identification of the risk of hazardous substance releases at the facilities that would be regulated under the proposed rule or the risk of federally financed response actions at such facilities. Additional relevant information on many of the sites discussed in these reports which helped inform EPA’s conclusions in this final rulemaking is documented in section IV.E below and in the Technical Support Document.

2. Federal and State Regulatory Requirements

EPA has determined that modern regulation of hardrock mining facilities, among other factors, reduces the risk of federally financed response actions to a low level such that no additional financial responsibility requirements for this industry are appropriate. This section summarizes the regulations that support that determination.

a. Federal Environmental Statutes

The proposed rule proposed to regulate facilities that engage in the extraction, beneficiation, and processing of metals, (e.g., copper, gold, iron, lead, magnesium, molybdenum, silver, uranium, and zinc) and non-metallic,

non-fuel minerals (e.g., asbestos, phosphate rock, and sulfur), other than placer mining, exploration only activities, and mines and processors disturbing less than five acres. This scope includes mines, processors, and smelters.

While much mining and beneficiation is exempt from RCRA, these activities are regulated under the Clean Water Act and the Clean Air Act. In addition, some waste material from covered mineral processing facilities is regulated under RCRA. Finally, permissions to mine on federal land are subject to review under the National Environmental Policy Act and may require the preparation of an Environmental Impact Statement.

Clean Water Act

The Clean Water Act (CWA) prohibits discharges to waters of the United States, unless in compliance with another portion of the Act. Principal among those other provisions is the permitting program established under section 402 of the Act, the National Pollution Discharge Elimination System (NPDES). Existing dischargers of toxic and nonconventional pollutants are required to install best available control technology that is economically achievable. New dischargers must meet new source performance standards, based on the best available demonstrated control technology. If these technology-based standards do not fully protect water quality, then a facility must adopt additional controls to meet applicable water quality standards (water quality-based effluent limitations).

Technology-based effluent limitations for hardrock mining are found at 40 CFR part 440. The Ore Mining and Dressing Effluent Guidelines apply to facilities in twelve subcategories as follows:

Iron Ore
Aluminum Ore
Uranium, Radium and Vanadium Ores
Mercury Ore
Titanium Ore
Tungsten Ore
Nickel Ore
Vanadium Ore (Mined Alone and Not as a Byproduct)
Antimony Ore
Copper, Lead, Zinc, Gold, Silver, and Molybdenum Ores
Platinum Ores
Gold Placer Mining

The Background Document for the proposed financial responsibility

70 See Proposed 40 CFR 320.60.
72 See 51 FR 24486.
73 33 U.S.C. 1311.
74 33 U.S.C. 1342.
75 33 U.S.C. 1311.
77 See Proposed 40 CFR 320.60.
78 82 FR 3475.
amended in 1984, these regulations limit pH and the concentration of metals in discharges.

Clean Air Act

The Clean Air Act regulates air emissions from industrial processes like mining and mineral processing. These include National Emissions Standards for Hazardous Air Pollutants (NESHAPs) as well as New Source Performance Standards (NSPS).

The 2011 NESHAP for gold ore processing and production facilities controls mercury air emissions from these facilities. 40 CFR part 63, subpart EEEEEE.

On June 12, 2002, EPA promulgated final air toxics standards for the Primary Copper Smelting major sources 40 CFR part 63, subpart QQQ. These regulations control emissions of arsenic, beryllium, cadmium, chromium, lead, manganese and nickel. On June 4, 1999, EPA promulgated a NESHAP for primary lead smelting (40 CFR part 63, subpart TTT) that controls emissions of lead. In 2007, EPA promulgated a NESHAP for zinc, cadmium and beryllium smelters (40 CFR part 63, subpart GGGGGG), and those regulations established a particulate matter standard. Under section 111 of the CAA, New Source Performance Standards (NSPS) applicable to metallic mineral-processing plants have been established (40 CFR part 60, subpart LL control emissions of particulate matter). EPA’s 1976 NSPS for primary lead smelting (40 CFR part 60, subpart R) controls emissions of particulate matter.

RCRA

While most hardrock mining and beneficiation waste is exempt from RCRA Subtitle C,79 mineral processing waste (other than twenty “special wastes”) are not.80 Thus, mineral processing facilities may be regulated under RCRA Subtitle C. The management of hazardous wastes is generally subject to strict minimum technology requirements.81 Land disposal of hazardous wastes is prohibited unless treatment standards are met.82

National Environmental Policy Act

The National Environmental Policy Act (NEPA) requires an environmental review of major federal actions significant to understanding the quality of the human environment.83 Major federal actions include the issuance of federal permits or permission to use federal lands.84 Mining activities on federal lands are generally subject to NEPA. Accordingly, the potential environmental impacts of those activities are considered and publicly disclosed before they occur. These reviews include consideration of impacts to surface water, ground water, air, soils, ecosystems, wetlands, endangered species, and flood plains.

b. Federal Land Management Laws

The Bureau of Land Management (BLM) and the Forest Service (herein referred to at the Federal Land Management Agencies (FLMAs), have both promulgated regulations that apply to hardrock mining operations on land they manage.

BLM has promulgated regulations under the Federal Land Policy and Management Act (43 U.S.C. 1701 et seq.) that apply to hardrock mining operations on BLM land. These regulations include a requirement to develop a plan for reclamation of disturbed areas and a financial guarantee sufficient to fund completion of the reclamation plan.85

In order to obtain a permit to mine on public lands, the operator must submit a plan of operations that includes plans for water management, rock characterization and handling, spill contingency, and reclamation.86 The plan of operations for the mine cannot be approved until thirty days after a final environmental impact statement has been prepared and filed with EPA.87

The required reclamation plan must detail stabilization of land disturbed for mining, reclaiming and reshaping the land, wildlife rehabilitation, controlling potentially hazardous materials, and post-closure management.88

Like BLM, the Forest Service also requires a plan of operation that includes a plan for reclamation of mining disturbances on Forest Service lands.89 The requirements for environmental protection are set forth in 36 CFR 228.8 and include compliance with all air quality, water quality, and solid waste standards; protection of scenic values; and reclamation to control erosion and water runoff, isolate, remove or control toxic materials, reshape and revegetate disturbed areas, and rehabilitate fisheries and wildlife habitat. The Forest Service requires a bond to cover the cost of stabilizing, rehabilitating, and reclaiming the area of operations.90 Like a BLM plan of operations, approval of a Forest Service plan of operations also is subject to NEPA.

The Forest Service regulations allow the Forest Service to require a modification to the Plan of Operations and reclamation plan (36 CFR 228.4(e)) and adjust the bond to cover the modified plan (36 CFR 228.13(c)).

EPA’s conclusion that BLM and Forest Service regulations address risks at hardrock mining facilities is further supported by the comments submitted by these agencies, discussed below.

c. Other Existing Regulatory Requirements

The proposed rule stated that addressing CERCLA liabilities is different from the mine reclamation bonding requirements required by BLM, the Forest Service, or state requirements that seek to ensure compliance with technical engineering requirements imposed through a permit, or to ensure proper closure or reclamation of an operating mine.91 This discussion in the proposed rule was intended to highlight legal distinctions between the section 108(b) requirements and the requirements of other federal and state programs. However, even when developing the proposed rule, EPA acknowledged the overlap between the risks to be addressed by section 108(b) and existing federal and state regulations. EPA now recognizes that the existence of these other programs, whatever legal differences there may be in their intent and implementation, are critical to understanding “the degree and duration of risk associated with the production, transportation, treatment, storage, or disposal of hazardous substances” as well as the risk to taxpayers of being required to fund response activities under CERCLA, which are the primary factors relevant to EPA’s determination of the need for and appropriate level of financial responsibility requirements under section 108(b).

For example, 16 of the 27 sites discussed in the Releases Report are called “CERCLA-like” releases. Thus, according to the Releases Report, these sites present the same type of risk that is to be addressed under section 108(b). However, as discussed below and in the Technical Support Document for this final rulemaking, we have documented no expenditure of funds by EPA for those “CERCLA-like” releases, which,
as is explained in the Releases Report, are being addressed under other state and Federal programs, demonstrating that modern regulation adequately addresses the risk of Fund financed response action posed by these sites.92

Even the methodology used in the proposed rule to develop the proposed financial responsibility requirements shows that the actual physical risks addressed by modern regulations are essentially the same as the risks to be addressed by section 108(b). The Background Document for the financial responsibility formula demonstrates that the costs of existing federal and state reclamation and closure requirements were used to develop costs for the categories of response activities that are the building blocks of financial responsibility requirements under the proposed rule.93 Thus, the proposed financial responsibility requirements largely address the same risks that are addressed by existing regulatory requirements.

This conclusion is further supported by comments submitted by the Forest Service, and a number of states opposing the proposed rule. The Forest Service demonstrated in their comments how their regulations address the same physical risks that are captured in the response categories that are the building blocks of the proposed section 108(b) financial responsibility formula.94 The states of Alaska, Nevada, New Mexico, and South Dakota each provided a similar analysis for their state, and the Interstate Mining Compact Commission provided analyses for Arizona, South Dakota, and Utah.95 The National Mining Association (NMA) also compiled similar information for 15 states.96

In conclusion, EPA is convinced by the arguments made by state and Federal commenters that the risks

92 The limited number of sites referenced in the Releases Report for which there were CERCLA actions and EPA expenditures are discussed below.
93 See CERCLA 108(b) Financial Responsibility Formula For Hardrock Mining Facilities, Background Document, Sept. 19, 2016 (EPA–HQ–SFUND–2015–0781–0500), at sections 2.1 and 2.2, and Appendix B. The formula also includes estimated costs for natural resources damages and public health assessments. However, both are a function of a release that requires a response action. In the formula, health assessment costs are simply a fixed cost of $550,000 and the natural resource damages are assumed based on a percentage of the response costs. Id. at section 5 and page 6–2.
98 82 FR 3479.

sought to be addressed by the proposed rule are already addressed by existing state and Federal programs. The proposed rule would have considered the risk reduction of existing regulations only as a means to reduce the amount of otherwise required financial responsibility and sought comment on several aspects of this approach. EPA is now convinced that those regulations obviate the need for additional financial responsibility requirements under section 108(b) on the hardrock mining sector. As stated by the Forest Service:

[T]he fact that EPA refers to existing regulations as a rationalization for building the requirements of a particular reduction [in financial responsibility] serves to underline that these existing regulations serve the purpose that EPA hopes is served by the proposed rule: To reduce the risk of a release of a hazardous or toxic substance. Therefore, the specific requirements in the reductions are unnecessary, because other programs with more site-specific presence than EPA has, are already requiring these actions, using site-specific conditions as criteria for design of the mitigations in question. Thus, the outcome is that EPA is attempting to regulate that which is already regulated.97

3. Risk of Payments From the Fund

According to the preamble of the proposed rule, EPA estimated that the historical costs of responding to releases from 243 hardrock mining and minerals processing facilities totaled $12.9 billion, of which approximately $4 billion was paid for through EPA’s Superfund program. EPA relied on this estimate to conclude that: “Such significant cleanup costs may be considered as an indication of the relative risks at these sites, and the potential magnitude of environmental liabilities associated with this industry overall.” 98

As discussed above, EPA has now determined that as a result of modern regulations, the degree and duration of risk associated with the modern production, transportation, treatment, storage or disposal of hazardous substances by the hardrock mining industry does not present a level of risk that taxpayer funded response actions that warrant imposition of financial responsibility requirements for this sector.

EPA acknowledges that the Agency has incurred response costs at mining sites. However, as many commenters have noted, the vast majority of those costs have been to address legacy practices. EPA also acknowledges that there are a handful of examples of sites where EPA has incurred response costs, notwithstanding regulation under the Clean Water Act, or other state and federal law. However, the Agency does not believe that these few examples are an appropriate basis for regulation under CERCLA section 108(b).

The record for the proposed rule includes background information on response costs, expenditures, and settlements at 185 NPL sites and 134 non-NPL sites to inform the proposed financial responsibility formula.99 To develop this information, EPA gathered and reviewed data available in the Comprehensive Environmental Response, Compensation, and Liability Information System (CERCLIS), the Integrated Financial Management System (IFMS), and the Office of Enforcement and Compliance Assurance (OECA) settlements database, as well as a 2004 report of the EPA Inspector General, and a 2010 report from the Government Accountability Office.100 As part of this analysis, EPA combined data from CERCLIS and IFMS into a Microsoft Access file to summarize Fund expenditures incurred at each hardrock mining facility for which EPA had data (as of 2011).101 A link to an FTP site containing these files was provided in the docket.102

While the purpose of this data collection was to support the development of the financial responsibility formula, it also can be used to examine Fund expenditures at specific sites. For example, the results of a query of the Microsoft Access file on site expenditures results in a table that has data for only eight of the 27 sites identified in the Releases Report.103 The

99 CERCLA 108(b) Financial Responsibility Formula For Hardrock Mining Facilities, Background Document, Sept. 19, 2016 (EPA–HQ–2015–0781–0500), at sections 2.1 and 2.2, and Appendix B. The formula also includes estimated costs for natural resources damages and public health assessments. However, both are a function of a release that requires a response action. In the formula, health assessment costs are simply a fixed cost of $550,000 and the natural resource damages are assumed based on a percentage of the response costs. Id. at section 5 and page 6–2.
100 Id. at 2–2. EPA was including cost information for 319 hardrock mining facilities.
101 Id. at 2–2. If EPA itself had incurred expenditures at a hardrock mining facility, those expenditures would have been included in the data pulled from these databases.
102 It also is available here: ftp://newftp.epa.gov/CERCLA108B.
103 See the site expenditure table from the D Site Exp.accdb file on the FTP site. These sites are Battey Hill, a gold and silver mine in South Carolina ($6.3 million), Brewer Gold, a gold and silver mine in South Carolina ($12.3 million), Cimarron Mine, a gold mine in New Mexico ($3.5 million), Formosa Mine, a copper and zinc mine in Oregon ($3.1 million), Gift Edge mine, a gold and silver mine in South Dakota ($75 million), Grouse Creek mine, a...
discussion of why the releases at these sites do not support the proposed rule is discussed in the Technical Support Document accompanying this final rulemaking.104 Of the eight, seven are gold or gold and silver mines. Of the seven, six were operational after the effective date of Clean Water Act effluent limitations applicable to cyanide heap leach mining processes. Thus, regulation does not always prevent releases. In fact, the release at the Summitville Mine in Colorado was significant and the response was very costly. As discussed in the Technical Support Document accompanying this final rulemaking, the costs of response at that site included costs of addressing acid mine drainage from legacy (since 1890) operations, unrelated to the releases from cyanide heap leach process. Further, Colorado has since changed its regulation to prevent a repeat of the releases that occurred from the heap leach process at Summitville.

