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# Rules and Regulations

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## DEPARTMENT OF AGRICULTURE

### Agricultural Marketing Service

### 7 CFR Part 1217

**[Document Number AMS–SC–16–0066]**

## Softwood Lumber Research, Promotion, Consumer Education and Industry Information Order; De Minimis Quantity Exemption Threshold

**AGENCY:** Agricultural Marketing Service, USDA.

**ACTION:** Final rule.

**SUMMARY:** This rule establishes a de minimis quantity exemption threshold under the U.S. Department of Agriculture's (USDA) Agricultural Marketing Service (AMS) regulations regarding a national research and promotion program for softwood lumber. In response to a 2016 federal district court decision, the U.S. Department of Agriculture (USDA) conducted a new analysis to determine a reasonable and appropriate de minimis threshold. Based on that analysis, this rule establishes the de minimis quantity threshold at 15 million board feet (mmbf) and entities manufacturing (and domestically shipping) or importing less than 15 mmbf per year will be exempt from paying assessments under the regulations.

**DATES:** *Effective Date:* November 27, 2017.

**FOR FURTHER INFORMATION CONTACT:** Maureen T. Pello, Marketing Specialist, Promotion and Economics Division, Specialty Crops Program, AMS, USDA, P.O. Box 831, Beavercreek, Oregon, 97004; telephone: (503) 632–8848; facsimile (503) 632–8852; or electronic mail: *Maureen.Pello@ams.usda.gov.*

**SUPPLEMENTARY INFORMATION:** This rule, affecting 7 CFR part 1217, is authorized under the Commodity Promotion, Research and Information Act of 1996 (1996 Act) (7 U.S.C. 7411–7425).

### 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 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 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules and promoting flexibility. This action falls within a category of regulatory actions that the Office of Management and Budget (OMB) 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).

### Executive Order 13175

This action has been reviewed in accordance with the requirements of Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. The review reveals that this rule will not have substantial and direct effects on Tribal governments and will not have significant Tribal implications.

### Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. It is not intended to have retroactive effect. Section 524 of the 1996 Act (7 U.S.C. 7423) provides that it shall not affect or preempt any other Federal or State law authorizing promotion or research relating to an agricultural commodity.

Under section 519 of the 1996 Act (7 U.S.C. 7418), a person subject to an order may file a written petition with USDA stating that an order, any provision of an order, or any obligation imposed in connection with an order, is not established in accordance with the law, and request a modification of an order or an exemption from an order. Any petition filed challenging an order, any provision of an order, or any obligation imposed in connection with an order, shall be filed within two years after the effective date of an order, provision, or obligation subject to challenge in the petition. The petitioner will have the opportunity for a hearing on the petition. Thereafter, USDA will issue a ruling on the petition. The 1996 Act provides that the district court of the United States for any district in which the petitioner resides or conducts business shall have the jurisdiction to review a final ruling on the petition, if the petitioner files a complaint for that purpose not later than 20 days after the date of the entry of USDA's final ruling.

### Background

This rule establishes a de minimis quantity exemption threshold under the Softwood Lumber Research, Promotion, Consumer Education and Industry Information Order (Order), codified at 7 CFR part 1217. This part is administered by the Softwood Lumber Board (Board) with oversight by USDA's Agricultural Marketing Service (AMS). In *Resolute Forest Products Inc.,* v. *USDA, et al.* (*Resolute*), the court found that, on the basis of the estimates and information submitted by the government to the court for review, the selection of 15 mmbf as the de minimis quantity (to be exempted) under part 1217 was arbitrary and capricious and that part 1217 was therefore promulgated unlawfully. The court did not vacate (or terminate) part 1217; the court remanded the matter to USDA and program requirements remain in effect.

To address the court's decision, USDA conducted a new analysis to determine a reasonable and appropriate de minimis quantity exemption. USDA analyzed various thresholds of exemption: 10, 15, 20, 25, and 30 mmbf. USDA also considered proposing no de minimis exemption. USDA's analysis of the data resulted in a determination that a de minimis level of 15 mmbf is reasonable and appropriate. The analysis was published in a proposed rule on May 30, 2017 (82 FR 24583). This final rule establishes the de minimis quantity threshold under part 1217 at 15 mmbf.

### Authority in the 1996 Act

The 1996 Act authorizes USDA to establish agricultural commodity research and promotion orders which may include a combination of promotion, research, industry

information, and consumer information activities funded by mandatory assessments. These programs are designed to maintain and expand markets and uses for agricultural commodities. As defined under section 513(1)(D) of the 1996 Act, agricultural commodities include the products of forestry, which includes softwood lumber.

The 1996 Act provides for a number of optional provisions that allow the tailoring of orders for different commodities. Section 516 of the 1996 Act provides permissive terms for orders. Section 516 states that an order may include an exemption of de minimis quantities of an agricultural commodity. Further, section 516(g) of the 1996 Act provides authority for other action that is consistent with the purpose of the statute and necessary to administer a program.

**Overview of the Softwood Lumber Program**

The softwood lumber program took effect in August 2011 (76 FR 46185) and assessment collection began in January 2012. Under part 1217, assessments are collected from domestic (U.S.) manufacturers and importers and are used by the Board for projects that promote market growth for softwood lumber products used in single and multi-family dwellings as well as commercial construction. The Board is composed of 19 industry members (domestic manufacturers and importers) who are appointed by the Secretary of Agriculture. The purpose of the program is to strengthen the position of softwood lumber in the marketplace, maintain and expand markets for softwood lumber, and develop new uses for softwood lumber within the United States.

**Relevant Order Provisions**

*Domestic Manufacturers*

The term 'domestic manufacturer' is defined in § 1217.8 to mean any person who is a first handler engaged in the manufacturing, sale and shipment of softwood lumber in the United States during a fiscal period and who owns, or shares in the ownership and risk of loss of manufacturing of softwood lumber or a person who is engaged in the business of manufacturing, or causes to be manufactured, sold and shipped such softwood lumber in the United States beyond personal use. The term does not include persons who re-manufacture softwood lumber that has already been subject to assessment. The term 'manufacture' is defined in § 1217.13 to mean the process of transforming (or turning) softwood logs into softwood lumber.

Domestic manufacturers are essentially sawmills that turn softwood logs into lumber. A domestic manufacturer may be a company that is a single sawmill, or it may be a company that is composed of multiple sawmills.

*Importers*

The term 'importer' is defined in § 1217.11 to mean any person who imports softwood lumber from outside the United States for sale in the United States as a principal or as an agent, broker, or consignee of any person who manufactures softwood lumber outside the United States for sale in the United States, and who is listed in the import records as the importer of record for such softwood lumber. Import records are maintained by the U.S. Customs and Border Protection (Customs or CBP). Both domestic manufacturers and importers may be referred to in this rulemaking as ''entities.''

*Expenses and Assessments*

Pursuant to § 1217.50, the Board is authorized to incur expenses for research and promotion projects as well as administration. The Board's expenses are paid by assessments upon domestic manufacturers and importers. Pursuant to § 1217.52(b), and subject to the exemptions specified in § 1217.53, each domestic manufacturer and importer must pay an assessment to the Board at the rate of $0.35 per thousand board feet of softwood lumber, except that no entity has to pay an assessment on the first 15 mmbf of softwood lumber otherwise subject to assessment in a fiscal year. Domestic manufacturers pay assessments based on the volume of softwood lumber shipped within the United States and importers pay assessments based on the volume of softwood lumber imported to the United States. Pursuant to paragraphs (d) and (j) in § 1217.52, respectively, domestic manufacturers and importers who pay their assessments to the Board must do so no later than the 30th calendar day of the month following the end of the quarter in which the softwood lumber was shipped or imported.

*Exemptions*

Section 1217.53 prescribes exemptions from assessment. Pursuant to paragraph (a) of that section, the original de minimis quantity exemption threshold under part 1217 was 15 mmbf. Thus, U.S. manufacturers and importers that domestically ship and/or import less than 15 mmbf feet annually have been exempt from paying assessments. Domestic manufacturers and importers that ship or import less than the de minimis quantity of softwood lumber must apply to the Board each year for a certificate of exemption and provide documentation as appropriate to support their request.

Pursuant to paragraph (b) of § 1217.53, domestic manufacturers and importers that ship or import 15 mmbf or more annually do not pay assessments on their first 15 mmbf domestically shipped or imported. This *exemption* is intended for the purpose of creating an equality amongst those within the industry with regard to the program's assessment. Just as those that manufacture or import under 15 mmbf do not have to pay assessments, those at or above this level may reduce their assessable volume by 15 mmbf.[1] For example, an entity that ships or imports 20 mmbf annually only has to pay assessments on 5 mmbf of softwood lumber. This *exemption* creates fairness; it levels the playing field because all entities, regardless of size, do not have to pay assessments on their first 15 mmbf shipped or imported. For purposes of this document, this exemption is referred to as the ''equity exemption.'' Pursuant to paragraphs (c) and (d) of § 1217.53, respectively, exports of softwood lumber from the United States and organic softwood lumber are also exempt from assessment.

*Reports and Records*

Pursuant to § 1217.70, domestic manufacturers and importers who pay their assessments directly to the Board must submit with their payment a report that specifies the quantity of softwood lumber domestically shipped or imported. Pursuant to § 1217.71, all domestic manufacturers and importers must maintain books and records necessary to verify reports for a period of 2 years beyond the fiscal year to which they apply, including those exempt. These records must be made available during normal business hours for inspection by Board staff or USDA.

*Other Relevant Order Provisions*

The original 15 mmbf quantity exemption threshold is referenced in other Order provisions. Section 1217.40 specifies that the Board is composed of domestic manufacturers and importers who domestically ship or import 15 mmbf or more of softwood lumber annually. Section 1217.41 specifies that

[1] USDA notes that the de minimis level and the equity exemption are purposefully aligned and any change in the de minimis would result in a corresponding modification to the equity exemption.

persons interested in serving on the Board must also domestically ship or import 15 mmbf or more softwood lumber annually. Finally, § 1217.101 regarding referendum procedures specifies that eligible domestic manufacturers and importers that can vote in referenda must domestically ship or import 15 mmbf or more of softwood lumber annually.

**Initial Referendum and Summary of Board Activities**

The softwood lumber program was implemented after notice and comment rulemaking and a May 2011 referendum demonstrating strong support for the program. Pursuant to § 1217.81(a), the program had to pass by a majority of those voting in the referendum who also represented a majority of the volume voted. Sixty-seven percent of the entities who voted, who together represented 80 percent of the volume, in the referendum favored implementation of the program. Entities that domestically shipped or imported 15 mmbf or more of softwood lumber annually were eligible to vote in the referendum. As previously mentioned, the program took effect in August 2011 and assessment collection began in January 2012.

The softwood lumber program has continued to operate at the 15 mmbf exemption threshold since its inception. During these years, the Board has funded a variety of activities designed to increase the demand for softwood lumber. The Board funded a U.S. Tall Wood Building Prize Competition that is helping to showcase the benefits of building tall structures with wood. The Board also funds research on wood standards; a communications program, which includes continuing education courses for architects and engineers; and a construction and design program that provides technical support to architects and structural engineers about using wood.

**Summary of USDA's Analysis of the De Minimis Quantity Under the Softwood Lumber Program**

The Secretary has authority under section 516 of the 1996 Act to exempt any de minimis quantity of an agricultural commodity otherwise covered by an order: ''An order issued under this subchapter may contain . . . authority for the Secretary to exempt from the order any de minimis quantity of an agricultural commodity otherwise covered by the order. . . .'' 7 U.S.C. 7415(a). A de minimis quantity exemption allows an industry to exempt from assessment small entities that could be unduly burdened from an order's requirements (*i.e.,* assessment and quarterly reporting obligations). Because the 1996 Act does not prescribe the methodology or formula for computing a de minimis quantity, the Secretary has discretion to determine a reasonable and appropriate quantity and establish this level through notice and comment rulemaking. Pursuant to section 525 of the 1996 Act, 7 U.S.C. 7424, the Secretary may issue such regulations as may be necessary to carry out an order.

In evaluating the merits of a de minimis quantity for the softwood lumber program, USDA considered several factors. These factors include: an estimate of the total quantity of softwood lumber covered under part 1217 (quantity assessed and quantity exempted); available funding to support a viable program; free rider implications; and the impact of program requirements on entities (above and below a de minimis threshold). USDA reviewed such factors in light of all available data and information to determine whether a de minimis quantity is reasonable. USDA balanced the multiple factors to assess whether one exemption threshold would work better than another when the factors are considered collectively. The analysis was based on the current assessment rate of $0.35 per thousand board feet.[2]

The following tables are republished from USDA's analysis of the de minimis quantity under the softwood lumber program contained in the May 2017 proposed rule (82 FR 24583).