Thus, Summitville mine is not an example of current risk. However, it also is important to understand that, according to a 1996 retrospective review of Summitville prepared by an EPA Region 8 employee and the Colorado Department of Natural Resources, the Colorado-issued Clean Water Act permit, which assumed no discharge from the heap leach process, was based on an erroneous water balance calculation for the site. The permit assumed that evaporation would be greater than precipitation.105 EPA’s financial responsibility formula similarly relies on water balance data, and could be subject to the same type of error, demonstrating that neither regulation nor financial responsibility requirements are infallible.106

Issues with the financial responsibility formula in the proposed rule are also discussed in, January 19, 2017 comments submitted by the Small Business Administration (SBA) Office of Advocacy. SBA used data in the record to compare the results of the proposed financial responsibility formula against actual site costs at six mining sites. The formula both underestimated, and in some cases greatly overestimated the costs of response. For example, at one mine the actual costs to address an open pit were $77,000, while the formula would have required financial responsibility in the amount of $197,900,000 for this response activity.107 At another site, the formula would have required evidence of financial responsibility to cover interim operation and maintenance at a level of $69 million while the actual costs reported by the site operator who is paying for the response action pursuant to its reclamation plan were over $96 million.108 EPA acknowledges that any formula with limited site specific information is necessarily a very imprecise means of determining potential response costs, and may significantly over or underestimate actual costs, as documented in the SBA comments. As noted by several commenters, financial assurance amounts established by state and other Federal regulatory programs are usually informed by site-specific assessments by on-the-ground regulators and are thus likely to better reflect actual response costs.

The conclusion that modern regulation has greatly reduced the risk of taxpayer financed response actions also is supported by the experience of other federal agencies. For example, in letters sent to Senator Murkowski, BLM and the Forest Service stated that no modern mines permitted since 1990 by either BLM or the Forest Service have been added to the NPL. When asked how many mining plans of operation BLM and Forest Service have approved since 1990, and how many of the corresponding sites have been placed on the NPL, BLM responded that it had approved 659 plans since 1990 and none had been added to the NPL and the Forest Service reported approval of 2,685 plans since 1990 with no sites being placed on the NPL.109 These data support a conclusion that federal financial responsibility programs (and related mining engineering and permitting requirements) have been effective at lowering risk, reducing taxpayer liability, and contrasts strongly with the historical record involving legacy mines.

States have had similar experience with their own programs. The state of Nevada, which has roughly one fourth of hardrock mines in the potentially regulated universe of mines developed by EPA for purposes of analysis in the proposed rule, has not had a case involving taxpayer funded response action since 1991, when the state’s new rules were put in place.110

EPA considered these examples of the limited payment experience of the Fund, as well as the record relating to payments covered by federal and state financial responsibility instruments required under other federal and state law, and payments made pursuant to settlements and voluntary response actions111 to further support EPA’s determination that the degree and duration of risk associated with the modern production, transportation, treatment, storage or disposal of hazardous substances by the hardrock mining industry does not present a level of risk of taxpayer funded response actions that warrant imposition of financial responsibility requirements for this sector.

C. Comments Supporting a Final Rulemaking

EPA received many comments on the proposed rule that expressed support for promulgation of financial responsibility requirements under section 108(b).

Sixty comments from individual private citizens encouraged EPA to issue final requirements, as did four mass mailing letter campaigns sponsored by the Idaho Conservation League, Water Legacy, Friends of the Boundary Waters Wilderness, and Earthworks. The main comment in support of the rule came

104 The Technical Support Document addresses all but two of the eight sites discussed in the Releases Report for which there is a record of Fund expenditures. Silver Mountain is a gold and silver mine that operated beginning in 1928 and that used cyanide heap leach mining processes. Further, Colorado has since changed its regulation to prevent a repeat of the releases that occurred from the heap leach process at Summitville.


111 EPA considers this information to be encompassed by the categories of information set forth in section 108(b)(2) (“payment experience of the Fund, commercial insurers, courts settlements and judgments, and voluntary claims satisfaction”).
from Earthworks, representing 35
different environmental groups.112
Earthworks, et al. commented that
CERCLA financial assurance regulations
are necessary to ensure enough funds are
available to complete cleanup actions without shifting the burden to
the general public. They also stated in
their comments that the proposed
regulations did not duplicate existing
state rules, which they argued do not
cover pipeline spills, tailings spills,
tailings impoundment failures and other
releases of hazardous materials which
commonly occur at hardrock mines, and
can result in substantial liabilities.113
In a separate comment on the proposed
rule, the Idaho Conservation League
stated that the state of Idaho’s financial
assurance requirements do not authorize
bonding for groundwater contamination
and water treatment in perpetuity and
that a section 108(b) rule is necessary to
close that gap.114
In their comments on the proposed
rule, Earthworks stated that: “Strong
CERCLA 108(b) regulations are
necessary to protect taxpayers from
incurring the cost of mine clean-up, and
to ensure that clean-up of hazardous
materials at mine sites occur in a timely
manner.” To support their conclusion, they
specifically mentioned a 2005 report by the Government
Accountability Office (GAO) that
concluded that EPA should “fully use
its existing authorities to better ensure
that those businesses that cause
pollution also pay to have their
contaminated sites cleaned up.”115
They also pointed to a 2004 report by
EPA’s Office of Inspector General (IG)
that identified 29 specific sites where,
according to the IG, cleanup work was
delayed or scaled back in ways harmful
to human health and the environment
because of funding shortfalls.116 In
addition to this report, Earthworks
identified in their comments other
examples of cleanup efforts at mines
that they stated remain uncompleted
due to insufficient funds being
available, or that took an inordinate
amount of time to complete, exposing
the public to dangerous substances.
As discussed in the specific case studies
and the accompanying Technical
Support Document, a number of the
examples cited by the IG and
Earthworks are not representative of the
risk posed by currently operating
hardrock mining facilities.
EPA appreciates Earthworks’ concern
that insufficient funds lead to
incomplete or slow cleanup and
restoration of mine sites. Earthworks
acknowledges that the universe of
entities that EPA proposed to regulate
under the proposed rule excluded mines
that are no longer operating. They
recommended that the universe be
expanded to cover mine operations that
are no longer active but still retain a
responsible party. They state that,
“Many past hardrock mining facilities
are already and/or will be the site of
CERCLA liabilities and necessary
response actions. The CERCLA 108(b)
regulations should apply to these
operations.”117 EPA disagrees with
this comment, and notes that the Agency has
determined the goals of a section 108(b)
rule as described in the proposal have
already been satisfied.
Earthworks also commented that
“CERCLA 108(b) regulations are
essential because they address risks and
liabilities that aren’t addressed in most
other State or federal land management
financial assurance programs, including
spills, accidental releases, and tailings
failures.”118 To support this conclusion,
they point to several instances in
ongoing mining operations where there are
impacts to natural resources and/or
groundwater due to ongoing mining
operations which other federal or state
rules fail to regulate. Earthworks also
submitted comments claiming the need
for financial responsibility for long-term
water treatment. EPA recognizes that
some historical mining operations have
resulted in the need for long-term water
treatment.119 However, modern
regulation of both process discharges
and runoff, as well as reclamation
requirements to control sources of
contamination, significantly address
those risks. Additionally, as discussed
above, while EPA acknowledges that the
risk of a release is never totally
eliminated by the requirements of other
programs, this residual risk is to be
evaluated in light of EPA’s discretion
under the statute on whether to set
section 108(b) requirements, and in light
of the other information in the record
for this action discussed elsewhere in
this final rulemaking. Viewed in this
manner, such residual risk does not
change EPA’s conclusion that it is not
appropriate to issue final section 108(b)
requirements for current hardrock
mining operations.
Water Legacy and Friends of the
Boundary Waters Wilderness submitted
separate comments expressing concern
that Minnesota’s financial assurance
laws, for instance, are not adequate to
cover mine pit seepage, waste rock pile
seepage, tailings dam seepage and/or
catastrophic dam failures.120 However,
as is discussed in the site examples
elsewhere in this final rulemaking and
accompanying Technical Support
Document, commenters submitted
information to demonstrate that most
releases at currently operating facilities
are being addressed by owners and
operators, and that the costs of these
incidents at modern operations are
generally not falling to the taxpayer.
EPA received comments from three
federally-recognized tribes and from
three Alaska Native Claims Settlement
Act (ANCSA) resource managers
regarding section 108(b) financial
responsibility. Tribal comments were
generally in support of the proposed
rule, and cited some concerns about the
potential negative impacts of hardrock
mining on commercial enterprises and
on subsistence living, along with the
need to more fully identify the benefits
of the rule. A primary ANCSA concern
was that the section 108(b) financial
responsibility requirements would
duplicate existing federal and state
requirements, resulting in a negative
impact on Alaska Natives and states,
that receive royalties through the
Regional and Village Corporations.
These comments are discussed in
section VIII.G.

Western Watersheds Project, Okanagan Highlands Alliance, Boise Chapter Great Old Broads for Wilderness, Copper Country Alliance, Nunamta Aulukestai, and Idaho Conservation League.
116 Ibid., page 5, 6.
117 Ibid., page 11.
118 Ibid., page 12.
119 Ibid., page 2.
D. Comments Opposing a Final Rulemaking

1. Comments Regarding Appropriateness of Information Used
   a. Use of Information Not Relevant to the Mines To Be Regulated Under the Rule

   Many commenters on the proposed rule, including mining companies, trade associations, as well as state and federal agencies, commented that EPA’s record incorrectly characterized the ongoing environmental risk at operating hardrock mining facilities by relying on information related to mines that were constructed and operated before current regulatory requirements were in place, rather than on information specific to current hardrock mining activities, which are highly regulated. Commenters argued that since the rule would not apply to inactive, non-operating sites, EPA should not rely on information related to such sites as part of its rulemaking record to justify the need for financial responsibility requirements for current hardrock mining operations. Several commenters disagreed with EPA’s assertion in the proposed rule that the $4 billion spent by EPA through the Superfund for cleanup costs at historical hardrock mining facilities is an indication of the relative risk present at the facilities covered by the proposed rule. Commenters argued that the 2009 Priority Notice and the proposed rule did not differentiate between costs associated with the highly-regulated mining practices of today and pre-regulation practices in developing that number.

   EPA agrees with commenters that information about facilities that present a level of risk similar to those proposed to be regulated is the most appropriate focus for the Agency’s record for this action. EPA also agrees with commenters that because mining practices have changed significantly over the past several decades, information related to risk presented by mines that operated before those changes occurred may not reflect the level of risk presented by currently operating facilities that include controls such as surface water containment structures, engineered storage facilities, water treatment, impermeable liners, and leak detection and recovery systems. Finally, EPA agrees with commenters that the cost of addressing releases from mines that operated without the controls in place today should not be assumed to be comparable to the cost of addressing releases from current operations, where controls such as monitoring assure early detection.

   Commenters objected to the use of 1980 in the Practices Report.121 (CERCLA was enacted in December 1980) as the point when “historic” mining practices changed over to “modern” ones. They felt this ignored the evolution of mining practices that took place since 1980, in response to other environmental laws, as well as state mining regulations which were still in their infancy in 1980. Some commenters seemed to agree that EPA should consider “modern” mining practices to have begun post-1990, and some suggested that the mid-1990s was the true beginning of modern hardrock mining practices. In evaluating the record for this rulemaking, EPA considered the issue of when mining operations became “modern” or “current.” EPA recognizes that there are not nationally-applicable federal standards governing the operation of mines,122 and that the current regulatory scheme of federal and state mining programs has evolved over time. Thus, the requirements of individual hardrock mining programs developed at different paces and sequences. One commenter provided a table demonstrating the evolution of hardrock mining programs over time, extending from 1972 to 2014, and including the adoption of regulations in Alaska, Arizona, Arkansas, Montana, New Mexico, Nevada, and Utah during that period of time.123 EPA has therefore concluded that no particular date in the past reliably distinguishes between “historic” or “legacy” and “current” or “modern” mines nationwide, and that a better approach is to consider operations taking place under the current applicable regulatory scheme as “current” operations, and mine operations that took place before the enactment of the currently applicable and relevant requirements as “historic” or “legacy.”

   b. Use of Data That Did Not Directly Demonstrate Risk at Current Hardrock Mining Operations

   Some commenters who opposed the rule objected to EPA’s analysis of the information presented in the 2009 Priority Notice relating to hardrock mining risk. Commenters objected that EPA relied on inappropriate information to demonstrate risk at current hardrock mining operations, by focusing on data that does not address potential exposure to CERCLA hazardous substances, or the possibility that a CERCLA response action may occur in the future, that is—Toxics Release Inventory (TRI), and data from the Hazardous Waste Biennial Report (BR).124 Commenters argued that EPA’s approach to identifying hardrock mining did not evaluate actual or potential risk.

   EPA agrees with commenters that information regarding releases from hardrock mining facilities does not, in and of itself, demonstrate risk. For example, as noted in EPA’s “Factors to Consider When Using Toxics Release Inventory Data” (2015), “TRI data do not reveal whether or to what degree the public is exposed to listed chemicals.”125 In fact, TRI data generally encompass releases that are permitted under the Clean Air Act (CAA), the Clean Water Act (CWA), or the Safe Drinking Water Act, as well as the lawful disposal of hazardous substances. Accordingly, EPA agrees that TRI data cannot help predict the risk associated with potential mismanagement and therefore cannot be used to support any determination under CERCLA section 108(b) that imposing financial responsibility requirements on a sector is appropriate.

   Similarly, EPA agrees that BRS data and National Response System (previously referred to as the Emergency Response Notification System (ERNS)) data do not provide information on the risk, if any, posed by the management of hazardous substances at hardrock mines.

   Another commenter stated that EPA’s methodology for assessing risk was simply to describe some of the major mining practices that contributed to past CERCLA releases and simplistically conclude that similar practices are used today. The commenter argued that this approach is not accurate because it fails to account for the major changes in mining practices and regulatory requirements that are applied to modern mines. EPA agrees that it is important to consider modern mining practices and current regulatory regimes and has adopted that approach in this final action.

   2. Comments That EPA Failed To Consider Relevant Information

   Commenters on the 2009 Priority Notice and the proposed rule objected...
that EPA failed to consider relevant information in the 2009 Priority Notice and the proposed rule, specifically on the role of federal and state regulatory programs and protective practices in reducing risks at current hardrock mining operations, and on information on reduced costs to the taxpayer from regulatory programs and cleanup by owners and operators. For example, the American Exploration and Mining Association (AEMA) commented that the Federal Land Management Agencies and the states have significantly evolved their financial assurance programs with specific emphasis on post-closure care and maintenance, thereby minimizing the long-term potential for releases of hazardous substances and un-bonded agency liability. AEMA further commented that existing financial responsibility programs are working at modern mines and there is no need for a costly EPA program.126

a. Comments Providing Information on the Role of Federal and State Programs and Protective Mining Practices in Reducing Risks at Current Hardrock Mining Operations

Many commenters who opposed the rule objected that EPA’s analysis failed to consider the technical or engineering requirements specified by other regulatory programs or the requirements that financial assurance be established to ensure that required measures will be funded when needed. The commenters stated that both types of requirements significantly decrease the risks posed by modern mines, including both risks to the environment and risks that potential future liabilities will not be funded by mining companies.127 EPA agrees that due to the increased regulation of hardrock mining practices over the past several decades, mining operations are conducted in a manner that does not present the same level of risk as practices of the past.

Commenters provided extensive information regarding the requirements of those programs including design standards, engineering controls, and environmental monitoring. Commenters argued that engineering controls and best practices reduce the degree and duration of risk associated with the modern production, transportation, treatment, storage, and disposal of hazardous substances to minimal levels and that no additional financial responsibility requirements are necessary to protect the taxpayer or the Superfund. Some of these federal and state programs are discussed below.

(1) Examples of Federal Programs

The regulations of the Bureau of Land Management (BLM) and the Forest Service, applicable to hardrock mining facilities, are described below.

Bureau of Land Management

BLM’s surface management regulations at 43 CFR part 3800, subpart 3809, govern the majority of the hardrock mining operations on the public lands that would be subject to the proposed rule. These regulations were first promulgated in 1980 pursuant to the agency’s authority under the Mining Law of 1872,128 and its mandate under section 302(b) of the Federal Land Policy and Management Act of 1976 to take any action to prevent “unnecessary or undue degradation” of the public lands.129 BLM also regulates the development of solid minerals subject to other mineral disposal authorities, such as phosphate, through the issuance of permits and leases under 43 CFR part 3500. BLM’s regulatory programs provide cradle-to-grave oversight of mining operations on the public lands. For example, BLM’s subpart 3809 regulations require operators to obtain authorization from BLM to conduct any surface disturbance greater than casual use.130 All operations under subpart 3809 must comply with the general and specific performance standards set forth in the regulations which govern, among other things, disposal of mining wastes and handling of acid-forming, toxic, or other deleterious materials.131 In addition, subpart 3809 requires all operations to comply with applicable federal and state laws and regulations, including laws related to air and water quality.132 For extractive mining operations and some exploration, operators under subpart 3809 must submit and obtain BLM approval of a plan of operations that includes plans for baseline data collection, water management, rock characterization and handling, spill contingency, and reclamation.133 BLM’s subpart 3809 regulations impose also requirements for design, operation, closure, and reclamation to ensure productive use of the land after mining. The required reclamation plan must detail stabilization of land disturbed for mining, reclaiming and reshaping the land, wildlife rehabilitation, controlling potentially hazardous materials, and post-closure management.

BLM’s regulations also require operators to provide a financial guarantee before they can begin all hardrock mining operations.134 Moreover, financial guarantees for mining operations must remain in effect until BLM determines that reclamation has been completed in accordance with the authorized operations and the agency releases the financial guarantee.135 BLM’s regulations also allow the agency to initiate forfeiture of the financial guarantee in the event the operator refuses to obtain permits and approvals.136

Forest Service

The U.S. Department of Agriculture (USDA) Forest Service regulations governing mining under the Mining Law of 1872 were promulgated in 1974137 and can be found at 36 CFR part 228, subpart A. Disposal of minerals such as phosphates, sodium, potassium, and hardrock minerals on acquired National Forest System lands are subject to the mineral leasing laws and are regulated by BLM under 43 CFR part 3500. Under the Forest Service regulations at 36 CFR part 228, subpart A, operators must submit and obtain approval of a plan of operations before conducting any operations that might cause significant disturbance of surface resources.138 The regulations are designed to minimize adverse environmental impacts both during and after mining operations. The regulations prohibit releases of hazardous substances, and require financial guarantee that is calculated to reasonably insure that operations and reclamation are conducted to avoid releases, and to respond to releases that may occur.139 USDA highlighted in its comments how well developed Plans of Operations, site inspections, and monitoring reduce environmental risks before, during, and after mine closure. Specifically, USDA stated that an operator complies with Forest Service

127 Freeport-McMoRan Inc; Fertilizer Institute; Mining Minnesota; New Mexico Environment Department and New Mexico Energy, Minerals, and Natural Resources Department; Colorado Department of Natural Resources, Division of Reclamation, Mining and Safety; National Mining Association.
129 43 U.S.C. 1732(b).
130 43 CFR 3809.10, 3809.11.
131 See 43 CFR 3809.420.
132 See 43 CFR 3809.5, 3890.420(b)(4), (b)(5).
133 43 CFR 3809.401.
134 See 43 CFR 3504.50, 3809.4500.
135 43 CFR 3504.71, 3809.590.
136 43 CFR 3504.65, 3809.585.
138 36 CFR 228.4(a).
regulations by developing a Plan of Operations, which requires that the operator submit enough detail that the agency can analyze various risks associated with the proposed operation and, through the NEPA process, identify proper mitigation measures to reduce or eliminate those risks. The regulations also require that, “all operations be conducted so as, where feasible, to minimize adverse environmental impacts on National Forest surface resources” (36 CFR 228.8). This allows the Agency to be very site-specific in its analysis of risk and mitigation.

A Plan of Operations must also include detailed reclamation and closure plans, which are reviewed and approved to minimize the potential future risk to the environment based on predicted outcomes. USDA further stated that Plans of Operation must include hazardous materials inventory and handling procedures, spill prevention plans, and transportation mitigation measures. USDA stated a Plan of Operations for a hardrock mining operation cannot be approved unless hazardous substances are managed so that the threat of present or future release is minimized. During the mine permitting process, the Forest Service actively engages in memorandums of understanding and agreements with other State and Federal Agencies to ensure that all parties’ permits are approved and implemented. Currently this can involve over forty separate permits and authorizations.

The Forest Service requires that mine operators provide a financial guarantee to assure complete reclamation and compliance with environmental laws under the following authorities: 16 U.S.C. 551; 30 U.S.C. 612; 36 CFR 228.8, 228.13. USDA stated that regulatory requirements (36 CFR 228.13) require operators to provide a bond sufficient to assure stabilization, reclamation, and rehabilitation of the area of operations. Environmental protection measures described in under 36 CFR 228.8 also include certification of compliance with all other applicable environmental standards. Forest Service regulations at 36 CFR 228.4(e) allow the agency to require a modification to the Plan of Operations to allow for bond adjustments to address unforeseen environmental effects. In its comments on the proposed rule the USDA stressed that financial guarantee requirements further reduce financial risk to the public. The operator must provide a financial guarantee that must be of sufficient amount to ensure that, upon closure, the operation no longer presents long-term risks to the environment and a liability to the Forest Service and the public. USDA further noted that any ongoing obligation to continue the protection of the environment is also provided for in a long-term financial assurance instrument required by the Forest Service.

Commenters also noted the role the NEPA plays in identifying risks at mining operations. NMA stated that a federal plan of operation is also scrutinized under NEPA, usually requiring the preparation of an environmental impact statement, which evaluates potential environmental impacts of the mining operation, assesses alternatives, and requires the identification of mitigation measures to reduce potentially significant environmental impacts. The Forest Service also offered several examples of the ways in which the NEPA process mitigates risk for mines which require the preparation of an environmental impact statement. Specifically, the Forest Service noted that it identifies closure requirements as part of the NEPA process after in-depth studies using site-specific data. Moreover, Forest Service noted that proposed reclamation requirements and potential for releases at mines on NFS lands are examined and disclosed in NEPA documents prepared for Forest Service approval of the plan of operations, which are reviewed by EPA. The Forest Service also noted that EPA reviews all NEPA documents, and comments on the adequacy of mitigation measures and reclamation plans in general. Once an operator incorporates source controls and mitigation measures into their plan, the Forest Service approves that plan, based on the expected outcomes and not the individual engineering standards used. EPA notes that the NEPA process applies to all federal agencies and thus is not limited to only mines on NFS lands.

(2) Examples of State Programs

A discussion of the mining programs of five states—Nevada, New Mexico, Alaska, Colorado, and Montana—is provided below. Of the 184 mining sites in the potentially regulated universe of mines developed by EPA for purposes of analysis in the proposed rule, roughly one fourth are located in Nevada, and roughly one tenth are located in New Mexico, Alaska, Colorado, and Montana combined. In addition to the examples discussed below, the record includes detailed information on the protectiveness of mineral programs in Arizona, Utah, South Dakota, and Idaho that were provided by those states and state organizations. Additional information on state programs was also provided by other commenters.

Nevada

The Bureau of Mining, Regulation, and Reclamation of Nevada requires closure and reclamation for hardrock mines under the Nevada Revised Statutes (NRS) 519A.010—NRS 519A.280 and the Nevada Administrative Code (NAC) 519A.010—NAC 519A.415. Nevada’s regulatory program was enacted in 1989–1990 and includes the authority for the Nevada Division of Environmental Protection (NDEP) to require financial assurance for long-term management of mine-impacted waters. Commenters reported that Nevada’s stringent regulations “impose extensive permitting, design, operation, monitoring, corrective action, closure, reclamation, and financial assurance requirements on hardrock mining

140 Ibid.
141 Ibid.
142 Ibid., page 5.
143 Ibid., page 4.
144 Ibid., page 4.
145 Ibid., page 1.
146 Ibid., page 3.
147 Ibid., page 3.
148 Ibid., page 5.
149 Ibid., page 5.
150 Ibid., page 5.
153 Ibid., page 5.
154 Ibid., page 7.
155 This number does not include the stand-alone mineral processors in the potentially regulated universe of 221 hardrock mining facilities developed by EPA for purposes of analysis in the proposed rule.
157 See the discussion of comments on state mining programs in below.
159 See comment from Nevada Division of Environmental Protection, comment number EPA–HQ–SFUND–2015–0781–2651 at page 1.
operations in the State. In addition, because many mines in Nevada operate on federal lands, Nevada and BLM and Forest Service have entered into Memoranda of Understanding to ensure coordination of financial assurance requirements across private and public lands. Mines in Nevada estimate the amounts of their required financial assurance through use of Nevada’s Standardized Reclamation Cost Estimator (SRCE). The SRCE is well-regarded amongst mining reclamation programs and is used by several other states and Federal agencies.

Nevada’s hardrock mining regulatory programs, including its reclamation surety program administered by NDEP, include stringent design standards, including standards in liner systems, dam safety, and tailings impoundments that are intended to manage and contain process wastes. The regulations also specify treatment of spent ore heaps at closure to ensure surface and groundwater impacts are prevented. NDEP provided comment that no modern mines that commenced operation after the promulgation of the Nevada mine reclamation financial assurance regulations have required public funding for proper closure or reclamation as evidence of the strength of Nevada’s program.

New Mexico

The New Mexico Mining Act (“Mining Act”) was adopted in 1993 with the purposes of “promoting responsible utilization and reclamation of lands affected by exploration, mining or the extraction of minerals.” The Mining Act broadly defines “mining” and “minerals” to cover the extraction and processing of hardrock minerals. Mining operations in New Mexico, both “existing” and “new,” are required to obtain permits which include closeout, or reclamation, plans. These plans, which are developed in coordination with closure plans required under the Water Quality Act, address the areas disturbed by mining including impacts from any of the thirteen site features identified by EPA as the sources of releases or threatened releases at hardrock mining sites. The reclamation and remediation of these site features, which include tailings, waste rock, leach piles and open pits, are addressed in the permits issued under the Mining Act and the Water Quality Act.

Mining operations in New Mexico are subject to significant compliance and enforcement provisions. The Mining Act mandates a specific set of minimum inspections for each class of facility including on-site inspection a month when a mine is conducting significant reclamation activities. If the agency determines that a facility is in violation of the Act, regulations or the permit or is creating an imminent danger to public health or safety or is causing significant environmental harm, the agency can order a cessation of mining or undertake administrative or judicial enforcement proceedings. Violations can result in civil penalties of up to $10,000 a day, and knowing or willful violations can bring criminal penalties.

Financial assurance is an integral and inseparable part of New Mexico’s regulation of hardrock mining and attendant reclamation requirements. Before a permit can be issued under the Mining Act, financial assurance must be filed with the agency. “The amount of the financial assurance shall be sufficient to assure the performance of the performance requirements of the permit, including closure and reclamation, if the work has to be performed by the director or a third-party contractor.” The financial assurance amount is based on a detailed engineering cost estimate to complete the approved reclamation plan and must be based on what it would cost the State, or the State’s contractor, to complete the reclamation plan. Financial assurance must include costs for: Contract administration; mobilization; demobilization; engineering redesign; profit and overhead; procurement costs; reclamation or closeout plan management; and contingencies.