Table 1 shows the estimate of the supply of U.S. softwood lumber used in the analysis, accounting for both U.S. shipments and imports. U.S. shipments were estimated using capacity[3] data from Forest Economic Advisors (FEA). Total imports was estimated using data from CBP.

TABLE 1—SUPPLY OF SOFTWOOD LUMBER IN THE U.S. (MMBF)

| Shipments [1] | Imports [2] | Supply [3] |
|---|---|---|
| 28,754 ..... | 12,495 | 41,249 |

[1] FEA; [2] CBP; [3] The sum of U.S. Shipments and Imports.

Table 2 shows assessable volume and revenue at exemption levels of 30, 25, 20, 15 and 10 mmbf, as well as with no exemptions. The table accounts for both the de minimis and equity exemptions under part 1217, and an assessment rate of $0.35 per thousand board feet.

TABLE 2—ASSESSABLE VOLUME AND ASSESSMENT REVENUE AT EXEMPTION LEVELS (MMBF) [1]

| Volume equal to or greater than | De minimis exemption only | De minimis and equity exemptions | Assessment revenue ($) [2] |
|---|---|---|---|
| 30 | 37,965 | 32,805 | $11,481,698 |
| 25 | 38,319 | 33,694 | 11,792,941 |
| 20 | 38,990 | 34,690 | 12,141,349 |
| 15 | 39,679 | 35,854 | 12,548,792 |
| 10 | 40,013 | 37,183 | 13,014,059 |
| No exemptions | 41,249 | 41,249 | 14,437,099 |

[1] 2015 data from FEA and CBP were used to construct this table.
[2] The product of total assessable volume, accounting for both de minimis and equity exemptions, and the assessment rate of $0.35 per thousand board feet.

[2] If the assessment rate changes significantly, USDA could revisit the de minimis threshold.

[3] A sawmill's operating capacity is the total amount of softwood lumber that it could manufacture (or produce) if fully utilizing all of its resources (such as labor and equipment).

Table 3 is the inverse of Table 2 in that it shows exempt volume at de minimis and equity exemptions of 30, 25, 20, 15 and 10 mmbf.

TABLE 3—EXEMPT VOLUME AT EXEMPTION LEVELS (MMBF) [1]

| Volume less than | De minimis exemption only | | De minimis and equity exemptions | |
|---|---|---|---|---|
| | Volume | % Exempt [2] | Volume | % Exempt [2] |
| 30 | 3,284 | 8 | 8,444 | 20 |
| 25 | 2,930 | 7 | 7,555 | 18 |
| 20 | 2,259 | 5 | 6,559 | 16 |
| 15 | 1,570 | 4 | 5,395 | 13 |
| 10 | 1,236 | 3 | 4,066 | 10 |

[1] 2015 data from FEA and CBP were used to construct this table.
[2] The quotient of total exempt volume and total 2015 U.S. supply (the sum of U.S. shipments and U.S. imports) of 41,249 MMBF.

Table 4 shows the number of entities (domestic manufacturers and importers) that would be assessed and the number of entities that would be exempt at the exemption thresholds of 30, 25, 20, 15 and 10 mmbf.

TABLE 4—ASSESSED AND EXEMPT ENTITIES AT EXEMPTION LEVELS (MMBF) [1]

| Volume (MMBF) | Assessed | | Exempt | |
|---|---|---|---|---|
| | Number of entities | % Assessed [2] | Number of entities | % Exempt [2] |
| 30 | 172 | 16 | 882 | 84 |
| 25 | 185 | 18 | 869 | 82 |
| 20 | 215 | 20 | 839 | 80 |
| 15 | 255 | 24 | 799 | 76 |
| 10 | 283 | 26 | 771 | 73 |
| None | 1,054 | 100 | ..... | 0 |

[1] 2015 data from FEA and CBP were used to construct this table.
[2] The quotient of No. of Entities and total domestic manufacturers and importers recorded in the industry (1,054) in 2015.

Based on its analysis, USDA determined the following: Exemption thresholds of 10 to 15 mmbf would exempt 10 to 13 percent of the total volume of softwood lumber (taking into account both the de minimis and equity exemptions). This is close to the range exempt under other research and promotion programs. While all of the exemption thresholds analyzed would generate sufficient revenue for a viable program, the additional revenue that could be collected if the de minimis level were reduced much lower than 15 mmbf would likely not be worth the additional costs. At this threshold, free rider implications would be minimal because only 4 percent of the volume of softwood lumber would be exempted as de minimis. Applying both the de minimis and equity exemptions at 15 mmbf would allow the program to assess almost 90 percent of the total volume of softwood lumber.

Further, the program functioned successfully in 2015 with assessment revenue of $12.905 million with de minimis and equity exemptions of 15 mmbf. The Board has conducted activities at this level of funding that have helped build demand for softwood lumber, including a prize competition for tall wood buildings, research on wood standards, and an education program for architects and engineers on building with wood. An independent evaluation completed in 2016 concluded that activities of the Board increased sales of softwood lumber between 2011 and 2015 by 1.683 bbf or $596 million. This equates to a return on investment of $15.55 of additional sales for every $1 spent on promotion by the Board.[4]

Therefore, when considering all of the factors collectively, USDA concludes that 15 mmbf is a reasonable and most appropriate de minimis quantity under part 1217.[5] Accordingly, this rule establishes the de minimis quantity threshold under part 1217 at 15 mmbf. Thus, no amendment to part 1217 is necessary.

## Final Regulatory Flexibility Act Analysis

In accordance with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), AMS is required to examine the impact of this final rule on small entities as defined by the Small Business Administration (SBA). The classification of a business as small, as defined by the SBA, varies by industry. If a business is defined as ''small'' by SBA size standards, then it is ''eligible for government programs and preferences reserved for 'small business' concerns.'' [6] Accordingly, AMS has considered the economic impact of this action on such entities.

The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions so that small businesses will not be disproportionately burdened. The SBA defines, in 13 CFR part 121, small agricultural producers as those having annual receipts of no more than $750,000 and small agricultural service firms (domestic manufacturers and importers) as those having annual receipts of no more than $7.5 million.[7]

[4] Prime Consulting, Softwood Lumber Board, Comprehensive Program ROI, 2012–2015, February 2016.

[5] As stated previously, the de minimis level and the equity exemption are purposefully aligned, and therefore this conclusion accounts for the equity exemption at 15 mmbf.

[6] *https://www.sba.gov/contracting/getting-started-contractor/make-sure-you-meet-sba-size-standards/small-business-size-regulations.*

[7] SBA does have a small business size standard for ''Sawmills'' of 500 employees (see *https://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf*). Based on USDA's understanding of the lumber industry, using this

Using an average price of $330 per thousand board feet,[8] a domestic manufacturer or importer who ships less than about 23 mmbf per year would be considered a small entity for purposes of the RFA. As shown in Table 4, there were 1,054 domestic manufacturers and importers of softwood lumber based on 2015 data. Of these, 864 entities shipped or imported less than 23 mmbf and would be considered to be small entities under the SBA definition. Thus, based on the $7.5 million threshold, the majority of domestic manufacturers and importers of softwood lumber would be considered small entities for purposes of the RFA.

This action establishes a de minimis quantity exemption threshold under part 1217. Part 1217 is administered by the Board with oversight by USDA. In response to a federal district court decision in *Resolute,* USDA conducted a new analysis to determine a reasonable and appropriate de minimis threshold. Based on this analysis, this final rule establishes the de minimis quantity threshold at 15 mmbf and entities manufacturing (and domestically shipping) or importing less than 15 mmbf per year would be exempt from paying assessments under part 1217. Authority for this action is provided in sections 516(a)(2), 516(g) and 525 of the 1996 Act.

Regarding the economic impact of the de minimis exemption, the exemption allows the Board to exempt from assessment small entities that would be unduly burdened by the program's obligations. At the 15 mmbf exemption threshold, small manufacturers and importers that domestically ship or import less than 15 mmbf of softwood lumber will not have to pay assessments under the program.

Additionally, larger manufacturers and importers will not have to pay assessments on the first 15 mmbf of softwood lumber domestically shipped or imported each year. This exemption is intended for the purpose of equity, whereby all entities who must pay assessments may reduce their assessable volume by 15 mmbf. This exemption benefits smaller manufacturers and importers whose annual shipments or imports are above the de minimis threshold of 15 mmbf. With this exemption, an entity that ships or imports a quantity of softwood lumber equal to the RFA-small business definition of 23 mmbf, would only pay assessments on no more than 8 mmbf of softwood lumber.

To calculate the impact of the assessment rate on the revenue of an assessment payer, the assessment rate is divided by an average price. Using an average 2015 price of $330 per thousand board feet, the assessment rate as a percentage of price could range from 0.106 percent at the current assessment rate to 0.151 percent at the maximum assessment rate. This analysis helps identify the impact of the assessment rate on the revenues of assessment payers. At the current assessment rate of $0.35 per thousand board feet to the maximum assessment rate of $0.50 per thousand board feet, assessment payers would owe between 0.106 percent and 0.151 percent of their revenues, respectively.

In its analysis of alternatives, USDA evaluated five different exemption thresholds—30, 25, 20, 15 and 10 mmbf using 2015 data—accounting for both the de minimis and equity exemptions, as well as having no exemptions under the program. USDA evaluated these alternatives based on the following factors: an estimate of quantity of softwood lumber covered under the program (quantity assessed and quantity exempted); available funding to support a viable program; free rider implications; and the impact of program requirements on entities (above and below a de minimis threshold). USDA conducted a balancing test among these factors to assess whether one exemption threshold works better than another when the factors are considered collectively.

In reviewing the quantity of assessable versus exempt softwood lumber at the alternative exemption thresholds, USDA found that at an exemption threshold of 30 mmbf, a total of 32.805 bbf would be assessed with 3.284 bbf, or 8 percent, exempt as de minimis, plus an additional 5.16 bbf exempt as equity for 20 percent of total volume exempt; at 25 mmbf, a total of 33.694 bbf would be assessed with 2.93 bbf, or 7 percent, exempt as de minimis, plus an additional 4.625 bbf exempt as equity for 18 percent total volume exempt; at a threshold of 20 mmbf, a total of 34.69 bbf would be assessed with 2.259 bbf, or 5 percent, exempt as de minimis, plus an additional 4.3 bbf exempt as equity for 16 percent total volume exempt; at a threshold of 15 mmbf, a total of 35.854 bbf would be assessed with 1.57 bbf, or 4 percent, exempt as de minimis, plus an additional 3.825 bbf exempt as equity for 13 percent total volume exempt; at a threshold of 10 mmbf, a total of 37.183 bbf would be assessed, with 1.236 bbf, or 3 percent, exempt as de minimis, plus an additional 2.83 bbf exempt as equity for 10 percent total volume exempt; and with no exemptions, a total of 41.249 bbf would be assessed. In reviewing the total volume exempt under the softwood lumber program (taking into account both the de minimis and equity exemptions), thresholds of 10 to 15 mmbf exempt between 10 and 13 percent of the volume, which is close to the range exempt under other programs.

In reviewing available funding to support a viable program at the alternative exemption thresholds, at an exemption threshold of 30 mmbf, estimated assessment revenue is $11.482 million; at 25 mmbf, estimated assessment revenue is $11.793 million (an additional $311,243); at a threshold of 20 mmbf, estimated assessment revenue is $12.141 million (an additional $348,408); at a threshold of 15 mmbf, estimated assessment revenue is $12.549 million (an additional $407,444); at a threshold of 10 mmbf, estimated assessment revenue is $13.014 million (an additional $465,267); and with no exemptions, estimated assessment revenue is $14.437 million (an additional $1.423 million).

Assessment revenue under the current softwood lumber program has ranged from about $10.638 million in 2012 to $12.905 million in 2015. At this level of revenue, the current program has seen success. The revenues reviewed at the different exemption thresholds are comparable to these levels or higher. Thus, all of the exemption thresholds analyzed would generate sufficient revenue for a viable program.

Regarding free riders, USDA notes that the key to assessing the free rider implications of a de minimis quantity is not the number of entities exempt under a program but rather the *volume* of product exempt. This is because assessments are based on volume shipped or imported and not on the number of entities; assessments are not paid by entities on a pro rata basis. In evaluating free rider implications at the alternative exemption thresholds, at an exemption threshold of 30 mmbf, 84 percent of the number of entities (or 882) would be exempt but only 8 percent of the volume would be exempt as de minimis; at a threshold of 25 mmbf, 82 percent of the number of entities (or 869) would be exempt, but only 7 percent of the volume would be exempt as de minimis; at a threshold of 20 mmbf, 80 percent of the number of entities (or 839) would be exempt, but

criteria would be impractical as sawmills often use contractors rather than employees to operate and, therefore, many mills would fall under this criteria while being, in reality, a large business. Therefore, USDA used agricultural service firm as a more appropriate criteria for this analysis.