The New Mexico Environment Department (NMED) regulates mining operations under the New Mexico Water Quality Act (“Water Quality Act”). Enacted in 1967, the Water Quality Act requires the New Mexico Water Quality Control Commission (“WQCC” or “Commission”) to adopt regulations to protect surface water and groundwater quality. The Commission must “adopt water quality standards for surface and ground waters of the state,” and must also adopt regulations requiring a permit for “the discharge of any water contaminant.” The Commission authorizes NMED to place conditions on discharge permits to protect groundwater, and must deny a discharge permit if the discharge would cause or contribute to contaminant levels in excess of water quality standards at any place of present or potential future use. The WQCC must adopt procedures for providing notice to interested persons and the opportunity for a public hearing, and must also adopt regulations “for the operation and maintenance of the permitted facility, including requirements, as may be necessary or desirable, that relate to the continuity of operation, personnel training and financial responsibility.”

Finally, the Water Quality Act was amended in 2009 to direct the WQCC to adopt regulations for the copper industry, resulting in a comprehensive and prescriptive set of copper mine regulations, and in accordance with the directives of the Water Quality Act, the Commission has adopted a body of implementing regulations codified in Title 20, Chapter 6 of the New Mexico Administrative Code.

The stated purpose of the Ground and Surface Water Protection Regulations is...
“to protect all ground water of the state of New Mexico which has an existing concentration of 10,000 [milligrams per liter] or less [total dissolved solids], for present and potential future use as domestic and agricultural water supply.” 183 The regulations include three categories of groundwater quality standards: (1) Maximum numerical standards for thirty-three contaminants for protection of human health; (2) maximum numerical standards for nine contaminants and a range for pH for protection of domestic water supplies; and (3) maximum numerical standards for five contaminants for protection of water for irrigation use. 184 The regulations also address discharge permits, 185 prohibiting any person from causing or allowing a water contaminant to “discharge so that it may move directly or indirectly into groundwater” unless that person is move directly or indirectly into contaminant to “discharge so that it may move directly or indirectly into groundwater.” 186 The regulations provide for notice to the public of a proposed discharge permit, and the opportunity to request a public hearing on the permit. 187 The regulations further provide that a discharge permit may include a closure plan to protect ground water after the cessation of the operations causing the discharge. The closure plan must include “a description of closure measures, maintenance and monitoring plans, post-closure maintenance and monitoring plans, financial assurance, and other measures necessary to prevent and/or abate . . . contamination.” 188

The Copper Mine Rule 189 was promulgated in 2013 and the state indicated that it is the most prescriptive rule governing copper mining operations in the United States. The Copper Mine Rule establishes specific operational, monitoring, contingency, closure, and post-closure requirements for copper mines to ensure protection of water quality and prevent the release of contaminants into the environment during operations and following closure. The Copper Mine Rule is supplemental to the general discharge permit regulations, and is implemented through the issuance of ground water discharge permits.

The Copper Mine Rule covers all aspects of mine operation and closure. The permit application requirements for copper mine facilities result in a comprehensive document that identifies all mine units at the facility including: Impoundments: pipelines; tanks; leach stockpiles; waste rock stockpiles; crushing, milling, concentrating, smelting and tailing impoundments; open pits; underground mines; and, truck and equipment washing units. 190 Each of these respective mine units is subject to prescriptive engineering design criteria to control and prevent the release of contaminants. 191 Existing mine units in operation prior to promulgation of the Copper Mine Rule have extensive groundwater monitoring to determine their effectiveness in preventing the release of contaminants to the environment. 192 Discharge permit requirements for existing mine units include operation of groundwater interceptor systems, as well as seepage and surface runoff capture systems to ensure impacts are contained as close as is practicable. 193 The Copper Mine Rule requires development and implementation of a site-wide water management plan describing in detail how impacted storm water and groundwater at the site is contained and managed. 194 Construction and operation of new mine units or expansion of existing mine units is subject to detailed engineering design requirements that include lined leach stockpiles, double lined process water impoundments, leak detection systems, flow metering, and extensive groundwater monitoring. 195 Proposals for new mine units such as waste rock stockpiles and tailing impoundments are required to include an aquifer evaluation to determine the nature and extent of any impacts to groundwater that may occur if these mine units are proposed to be unlined. 196 Based on the aquifer evaluation, the Copper Mine Rule requires a design report for proposed interceptor systems to ensure containment of groundwater impacted by the stockpile or tailing impoundment such that applicable standards will not be exceeded at monitoring well locations. 197 As previously stated, monitoring wells must be located as close as practicable to the various mine units being monitored. 198 Impacted water collected at a mine site typically is used in the process water system, offsetting use of potable water. Any impacted water in excess of process water requirements must be treated prior to release. 199 In the event a demonstration of containment cannot be satisfactorily made, a liner system placed beneath waste rock or tailing impoundments may be required. 200 The Copper Mine Rule also contains prescriptive requirements for closure of mine units that have the potential to impact water quality 201 including requirements for process solution reduction plans 202 and closure water management and water treatment plans. 203 There are prescriptive engineering design requirements for surface re-grading and cover design to ensure storm water is routed off and away from encapsulated mine waste, and that infiltration into mine waste is minimized. 204 It should be noted that the prescriptive closure design criteria are based on designs that have been implemented successfully not only at copper mines in New Mexico, but mimic successful closure design that has been consistently required and applied at other mine sites in New Mexico.

Under these regulations, any hardrock mine that has the potential to impact groundwater must obtain a permit from NMED. The Water Quality Act provides numerous enforcement mechanisms for violations of the provisions of the Act, the regulations, a water quality standard adopted pursuant to the Act, or a condition of a permit issued pursuant to the Act. 205 These include injunctive relief ordered by a district court; suspension or termination of a permit allegedly violated; 206 civil penalties of up to $15,000 per day of noncompliance for a violation of the Water Quality Act permit provisions at NMSA 1978, Section 74–6–5, including regulations adopted or a permit issued pursuant to that section; 207 up to $10,000 per day for each violation of the Water Quality Act or regulations other than Section 74–6–5; up to $25,000 per day for each day of continued noncompliance with a compliance order; and criminal penalties. 208 The New Mexico state commenters indicated that NMED and the New Mexico Energy, Minerals, and Natural Resources Department work closely together pursuant to a Joint Powers

183 Ibid., page 6–7.
184 Ibid., page 6–7.
185 Ibid., page 6–7.
186 Ibid., page 6–7.
187 Ibid., page 6–7.
188 Ibid., page 6–7.
189 Ibid., page 6–7.
190 Ibid., page 6–7.
191 Ibid., page 6–7.
192 Ibid., page 6–7.
193 Ibid., page 6–7.
194 Ibid., page 6–7.
195 Ibid., page 6–7.
196 Ibid., page 6–7.
197 Ibid., page 6–7.
198 Ibid., page 6–7.
199 Ibid., page 6–7.
200 Ibid., page 6–7.
201 Ibid., page 6–7.
202 Ibid., page 6–7.
203 Ibid., page 6–7.
204 Ibid., page 6–7.
205 Ibid., page 6–7.
206 Ibid., page 6–7.
207 Ibid., page 6–7.
208 Ibid., page 6–7.
Agreement in drafting and issuing permits for hardrock mining facilities to ensure that financial assurance and other permit requirements are consistent, integrated, and complementary. These agencies allow permitted facilities to submit a single financial assurance instrument, or set of instruments, that are jointly held by the agencies, meeting the financial assurance requirements of both statutes. They also have Memoranda of Understanding with BLM and the Forest Service to avoid duplication where federal land is involved. Through mining permits issued under the Mining Act, and groundwater discharge permits issued under the Water Quality Act, the Agencies have jointly required permittees to establish financial assurance for all operating hardrock mines in New Mexico, as well as many that are no longer operating.

Freeport McMoRan Inc. commented that there are existing, state-imposed financial assurance requirements, often amounting to hundreds of millions of dollars per mine, that might be sufficient to protect against risks,209 and offered the example that EPA itself has adopted state reclamation requirements specified in New Mexico law, as the CERCLA remedy for the Questa mine site.

Alaska

The Alaska Department of Environmental Conservation requires financial assurance to prevent releases from mines to water.210 Financial assurance for reclamation at mines on state, private, municipal, and federal land is managed by the Alaska Department of Natural Resources under authority granted by the Alaska Mine Reclamation Act.211 The act describes a general reclamation standard which "prevents unnecessary or undue degradation of land and water resources"212. Under the mine permitting process undertaken for most large mines in Alaska, coordination with federal, state, and local governments is employed to review mine plans.213 As evidence of the stringency of Alaska’s requirements, AEMA offered comment that large mines in Alaska are required to undergo a comprehensive third-party environmental audit every five years.214 Alaska requires further safeguards for mines where the plan includes a dam. These requirements include operation and maintenance plans and contingencies in an emergency action plan.215 Alaska made the “Guidelines for Cooperation with the Alaska Dam Safety Program” guidance available which outlines regulatory requirements applying to dams, including design standards, methods of analysis, [. . .] performance requirements and risk profile of the facility, operation, maintenance and monitoring requirements, emergency action planning and incident reporting, periodic safety inspections” as well as financial assurance.216

Colorado

In 1976, the Colorado state legislature passed the Mined Land Reclamation Act 217 (MLRA) establishing a Mined Land Reclamation Board ("Board").218 The MLRA provided far more structure for permitting mine sites and, importantly, oversight of reclaiming these sites. The MLRA's legislative declaration stated:

It is the declared policy of this state that the extraction of minerals and the reclamation of land affected by such extraction are both necessary and proper activities. It is further declared to be policy of this state that both such activities should be and are compatible. It is the intent of the general assembly by enactment of this article to foster and encourage the development of an economically sound and stable mining and minerals industry and to encourage the orderly development of the state's natural resources while requiring those persons involved in mining operations to reclaim land affected by such operations so that the affected land may be put to a use beneficial to the people of this state. It is the further intent of the general assembly by the enactment of this article to conserve natural resources, to aid in the protection of wildlife and aquatic resources, to establish agricultural, recreational, residential, and industrial sites, and to protect and promote the health, safety, and general welfare of the people of this state.219

In 1984, the Colorado Division of Reclamation, Mining, and Safety (DRMS) permitted the Summitville mine.220 This was a high elevation mine located in the historic mining district of Summitville in Southwest Colorado. Errors were made in the permitting review and initial build out of this mine site. The financial assurance at Summitville was not site-specific but based on a formulaic approach, and ultimately proved to be far short of the actual reclamation cost.221 The large cyanide heap leach operation almost immediately encountered problems with construction and water treatment.222 Ultimately, the operator walked away from the site after a significant environmental release leaving the state with an insufficient financial assurance.

The state indicated that it learned from the errors at Summitville, and the state legislature subsequently passed major programmatic revisions to the MLRA in 1993, strengthening permitting and enforcement provisions.223 Most importantly, the MLRA was specifically amended to create a new class of mining sites now known as Designated Mining Operations (DMOs) and to clearly require financial assurance for all sites based on site specific, not formulaic, criteria.224 The DMO amendment is the backbone of Colorado’s hardrock regulatory program and requires operators to submit an Environmental Protection Plan with numerous technical elements that were previously not required in light of lessons learned from Summitville.225 A DMO’s Environmental Protection Plan now describes how the operator assures protection of all areas that have the potential to be affected by designated chemicals, toxic or acid forming materials, or acid mine drainage.226 The plan must include an Emergency Response Plan and must implement any measures required by Colorado Parks and Wildlife for the protection of wildlife or Colorado Water Quality Control Division for the protection of water quality.227 Other aspects of the DMO amendment required submission of information to evaluate the potential for adverse impacts associated with acid mine drainage or acid or toxic producing materials to leach facilities, heap leach pads, tailing storage or disposal areas, impoundments, waste rock piles, stockpiles (temporary or
Pursuant to the MLRA, DRMS regulates substances into the environment.234

prevent the release of hazardous mine.232

four years) through the life of the mine. DRMS now calculates financial

amount of financial assurance necessary for the state to complete reclamation. DRMS does not calculate site-specific financial assurance prior to the 1993 amendments. As part of the 1993 amendments, language was removed that had allowed sites to be permitted for an established amount (depending on permit type) and language was inserted to mandate that DRMS require, on a site-specific calculation, the total amount of financial assurance necessary for the state to complete reclamation. DRMS now calculates financial assurance amounts during permitting and periodically (at a minimum every four years) through the life of the mine.232

The MLRA minimizes the adverse impacts of hardrock mining in Colorado by requiring every operator to obtain a permit and adhere to rigorous reclamation standards, both during and after mining.233 Many of the MLRA’s reclamation standards are designed to prevent the release of hazardous substances into the environment.234 Pursuant to the MLRA, DRMS regulates mining in Colorado to protect the health, safety and welfare of the people of Colorado and to ensure that affected lands are appropriately reclaimed by those operating mines and mills.235 See Section 34–32–102, C.R.S. Under Section 34–32–109, C.R.S., any operator of a mine or mill must obtain and maintain a reclamation permit.236 To ensure that reclamation obligations are performed, Section 34–32–117(1), C.R.S., provides that no mining and reclamation permit may be issued until the Board receives performance and financial warranties.237 Pursuant to Section 34–32–117(3)(a), C.R.S., a financial warranty consists of a written promise to the Board to be responsible for reclamation costs together with proof of financial capability.238 Each operator must submit a financial warranty sufficient to assure compliance with applicable reclamation standards, as incorporated in the operation’s reclamation permit.239 See Section 34–32–117, C.R.S. During the life of a mine, DRMS requires financial assurance for water quality treatment, as well.240

Under the MLRA, reclamation must be conducted, both during and after the mining operation, in accordance with a reclamation plan that meets certain performance standards.241 Many of the reclamation standards are designed to prevent releases of hazardous substances and prevent adverse impacts on surrounding properties.242 See Section 34–32–116, C.R.S. (requiring measures to minimize disturbance to the hydrologic balance, protect outside areas from damage, and control erosion and attendant air and water pollution).243 MLRA’s financial assurances ensure that DRMS can complete reclamation according to those standards if the operator is unwilling or unable.244 Regulatory financial assurances require enormous expertise, and must be established by fact-intensive case-by-case review.245 DRMS calculates the financial assurance amount by developing and aggregating task-by-task cost estimates using current reference materials as well as the regional expertise of its staff.246 Applicants may submit initial estimates; however, DRMS rigorously reviews those estimates. DRMS is also charged with continuously reviewing the adequacy of financial warranties and uses the same methods.247 DRMS and the Board have promulgated a robust set of rules and regulations specific to the oversight of the hardrock mining industry that implement the MLRA.248 The rules contain specific performance requirements for hardrock mining to protect, for example, both surface and groundwater, impacts to wildlife, and offsite impacts including erosion controls.249 The rules are evidence of how DRMS minimizes the risk associated with the potential for releases from hardrock mine facilities.250

Colorado’s regulatory program is predicated on three essential independent but interrelated elements; permitting, inspection and enforcement251 that allow DRMS to carefully plan for mining and reclamation through the permitting process which is anchored by a thorough financial warranty calculation.252 It also allows DRMS to periodically review sites through inspections to determine compliance with their permits and, if necessary, take enforcement action to remedy non-compliance.253

The permitting process requires prospective operators to, among other things, assess baseline conditions for hydrology, soils, vegetation, land use, climate, geology, and plan for a number of other factors such as chemical and toxic materials handling plans, as they develop their mining and reclamation plans.254 Many of these plans are required to be certified by a registered professional engineer to ensure design integrity and performance, particularly with respect to any environmental protection facility.255 A financial warranty is then calculated utilizing the specific factors associated with these plans, including cost details associated with construction of environmental protection facilities and costs associated with demolition and removal of some of these same facilities and structures.256 Other aspects included in these calculations address volumes of topsoil to be removed and replaced, volumes of overburden to be moved and regraded, waste piles and tailings impoundments to be constructed, capped and reclaimed.