[8] Random Lengths Publications, Inc.; *www.randomlengths.com.*

only 5 percent of the volume would be exempt as de minimis; at a threshold of 15 mmbf, 76 percent of the number of entities (or 799) would be exempt, but only 4 percent of the volume would be exempt as de minimis; and at a threshold of 10 mmbf, 73 percent of the number of entities (or 771) would be exempt, but only 3 percent of the volume would be exempt as de minimis.

In evaluating the impact of the program's requirements at the alternative exemption thresholds, entities that ship or import at or above the de minimis threshold must pay assessments to the Board. Assessment payers must also submit a report to the Board each quarter of the volume of softwood lumber shipped or imported for the respective quarter. Entities that ship or import below the de minimis threshold must apply to the Board each year for a certificate of exemption and provide documentation as appropriate to support their request. The reporting and recordkeeping requirements are detailed in the section below titled Paperwork Reduction Act.

At an exemption threshold of 30 mmbf, 172 entities would pay assessments and 882 would be exempt; at 25 mmbf, 185 entities would pay assessments and 869 would be exempt; at 20 mmbf, 215 entities would pay assessments and 839 would be exempt; at 15 mmbf, 255 entities would pay assessments and 799 would be exempt; at 10 mmbf, 283 entities would pay assessments and 771 would be exempt. Thus, as the exemption threshold is reduced, more entities would be subject to the assessment and quarterly reporting obligation under part 1217.

Further, in considering program compliance costs, USDA estimates the cost of an on-site audit of a single entity at $5,000 or more. Thus, the cost to pursue a compliance case against an entity that shipped less than 10 mmbf, 9 mmbf for example, would outweigh the revenue that would be collected from that entity of $3,150. Similarly, the assessment revenue that would be collected from an entity that shipped less than 15 mmbf, 12 mmbf for example, would amount to $4,200. The benefit of assessing smaller manufacturers, $3,150 at 9 mmbf and $4,200 at 12 mmbf, does not outweigh the cost of pursuing compliance cases against them at $5,000 per entity. The point at which the assessment revenue that would be collected from an entity outweighs the estimated cost of $5,000 to pursue a compliance case is an entity with volume equal to or greater than 14.3 mmbf.[9] This level is close to 15 mmbf. By this analysis, the selection of 15 mmbf as the de minimis quantity is reasonable.

Analysis of the 23 mmbf–RFA small business threshold as a reasonable option for de minimis shows that 190 entities would be subject to assessment and 864 entities would be exempt. In terms of volume, 38.44 bbf would be assessed, or 93 percent of total volume, and 2.809 bbf would be exempt, or 7 percent of total volume.

Based upon the analysis contained herein, any of the exemption thresholds reviewed would be reasonable because they would exempt from 3 to 8 percent of the volume of softwood lumber as de minimis. However, when the total volume exempt under the softwood lumber program is considered (taking into account both the de minimis and equity exemptions), thresholds of 10 to 15 mmbf exempt between 10 and 13 percent of the volume, which is close to the range exempt under other programs. While all of the exemption thresholds analyzed would generate sufficient revenue for a viable program, the additional revenue that could be collected if the de minimis level were reduced much lower than 15 mmbf would likely not be worth the additional costs. The softwood lumber program operated successfully since its inception at an exemption threshold of 15 mmbf.[10]

**Paperwork Reduction Act**

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the information collection and recordkeeping requirements imposed by part 1217 have been approved previously under OMB control number 0581–0093. This rule imposes no additional reporting and recordkeeping burden on domestic manufacturer and importers of softwood lumber. The reporting requirements pertaining to this rule are described in the following paragraphs.

As previously mentioned, pursuant to § 1217.53(a), domestic manufacturers and importers who domestically ship or import less than the de minimis threshold must apply to the Board each year for a certificate of exemption and provide documentation as appropriate to support their request. The reporting burden for this collection of information is estimated to average 0.25 hours per domestic manufacturer or importer per report, or 0.25 hours per year (1 request per year per exempt entity). This computes to a total annual burden of 199.75 hours (0.25 hours times 799 exempt entities at the 15 mmbf de minimis exemption threshold from Table 4).

Further, pursuant to § 1217.70, domestic manufacturers and importers that ship or import at or over the de minimis exemption level and pay their assessments directly to the Board must submit a shipment/import report for each quarter when assessments are due. The reporting burden for this collection of information is estimated to average 0.5 hours per domestic manufacturer or importer per report, or 2 hours per year (4 reports per year times 0.5 hours per report). This computes to a total annual burden of 510 hours (255 assessed entities (from Table 4—No. of Assessed Entities at 15 mmbf) at 2 hours each equals 510 hours).

All domestic manufacturers and importers must also maintain records sufficient to verify their reports. The recordkeeping burden for keeping this information is estimated to average 0.5 hours per record keeper maintaining such records, or 527 hours (1,054 total entities assessed (from Table 4—No. of Assessed Entities at no exemption) times 0.5 hours).

As with all Federal promotion programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies. Finally, USDA has not identified any relevant Federal rules that duplicate, overlap, or conflict with this rule.

USDA 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.

Regarding outreach efforts, USDA initiated this action in response to a May 2016 federal court decision in *Resolute.* This rule establishes the de minimis quantity exemption under part 1217.

A proposed rule concerning this action was published in the **Federal Register** on May 30, 2017 (82 FR 24583). The Board distributed copies of the proposed rule via email to domestic manufacturers and importers. The proposal was also made available through the internet by USDA and the

[9] This figure is computed by dividing the estimated cost to pursue a compliance case against an entity of $5,000 by the assessment rate of $0.35 per thousand board feet.

[10] An independent evaluation of the softwood lumber program showed that the activities of the Board increased sales of softwood lumber between 2011 and 2015 by 1.683 bbf or $596 million. This equates to a return on investment of $15.55 of additional sales for every $1 spent on promotion by the Board. By this metric, part 1217 to date has been effective. USDA therefore finds that 15 mmbf is a reasonable exemption level for de minimis.

Office of the Federal Register. A 60-day comment period ending July 31, 2017, was provided to allow interested persons to submit comments.

**Analysis of Comments**

Thirty-three comments were received in response to the proposed rule. Of those 33 comments, one was outside the scope of the rulemaking and the remaining 32 supported the 15 mmbf exemption threshold. The following is an analysis of those 32 comments.

Several commenters reiterated the data presented in the proposed rule. They cited Table 3 which shows that, at the 15 mmbf threshold, entities that pay into the program account for 96 percent of the U.S. softwood lumber market volume. Thus, free rider concerns are minimal. Reducing the exemption level by a third (down to 10 mmbf) would only increase that number to 97 percent of the U.S. market and would not be worth the additional effort. There are a large number of small manufacturers and importers who account for a small percentage of the softwood lumber shipped in the United States. The commenters opined that the cost of collecting an assessment from such a large number of entities outweighs the revenue that could be collected from such a small amount of volume. They agreed that Board staff time would be better spent on promotion activities than trying to collect a small amount of revenue from several small entities.

One commenter opined that the methodology used by USDA to determine the de minimis threshold was comprehensive and explored tradeoffs involved in setting a threshold below which it is counterproductive to the collection of assessments to further the program. The commenter stated that ''. . . USDA dealt with a large amount of data on imports that it appropriately scrubbed to exclude obvious errors and outliers.'' Within the populations of domestic manufacturers and importers categorized based on volume, USDA conducted a series of ''what if'' analyses to determine the impact of various de minimis levels on revenue in terms of ''. . . administrative costs, the compliance burden on respondents and the potential for ''free rider'' benefits.'' The commenter also observed that USDA compared the results to other federal promotion programs authorized under the 1996 Act and overseen by USDA where it found that 8 of 10 programs exempt a de minimis quantity from assessment, and that half of those programs exempt between 3 and 11 percent of the total quantity covered by the program as de minimis. Among the range of alternatives that USDA analyzed, the 10 and 15 mmbf thresholds came closest to this range. The commenter stated that USDA also compared the benefits derived from these thresholds with the likely compliance costs incurred, which USDA estimated at $5,000 per entity. The point at which revenues collected from entities that would fall below the compliance cost was found to be at 14.3 mmbf, which is closest to the 15 mmbf threshold. The combination of these results led USDA to conclude that 15 mmbf is the most appropriate benchmark between volumes assessed and not assessed. The commenter concluded that, ''. . . while there is no special formula for computing a de minimis threshold . . . .'' the commenter believes that USDA selected a reasonable exemption amount based on the industry's structure and the program's benefits and costs.

Six commenters opined that the 15 mmbf threshold appropriately separates the high production manufacturers from small entities that manufacture specialty products and sell into mostly local and niche markets. They agreed that specialty products do not benefit as much from a national promotion program, and that growth in market share benefits entities that manufacture larger volumes to a greater degree than those that fall below the 15 mmbf threshold.

Several commenters expressed concern with the administrative burden that complying with a mandatory promotion program could place on small entities below the 15 mmbf threshold. One commenter stated that, on a per board foot ratio, the costs to participate in the program are lower for larger entities than smaller entities. Many small entities still record their shipments by hand. Larger entities, on the other hand, can afford to invest in automated computer reporting systems and can have personnel dedicated to efficiently analyzing their reporting. Thus, the administrative costs for smaller entities to participate in the program are higher than the costs for larger entities.

Two commenters also referenced the part's 8 percent cap on administrative expenses. They opined that the revenue gained from collecting assessments from numerous small entities would not be sufficient to justify the additional costs and administrative complexities.

Three commenters expressed support for the equity exemption. They opined that the equity exemption makes the program fair for everyone. One commenter opined that the equity exemption mitigates the free rider problem because larger entities do not have to pay assessments on their first 15 mmbf shipped. Without the equity exemption, assessment payers would pay more, thereby increasing the free rider impact.[11]

Two commenters discussed the efforts of the Blue Ribbon Commission (BRC), the proponent group, in promulgating the program. They stated that the BRC surveyed the industry on issues related to the program, including the de minimis exemption threshold. They stated that the BRC sought a level that would generate maximum revenue for the program while being mindful of the cost of administering the program and collecting assessments. The BRC's survey found that 15 mmbf was the appropriate level that was broadly accepted by the industry.

Several commenters also expressed their overall support for the softwood lumber program. They agreed that the program provides a strong, unified voice for the industry. One commenter stated that the program has contributed significantly to strengthening the position of softwood lumber in the market place as well as expanding and developing new markets for softwood lumber. The commenters also agreed that funding for the program has been appropriate since assessment collection began in 2012. None of the commenters supported increasing the exemption threshold thereby reducing funding for the program.

No changes have been made to the proposed rule based on the comments received.

After consideration of all relevant matters presented, including the available information and comments received, it is hereby found that this rule, is consistent with and will effectuate the purposes of the 1996 Act.

**List of Subjects in 7 CFR Part 1217**

Administrative practice and procedure, Advertising, Consumer information, Marketing agreements, Promotion, Reporting and recordkeeping requirements, Softwood lumber.

[11] For example, as explained in the May 2017 proposed rule, if the thresholds for de minimis and equity exemptions were 10 mmbf, Company A that ships 8 mmbf annually would pay no assessments, and Company B that ships 30 mmbf annually would have to pay assessments on 20 mmbf of softwood lumber. At an assessment rate of $0.35 per thousand board feet, this would compute to $7,000 in assessments. Without the equity exemption, Company A would still pay no assessments but Company B would have to pay assessments on 30 mmbf. This would compute to $10,500 in assessments, which is an additional burden of $3,500. Thus, the equity exemption reduces the burden of free riders on entities funding the program. It creates fairness because it exempts from assessment an equal volume from all entities, regardless of their size.

The authority citation for 7 CFR part 1217 continues to read as follows:

**Authority:** 7 U.S.C. 7411–7425; 7 U.S.C. 7401.

Dated: October 19, 2017.

**Bruce Summers,**

*Acting Administrator.*

[FR Doc. 2017–23094 Filed 10–25–17; 8:45 am]

**BILLING CODE 3410–02–P**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

### 14 CFR Part 25

**[Docket No. FAA–2017–0862; Special Conditions No. 25–703–SC]**

## Special Conditions: Boeing Model 777–300ER Airplanes; Passenger-Cabin High-Wall Suites

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Final special conditions; request for comments.

**SUMMARY:** These special conditions are issued for Boeing Model 777–300ER airplanes with high-wall suites installed in the passenger cabin. This installation is novel or unusual, and the applicable airworthiness regulations do not contain adequate or appropriate safety standards for this interior configuration. These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

**DATES:** This action is effective on Boeing on October 26, 2017. Send your comments by December 11, 2017.

**ADDRESSES:** Send comments identified by docket number FAA–2017–0862 using any of the following methods:

- *Federal eRegulations Portal:* Go to *http://www.regulations.gov/* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30, U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE., Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at 202–493–2251.