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234 Ibid.
235 Ibid.
236 Ibid.
237 Ibid.
238 Ibid.
239 Ibid.
240 Ibid.
241 Ibid.
242 Ibid.
243 Ibid.
244 Ibid.
245 Ibid.
246 Ibid.
247 Ibid.
248 Ibid., page 7.
249 Ibid.
250 Ibid.
251 Ibid.
252 Ibid.
253 Ibid.
254 Ibid.
255 Ibid.
256 Ibid.
and types and amounts of vegetation to be reestablished.\textsuperscript{257}

Once an application is approved and the financial and performance warranties are posted, a permit is issued.\textsuperscript{258} Upon permit issuance, the site inspection frequency is determined and the site is inspected at an appropriate frequency throughout its mining and reclamation life.\textsuperscript{259} If a violation occurs at a permitted site, this matter is presented to the Board for adjudication which includes finding a violation, possibly issuing a cease and desist order, assessing civil penalties and requiring corrective actions to remedy the violation.\textsuperscript{260} Failure by an operator to remedy a violation could lead to permit revocation and, ultimately, financial warranty forfeiture.\textsuperscript{261}

Montana

In the state of Montana, hardrock mining is regulated by the Montana Department of Environmental Quality pursuant to the Montana Metal Mine Reclamation Act (MMR Act).\textsuperscript{262} The intent of the legislation is to "provide adequate remedies for the protection of the environmental life support system from degradation and provide adequate remedies to prevent unreasonable depletion and degradation of natural resources."\textsuperscript{263} and the "proper reclamation of mined land and former exploration areas not brought to mining stage is necessary to prevent undesirable land and surface water conditions detrimental to the general welfare, health, safety, ecology, and property rights of the citizens of the state." \textsuperscript{264}

The state legislature has amended the MMR Act several times over the years, including reforms to address bankruptcies of mining companies. For example, in the 1999 legislative session following the bankruptcy of the Pegasus Gold Corp. the previous year, section 82–4–390 was added to the MMR Act to prohibit open pit mining for gold and silver using the heap leach or vat leach with cyanide ore-processing agents except for certain mines that were already in operation as of November 3, 1998. In another example, section 82–4–338 concerning performance bonding requirements was substantially amended in the 2007 legislative session and now authorizes the Department of Environmental Quality to take action, including accessing the financial assurance bond and suspending the permit, to abate an imminent danger to public health, public safety or the environment caused by violation of this law.\textsuperscript{265}

Montana has also enacted state laws to protect water \textsuperscript{266} and air \textsuperscript{267} quality, to regulate hazardous and solid waste disposal,\textsuperscript{268} and to assess environmental impacts.\textsuperscript{269} The Department of Environmental Quality has developed regulations implementing the MMR Act that require compliance with the environmental laws contained in Title 75 of the Montana Code. For example, reclamation activities must assure long-term compliance with the air and water quality laws\textsuperscript{270} and that operating permits must prevent acid mine drainage through the construction of earth dams or other devices to control water drainage. \textsuperscript{271} In another example, permit modifications require an assessment of environmental impacts pursuant to the state equivalent of NEPA.\textsuperscript{272}

In its comments on the proposed rule, the Montana Department of Environmental Quality stated that the proposed rule was unnecessary because the state’s environmental laws and the MMR Act sufficiently regulate environmental and financial risks posed by current mining operations in the state.\textsuperscript{273}

Comments on State Mining Programs

Freeport-McMoRan Inc. commented that state regulatory programs are comprehensive, staffed by experienced professionals, and effective. In evaluating the risks of hardrock mining EPA did not take into account common elements of current mining regulation, including the detailed, mandatory closure and reclamation requirements designed to restore large land areas disturbed by mining to an appropriate post-mining land uses, the long-term water management requirements

\begin{equation}
\text{Montana Code Annotated, section 82–3–338(10).}
\end{equation}

\textsuperscript{266} Montana Code Annotated, section 82–3–338(10).

\textsuperscript{267} Montana Code Annotated, Title 75, Chapter 5.

\textsuperscript{268} Montana Code Annotated, Title 75, Chapter 2.

\textsuperscript{269} Montana Code Annotated, Title 75, Chapter 10.

\textsuperscript{270} Montana Administrative Rules, 17.24.102(13)(f).

\textsuperscript{271} Montana Administrative Rules, 17.24.115(1)(d).

\textsuperscript{272} Montana Administrative Rules, 17.24.119.


\textsuperscript{274} See comments from Freeport McMoRan Inc.

\textsuperscript{275} See comments from The Fertilizer Institute.

\textsuperscript{276} See comments from National Mining Association.

\textsuperscript{277} See comments from Newmont Mining Corporation.
environment should not focus on mines of an earlier era, and that the targeted regulated universe—currently operating mines using contemporary mining practices—pose comparatively minimal risks of releases.

NMA noted that new facilities are specifically designed, constructed, operated, and closed in a manner to prevent environmental degradation and avoid the types of problems that were caused by past practices. NMA pointed out that historical operating practices that led to the need for large-scale CERCLA type responses in the past (e.g., direct disposal of tailings into streams, uncontrolled infiltration/discharge of mine impacted water, discharge of mine waste into dumps or impoundments without mitigating potential release mechanisms, etc.) are no longer utilized by the modern mining industry or compliant with current state and federal regulatory requirements. Rather, NMA notes that the mining industry routinely designs modern mining operations using detailed scientific and engineering investigations such as groundwater and surface water modeling, environmental risk assessments, and stability analyses which contribute to sound design and operating practices intended to protect human health and the environment.

NMA further stated that risks are further reduced at currently operating hardrock mining sites using technologies such as secondary containment systems, seepage collection systems, surface water management systems, liners, and active monitoring systems to detect and eliminate the risk of a release. In the event that a release or potential release is identified through installed monitoring systems, remedial actions are immediately implemented as required by regulatory programs using technologies such as interceptor wells, cutoff walls, and hydraulic capture zones.

NMA stated that as federal and state mining programs and groundwater protections have matured, monitoring, reporting, and corrective action have become core components of hardrock mining programs and permits, citing, for example, BLM’s current regulations, promulgated in 2001, which require operators to submit a comprehensive monitoring plan that demonstrates a degree of risk associated with BLM’s surface management regulations and other Federal and State environmental laws and regulations, provides early detection of potential problems, and supplies information that will assist in directing corrective actions should they become necessary.

Numerous other commenters, including MiningMinnesota, AEMA, Energy Fuels Resources, and General Moly, Inc. supported NMA’s views, noting that advances in engineering controls, technology, mining industry best practices, and FLMA and state regulatory programs have lowered the “degree and duration of risk” to a point that CERCLA 108(b) financial responsibility requirements are not required. These commenters further elaborated that the FLMA and state mine regulatory and financial assurance programs coupled with engineering controls and best practices reduce the degree and duration of risk associated with the production, transportation, treatment, storage, or disposal of hazardous substances and that these FLMA and state reclamation and closure requirements require more than simply reshaping land and revegetation—by requiring a mine to be designed, built, operated and closed to prevent the release of hazardous substances and ensure no adverse environmental impacts through the entire mine life cycle, including closure and post-closure. As such, the commenters believe no additional financial responsibility requirements are necessary to protect the taxpayers or the Superfund Trust Fund.

The Idaho Mining Association (IMA) echoed the same message, noting that modern mining techniques and best practices in the mining industry use technology and appropriate controls in combination with FLMA and state programs to lower risk of release such that EPA’s proposed rule is not necessary.

For the planned Donlin Gold project in Alaska, Calista Corporation noted in its comments that one of the primary goals has been to avoid environmental and human health risks both from planned operations and potential unanticipated releases of hazardous substances such as tailings, acid rock drainage, mercury, cyanide, and fuel oil. For example, the Donlin Gold tailings storage facility design is state-of-the-art and includes: (1) Downstream, rock fill dam construction keyed into bedrock, (2) a geo-synthetic liner, and (3) dry closure to minimize long-term water management needs.

Freeport-McMoRan provided numerous specific examples of how the hardrock mining industry has improved its management of environmental impacts:

• In the area of managing the acidic content of waste rock, the industry employs a far more sophisticated and technology-driven approach that includes a thorough geochemical analysis of the ore reserve body being mined. Using up-to-date information, trucks equipped with GPS systems are routed to specific designated disposal locations based on the acidic potential of the waste rock. These locations in turn are selected based on geochemical modeling that can project out far into the future. Potentially acid-generating material is disposed of in engineered facilities designed to minimize the potential for acid generation by encapsulation or neutralization and thereby reducing the potential for acid rock drainage and seepage.

• The changes to the design and operation of tailings ponds over the last 25 years are also quite extensive. At the operational level, qualified internal tailings-dedicated engineers and onsite managers lead tailings stability. Sites with tailings dams follow established operations, maintenance and communication protocols. In this process, items regularly inspected and monitored are: Phreatic level trends, deposition plans and adherence to good operational construction practices, water management controls (including pool size and location relative to dam faces), seepage management, decant systems and other stability components.

• Prior to the revisions to state mining programs during the late 1980s and into the early 1990s, it was not uncommon for waste rock stockpiles, tailings impoundments, leach pads and ponds to be built with limited or no engineering and design review, limited quality control and questionable operational practices. For example, some leach pads were built on somewhat compacted sub-grade over lain with solvent welded poly-vinyl chloride (PVC) plastic sheeting, many times installed by mine site employees without specific expertise in the construction of these systems. These pads usually had ditches lined with Hypalon sheeting due to this material’s superior ultraviolet light resistance compared to PVC. Many of these sites have been decommissioned, closed, and
replaced by more environmentally robust options.

- Modern tailings disposal facilities are engineered and constructed utilizing environmental protection controls. These facilities are constructed utilizing geologic containment or engineered liners to contain the fluid portion of the tailings. As time passes following deposition, the solid fraction of the tailings consolidates, reducing the interstitial pore space and thereby decreasing the hydraulic permeability to a value that is often less than the liner material used during construction. These facilities are often equipped with controls, such as barge pump back systems and containment/collection wells at the toes of the units, to capture any seepage and allow for the recycling of captured water. Upon closure, these facilities take measures to minimize net infiltration into the tailings, such as by utilizing stormwater controls and ensuring that there is positive drainage during storm events. Tailings facilities are also covered and revegetated to produce a passive evapotranspiration mechanism which further reduces net infiltration. These tailings disposal facilities are operated following Tailings Management Plans which are included in the application for environmental protection permits issued by state regulating agencies.

- Prior to the placement of waste rock, the proposed site is evaluated for environmental risks including upstream stormwater run-on, seeps and springs upwelling from beneath the proposed facility, proximity to streams and rivers and other site specific exposures. The waste rock facility must be designed and built in accordance with engineering and construction details required by a mine’s state-issued permit, which must be based on geotechnical stability analyses. Stormwater management measures, such as diversion features to intercept water and direct it around the waste rock facility, and facility management plans that govern the placement of potentially-reactive material are also employed to limit contact with potentially acid-producing materials. Other management strategies that may be employed to limit contact with potentially acid-generating material may include blending with neutralizing rock, segregation in cells that are set back a prescribed distance from the base and edges of the facility and are covered or encapsulated in neutralizing material, and landform design to minimize stormwater ponding. Concurrent reclamation is also often incorporated to further reduce the potential for net infiltration into the waste rock facility and return the area to a productive post-mining land use.

Waste rock facility inspections by the operator and regulatory inspectors are also performed on schedules based upon regulatory requirements imposed by laws, regulations and permit stipulations. These inspections include looking for seepage from the facility, slope stability, stormwater ponding and other prescribed conditions. Any issues observed must be corrected per the regulatory and permit requirements imposed. These inspections are conducted during operation and continue through the closure period following reclamation of the facility.