*Privacy:* The FAA will post all comments it receives, without change, to *http://www.regulations.gov/,* including any personal information the commenter provides. Using the search function of the docket Web site, anyone can find and read the electronic form of all comments received into any FAA docket, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). DOT's complete Privacy Act Statement can be found in the **Federal Register** published on April 11, 2000 (65 FR 19477–19478).

*Docket:* Background documents or comments received may be read at *http://www.regulations.gov/* at any time. Follow the online instructions for accessing the docket or go to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** John Shelden, Airframe and Cabin Safety Section, AIR–675, Transport Standards Branch, Policy and Innovation Division, Aircraft Certification Service, 1601 Lind Avenue SW., Renton, Washington 98057–3356; telephone 425–227–2785; facsimile 425–227–1232; email *john.shelden@faa.gov.*

**SUPPLEMENTARY INFORMATION:** The substance of these special conditions has been subject to the notice and comment period in several prior instances and has been derived without substantive change from those previously issued. It is unlikely that prior public comment would result in a significant change from the substance contained herein. Therefore, because a delay would significantly affect the certification of the airplane, the FAA has determined that prior public notice and comment are unnecessary and impracticable.

In addition, since the substance of these special conditions has been subject to the public comment process in several prior instances with no substantive comments received, the FAA finds it unnecessary to delay the effective date and finds that good cause exists for adopting these special conditions upon publication in the **Federal Register**.

### Comments Invited

We invite interested people to take part in this rulemaking by sending written comments, data, or views. The most helpful comments reference a specific portion of the special conditions, explain the reason for any recommended change, and include supporting data.

We will consider all comments we receive by the closing date for comments. We may change these special conditions based on the comments we receive.

### Background

On December 19, 2014, Boeing applied for a type certificate design change to Type Certificate (TC) No. T00001SE to install high-wall suites in the passenger compartment of Boeing Model 777–300ER airplanes.

The Model 777 series airplane is a swept-wing, conventional-tail, twin-engine, turbofan- powered, transport-category airplane. The airplane has seating for 365 passengers and a maximum takeoff weight of 775,000 pounds.

### Type Certification Basis

Under the provisions of title 14, Code of Federal Regulations (14 CFR) 21.101, Boeing must show that the Model 777–300ER airplane, as changed, continues to meet the applicable provisions of the regulations listed in Type Certificate No. T00001SE or the applicable regulations in effect on the date of application for the change, except for earlier amendments as agreed upon by the FAA.

If the Administrator finds that the applicable airworthiness regulations (*i.e.,* 14 CFR part 25) do not contain adequate or appropriate safety standards for the Boeing Model 777–300ER airplane because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.

Special conditions are initially applicable to the model for which they are issued. Should the type certificate for that model be amended later to include any other model that incorporates the same novel or unusual design feature, or should any other model already included on the same type certificate be modified to incorporate the same novel or unusual design feature, these special conditions would also apply to the other model under § 21.101.

In addition to the applicable airworthiness regulations and special conditions, the Boeing Model 777–300ER airplane must comply with the fuel-vent and exhaust-emission requirements of 14 CFR part 34, and the noise-certification requirements of 14 CFR part 36.

The FAA issues special conditions, as defined in 14 CFR 11.19, in accordance with § 11.38, and they become part of

the type-certification basis under § 21.101.

**Novel or Unusual Design Features**

The Boeing Model 777–300ER airplane will incorporate the following novel or unusual design features:

A passenger cabin with six high-wall suites arranged in two rows of three suites each.

**Discussion**

The Boeing Model 777–300ER airplane will include, as a customer option, a passenger cabin with six high-wall suites arranged in two rows of three suites each, in a 1–1–1 configuration. The suites have doors and walls that are taller than has been previously certified by the FAA on Boeing 777 series airplanes. The walls extend from the floor to the ceiling or close to the ceiling.

The characteristics of the suite design are unique such that the suites are not fully open to the cabin, as are conventional mini-suites with partial-height surrounds, and they are not remote from the main cabin, as are overhead crew rests. Likewise, unique but suitable fire-protection requirements for smoke detection and firefighting are needed for this configuration. Furthermore, the proposed suite design necessitates the development of additional conditions that do not currently exist within associated airworthiness standards, including, but not limited to, alerting and lighting when oxygen masks are needed, crew procedures for managing hazards and suite occupants, and maintaining cabin-egress route dimensions after deformations of the walls and seats.

These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

**Applicability**

As discussed above, these special conditions are applicable to the Boeing Model 777–300ER airplane with high-wall, single-occupant suites with doors installed. Should Boeing apply at a later date for a change to the type certificate to include another model incorporating the same novel or unusual design feature, these special conditions would apply to that model as well.

**Conclusion**

This action affects only certain novel or unusual design features on one model series of airplane. It is not a rule of general applicability.

**List of Subjects in 14 CFR Part 25**

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

The authority citation for these special conditions is as follows:

**Authority:** 49 U.S.C. 106(g), 40113, 44701, 44702, 44704.

**The Special Conditions**

Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type certification basis for Boeing Model 777–300ER airplanes.

Note: In these special conditions, ''suite'' means high-wall suite.

1. Where suites are installed, a supplemental oxygen system must provide the following:

a. The supplemental oxygen system for each suite must include a minimum of two oxygen masks and meet the same 14 CFR part 25 regulations as do the supplemental oxygen system for the main passenger-cabin occupants.

b. An aural alert to warn occupants and to indicate the need to don oxygen masks in the event of decompression. The aural alert must activate concurrently with deployment of the oxygen masks in the main passenger cabin.

c. The illumination level of the normal suite lighting system must be activated automatically and must be sufficient for each occupant to locate a deployed oxygen mask.

d. If a chemical oxygen generator is used as the oxygen supply source, the suite oxygen installation must meet §§ 25.795(d) and 25.1450.

2. A smoke-detection or fire-detection system (or systems) must be provided that monitors each occupiable space within the suite. Flight tests must be conducted to show compliance with this requirement. If a fire occurs, each system (or systems) in the affected suite must provide:

a. A visual indication to the flight deck within one minute after the start of a fire.

b. An aural warning in the suite area where detection has occurred.

c. A warning in the main passenger cabin. This warning must be readily detectable by a flight attendant, taking into consideration the locations of flight attendants throughout the main passenger compartment during various phases of flight.

3. Passenger-management procedures must be provided should occupants need to be moved in the event of smoke detection, or firefighting within the suite or where suites are installed:

a. A limitation must be included in the airplane flight manual (AFM) or other suitable means requiring that crewmembers be trained in the suite passenger-management procedures.

b. Approved procedures describing methods for suite passenger management must be established. These procedures must be transmitted to the operator for incorporation into its training programs and appropriate operational manuals.

4. The design of each suite, and the location of the firefighting equipment where suites are installed, must allow the crewmembers to conduct effective firefighting in the suite. For a manual, hand-held extinguishing system (designed as the sole means to fight a fire) for the suite:

a. A limitation must be included in the AFM or other suitable means requiring that crewmembers be trained in the firefighting procedures.

b. Each suite design must allow crewmembers equipped for firefighting to have unrestricted access to all parts of the suite compartment.

c. The time for a crewmember in the main passenger cabin to react to the fire alarm and gain access to the suite must not exceed the time it would take for the compartment to become filled with smoke, thus making it difficult to locate the fire source(s).

d. Approved procedures describing methods for searching the suite compartment for fire source(s) must be established. These procedures must be transmitted to the operator for incorporation into its training programs and appropriate operational manuals.

5. A means must be provided to prevent hazardous quantities of smoke or extinguishing agent originating in each suite from entering any other occupiable compartments.

a. Small quantities of smoke may penetrate from the suite into other occupied areas during the one-minute smoke detection time.

b. Hazardous quantities of smoke may not enter any occupied compartment during access to manually fight a fire in the suite. A small amount of smoke may enter the occupied compartments while a firefighter enters and exits the suite, and is not considered hazardous provided the smoke dissipates quickly.

c. Flight tests must be conducted to show compliance with this requirement.

6. If waste-disposal receptacles are fitted in the suite, the suite must be equipped with an automatic fire-extinguishing system that meets the performance requirements of § 25.854(b).

7. Each stowage compartment in the suite must be completely enclosed. All enclosed stowage compartments within the suite compartment that are not

limited to stowage of emergency equipment or airplane- supplied equipment (*i.e.,* bedding) must meet the design criteria described in the table below. Enclosed stowage compartments greater than 57 feet 3 inches cubic interior volume are not permitted by these special conditions.

DESIGN CRITERIA FOR ENCLOSED STOWAGE COMPARTMENTS NOT LIMITED TO STOWAGE OF EMERGENCY OR AIRPLANE-SUPPLIED EQUIPMENT

| Fire protection features | Applicability of fire-protection requirements by interior volume | | |
|---|---|---|---|
| | Less than 25 cubic feet | 25 Cubic feet to less than 57 Cubic feet | 57 cubic feet |
| Compliant Materials of Construction [1] | Yes | Yes | Yes. |
| Smoke or Fire Detectors [2] | No | Yes | Yes. |
| Liner [3] | No | Conditional | Yes. |
| Fire Location Detector [4] | No | Yes | Yes. |

[1] Compliant Materials of Construction: The material used in constructing each enclosed stowage compartment must at least be fire resistant and must meet the flammability standards established for interior components (*i.e.,* 14 CFR part 25 Appendix F, Parts I, IV, and V) per the requirements of § 25.853. For compartments less than 25 ft.3 in interior volume, the design must ensure the ability to contain a fire likely to occur within the compartment under normal use.

[2] Smoke or Fire Detectors: Enclosed stowage compartments equal to or exceeding 25 ft.3 in interior volume must be provided with a smoke- or fire-detection system to ensure that a fire can be detected within a one-minute detection time. Flight tests must be conducted to show compliance with this requirement. Each system (or systems) must provide:

☐ A visual indication in the flight deck within one minute after the start of a fire.

☐ An aural warning in the suite compartment.

☐ A warning in the main passenger cabin. This warning must be readily detectable by a flight attendant, taking into consideration the locations of flight attendants throughout the main passenger compartment during various phases of flight.

[3] Liner: If material used in constructing the stowage compartment can be shown to meet the flammability requirements of a liner for a Class B cargo compartment (*i.e.,* § 25.855 at Amendment 25–116, and Appendix F, part I, paragraph (a)(2)(ii)), then no liner would be required for enclosed stowage compartments equal to or greater than 25 ft.3 but less than 57 ft.3 in interior volume. For all enclosed stowage compartments equal to 57 ft.3 in interior volume, a liner must be provided that meets the requirements of § 25.855 for a Class B cargo compartment.

[4] Fire Location Detector: If a suite compartment has enclosed stowage compartments exceeding 25 ft.3 interior volume that are located separately from the other stowage compartments (located, for example, away from one central location, such as the entry to the suite compartment or a common area within the suite compartment, where the other stowage compartments are), that suite compartment would require additional fire-protection features and/or devices to assist the firefighter in determining the location of a fire.

8. Where suites are installed, the design of each suite must:

a. Maintain minimum main aisle(s), cross aisle(s), and passageway(s) requirements of § 25.815 when subjected to the ultimate inertia forces listed in § 25.561(d).

b. Prevent structural failure or deformation of components that could block access to the available evacuation routes (*e.g.,* seats, doors, contents of stowage compartments, etc.).

9. In addition to the requirements of § 25.562 for seat systems, which are occupiable during taxi, takeoff, and landing, the suite structure must be designed for the additional loads imposed by the seats as a result of the conditions specified in § 25.562(b).

Issued in Renton, Washington, on October 19, 2017.

**Suzanne Masterson,**

*Acting Manager, Transport Standards Branch, Policy and Innovation Division, Aircraft Certification Service.*

[FR Doc. 2017–23256 Filed 10–25–17; 8:45 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

### 14 CFR Part 39

**[Docket No. FAA–2017–0332; Product Identifier 2016–NM–164–AD; Amendment 39–19084; AD 2017–22–04]**

**RIN 2120–AA64**

## Airworthiness Directives; The Boeing Company Airplanes

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Final rule.

**SUMMARY:** We are adopting a new airworthiness directive (AD) for certain The Boeing Company Model 737–200, –200C, –300, –400, and –500 series airplanes. This AD was prompted by reports of skin doublers that disbonded from their skin panels. This AD requires repetitive inspections of fuselage skin panels, and applicable on-condition actions. We are issuing this AD to address the unsafe condition on these products.

**DATES:** This AD is effective November 30, 2017.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of November 30, 2017.

**ADDRESSES:** For service information identified in this final rule, 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, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221. It is also available on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2017–0332.

**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–2017–0332; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the regulatory evaluation, any comments received, and other information. The address for the Docket Office (phone: 800–647–5527) is Docket Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200

New Jersey Avenue SE., Washington, DC 20590.

**FOR FURTHER INFORMATION CONTACT:** Jennifer Tsakoumakis, Aerospace Engineer, Airframe Section, FAA, Los Angeles ACO Branch, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 562–627–5264; fax: 562–627–5210; email: *jennifer.tsakoumakis@faa.gov.*

**SUPPLEMENTARY INFORMATION:**

**Discussion**

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain The Boeing Company Model 737–200, –200C, –300, –400, and –500 series airplanes. The NPRM published in the **Federal Register** on May 2, 2017 (82 FR 20450). The NPRM was prompted by reports of skin doublers that disbonded from their skin panels. The NPRM proposed to require repetitive inspections of fuselage skin panels, and applicable on-condition actions. We are issuing this AD to detect and correct disbonded skin panels, which could result in fuselage skin cracking, rapid decompression, and loss of structural integrity of the airplane.

**Comments**

We gave the public the opportunity to participate in developing this final rule. The following presents the comments received on the NPRM and the FAA's response to each comment.

**Effect of Winglets on Accomplishment of the Proposed Actions**

Aviation Partners Boeing stated that accomplishing Supplemental Type Certificate (STC) ST01219SE does not affect the ability to accomplish the actions specified in the NPRM.

We concur with the commenter. We have redesignated paragraph (c) of the proposed AD as paragraph (c)(1) and added paragraph (c)(2) to this AD to state that installation of STC ST01219SE does not affect the ability to accomplish the actions required by this AD. Therefore, for airplanes on which STC ST01219SE is installed, a ''change in product'' alternative methods of compliance (AMOC) approval request is not necessary to comply with the requirements of 14 CFR 39.17.

**Request To Revise ''Explanation of Certain Compliance Times'' Section**

Boeing requested that the ''Explanation of Certain Compliance Times'' section in the preamble of the NPRM be revised to clarify that only disbonded skin panels need to be replaced. Boeing noted that, if a panel is disbonded, it is considered a suspect panel that went through improper processing during the phosphoric acid anodization phase of manufacturing. Boeing stated that the suspect panel could develop an additional disbond, which could lead to further damage, and then the inspections described in the service information might not be adequate.

We acknowledge the commenter's request to clarify that only disbonded skin panels need to be replaced, for the reasons provided by the commenter. We agree with the rationale for the request. However, the ''Explanation of Certain Compliance Times'' section only appears in the preamble of the NPRM and is not carried over into this final rule; therefore, no change to this final rule is necessary regarding this issue.

**Request To Include Previously Accomplished Actions as Terminating Actions**

Qantas requested that we include previously accomplished repairs as terminating actions in paragraph (i) of the proposed AD. Qantas requested that paragraph (i) of the proposed AD be revised to include a provision for previously installed repairs (solid skin panel replacements) that were approved by an authorized representative of the Boeing Commercial Airplanes Organization Designation Authorization (ODA) via FAA Form 8110–3, ''Statement of Compliance with the Federal Aviation Regulations.'' Qantas stated that Boeing ODA-approved repairs completed prior to issuance of Boeing Alert Service Bulletin 737–53A1349, dated August 23, 2016, were not addressed in the NPRM. Qantas also suggested that solid skin panel replacements approved via FAA Form 8100–9, ''Statement of Compliance with Airworthiness Standards,'' be included as terminating action. Qantas stated that including skin panel replacements approved via FAA Form 8100–9 as terminating action could help avoid operators' requests for AMOCs. In addition, Qantas recommended that the language used for approved repairs by an authorized representative of the Boeing ODA be revised, as it is not specific to FAA Form 8110–3 or FAA Form 8100–9.

We agree with the commenter's request. Paragraph (i)(1) of this AD (paragraph (i) of the proposed AD) addresses previously installed repairs approved by an authorized representative of the Boeing ODA. Existing Boeing ODA-approved repairs or preventative modifications are included in notes in Part 1, Part 2, and Part 8 of the Accomplishment Instruction and in note (a) to tables 1 through 8 in paragraph 1.E., ''Compliance,'' of Boeing Alert Service Bulletin 737–53A1349, dated August 23, 2016. Note (a) states, ''If any Boeing ODA approved preventative modification or repair was previously installed via FAA Form 8100–9 or [structural repair manual] SRM repair doubler (except disbond repair), initial and repeat inspections are not required at the repaired location only.''

However, repairs that were not approved by the Boeing ODA and replacements not done using Boeing Alert Service Bulletin 737–53A1349, dated August 23, 2016, were not addressed in the proposed AD. Therefore, we have redesignated paragraph (i) (in the proposed AD) as paragraph (i)(1) and added paragraph (i)(2) to this AD to state that any skin panel replacement done before the effective date of this AD terminates the inspections required by paragraph (g) of this AD for that skin panel only, provided the replacement was done using a skin panel manufactured on or after April 1, 1997, and the replacement was done using an FAA-approved method. A replacement accomplished using an FAA-approved method would still address the unsafe condition and the need for the inspections required by paragraph (g) of this AD would be terminated.

We have also added paragraph (i)(3) to this AD to state that any FAA-approved reinforced repair doubler (except disbond repair) installed before the effective date of this AD terminates the inspections required by paragraph (g) of this AD at the repaired location only.

**Request To Allow Termination of All Inspections**

Southwest Airlines (SWA) requested that we allow the terminating action specified in paragraph (i) of the proposed AD to terminate the initial inspections in paragraph (g) of the proposed AD and not only the repetitive inspections in paragraph (g) of the proposed AD. Specifically, SWA requested that paragraph (i) of the proposed AD be revised to include the provision that replacement of any skin panel in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1349, dated August 23, 2016, except as specified in paragraph (h)(2) of the proposed AD, terminates the requirement for the initial inspection specified in paragraph (g) of the proposed AD, for the replaced skin panel only. SWA noted that an operator could replace a skin panel prior to doing

the initial inspection specified in paragraph (g) of the proposed AD, therefore the operator would not be required to do the initial or repetitive inspections specified in paragraph (g) of the proposed AD.

We agree with the commenters' requests. We have clarified paragraph (i)(1) of this AD (paragraph (i) of the proposed AD) to state that accomplishment of any skin panel replacement using a skin panel manufactured on or after April 1, 1997, terminates the inspections required by paragraph (g) of this AD for that skin panel only, provided the replacement is done as specified in the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1349, dated August 23, 2016, except as required by paragraph (h)(2) of this AD.

**Request To Include an Additional Terminating Action for AD 2003–14–06**

SWA requested that paragraph (j) of the proposed AD be revised to include a provision that replacement of skin panels, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1349, dated August 23, 2016, except as required by paragraph (h)(2) of the proposed AD, terminates all of the requirements of AD 2003–14–06, Amendment 39–13225 (68 FR 40759, July 9, 2003; corrected July 21, 2003 (68 FR 42596) (''AD 2003–14–06'')). SWA noted that an operator could replace a skin panel prior to doing the initial inspection specified in paragraph (g) of the proposed AD; therefore, the operator would not be required to do the initial or repetitive inspections specified in paragraph (g) of the proposed AD, and all of the requirements of AD 2003–14–06 would be terminated.

We agree with the commenter's request. We redesignated paragraph (j) in the proposed AD as paragraph (j)(1) and added paragraph (j)(2) to this AD to include a statement that replacement of any skin panel with a skin panel manufactured on or after April 1, 1997, as specified in the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1349, dated August 23, 2016, except as required by paragraph (h)(2) of this AD, terminates all of the requirements of AD 2003–14–06 for that skin panel only.

**Conclusion**

We reviewed the relevant data, considered the comments received, and determined that air safety and the public interest require adopting this final rule with the changes described previously and minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM.

We also determined that these changes will not increase the economic burden on any operator or increase the scope of this final rule.

**Related Service Information Under 1 CFR Part 51**

We reviewed Boeing Alert Service Bulletin 737–53A1349, dated August 23, 2016. The service information describes procedures for repetitive inspections of fuselage skin panels for cracking, corrosion, and existing disbond repairs; 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.

**Costs of Compliance**

We estimate that this AD affects 169 airplanes of U.S. registry. We estimate the following costs to comply with this AD:

ESTIMATED COSTS

| Action | Labor cost | Parts cost | Cost per product | Cost on U.S. operators |
|---|---|---|---|---|
| External general visual and detailed inspections. | 180 work-hours × $85 per hour = $15,300 per inspection cycle. | $0 | $15,300 per inspection cycle | $2,585,700 per inspection cycle. |
| External high frequency bond test inspection. | 450 work hours × $85 per hour = $38,250 per inspection cycle. | 0 | $38,250 inspection cycle ..... | $6,464,250 per inspection cycle. |
| Ultrasonic disbond inspection and internal detailed skin inspection. | 630 work-hours × $85 per hour = $53,550 per inspection cycle. | 0 | $53,550 per inspection cycle | $9,049,950 per inspection cycle. |

We estimate the following costs to do any necessary on-condition actions that will be required based on the results of the inspections. We have no way of determining the number of aircraft that might need these on-condition actions:

ON-CONDITION COSTS PER SKIN PANEL

| Action | Labor cost | Parts cost | Cost per product |
|---|---|---|---|
| On-condition inspections ..... | Up to 25 work-hours × $85 per hour = $2,125 ..... | $0 ..... | Up to $2,125. |
| Repairs ..... | Up to 68 work-hours × $85 per hour = $5,780 ..... | Up to $100 ..... | Up to $5,880. |
| Skin panel replacement ..... | 304 work-hours × $85 per hour = $25,840 ..... | $95,000 ..... | $120,840. |

**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 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**

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

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

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

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

(3) Will not affect intrastate aviation in Alaska, 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.

**Adoption of the Amendment**

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

## PART 39—AIRWORTHINESS DIRECTIVES

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

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

**§ 39.13 [Amended]**

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

**2017–22–04 The Boeing Company:** Amendment 39–19084; Docket No. FAA–2017–0332; Product Identifier 2016–NM–164–AD.

**(a) Effective Date**

This AD is effective November 30, 2017.

**(b) Affected ADs**

This AD affects AD 2003–14–06, Amendment 39–13225 (68 FR 40759, July 9, 2003; corrected July 21, 2003 (68 FR 42956)) (''AD 2003–14–06'').

**(c) Applicability**

(1) This AD applies to The Boeing Company Model 737–200, –200C, –300, –400, and –500 series airplanes, certificated in any category, as identified in Boeing Alert Service Bulletin 737–53A1349, dated August 23, 2016.

(2) Installation of Supplemental Type Certificate (STC) ST01219SE (*http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgstc.nsf/0/EBD1CEC7B301293E86257CB30045557A?OpenDocument&Highlight=st01219se*) does not affect the ability to accomplish the actions required by this AD. Therefore, for airplanes on which STC ST01219SE is installed, a ''change in product'' alternative method of compliance (AMOC) approval request is not necessary to comply with the requirements of 14 CFR 39.17.

**(d) Subject**

Air Transport Association (ATA) of America Code 53, Fuselage.

**(e) Unsafe Condition**

This AD was prompted by reports of skin doublers that disbonded from their skin panels. We are issuing this AD to detect and correct disbonded skin panels, which could result in fuselage skin cracking, rapid decompression, and loss of structural integrity of the airplane.

**(f) Compliance**

Comply with this AD within the compliance times specified, unless already done.

**(g) Actions Required for Compliance**

Except as required by paragraph (h) of this AD: Do all applicable actions identified as required for compliance (''RC'') in, and in accordance with, the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1349, dated August 23, 2016. Do the actions at the applicable times specified in paragraph 1.E., ''Compliance,'' of Boeing Alert Service Bulletin 737–53A1349, dated August 23, 2016.

**(h) Exceptions to Service Information Specifications**

(1) Where Boeing Alert Service Bulletin 737–53A1349, dated August 23, 2016, uses the phrase ''after the original issue of this service bulletin,'' for purposes of determining compliance with the requirements of this AD, the phrase ''after the effective date of this AD'' must be used.

(2) Where Boeing Alert Service Bulletin 737–53A1349, dated August 23, 2016, specifies contacting Boeing for instructions, and specifies that action as ''RC'' (Required for Compliance): This AD requires using a method approved in accordance with the procedures specified in paragraph (k) of this AD.

(3) For replaced skin panels identified in table 9 of paragraph 1.E., ''Compliance,'' of Boeing Alert Service Bulletin 737–53A1349, dated August 23, 2016, on which the one-time internal inspection specified in Boeing Service Bulletin 737–53–1179, Revision 2, dated October 25, 2001, has not been done: The compliance time for accomplishment of the actions specified in Part 8 of the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1349, dated August 23, 2016, is at the latest of the times specified in paragraphs (h)(3)(i), (h)(3)(ii), and (h)(3)(iii) of this AD.