Several commenters also commented on the usefulness of environmental management systems (EMSs) and best management practices (BMPs). For example, NMA commented that the introduction of EMSs in the 1990s was another key development for improved environmental performance—a framework that helps an organization meet its regulatory compliance requirements and otherwise achieve its environmental goals through consistent review, evaluation, and improvement of its environmental performance. This consistent review and evaluation are intended to identify opportunities for continuous improvement in the environmental performance of the organization. NMA states that many HRM facilities have implemented EMS programs, noting that at EPA’s request, it, in association with the Society for Mining, Metallurgy, and Exploration (“SME”), developed a model EMS guide to address the agency’s concerns about the ability of smaller and medium size mining companies to develop and implement EMS programs. The objective of the EMS guide is to assist companies in achieving reliable regulatory compliance, reducing adverse impacts to the environment, improving environmental stewardship, and continually improving environmental performance. NMA notes the most commonly used framework for an EMS is the one developed by the International Organization for Standardization (ISO) for the ISO 14001 standard. Established in 1996, this framework is the official international standard for an EMS and includes an optional third-party certification component, meaning an independent certification body audits an organization’s practices against the requirements of the standard. Many HRM facilities have taken this extra certification step. The ISO 14001, first published in 1996, underwent significant revisions in both 2004 and 2015.

Freeport-McMoRan similarly commented that EPA did not consider the implementation of EMSs—under standards developed by reputable third-party organizations, such as the International Standards Organization and the International Council on Mining and Metals. The commenter noted that such standards commit participants to continuing process improvement above and beyond minimum legal requirements. Likewise, standards for sustainability, such as ICMM’s, require third party assurance and verification programs. Freeport-McMoRan stated these private initiatives supplement state programs, adding an additional layer of best practices and external review above and beyond what is legally required. The Arizona Department of Environmental Quality (ADEQ) supported this approach, noting the usefulness of its Voluntary Environmental Stewardship Program (VESP) and Voluntary Remediation Program (VRP) that are innovative systems not based on enforceable commitments required for reductions. ADEQ also stated the usefulness of EMSs, ISO certification, third party inspection programs, or similar types of state and federal programs for reducing risk from mining operations and specifically noted that Freeport-McMoRan, with mines in Arizona, employs industry best practices of an ISO14000 environmental management system.

With respect to BMPs, the Forest Service commented that EPA acknowledges that “...today, BMPs have been developed that can mitigate potential impacts from mining to meet EPA’s goal . . . that the engineering requirements will result in a minimum degree and duration of risk associated with the production, transportation, treatment, storage, or disposal, as applicable, of all hazardous substances present at that site feature.” However, comments submitted by Earthworks, et al. raise concern about the use of BMPs, noting that no data was provided to demonstrate that these rules have reduced, or prevented, releases of hazardous materials. Earthworks further noted that numerous reports document substantial impacts at modern hardrock mines, particularly those associated

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with the release of hazardous materials. EPA recognizes that substantial advances have been made in the development of mining practices and the implementation of federal and state regulatory programs to address releases at hardrock mining facilities. While the risk of a release is never totally eliminated, commenters provided information regarding state regulation of hardrock mining facilities, including detailed information on controls those programs require to prevent releases. This information indicates that state and voluntary programs improve in response to incidents. Barrick Gold commented that EPA cited some releases including at the Summitville and Zortman-Landusky mines, which the commenter stated cannot occur again because federal land management agencies and state regulators have strengthened requirements and practices to prevent the issues that occurred previously. Specifically, they stated that regulations and policy were modified to more carefully identify risks of acid rock drainage or other water contamination, to control potential sources through mine design and to assure those measures are implemented through permit and monitoring obligations. The Colorado Department of Natural Resources, Division of Reclamation, Mining, and Safety’s comments support Barrick’s statements, stating that “the state learned from the errors at Summitville, and the state legislature passed major programmatic revisions to the Mined Land Reclamation Act (MLRA)” that “strengthened permitting and enforcement provisions. Most importantly, the MLRA was specifically amended [. . .] to clearly require financial assurance for all sites based on site specific, not formulaic, criteria.”

The Nevada Mining Association’s comments reference Nevada’s continual improvement of its regulatory programs to ensure effectiveness and efficiency. This comment argues that state programs are not static and rather make constant improvements. Comments from the Small Business Administration Office of Advocacy explained that the bonding requirements of the Nevada program have been more recently upgraded, in part, because of the experience gained from administering mines through bankruptcies in the early 1990s. NMA notes improvements to federal and state programs made in response to bankruptcies in the mining industry experienced in the 1990s and early 2000s. One coordinated improvement of Federal Land Management Agencies and Nevada cited is the development of the SRCE mentioned above.

Additionally, a commenter operating in several states stated that EPA’s evaluation of risk failed to consider important aspects of modern mining, including the deployment of voluntary industry programs (e.g., the International Council on Mining and Metals (ICMM) Sustainable Development Framework) and robust environmental management systems with third-party certification. A commenter also noted the International Cyanide Management Code for the Manufacture, Transportation, and Use of Cyanide in the Production of Gold, which was developed under the guidance of the United Nations Environment Program. The code focuses exclusively on the safe management of cyanide and cyanidation mill tailings and leach solutions. Companies that adopt the Cyanide Code must have their mining and processing operations that use cyanide to recover gold and/or silver audited by an independent third party to determine the status of Cyanide Code implementation. The requirements under the code include storage and mixing location and containment, secondary containment, lining for leach ponds, and spill prevention and containment. Similarly, another commenter stated that EPA failed to adequately recognize the impacts of the development and adoption of industry BMP’s, other voluntary programs, and environmental management systems. EPA acknowledges that the requirements of current federal and state programs can reduce risk at hardrock mining facilities, and that when determining the need for section 108(b) requirements for hardrock mining facilities at proposal, EPA did not adequately consider their impact. EPA agrees with commenters opposing the proposed rule that those reductions in risk should be considered in determining the need for final requirements under section 108(b) for current hardrock mining operations. The Agency is thus convinced by those commenters and its own further investigations that the rulemaking record supporting requirements under section 108(b) for currently operating facilities was incomplete in not adequately considering the risk reductions currently obtained by other Federal and state regulatory programs. While EPA also acknowledges that the risk of a release is never totally eliminated by other programs, this residual risk is to be evaluated in light of EPA’s discretion under the statute on whether to set section 108(b) requirements, and in light of the other information in the record for today’s action discussed elsewhere in this final rulemaking. Viewed in this manner, such residual risk does not change EPA’s conclusion that it is not appropriate to issue final section 108(b) requirements for current hardrock mining operations.

Finally, it should be noted that in addition to the federal and state mining programs that regulate mine operation and closure, hardrock mining facilities are regulated under a number of other federal programs, discussed above, which contribute to reduction in risk at these facilities. For example, mines are generally required under the Clean Water Act regulations to obtain NPDES permits, and to meet federal water quality standards for point-source discharges to water sources from industrial operations. Requirements of the Safe Drinking Water Act include permitting and technical standards for underground injection wells that might be used in mineral extraction. And, requirements under the CAA apply National Emission Standards for Hazardous Air Pollutants to hazardous air releases from mining and processing operation sources.

b. Comments Providing Information on Reduced Costs to the Taxpayer Resulting From Effective Hardrock Mining Programs and Owner or Operator Responses

Commenters also argued that the reduced risk at modern hardrock mining facilities is evidenced by the fact that there are very few cases where modern hardrock mining facilities have been addressed by Superfund and/or at taxpayer expense.

See Id., Appendix D page at 8.
Several commenters disagreed with EPA’s assertion in the proposal that the estimated $4 billion spent by EPA through the Superfund for cleanup costs at historical hardrock mining facilities is an indication of the relative risk present at the facilities covered by the proposed rule. Commenters stated that EPA did not differentiate between costs associated with the highly-regulated mining practices of today and pre-regulation practices in developing that number. EPA agrees that the analysis discussed in the preamble to the proposed rule did not adequately distinguish between legacy and current mines.

Commenters argued that such analyses would further demonstrate that any risks from modern operations entail much less costly responses, and that the bulk of the observed historical response costs are attributable to pre-regulation practices.

In addition, many commenters stated that the risk that there will be inadequate funding to cover CERCLA liabilities at hardrock mining facilities in the future is adequately addressed by existing federal and state financial assurance programs. Commenters provided numerous examples of existing trust, bonds, and letters of credit (LDCs) available to pay for necessary actions at these sites.

Commenters also provided examples of facilities where the response costs have been paid for by owners and operators at no cost to taxpayers.

Since a goal of section 108(b) requirements is to provide funds to address CERCLA liabilities at sites, evidence of such privately-funded responses contributes to support for the decision that financial responsibility requirements under section 108(b) for current hardrock mining operations are not appropriate.

E. Evidence Rebutting EPA’s Site Examples

In developing the 2009 Priority Notice and the proposed rule, EPA cited examples of hardrock mining facilities where releases of hazardous substances have occurred, and in some cases where CERCLA or CERCLA-like actions were necessary, as evidence of risk associated with hardrock mining operations.

The examples fell into three categories: (1) Examples now not relevant to the mines to be regulated under the rule, (2) examples reflecting a reassessment of costs to the taxpayers based on new information, and (3) examples where program requirements were subsequently modified to address the problem.

Commenters on the proposed rule provided information to rebut the facts associated with the case studies and their significance in support of the 2009 Priority Notice and the proposed rule, by pointing out that response actions were due to legacy contamination, were privately funded, were covered by financial assurance under other law, or were the result of situations that have been subsequently addressed by state law. The information provided by these case studies formed a significant portion of the record on which the 2009 Priority Notice and the proposed rule were based. This additional information provided by commenters has caused EPA to reevaluate its conclusions in the proposed rule regarding the level of potential taxpayer liability from modern mines operating under currently existing regulatory programs.

One example in each of the three categories is discussed below. A full discussion of the case studies and the evidence provided in rebuttal can be found in a support document entitled “CERCLA Section 108(b) Hardrock Mining Final Rule: Technical Support Document,” which is available in the docket for this rulemaking.

1. Example of Sites Now Not Relevant to the Mines To Be Regulated Under the Rule

Commenters provided information demonstrating that several of the site examples relied upon in the proposed rule are not relevant to an evaluation of the risk at current hardrock mining operations because they relate to historic mining activities that do not reflect current mining practices or regulatory regimes at the state or federal level. EPA agrees that the historical mining practices, and environmental contamination that may have occurred as a result of such practices, are not an accurate representation of the risks associated with current hardrock mining operations. Many of the sites referenced in the proposed rule, the 2009 Priority Notice, and record of support, are not relevant to EPA’s assessment of risk posed by current hardrock mining operations that are already subject to applicable federal and state regulatory regimes.

This mine was included in the preamble of the proposed rule as an example of the impacts that can occur from large-scale operations. For example, the discussion of this mine references the large-scale disturbance of land, accumulation of waste rock, and leaching of hazardous substances and acid rock drainage, but it does not provide details about the history of the mine or context about whether certain activities are best characterized as legacy mining activities or ones that reflect current mining practices and regulatory regimes.

According to Rio Tinto’s comments and EPA’s record for the site, there has been active mining in the canyon since the 1860s and that the historic mining activities “based on a less sophisticated understanding of environmental sciences and substantially less regulation by emerging environmental protection laws in an early stage of development.” According to the record for this action, EPA has secured more than $270 million to pay for response actions for this site through enforcement orders and consent decrees. Rio Tinto in its comments acknowledges that accidents do happen and that reporting, inspections, and enforcement can help prevent and address problems that do occur. In its comments, NMA stated that the cooperation between the mining company, EPA, and the state is a model for addressing legacy environmental contamination at mining sites.

EPA has touted the cooperative effort to clean up the site as a “major accomplishment of the Superfund program and law.”


See a discussion of this issue in the Technical Support Document for this final rulemaking, Ibid.

See the Releases Report, the Practices Report, and the Evidence Report. NMA comments included a detailed critique of the Practices Report prepared by the Society for Mining Metallurgy and Exploration, Inc., as Appendix D to its comments.


See comment from the National Mining Association, EPA–HQ–SFUND–2015–0781–2794, Appendix F.

See comment from the National Mining Association, EPA–HQ–SFUND–2015–0781–2794, table C.
discussion of this mine can be found in the Technical Support Document for this final rulemaking.\textsuperscript{306} EPA agrees that this mine, which has an expansive footprint but whose current operations are subject to considerable oversight by regulatory authorities, is not a relevant example on which to base a rule under section 108(b).

2. Example Reflecting Reassessment of Costs to the Taxpayers Based on Additional Information

As discussed above, a goal of regulations under section 108(b) is to increase the likelihood that owners and operators will provide funds necessary to address the CERCLA liabilities at their facilities. In doing so, section 108(b) requirements assure that owners and operators, rather than the taxpayers, bear the costs associated with necessary responses to releases and potential releases of hazardous substances at their sites. Commenters on the proposed rule objected that EPA did not properly consider whether a release resulted in expenditure of taxpayer funds to determine the need for a rule under section 108(b). EPA’s reconsideration of these case studies supports the determination that section 108(b) financial responsibility requirements at hardrock mining facilities are not necessary to provide funds to address CERCLA liabilities at sites. Many of the sites referenced in the proposed rule, the 2009 Priority Notice, and record of support, are not relevant to EPA’s assessment of risk posed to the taxpayer because cleanup is being paid for by private parties. Golden Sunlight Mine in Montana is an example of such a site.

The Releases Report presented this mine as an example of a current mine with releases to the environment where a response action was necessary. NMA and Barrick Gold both commented that the releases from the tailings facility detected in 1993 were discovered by monitoring implemented at the behest of state mining permits at the site and corrective action was taken by the operator.\textsuperscript{307} In the proposed rule, the agency described the actions by the owner/operator to immediately repair the bentonite cut-off wall to control seepage from the tailings impoundments. The facility has also installed an extensive system of monitoring wells and several hydrogeologic investigations have been undertaken to continue to monitor, evaluate, and control leakage from the tailings impoundment.