(i) Within 50,000 flight cycles after the skin panel replacement.

(ii) Within 20,000 flight cycles after July 14, 2003 (the effective date of AD 2003–14–16).

(iii) Within 4,500 flight cycles after the effective date of this AD.

**(i) Terminating Action for Required Inspections**

(1) Accomplishment of any skin panel replacement using a skin panel manufactured on or after April 1, 1997, terminates the inspections required by paragraph (g) of this AD for that skin panel only, provided the replacement is done as specified in the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1349, dated August 23, 2016, except as required by paragraph (h)(2) of this AD.

(2) Accomplishment of any skin panel replacement done before the effective date of this AD terminates the inspections required by paragraph (g) of this AD for that skin panel only, provided the conditions specified in paragraphs (i)(2)(i) and (i)(2)(ii) of this AD are met.

(i) The replacement was done using a skin panel manufactured on or after April 1, 1997.

(ii) The replacement was done using an FAA-approved method.

(3) Installation of an FAA-approved reinforced repair doubler (except disbond repair) before the effective date of this AD terminates the inspections required by paragraph (g) of this AD at the repaired location only.

**(j) Terminating Action for AD 2003–14–06**

(1) Accomplishment of the initial inspections required by paragraph (g) of this AD terminates all requirements of AD 2003–14–06.

(2) Accomplishment of any skin panel replacement with a skin panel manufactured on or after April 1, 1997, as specified in the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1349, dated August 23, 2016, except as required by paragraph (h)(2) of this AD, terminates all requirements of AD 2003–14–06 for that skin panel only.

**(k) Alternative Methods of Compliance (AMOCs)**

(1) The Manager, Los Angeles ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested 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 manager of the certification office, send it to the attention of the person identified in paragraph (l) of this AD. Information may be emailed to: *9–ANM–LAACO–AMOC–Requests@faa.gov.*

(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.

(4) Except as required by paragraph (h)(2) of this AD: For service information that contains steps that are labeled as Required for Compliance (RC), the provisions of paragraphs (k)(4)(i) and (k)(4)(ii) of this AD apply.

(i) The steps labeled as RC, including substeps under an RC step and any figures identified in an RC step, must be done to comply with the AD. If a step or substep is labeled ''RC Exempt,'' then the RC requirement is removed from that step or substep. An AMOC is required for any deviations to RC steps, including substeps and identified figures.

(ii) Steps not labeled as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the RC steps, including substeps and identified figures, can still be done as specified, and the airplane can be put back in an airworthy condition.

**(l) Related Information**

For more information about this AD, contact Jennifer Tsakoumakis, Airframe Section, FAA, Los Angeles ACO Branch, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 562–627–5264; fax: 562–627–5210; email: *jennifer.tsakoumakis@faa.gov*.

**(m) Material Incorporated by Reference**

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Boeing Alert Service Bulletin 737–53A1349, dated August 23, 2016.

(ii) Reserved.

(3) 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.*

(4) You may view this service information at the FAA, Transport Standards Branch, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

(5) You may view this service information that is incorporated by reference 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: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Renton, Washington, on October 11, 2017.

**Dionne Palermo,**

*Acting Director, System Oversight Division, Aircraft Certification Service.*

[FR Doc. 2017–22950 Filed 10–25–17; 8:45 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF TRANSPORTATION

## Federal Aviation Administration

## 14 CFR Part 39

**[Docket No. FAA–2017–0521; Product Identifier 2016–NM–189–AD; Amendment 39–19086; AD 2017–22–06]**

**RIN 2120–AA64**

## Airworthiness Directives; Bombardier, Inc., Airplanes

**AGENCY:** Federal Aviation Administration (FAA), Department of Transportation (DOT).

**ACTION:** Final rule.

**SUMMARY:** We are adopting a new airworthiness directive (AD) for certain Bombardier, Inc., Model CL–600–2B16 (CL–601–3A, CL–601–3R, and CL–604 Variants) airplanes. This AD was prompted by reports of fuel leaks in the engine and auxiliary power unit (APU) electrical fuel pump (EFP) cartridge/canister electrical connectors and conduits. This AD requires repetitive inspections for fuel leakage at the engine and APU fuel pumps, and related investigative and corrective actions if necessary. We are issuing this AD to address the unsafe condition on these products.

**DATES:** This AD is effective November 30, 2017.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of November 30, 2017.

**ADDRESSES:** For service information identified in this final rule, contact Bombardier, Inc., 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; Widebody Customer Response Center North America toll-free telephone 1–866–538–1247 or direct-dial telephone 1–514–855–2999; fax 514–855–7401; email *ac.yul@aero.bombardier.com;* Internet *http://www.bombardier.com.* You may view this referenced service information at the FAA, Transport Standards Branch, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221. It is also available on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2017–0521.

**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–2017–0521; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (telephone 800–647–5527) is Docket Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

**FOR FURTHER INFORMATION CONTACT:** Steven Dzierzynski, Aerospace Engineer, Avionics and Administrative Services Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7367; fax 516–794–5531.

**SUPPLEMENTARY INFORMATION:**

**Discussion**

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain Bombardier, Inc., Model CL–600–2B16 (CL–601–3A, CL–601–3R, and CL–604 Variants) airplanes. The NPRM published in the **Federal Register** on June 2, 2017 (82 FR 25556) (''the NPRM''). The NPRM was prompted by reports of fuel leaks in the engine and APU EFP cartridge/canister electrical connectors and conduits. The NPRM proposed to require repetitive inspections for fuel leakage at the engine and APU fuel pumps, and related investigative and corrective actions if necessary. We are issuing this AD to detect and correct fuel leaks in certain fuel pumps to remove a potential fuel ignition hazard.

Transport Canada Civil Aviation (TCCA), which is the aviation authority for Canada, has issued Canadian Airworthiness Directive CF–2016–32R1, dated October 12, 2016 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for certain Bombardier, Inc., Model CL–600–2B16 (CL–601–3A, CL–601–3R, and CL–604 Variants) airplanes. The MCAI states:

Fuel leaks have been reported in the engine and auxiliary power unit (APU) electrical fuel pump (EFP) cartridge/canister electrical connectors and conduits on production aeroplanes. Initially, Bombardier had determined that the subject discrepancy was limited to the new pump canister installations on 24 production aeroplanes. Bombardier also reported the possibility of cut insulation on the electric harness wires of the newly installed canister housing assemblies.

Emergency [Canadian] AD CF–2014–17 [which corresponds to FAA AD 2014–15–17, Amendment 39–17919 (79 FR 44268, July 31, 2014)] was issued to limit landing light operation on-ground in order to address a potential fire hazard as result of a possible fuel leak from the APU, EFP electrical conduit in the landing light compartment. In addition, [Canadian] AD CF–2014–21 [which corresponds to FAA AD 2014–20–01, Amendment 39–17974 (79 FR 59640, October 3, 2014), superseded by FAA AD 2016–10–10, Amendment 39–18521 (81 FR 31497, May 19, 2016) (''AD 2016–10–10'')] was issued to mandate removal of then identified 24 discrepant EFP canister assemblies from service.

Bombardier has recently determined that the subject fuel leaks may not be limited to the 24 units affected by [Canadian] AD CF–2014–21 [(AD 2016–10–10)], but may potentially affect other in-service [Bombardier Model] CL–600–2B16 aeroplanes. Until such time that a final fix for the fuel leak problem is realized, Bombardier as an interim mitigating action, has issued [Service Bulletin] SB 604–28–022 and SB 605–28–010 that introduces [a] repeat [general visual] inspection and if required, rectification [related investigative and corrective actions] of subject fuel leaks on affected aeroplanes. [Canadian] AD CF–2016–32 was issued on 29 September 2016 to mandate compliance with applicable Bombardier SBs, to mitigate any potential safety hazard resulting from fuel leaks.

Revision 1 of this [Canadian] AD is being issued to correct a typographic error in paragraph B.1. of the [Canadian AD] Corrective Actions.

You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2017–0521.

**Comments**

We gave the public the opportunity to participate in developing this AD. The following presents the comment received on the NPRM and the FAA's response.

Request To Delay Issuance Until the Release of New Service Information

Bombardier, Inc., indicated its intent to revise Bombardier Service Bulletin 604–28–022, dated October 19, 2015; and Bombardier Service Bulletin 605–28–010, dated October 19, 2015. Bombardier, Inc., stated that these revisions will change the inspection instructions. Bombardier, Inc., further added that it plans to publish new service information to introduce similar inspections on Model CL–650 airplanes.

We infer that Bombardier, Inc., is requesting that we delay the issuance of this final rule until after the revised service information is released and then refer to the revised service information. We disagree with the commenter's request. We do not consider that delaying this action until release of the planned service information is warranted since the service information incorporated by reference in this AD adequately addresses the unsafe condition. We might consider additional rulemaking once the revised service information is released, or if new service information is issued for Model CL–650 airplanes, which are not included in the applicability of this AD. We have not changed this AD in this regard.

**Conclusion**

We reviewed the relevant data, considered the comment received, and determined that air safety and the public interest require adopting this AD as proposed except for minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM.

**Related Service Information Under 1 CFR Part 51**

Bombardier, Inc., has issued Service Bulletin 604–28–022, dated October 19, 2015; and Service Bulletin 605–28–010, dated October 19, 2015. This service information describes procedures for repetitive general visual inspections for fuel leakage at the engine and APU fuel pumps, and related investigative and corrective actions if necessary. These documents are distinct since they apply to airplanes in different configurations. 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.

**Costs of Compliance**

We estimate that this AD affects 121 airplanes of U.S. registry.

We estimate the following costs to comply with this AD:

ESTIMATED COSTS

| Action | Labor cost | Parts cost | Cost per product | Cost on U.S. operators |
|---|---|---|---|---|
| Inspections | 1 work-hour × $85 per hour = $85 per inspection cycle. | $0 | $85 per inspection cycle. | $10,285 per inspection cycle. |

For Model CL–600–2B16 airplanes having serial numbers 5701 through 5955 inclusive, 5957, 5960 through 5966 inclusive, 5968 through 5971 inclusive, and 5981, we estimate the following costs to do any necessary replacements that would be required based on the results of the required inspection. We have no way of determining the number of aircraft that might need these replacements:

ON-CONDITION COSTS

| Action | Labor cost | Parts cost | Cost per product |
|---|---|---|---|
| Replace o-ring in affected pump | 3 work-hours × $85 per hour = $255 | $17 | $272 |
| Replace cartridge in affected pump | 2 work-hours × $85 per hour = $170 | 8,618 | 8,788 |

For Model CL–600–2B16 airplanes having serial numbers 5301 through 5665 inclusive, we have received no definitive data that would enable us to provide cost estimates for the on-condition actions specified in this AD.

According to the manufacturer, 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 for affected individuals. As a result, 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.

This 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 AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

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

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

2. Is not a ''significant rule'' under 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.

**Adoption of the Amendment**

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

## PART 39—AIRWORTHINESS DIRECTIVES

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

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

**§ 39.13 [Amended]**

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

**2017–22–06 Bombardier, Inc.:** Amendment 39–19086; Docket No. FAA–2017–0521; Product Identifier 2016–NM–189–AD.

**(a) Effective Date**

This AD is effective November 30, 2017.

**(b) Affected ADs**

None.

**(c) Applicability**

This AD applies to Bombardier, Inc., Model CL–600–2B16 (CL–601–3A, CL–601–3R, and CL–604 Variants) airplanes, certificated in any category, having serial numbers 5301 through 5665 inclusive, 5701 through 5955 inclusive, 5957, 5960 through 5966 inclusive, 5968 through 5971 inclusive, and 5981.

**(d) Subject**

Air Transport Association (ATA) of America Code 28, Fuel.

**(e) Reason**

This AD was prompted by reports of fuel leaks in the engine and auxiliary power unit (APU) electrical fuel pump (EFP) cartridge/canister electrical connectors and conduits. We are issuing this AD to detect and correct fuel leaks in certain fuel pumps to remove a potential fuel ignition hazard.

**(f) Compliance**

Comply with this AD within the compliance times specified, unless already done.

**(g) General Visual Inspections and Corrective Actions—Model CL–600–2B16 Airplanes, Serial Numbers 5301 through 5665 Inclusive**

For Model CL–600–2B16 airplanes having serial numbers 5301 through 5665 inclusive: Within 600 flight hours or 12 months, whichever occurs first, after the effective date of this AD, do the inspections specified in paragraphs (g)(1), (g)(2), and (g)(3) of this AD, and do all applicable corrective actions, in accordance with the Accomplishment Instructions of Bombardier Service Bulletin 604–28–022, dated October 19, 2015; except where Bombardier Service Bulletin 604–28–022, dated October 19, 2015, specifies to contact the manufacturer, before further flight accomplish corrective actions in accordance with the procedures specified in paragraph (i)(2) of this AD. Do all applicable corrective actions before further flight. Repeat the inspections at intervals not to exceed 600 flight hours or 12 months, whichever occurs first.