As discussed in the Technical Support Document and elsewhere in the preamble, Montana substantially reformed its mining laws over the past couple of decades. Montana Department of Environmental Quality commented on the proposed rule that Montana State Law “requires Hard Rock operators to submit to Montana Department of Environmental Quality a bond in an amount no less than the estimated cost to the state to ensure compliance with Montana’s Air Quality Act, Montana’s Water Quality Act, the Metal Mine Reclamation Act, and the permit issued by DEQ under the Metal Mine Reclamation Act (MMRA). The site is also subject to Montana’s Environmental Policy Act (MEPA) which is patterned after NEPA. The mine has been the subject of several environmental assessments and one environmental impact statement for amendments to its operating permit. In addition, and at a minimum, Montana Department of Environmental Quality is required to perform a comprehensive bond review every five years for each Hard Rock operation to ensure that the bonding level is appropriate.”\textsuperscript{308}

The Agency researched Montana’s requirement to perform a comprehensive bond review every five years as it applies to the Golden Sunlight Mine. The agency found a final bond determination for Golden Sunlight Mine dated July 28, 2017 in which Montana DEQ determined that the current bonding level of $112,153,980 did not represent the present cost of compliance with the MMRA, the administrative rules, and Operating Permit No. 00065. After negotiations between Montana Department of Environmental Quality, the Bureau of Land Management, and the mine owner, and a 30-day comment period, the bond amount was increased to $146,564,163. The next comprehensive bond review will be in 2020.\textsuperscript{309} Further discussion of this mine can be found in the Technical Support Document for this final rulemaking.\textsuperscript{310}

3. Example Where Program Requirements Were Subsequently Modified To Address the Problem

Commenters provided information to demonstrate that when problems have arisen at hardrock mining facilities, states have responded by improving their programs to prevent similar problems in the future and that there is, therefore, no need for financial responsibility requirements under section 108(b). Commenters provided examples of such state program modifications to rebut evidence provided in the record supporting the proposed rule. Barite Hill/Nevada Goldfields Facility in South Carolina is an example of a situation where program modifications reduced future risk.

As was discussed in the proposed rule, the Barite Hill/Nevada Goldfields was a gold and silver surface mine located in McCormick, South Carolina that was operated by Nevada Goldfields.\textsuperscript{311} The mine operated an open pit cyanide heap leach operation on the property from 1989 to 1994. Nevada Goldfields conducted mine reclamation activities from 1995 to 1999, when it filed for bankruptcy and abandoned the site, turning over control to the South Carolina Department of Health and Environmental Control.\textsuperscript{312} NMA commented that EPA’s description of the mine in the proposed rule included mischaracterizations and omissions, including that significant changes were made to South Carolina Mining Act in 1990 that specified reclamation requirements and provided enforcement tools. NMA also stated that the most recent facility that had been permitted in the state had a waste rock management plan for a cyanide mine drainage.\textsuperscript{313} EPA has confirmed that South Carolina finalized regulations implementing this new authority in 1992, including requirements that a mine obtain a reclamation bond as a condition for receiving a mining permit, and that the recently permitted gold mine is subject to stricter environmental and financial assurance requirements.\textsuperscript{314} These regulations were not completed in time to significantly reduce risks at Nevada Goldfields, which ceased active mining in 1994, but EPA believes that similar mines operating in South Carolina today under

\textsuperscript{307} National Mining Association comments on proposed rule appendix table C-2 pg 6; Barrick Gold July 11, 2017 comments on proposed rule page 20.
the current regulations would have significantly reduced risks of unpermitted releases and taxpayer liability. Further discussion of this mine can be found in the Technical Support Document for this final rulemaking.

F. Information Regarding Financial Responsibility Instrument Availability

During the public comment period for the proposed rule, commenters representing or participating in the insurance, surety and banking industries identified several concerns with EPA’s proposed instrument terms, and expressed concern that those terms could impact the availability of instruments. Similarly, entities in the mining industry expressed concerns that instruments may not be available for the amounts proposed in the forms specified. Information provided by commenters on likely lack of available instruments to satisfy section 108(b) requirements provides further support for EPA’s determination that the proposed financial responsibility requirements are not appropriate.

EPA considered the capacity of the financial market to provide instruments as part of the development of the proposed rule. The Conference Committee Report for the Consolidated Appropriations Act (2016) instructed EPA to conduct a study of the market capacity regarding the necessary instruments for meeting any new section 108(b) financial responsibility requirements. EPA accordingly developed a study, which suggested significant uncertainty exists around the ultimate availability of instruments. Many commenters expressed concerns regarding the uncertainty inherent in the study as well as expressed concerns that financial responsibility instruments may not be universally available and affordable.

The concerns raised by commenters regarding the terms and conditions of the proposed instruments as well as the comments on the market capacity study have contributed to uncertainty regarding the availability of instruments to owners and operators seeking to comply with the proposed section 108(b) requirements. If instruments were not available, owners and operators would be unable to comply with section 108(b) requirements, and the goal of the rule to provide funds to address CERCLA liabilities at sites would not be achieved.

The issue of availability of instruments is discussed in more detail in section VII.D. of this final rulemaking.

V. Decision to Not Issue the General Facility Requirements of Subparts A Through C in This Final Rulemaking

The Agency also has decided not to issue as final any provisions of the proposed rule, including the general financial responsibility requirements in subparts A through C. EPA would include general facilities requirements, such as these, in the first of any subsequent rulemaking proposals under section 108(b), rather than issue final requirements under those subparts at this time.

EPA decided on this approach because there is no need to issue final requirements in subparts A through C at this time as they would not be applicable to any classes of facilities until such time as final section 108(b) regulations applicable to classes of facilities are issued.

In addition, the Agency received significant comment on the general financial responsibility provisions of the proposed rule, many of which identified significant issues with those portions of the proposal. These included, for example, the financial industry’s concerns regarding certain provisions included with the language of the instruments, as described in detail below. By issuing a new proposed set of general requirements for any subsequent industry class, EPA would be able to gather additional information as appropriate. Accordingly, EPA would be able to present a new set of general facility requirements in any subsequent proposal, with an additional opportunity for public comment, rather than having to create a proposal to modify existing requirements, thus avoiding potential confusion to commenters.

VI. Obstacles To Developing and Implementing Section 108(b) Financial Responsibility Requirements for Hardrock Mining Facilities

EPA decided not to issue final requirements under section 108(b) for hardrock mining facilities because the Agency believes that final requirements are not appropriate. Furthermore, the Agency encountered a set of challenges that validate the decision not to issue final regulations. First, challenges remain regarding the potential disruption of state, tribal, and local mining programs by section 108(b) requirements. Second, section 108(b) continues to present particular challenges regarding the determination of a financial responsibility amount. Third, the Agency’s evaluation of the economic impacts of the proposed rule does not support the need for a rule. Fourth, concerns regarding the availability of instruments remain. Finally, section 108(b) continues to present challenges in identifying the facility for purposes of the rule. These concerns were raised by commenters, and are discussed in detail below.

A. Potential Disruption of State, Tribal, or Local Mining Programs

In the proposed rule, EPA acknowledged the role that effective reclamation and closure requirements at hardrock mining facilities under federal and state programs can have in reducing the likelihood of releases or potential releases of hazardous substances to the environment. EPA also documented that federal and state mining regulatory programs require financial assurance to support implementation of reclamation and closure requirements.

Numerous observers raised questions about the effects of an express preemption provision in CERCLA section 114(d) during EPA’s development of the proposed rule. This provision states in part:

Except as provided in this subchapter, no owner or operator of a . . . facility who establishes and maintains evidence of financial responsibility in accordance with this subchapter shall be required under any State or local law, rule or regulation to establish or maintain any other evidence of financial responsibility in connection with liability for the release of a hazardous substance from such . . . facility. Evidence of compliance with the financial responsibility requirements of this subchapter shall be accepted by a State in lieu of any other requirement of financial responsibility imposed by such State in connection with liability for the release of a hazardous substance from such . . . facility.

EPA discussed its views on the preemption provision in the proposed rule. Specifically, EPA explained that it did not intend for its section 108(b) regulations to result in widespread displacement of state mine bonding programs under section 114(d), nor did
it believe that such preemption is intended by CERCLA, necessary, or appropriate. In support of this conclusion, EPA discussed the language of paragraph (d) and section 114 as a whole, and considered whether state bonding programs were “in connection with liability for the release of a hazardous substance” as that term is used in section 114(d), and also took into account relevant policy considerations.318

Commenters on the proposal nevertheless continued to express concern that preemption would indeed occur if section 108(b) requirements were implemented at facilities, resulting in disruption of those programs not only from successful preemption challenges, but also from the mere need to defend against those challenges.319

Although EPA discussed its views on the question in the proposed rule, it will be the courts, rather than EPA, that will decide the effect of section 114(d). Thus, EPA cannot ensure that preemption will not occur if financial responsibility under section 108(b) requirements is in place at a facility. EPA thus understands why states and local governments have concerns that they would have to defend preemption challenges, and concerns over the possibility that preemption could occur.

EPA also recognizes that the potential impact of preemption of financial assurance requirements extends beyond the concerns relating to the financial impacts, as financial assurance is an integral part of state mining programs—that is, financial assurance can provide enforcement leverage to regulators, and can prevent delays in conducting closure and reclamation at a site should the owner or operator become unwilling or unable to do so, thus minimizing environmental harm.

For all of these reasons, EPA believes that preemption of state financial assurance requirements, should it occur, would be an undesirable and damaging consequence of section 108(b) requirements. The Agency’s decision not to issue final requirements under section 108(b) for hardrock mining facilities avoids this undesirable outcome. B. Challenges To Determine the Level of Financial Responsibility

In developing the proposed rule, EPA considered four approaches to identify a financial responsibility amount for a facility—fixed amount, site-specific amount, parametric approach, and formulaic approach, and described three of those approaches in the proposed rule. EPA also identified some of the challenges of the three approaches described and sought comment on various aspects of these approaches. Under a fixed amount approach, the Agency would identify a standard cost for the class of regulated facilities. This method would not rely on site-specific factors but rather on historical costs associated with similar facilities to calculate an expected future amount. This approach is best applied where the costs at issue are fairly uniform, as the wider the variation, the lower the accuracy of the financial responsibility amount for that cost. If there is wide variation in the costs associated with the facilities within the class to which the fixed amount is applied, the result can be significant over-regulation at those facilities with lower levels of liabilities, and significant under-regulation of facilities with higher levels of liabilities. At the same time, this approach has advantages in that it requires a lower level of effort on the part of the regulated community and the Agency to implement because the rule does not require a site-specific calculation to be developed, submitted, or evaluated. EPA proposed the use of a fixed amount for the health assessment component of the financial responsibility amount from hardrock mining facilities.

The second method considered by EPA was a site-specific approach. Under this approach, the owner or operator would calculate the cost of conducting known activities to address identified problems. This approach is the most precise of the three approaches considered by EPA. However, it is also the most resource intensive to implement. It requires gathering detailed information about the site, including an assessment of the site conditions, and is most easily implemented where a release has occurred, a response is necessary, and a remedy determination has been made. In fact, EPA already requires financial responsibility identified on a site-by-site basis when requiring parties to carry out response actions under CERCLA. EPA notes that state regulatory programs

318 R2 FR 3403–04.

1. Overall Concerns Regarding Cost and Economic Impact
EPA received significant comments on the Regulatory Impact Analysis (RIA) for the proposed section 108(b) rule that...
highlight detrimental economic outcomes of concern to commentators. In addition to numerous comments critical of various methodological and data limitations in the RIA, the leading criticism focuses on the disparity between projected industry costs in comparison with the rule’s predicted transfer of liability costs from the government to the hardrock mining industry.

Using a period of analysis from 2021 to 2055, and assuming a seven percent social discount rate, EPA estimated the annualized compliance costs for industry to procure third-party instruments would be approximately $111 to $171 million (the net present value (NPV) of which is $1.4 to 2.2 billion over 34 years). These values represent the proposed rule’s estimated incremental costs to industry.321

EPA then also quantified the transfer of potential CERCLA-related costs from the government to private industry that the proposed rule would yield. Based on an assumed facility default rate of 7.5 percent, the rule was expected to transfer a burden of just $15 to $20.5 million in annual liability from the federal government to the regulated industry (or $511 to $527 million over 34 years).

Based on these estimates, commentators objected that the projected annualized costs to industry ($111–$171 million) are a magnitude of order higher than the avoided costs to the government ($15–15.5 million) sought by the rule. Estimates of government cost savings in the baseline, and industry compliance costs under the rule, do not occur under different regulatory scenarios and are therefore not readily comparable. However, these findings do reveal that the costs borne by industry far exceed the relative scale of cost savings gained by the government as a result of the rule. In the words of one owner/operator, “the proposed rules inflict grossly disproportionate burdens on the hardrock mining industry relative to the small benefit that it is intended to provide to the taxpayers.”322

Beyond these concerns, commentators also took significant issue with the broader economic impacts that the rule could have on the hardrock mining industry and the nation. A trade association noted that the cost of compliance relative to cash flow will be devastating to many companies.323 According to some, the high cost of compliance will result in existing mines closing, and new mines not being built. Another commenter stated that the high costs of the rule would force companies into bankruptcy, which they suggested is an unacceptable environmental risk without any demonstrated benefits.324 That commenter stated that it takes much effort and expertise over several years to administer a bankruptcy, so it is important to keep operators in business to conduct their own reclamation responsibilities.325

State mining associations also repeatedly commented on the importance of the hardrock mining sector in their individual states.326 States commented that they would be grievously harmed financially if facilities reduced operations, ceased planned expansions, or otherwise closed or went bankrupt. In states where mining is prevalent, those states count heavily upon the tax and permitting revenues, mines, jobs, etc. that come from the industry.

According to AEMA the cash collateral required to obtain a section 108(b) financial responsibility instrument could be significant and also very problematic, because this cash collateral requirement reduces the capital that companies have available to conduct reclamation activities, advance environmental improvement initiatives, and pursue development opportunities. Ultimately, AEMA commented that the drain on corporate capital from the section 108(b) financial responsibility program would reduce the domestic production of minerals, cost hardrock mining jobs, and economically devastate mining dependent rural communities.327

In an effort to further emphasize the adverse economic impacts of the proposed rule, an analysis was independently conducted by Dr. Gordon Rausser of OnPoint Analytics, on behalf of Freeport McMoRan, and submitted for the record in this rulemaking.328

321 The majority of the industry costs represented a transfer from the regulated industry to the financial industry in association with the procurement of third-party instruments, and hence the quantified annualized net social costs were estimated at $30 million to $44 million.