(1) Do a general visual inspection for traces of fuel coming from the right-hand engine boost pump at the location of the belly fairing screw (FS412, BL 0.0).

(2) Do a general visual inspection for traces of fuel coming from the left-hand engine boost pump at the location of the belly fairing screw (FS412, BL 0.0).

(3) Do a general visual inspection for traces of fuel coming from the EFP electrical wiring conduit outlet at the lower body fairing area for engine EFPs and at the right-hand landing light compartment for the APU EFP.

**(h) General Visual Inspections and Related Investigative and Corrective Actions—Model CL–600–2B16 Airplanes Having Serial Numbers 5701 through 5955 Inclusive, 5957, 5960 through 5966 Inclusive, 5968 through 5971 Inclusive, and 5981**

For Model CL–600–2B16 airplanes having serial numbers 5701 through 5955 inclusive, 5957, 5960 through 5966 inclusive, 5968 through 5971 inclusive, and 5981: Within 600 flight hours or 12 months, whichever occurs first, after the effective date of this AD, do the inspections specified in paragraphs (h)(1), (h)(2), and (h)(3) of this AD, and do all applicable related investigative and corrective actions, in accordance with the Accomplishment Instructions in Bombardier Service Bulletin 605–28–010, dated October 19, 2015; except where Bombardier Service Bulletin 605–28–010, dated October 19, 2015, specifies to contact the manufacturer, before further flight accomplish corrective actions in accordance with the procedures specified in paragraph (i)(2) of this AD. Do all applicable related investigative and corrective actions before further flight. Repeat the inspections at intervals not to exceed 600 flight hours or 12 months, whichever occurs first.

(1) Do a general visual inspection for traces of fuel coming from the right-hand engine boost pump at the location of the belly fairing screw (FS412, BL 0.0).

(2) Do a general visual inspection for traces of fuel coming from the left-hand engine boost pump at the location of the belly fairing screw (FS412, BL 0.0).

(3) Do a general visual inspection of the right-hand landing light compartment for traces of fuel coming from the APU EFP.

**(i) Other FAA AD Provisions**

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, New York ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested 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 manager of the certification office, send it to ATTN: Program Manager, Continuing Operational Safety, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; fax 516–794–5531. 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.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, New York ACO Branch, FAA; or Transport Canada Civil Aviation (TCCA); or Bombardier, Inc.'s TCCA Design Approval Organization (DAO). If approved by the DAO, the approval must include the DAO-authorized signature.

**(j) Related Information**

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) Canadian AD CF–2016–32R1, dated October 12, 2016, for related information. This MCAI may be found in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2017–0521.

(2) For more information about this AD, contact Steven Dzierzynski, Aerospace Engineer, Avionics and Administrative Services Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7367; fax 516–794–5531.

(3) Service information identified in this AD that is not incorporated by reference is available at the addresses specified in paragraphs (k)(3) and (k)(4) of this AD.

**(k) Material Incorporated by Reference**

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(i) Bombardier Service Bulletin 604–28–022, dated October 19, 2015.

(ii) Bombardier Service Bulletin 605–28–010, dated October 19, 2015.

(3) For service information identified in this AD, contact Bombardier, Inc., 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; Widebody Customer Response Center North America toll-free telephone 1–866–538–1247 or direct-dial telephone 1–514–855–2999; fax 514–855–7401; email *ac.yul@aero.bombardier.com;* Internet *http://www.bombardier.com.*

(4) You may view this service information at the FAA, Transport Standards Branch, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

(5) You may view this service information that is incorporated by reference 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: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Renton, Washington, on October 17, 2017.

**Jeffrey E. Duven,**

*Director, System Oversight Division, Aircraft Certification Service.*

[FR Doc. 2017–23015 Filed 10–25–17; 8:45 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF ENERGY

## Federal Energy Regulatory Commission

## 18 CFR Parts 4, 5, and 16

**[Docket No. PL17–3–000]**

## Policy Statement on Establishing License Terms for Hydroelectric Projects

**AGENCY:** Federal Energy Regulatory Commission, Department of Energy.

**ACTION:** Policy statement.

**SUMMARY:** The Federal Energy Regulatory Commission (Commission) is giving notice of a new policy on establishing license terms for hydroelectric projects. In this Policy Statement, the Commission adopts a 40-year default license term for original and new licenses for hydropower projects located at non-federal dams. The Policy Statement also sets forth when the Commission will consider issuing those projects a license with a term for less or more than 40 years.

**DATES:** This policy statement will be applicable as of October 26, 2017.

**FOR FURTHER INFORMATION CONTACT:**

Nicholas Jayjack, (Technical Information), Office of Energy Projects, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, (202) 502–6073.

Carolyn Clarkin, (Legal Information), Office of the General Counsel—Energy Projects, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, (202) 502–8563.

**SUPPLEMENTARY INFORMATION:**

1. In this Policy Statement, the Commission sets forth a new policy on establishing license terms for original and new licenses for hydropower projects located at non-federal dams. The goal of this action is to provide more certainty for stakeholders regarding the Commission's regulatory process, reduce regulatory burden, increase administrative efficiency for all stakeholders, and further encourage licensees to negotiate settlement agreements and promptly seek authorization to implement voluntary environmental, recreational, and developmental enhancements.

### I. Background

*A. Current License Term Policy*

2. Section 6 of the Federal Power Act (FPA) [1] provides that hydropower licenses shall be issued for a term not to exceed 50 years. There is no minimum license term for original licenses. FPA section 15(e) [2] provides that any ''new license'' [3] shall be for a term that the Commission determines to be in the public interest, but not less than 30 years or more than 50 years.

3. It is current Commission policy to set a 50-year term for licenses issued for projects located at federal dams.[4] For projects located at non-federal dams, the Commission sets a 30-year term where there is little or no authorized redevelopment, new construction, or environmental mitigation and enhancement; a 40-year term for a license involving a moderate amount of these activities; and a 50-year term where there is an extensive amount of such activity.[5] The Commission previously established this policy to ease the economic impact of new costs, promote balanced and comprehensive development of renewable power generating resources, and encourage licensees to be good environmental stewards.[6]

4. Determining whether the measures required under a license are minimal, moderate, or extensive is highly case-

[1] 16 U.S.C. 799 (2012).

[2] 16 U.S.C. 808(e) (2012).

[3] ''New license'' is the term used in the FPA to refer to a license issued to replace a project's expiring license.

[4] *City of Danville, Virginia,* 58 FERC ¶ 61,318, at 62,020 (1992) (citing *Little Falls Hydroelectric Associates,* 27 FERC ¶ 61,376 (1984)).

[5] *Id.* (addressing original licenses); *Consumers Power Co.,* 68 FERC ¶ 61,077, at 61,384 (1994) (addressing new licenses). Projects that entail construction of a new dam have generally received 50-year licenses. *City of Danville, Virginia,* 58 FERC ¶ 61,318 at 62,020 (citing *Little Falls Hydroelectric Associates,* 27 FERC ¶ 61,376).

[6] *Consumers Power Co.,* 68 FERC ¶ 61,077 at 61,384.

specific and largely based on a qualitative analysis of the record before the Commission. In establishing the appropriate license term, staff initially examines the nature and extent of the required measures in the context of the project at issue,[7] and then uses the cost of measures as a check on a qualitative conclusion that the measures required under the license are minimal, moderate, or extensive. The Commission's current policy takes a forward-looking approach, such that any measures adopted under a prior license term are not considered.[8] It has also been the Commission's policy to coordinate, to the extent feasible, license terms for projects in the same river basin to maximize consideration of cumulative impacts when the projects are due to be relicensed.[9]

5. The length of an original license has not been contested on rehearing for some time; however, licensees and other parties have recently contested the length of a new license in several relicensing proceedings. The arguments raised in these cases include that the Commission, when establishing the license term, should have considered, or given more weight to: Previously-authorized capacity-related investments or environmental enhancements made by the licensee before issuance of the new license; [10] total cost of the relicensing process; [11] losses in generation value related to environmental measures; [12] the license terms of projects that the license applicant states are similarly situated to its project; [13] and the license term provided for in settlement agreements.[14] In each circumstance, the Commission declined to extend the length of the license.

*B. Notice of Inquiry on Establishing License Terms for Hydroelectric Projects*

6. On November 17, 2016, the Commission issued a notice of inquiry (NOI) to seek comments on whether, and if so how, the Commission should revise its current license term policy. The NOI invited comments on five potential license term policy options: (1) Retain the current policy; (2) modify the current policy to consider voluntary authorized actions implemented under the prior license (''previously-authorized voluntary actions''); (3) replace the current license term policy with a policy for a 50-year default license term unless a lesser license term would be in the public interest (for example, to better coordinate the license terms of projects in the same river basin); (4) add a more quantitative cost-based analysis to the current policy; and (5) alter the current policy to accept license terms agreed upon in settlement agreements, when appropriate. Comments on alternative policy options were also encouraged. The NOI established January 24, 2017, as the deadline for comments, which staff extended to March 24, 2017.

7. Industry members, federal and state resource agencies, environmental and recreation groups, and individuals filed comments. Most commenters support revising the current policy. Several commenters state that under the current policy stakeholders lack certainty, and, consequently, license applicants lack guidance on what measures will yield longer license terms and are deterred from proposing additional protection, mitigation, and enhancement measures. Further, many commenters state that because the policy is forward-looking, licensees delay seeking authorizations for capacity upgrades and environmental and recreational enhancements until they apply for a new license. Some industry commenters state that under the current policy, license applicants and settlement parties cannot use the license term as a bargaining chip because the Commission might reject that term in the license order. To address these concerns, many commenters recommend that the Commission consider previously-authorized voluntary actions and defer to the license term that was negotiated as part of a settlement agreement.

8. Commenters disagree on the 50-year default license term policy option. Industry commenters generally support the 50-year default license term because they state it would provide a clear, predictable standard. Industry commenters add that such policy would eliminate the current ''penalty'' for efficient, well-maintained, and relatively low-impact projects that do not require substantial environmental or developmental measures and therefore only receive a 30-year license.

9. In contrast, environmental groups, individuals, and most resource agencies oppose the 50-year default license term option. Several resource agencies argue that this option would provide little incentive for a license applicant to voluntarily propose or agree to mitigation measures because such measures would no longer factor into the Commission's license term decision. The resource agencies also contend that such policy would result in applicants focusing their license application study efforts on disproving project effects rather than on identifying potential mitigation measures.

10. Most commenters recommend against the policy option to adopt a more quantitative cost-based analysis. Many commenters state that it would be difficult to develop a quantitative cost-based analysis that takes into account the diverse hydropower fleet and environmental and recreational values.

11. As an alternative to the five policy options, several industry commenters recommend that the Commission adopt a 40-year default license term with credit (up to an additional 10 years) for previously-authorized actions and deference to settlement agreements. They state that under this alternative, licenses should be issued for less than 40 years only when a license applicant has agreed to a settlement agreement with a negotiated license term of less than 40 years, or voluntarily coordinates its license term with other projects in a river basin.

## II. Discussion

12. The extensive comments received have given the Commission a deeper understanding of the effects that the current license term policy has on stakeholders in hydropower licensing proceedings. The Commission recognizes the importance of providing license applicants and other stakeholders as much certainty as possible. License applicants expend significant financial resources on preparing their license applications and complying with their licenses thereafter.

[7] For example, one type of fishway may be more expensive than another, and a fishway type that might be considered extensive for a small project could be seen as minimal for a larger one.

[8] *See, e.g., Duke Energy Carolinas, LLC,* 156 FERC ¶ 61,010, at P 19 (2016) (*Duke Energy*) (stating Commission's long-standing policy is to only consider measures required in the new license) (citing *Alabama Power Co.,* 155 FERC ¶ 61,080, at P 72 (2016); *Georgia Power Co.,* 111 FERC ¶ 61,183, at P 12 (2005); *Ford Motor Co.,* 110 FERC ¶ 61,236, at PP 6–8 (2005)).

[9] 18 CFR 2.23 (2017); *see also Public Utility of District No. 1 of Chelan County, Washington,* 127 FERC ¶ 61,152, at P 18 (2009) (*Chelan PUD*).

[10] *See, e.g., Duke Energy,* 156 FERC ¶ 61,010 at P 12; *Alabama Power Co.,* 155 FERC ¶ 61,080 at P 71; *Public Utility District No. 1 of Douglas County, Washington,* 143 FERC ¶ 61,130, at PP 12–13 (2013) (*Douglas PUD*); *Chelan PUD,* 127 FERC ¶ 61,152 at PP 12–13; *Georgia Power Co.,* 111 FERC ¶ 61,183 at P 10; *Ford Motor Co.,* 110 FERC ¶ 61,236 at P 6.