325 Ibid., page 1.


These industry supported analyses found that when all impacts are considered (including impacts on cash flow, production, and available resources), the proposed rule is estimated to cost the U.S. hardrock mining industry ten times the amount projected in the RIA—a cost reported to be between 23 percent and 66 percent of annual industry profits. The study also estimates that U.S. investment in the hardrock mining industry would drop by more than $5.6 billion, and that between 3,486 to 10,110 jobs would be lost in the U.S. hardrock mining industry should the proposed rule have become final.329

Lastly, commentators note that while mining occurs at the local level, the mining sector is a global industry. A commenter stated that increased costs have implications at the state and local levels, but these same increased costs could place U.S. mining at a competitive disadvantage. The commenter further explained that those increases could be a disincentive to investment in domestic projects and an incentive to focus on operations and production outside of the U.S.330 The commenter continued to speculate that this could further result in a shortage of strategic metals at home. The commenter explained by way of an example that lithium is viewed as a strategic mineral currently in high demand globally as a lubricant, for use in steel and aluminum production, and in batteries and in electrolytes and electrodes.331 Finally, the commenter stated that lithium mining is an area of considerable expansion in the U.S., and implied that could be threatened under the proposed rule.332

EPA’s decision not to issue final requirements under section 108(b) for hardrock mining facilities will not alleviate potential burden on owners and operators, and will help prevent any disruptions to markets in the U.S. and abroad. EPA further seeks to avoid negatively impacting facility resources that could otherwise have greater benefits to the economy. The state of Idaho, for example, commented that the proposed requirements may divert funds from uses such as the implementation of environmental protection and enhancement programs, reclamation projects, exploration and


331 Ibid.

332 Ibid.
2. Concerns Particular to Impacts on Small Entities/Businesses

Concerns raised by commenters also point to the burden that the proposed rule could impose on small entities. In the RIA of the proposed rule, EPA assessed the economic impacts on small entities. Of the 221 mines and mineral processing facilities in the potentially regulated universe, EPA identified approximately 53 facilities that were owned by 44 small businesses. Twelve additional mines have owners of unknown size (due to lack of available company data). For these small entities, EPA compared the estimated annualized compliance costs with their annual revenues in order to assess whether these small entities could be expected to incur costs that constitute a significant impact; and whether the number of those small entities estimated to incur a significant impact represent a substantial number of small entities. Results of the analysis showed that 80 percent to 87 percent of these small entities may face an average annual compliance cost that is greater than one percent of their revenues. Similarly, 57 percent to 75 percent of these small entities may experience impacts upon revenues that exceed three percent. These impact estimates were found by EPA to surpass the significant impact thresholds as set forth by the Regulatory Flexibility Act.

In line with these findings, many of the commenters likewise suggested that a major number of small entities under the proposed rule would face significant annualized costs which would either severely hinder their ability to operate, cause them to cease operations, or be a barrier to them being able to acquire financing to begin new operations. In light of the findings from the Agency’s own small entity analyses, and the comments of concern raised by the regulated community, EPA agrees that the proposed financial responsibility requirements could prove particularly burdensome for small businesses. Such impacts will be avoided in the absence of such requirements under this final decision.

D. Concerns Regarding Financial Responsibility Instrument Availability

As discussed above, during the public comment period for the section 108(b) hardrock mining rule, commenters representing or participating in the insurance, surety, and banking industries identified several concerns with EPA’s proposed instrument terms, and expressed concern that those terms could impact the availability of instruments. Similarly, entities in the mining industry expressed concerns that instruments may not be available for the amounts proposed in the forms specified. EPA agrees with these concerns.

Section 108(b) discusses particular instruments for EPA to consider in its regulations. Specifically, paragraph (b)(2) states that financial responsibility may be established by any one, or any combination, of the following: insurance, guarantee, surety bond, letter of credit, or qualification as a self-insurer. Paragraph (b)(2) further authorizes the President to specify policy or other contractual terms, conditions, or defenses that are necessary, or that are unacceptable in establishing evidence of financial responsibility. Paragraph (b)(2) also requires EPA to cooperate with and seek the advice of the commercial insurance industry to the maximum extent practicable when developing financial responsibility requirements. Paragraph (b)(4) provides direction on how the section 108(b) instruments are to address multiple owners and operators at a single facility.

Section 108(c) also includes a “direct action” provision, under which CERCLA claims can be brought directly against an insurer or other entity issuing an instrument pursuant to the section 108(b) regulations. Section 108(c)(2) provides that any claim authorized by section 107 or section 111 may be asserted directly against any guarantor providing evidence of financial responsibility under section 108(b) if the person is liable under section 107 and: (1) Is in bankruptcy, reorganization, or arrangement pursuant to the Federal Bankruptcy Code, or (2) is likely to be solvent at the time of judgment but over whom jurisdiction in the federal courts cannot be reached with reasonable diligence.

The areas of most significant concern identified by commenters are: (1) The specification that the instruments need pay to multiple claimants; (2) the direct action provisions in the instruments; and (3) the continuity of coverage provisions that subject providers to potential liability. These three features of the proposed section 108(b) financial responsibility program and the comments received regarding each are discussed below.

The Specification That the Instruments Need Pay to Multiple Claimants

EPA proposed that instruments would be payable to the full range of potential future CERCLA claimants, and not solely to a currently designated beneficiary specified in instruments. Financial industry representatives commenting on the proposed rule expressed concerns that the proposed financial mechanisms would not have a single designated beneficiary. Commenters argued that instrument providers would be required to undertake more due diligence and exercise more discretion while also potentially being subject to more liability themselves absent a specified designated beneficiary.

Direct Action Provision

Commenters also expressed concern that providers of instruments may be subject to direct action suit. However, the CERCLA statute itself, at section 108(c)(2), includes a direct action provision that expressly authorizes, in specified circumstances, any claim under section 107 and section 111 be made directly against the guarantor providing evidence of financial responsibility. Commenters from the surety industry claimed that the direct action provision significantly increased their risk exposure and included too broad of a trigger (bankruptcy). Banking industry representatives asserted that the provision was at odds with relevant commercial law and practice and would significantly deter banks from providing such instruments and services. The insurance industry commented that direct action creates the potential for significant increase in defense costs and administrative costs associated with the management of multiple lawsuits.

Continuity of Coverage Provisions

To address the risk that the facility would no longer have financial responsibility when necessary, EPA proposed that owners and operators using a letter of credit, surety bond or insurance to demonstrate financial responsibility also establish a standby trust. In the event the instrument issuer intended to cancel the instrument and the owner or operator failed to obtain alternate financial responsibility, EPA could draw on the instrument and fund the standby trust.

Commenters from the surety and insurance industry suggested that the requirements for prescriptive cancellation provisions that include potential issuer liability would limit the interest on behalf of sureties and insurers in providing mechanisms.
Commenters also suggested that this proposed provision in combination with the difficult-to-predict date at which a facility may be released from the proposed financial responsibility requirements created unwelcome uncertainty around the duration of the provider’s obligation.

Based on the negative comments received, EPA believes there is uncertainty around the adequate availability of instruments were final regulations to be promulgated at this time. This uncertainty necessarily means it is also unclear whether regulated entities would be able to obtain the necessary instruments when faced with a regulatory obligation under section 108(b) to obtain an instrument. This information thus also indicates that issuance of section 108(b) requirements for current hardrock mining operations is not appropriate.

E. Challenges To Identify the Facility

Many commenters on the rule raised concerns regarding the applicability of section 108(b) to historical mining areas at facilities. The question of what the relevant facility is for purposes of section 108(b) regulations arose in several contexts—developing requirements for applicability of the rule, determining a financial responsibility amount, and developing conditions for payment of funds from the instruments. This was another difficult challenge EPA encountered in developing the proposed rule.

In a typical CERCLA response action, the definition of the facility relies on a site-by-site determination based on site-specific conditions, and the facility is defined by where contamination comes to be located, as understood by EPA at a particular point in time, and is typically formally delineated in a decision document identifying the response actions to be taken. The relevant facility may include areas owned and/or operated by several parties and the facility is defined without regard to ownership. In addition, particular parties’ CERCLA liability is determined through settlements and/or litigation.

For the reasons discussed in the proposed rule, for purposes of determining the proposed rule’s applicability, and for determining the financial responsibility amount, EPA found it necessary to consider the relevant facility to be only the current owner(s) or operator(s). Two effects of this approach were to not require a financial responsibility amount under the proposed rule based on conditions present at historic areas of the mine, or to require evidence of financial responsibility from parties other than the current owner(s) or operator(s). This approach—that EPA found necessary to implement section 108(b)—has no effect on CERCLA liability for parties that may be involved at a CERCLA site, or on the definition of facility for purposes of a CERCLA response. Thus, in the context of a particular response action, the facility may be defined to include an area broader than the current operations, and CERCLA liability may attach to parties other than the current owner or operator. Thus, there is an inconsistency in these respects between what EPA believed was necessary for practical development of section 108(b) instruments, and the definition that would apply when the instruments are invoked.

This difficulty was also identified by outside parties to EPA. Instrument providers, during pre-proposal outreach cited the inability to distinguish between and establish separate amounts for historic releases and potential future releases as a factor that may increase the cost and difficulty of obtaining instruments. Specifically, representatives of insurance companies noted that combining two distinct types of coverage (e.g., coverage for cleanup of known existing releases and coverage for liabilities that may arise from future releases) will increase premiums. Another insurance representative commented that amounts of coverage may be limited by reinsurance treaties if the two types of coverage were combined. Relatedly, a representative from a surety also noted that separating out known pre-existing issues and releases from current operations that have not yet occurred into separate mechanisms would likely enhance availability. Yet it was the impossibility of predetermining the source of any contamination that would ultimately be the subject of a CERCLA claim, or where contamination would ultimately come to be located, that was a factor in EPA’s decision to propose instruments that could pay for any CERCLA section 107 or section 111 claims against a current owner or operator, irrespective of whether the claim arose as a result of current or historical operations.

Commenters’ concerns also highlight another source of uncertainty for instrument availability. Thus, this issue raises similar concerns as in section E. Above. Therefore, this information further supports EPA’s determination that issuance of section 108(b) requirements for current hardrock mining operations is not appropriate.

VII. Statutory and Executive Order Reviews

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

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review, because it may raise novel legal or policy issues [3(f)(4)], although it is not economically significant. Any changes made in response to OMB recommendations have been documented in the docket. EPA prepared an economic analysis for the proposed rule, but that analysis is not relevant for this final rulemaking because no regulatory provisions are being finalized.

B. Executive Order 13771: Reducing Regulation and Controlling Regulatory Costs

This action is not an Executive Order 13771 regulatory or deregulatory action, because this action does not alter any regulatory requirements.

C. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the PRA, because this action does not impose any regulatory requirements.

D. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action will not impose any requirements on small entities.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments, because this action does not impose any regulatory requirements.

F. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national

336 Additional information about these statutes and Executive Orders can be found at https://www.epa.gov/laws-regulations/laws-and-executive-orders.
government and the states, or on the distribution of power and responsibilities among the various levels of government.

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

This action does not have tribal implications as specified in Executive Order 13175, because this action imposes no regulatory requirements. Thus, Executive Order 13175 does not apply to this action. However, EPA consulted with tribes and Alaska Native Corporations and Alaska Native Villages during the rulemaking process.

EPA received comments from three federally-recognized tribes and from three Alaska Native Claims Settlement Act (ANCSA) resource managers regarding section 108(b) financial responsibility. Tribal comments were generally in support of the proposed rule, and cited some concerns about the potential negative impacts of hardrock mining on commercial enterprises and on subsistence living, along with the need to more fully identify the benefits of the rule. A primary ANCSA concern was that the section 108(b) financial responsibility requirements would duplicate existing federal and state requirements, resulting in a negative impact on Alaska Natives and states, that receive royalties through the Regional and Village Corporations. Other ANCSA comments related primarily to the calculation of the financial responsibility amount, and requested that EPA consult with them early in the regulatory development process. EPA acknowledged the challenges in determining a financial responsibility amount, and provided the opportunity for federally-recognized tribes and ANCSA resource managers to consult with the Agency during the public comment period.

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

This action is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866, and because EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children, since this action imposes no regulatory requirements.

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

This action is not a “significant energy action” because it is not likely to have a significant adverse effect on the supply, distribution or use of energy.

J. National Technology Transfer and Advancement Act

This rulemaking does not involve technical standards.

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

EPA believes that this action is not subject to Executive Order 12898 (59 FR 7629, February 16, 1994) because it does not establish an environmental health or safety standard, since this action imposes no regulatory requirements.

L. Congressional Review Act (CRA)

This action is subject to the CRA, and EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 320

Environmental protection, Financial responsibility, Hardrock mining, Hazardous substances.

Dated: December 1, 2017.

E. Scott Pruitt,
Administrator.

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BILLING CODE 6560–50–P
The President

Proclamation 9697—Honoring the Victims of the Tragedy in Parkland, Florida
Proclamation 9697 of February 15, 2018

Honoring the Victims of the Tragedy in Parkland, Florida

By the President of the United States of America

A Proclamation

Our Nation grieves with those who have lost loved ones in the shooting at the Marjory Stoneman Douglas High School in Parkland, Florida. As a mark of solemn respect for the victims of the terrible act of violence perpetrated on February 14, 2018, by the authority vested in me as President of the United States by the Constitution and the laws of the United States of America, I hereby order that the flag of the United States shall be flown at half-staff at the White House and upon all public buildings and grounds, at all military posts and naval stations, and on all naval vessels of the Federal Government in the District of Columbia and throughout the United States and its Territories and possessions until sunset, February 19, 2018. I also direct that the flag shall be flown at half-staff for the same length of time at all United States embassies, legations, consular offices, and other facilities abroad, including all military facilities and naval vessels and stations.

IN WITNESS WHEREOF, I have hereunto set my hand this fifteenth day of February, in the year of our Lord two thousand eighteen, and of the Independence of the United States of America the two hundred and forty-second.

[Signature]
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H.R. 582/P.L. 115–127
Kari’s Law Act of 2017 (Feb. 16, 2018; 132 Stat. 326)

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