[11] *See, e.g., Duke Energy,* 156 FERC ¶ 61,010 at P 12.

[12] *See, e.g., id.*

[13] *See, e.g., id.* P 20; *Alabama Power Co.,* 155 FERC ¶ 61,080 at P 71; *Duke Energy Progress, Inc.,* 153 FERC ¶ 61,056, at P 39 (2015); *Douglas PUD,* 143 FERC ¶ 61,130 at P 15.

[14] *See, e.g., Duke Energy Progress, Inc.,* 153 FERC ¶ 61,056 at P 40; *Douglas PUD,* 143 FERC ¶ 61,130 at P 18; *Chelan PUD,* 127 FERC ¶ 61,152 at P 16.

Further, stakeholders need certainty to determine the protection, mitigation, and enhancement measures that they will negotiate and license applicants will propose.

13. The current policy also affects the Commission's staff and resources needed to review and process license applications. Staff anticipate that over 300 projects will enter the relicensing process through 2025. Under the current policy, staff would establish the license term for each of those projects case by case.

14. After considering this matter and the comments on the NOI, the Commission has decided it is in the public interest to change its license term policy. With this Policy Statement, the Commission establishes a 40-year default license term policy for original and new licenses for hydropower projects located at non-federal dams.[15]

15. There are three circumstances where the Commission will consider issuing a license for less or more than 40 years. First, the Commission will establish a shorter or longer term if necessary to coordinate license terms for projects located in the same river basin. Second, the Commission will defer to a shorter or longer term explicitly agreed upon in a generally-supported comprehensive settlement agreement, provided that such term does not conflict with coordination. Settlement agreements that state the settlement signatories would not oppose a certain term or would support a term within a range of years will not be considered to include an explicitly agreed upon license term.[16]

16. Third, the Commission will consider a longer license term—provided that doing so is consistent with coordinating license terms within a basin—when a license applicant specifically requests a longer license term based on significant measures expected to be required under the new license or significant measures implemented during the prior license term that were not required by that license or other legal authority [17] and for which the Commission has not already given credit through an extension of the prior license term. The Commission will consider, on a case-by-case basis, measures and actions that enhance non-developmental project purposes (*i.e.,* environmental, project recreation, water supply), and those that enhance power and developmental purposes, together with the cost of those measures and actions to determine whether they are significant and warrant the granting of a longer license term. Maintenance measures and measures taken to support the licensing process will not be considered. As guidance, we note that the Commission has found that measures including the construction of pumped storage facilities, fish passage facilities, fish hatcheries, substantial recreation facilities, dams, and powerhouses warranted longer license terms.

17. There are a number of reasons for establishing a 40-year default license term with exceptions for coordination, deference to generally-supported comprehensive settlement agreements, and consideration of previously-authorized voluntary actions. This policy will provide significant certainty to licensees, resource agencies, and other stakeholders. A 40-year default license term will provide a simpler method for Commission staff to establish license terms, and, thus, increase administrative efficiencies. A case-specific assessment will only be required for those license applications that request a longer license term, and are not explicitly supported by a generally-supported comprehensive settlement agreement. Because many projects would be relicensed less frequently, the policy would also lower administrative costs for all stakeholders, provide licensees longer license terms to recoup costs, and reduce regulatory burden. Further, the policy will place efficient, low-impact projects that require minimal measures—and thus, would receive a 30-year term under the current policy—on more equal footing with projects that require more measures.

18. The policy may also encourage licensees to voluntarily make capacity upgrades and enhance recreational and environmental resources during the prior license term. Affected resources will benefit from licensees undertaking preventative or remedial measures sooner rather than later. In addition, the policy may further encourage license applicants to engage with stakeholders to negotiate a license settlement agreement. Because a generally-supported comprehensive settlement agreements represent stakeholder values, terms negotiated as part of those agreements are in the public interest, provided they do not conflict with coordination.

19. A 40-year default license term will not adversely affect environmental and recreation resources. All of our licenses contain extensive environmental and recreation measures. While under our new policy some projects may be relicensed less frequently and unanticipated project effects on environmental resources may go unmitigated for longer durations of time than before, there are many tools available to address these unanticipated effects in a timely manner. The Commission may address serious, unanticipated environmental effects using its standard reopener article,[18] and licensees often file applications for license amendments to address significant, unanticipated environmental issues. Further, resource agencies frequently reserve authority to address those effects under FPA section 4(e) (federal reservation) [19] and section 18 (fishway prescription),[20] and in water quality certifications issued under section 401 of the Clean Water Act. Stakeholders have also negotiated with or encouraged licensees to propose measures that include adaptive management approaches to allow for appropriate modifications as additional information is gathered, new technologies develop, and societal and environmental needs change.

20. This Policy Statement will apply to all licenses issued following its publication in the **Federal Register** with no retroactive application. License applicants with pending license applications may file a comprehensive settlement agreement, or addendum to an existing agreement, that includes an explicitly agreed upon license term or may make a filing demonstrating why the Commission should award them a longer license term than 40 years. The Commission, however, will not entertain applications to amend existing licenses to extend their license terms simply on the basis of this new license term policy. Pursuant to current policy, licensees that seek to extend existing licenses with terms of less than 50

[15] This policy does not apply to pilot hydrokinetic projects, which have terms of up to five years. *See* FERC, *Licensing Hydrokinetic Pilot Projects, www.ferc.gov/industries/hydropower/gen-info/licensing/hydrokinetics/pdf/white_paper.pdf.*

[16] *See, e.g., Chelan* PUD, 127 FERC ¶ 61,152 at n.27 (settlement states that the signatories do not oppose the licensee's efforts to seek a 50-year term); *Duke Energy,* 156 FERC ¶ 61,010 at P 24 (settlement states the signatories agree to support a license term that is not less than 40 years nor more than 50 years).

[17] *See, e.g., Chelan PUD,* 127 FERC ¶ 61,152, at P 14 (stating that the licensee acted in order to comply with the Endangered Species Act, not to simply voluntarily resolve relicensing issues early).

[18] Each license incorporates a Commission L-Form that includes standard reopener clauses to enhance fish and wildlife resources. *See Standardized Conditions for Inclusion in Preliminary Permits and Licenses Issued Under Part I of the Federal Power Act,* 54 F.P.C. 1792 (1975).

[19] 16 U.S.C. 797(e) (2012) (licenses for projects located on federal reservations are subject to and contain conditions as the Secretary of the department under whose supervision such reservation falls shall deem necessary).

[20] 16 U.S.C. 811 (2012) (Secretaries of the Interior and Commerce may prescribe fishway prescriptions).

years, must justify such requests, for example by proposing development, environmental, and recreation enhancements in a license amendment application accompanied by a request that the Commission extend their license term.[21]

### III. Document Availability

21. In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the Internet through FERC's Home Page (*http://www.ferc.gov*) and in FERC's Public Reference Room during normal business hours (8:30 a.m. to 5:00 p.m. Eastern time) at 888 First Street NE., Room 2A, Washington, DC 20426.

22. From FERC's Home Page on the Internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field. User assistance is available for eLibrary and the Commission's Web site during normal business hours from FERC Online Support at 202–502–6652 (toll free at 1–866–208–3676) or email at *ferconlinesupport@ferc.gov,* or the Public Reference Room at (202) 502–8371, TTY (202)502–8659. Email the Public Reference Room at *public.referenceroom@ferc.gov.*

By the Commission.

Issued: October 19, 2017.

**Nathaniel J. Davis, Sr.,**

*Deputy Secretary.*

[FR Doc. 2017–23286 Filed 10–25–17; 8:45 am]

**BILLING CODE 6717–01–P**

[21] *See, e.g., Idaho Power Co.,* 132 FERC ¶ 62,001 (2010) (10-year extension of the license term due to the costs of replacing the project's existing powerhouse and increasing generating capacity); *PPL Holtwood, LLC,* 129 FERC ¶ 62,092 (2009) (16-year extension of license term due to costs associated with the constructing a new powerhouse, installing two turbine generating units at the existing powerhouse, and various environmental measures).

## DEPARTMENT OF JUSTICE

## Drug Enforcement Administration

## 21 CFR Part 1308

**[Docket No. DEA–473]**

## Schedules of Controlled Substances: Temporary Placement of ortho-Fluorofentanyl, Tetrahydrofuranyl Fentanyl, and Methoxyacetyl Fentanyl Into Schedule I

**AGENCY:** Drug Enforcement Administration, Department of Justice.

**ACTION:** Temporary amendment; temporary scheduling order.

**SUMMARY:** The Administrator of the Drug Enforcement Administration is issuing this temporary scheduling order to schedule the synthetic opioids, *N*-(2-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)propionamide (*ortho*-fluorofentanyl or 2-fluorofentanyl), *N*-(1-phenethylpiperidin-4-yl)-*N*-phenyltetrahydrofuran-2-carboxamide (tetrahydrofuranyl fentanyl), and 2-methoxy-*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylacetamide (methoxyacetyl fentanyl), into Schedule I. This action is based on a finding by the Administrator that the placement of *ortho*-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl into Schedule I of the Controlled Substances Act is necessary to avoid an imminent hazard to the public safety. As a result of this order, the regulatory controls and administrative, civil, and criminal sanctions applicable to Schedule I controlled substances will be imposed on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analysis, or possess), or propose to handle, *ortho*-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl.

**DATES:** This temporary scheduling order is effective October 26, 2017, until October 28, 2019. If this order is extended or made permanent, the DEA will publish a document in the **Federal Register**.

**FOR FURTHER INFORMATION CONTACT:** Michael J. Lewis, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812.

**SUPPLEMENTARY INFORMATION:**

### Legal Authority

Section 201 of the Controlled Substances Act (CSA), 21 U.S.C. 811, provides the Attorney General with the authority to temporarily place a substance into Schedule I of the CSA for two years without regard to the requirements of 21 U.S.C. 811(b) if he finds that such action is necessary to avoid an imminent hazard to the public safety. 21 U.S.C. 811(h)(1). In addition, if proceedings to control a substance are initiated under 21 U.S.C. 811(a)(1), the Attorney General may extend the temporary scheduling [1] for up to one year. 21 U.S.C. 811(h)(2).

Where the necessary findings are made, a substance may be temporarily scheduled if it is not listed in any other schedule under section 202 of the CSA, 21 U.S.C. 812, or if there is no exemption or approval in effect for the substance under section 505 of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 355. 21 U.S.C. 811(h)(1). The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Administrator of the DEA. 28 CFR 0.100.

### Background

Section 201(h)(4) of the CSA, 21 U.S.C. 811(h)(4), requires the Administrator to notify the Secretary of the Department of Health and Human Services (HHS) of his intention to temporarily place a substance into Schedule I of the CSA.[2] The Administrator transmitted notice of his intent to place *ortho*-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl in Schedule I on a temporary basis to the Assistant Secretary for Health of HHS by letter. Notice for these actions was transmitted on the following dates: May 19, 2017 (*ortho*-fluorofentanyl) and July 5, 2017 (tetrahydrofuranyl fentanyl and methoxyacetyl fentanyl). The Assistant Secretary responded by letters dated June 9, 2017 (*ortho*-fluorofentanyl) and July 14, 2017 (tetrahydrofuranyl fentanyl and methoxyacetyl fentanyl), and advised that based on review by the Food and Drug Administration (FDA), there are currently no investigational new drug applications or approved new drug applications for *ortho*-

[1] Though DEA has used the term ''final order'' with respect to temporary scheduling orders in the past, this document adheres to the statutory language of 21 U.S.C. 811(h), which refers to a ''temporary scheduling order.'' No substantive change is intended.

[2] As discussed in a memorandum of understanding entered into by the Food and Drug Administration (FDA) and the National Institute on Drug Abuse (NIDA), the FDA acts as the lead agency within the HHS in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518, Mar. 8, 1985. The Secretary of the HHS has delegated to the Assistant Secretary for Health of the HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460, July 1, 1993.

fluorofentanyl, tetrahydrofuranyl fentanyl, or methoxyacetyl fentanyl. The Assistant Secretary also stated that the HHS has no objection to the temporary placement of *ortho*-fluorofentanyl, tetrahydrofuranyl fentanyl, or methoxyacetyl fentanyl into Schedule I of the CSA. The DEA has taken into consideration the Assistant Secretary's comments as required by 21 U.S.C. 811(h)(4). *ortho*-Fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl are not currently listed in any schedule under the CSA, and no exemptions or approvals are in effect for *ortho*-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl under section 505 of the FDCA, 21 U.S.C. 355. The DEA has found that the control of *ortho*-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl in Schedule I on a temporary basis is necessary to avoid an imminent hazard to the public safety, and as required by 21 U.S.C. 811(h)(1)(A), a notice of intent to issue a temporary order to schedule *ortho*-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl was published in the **Federal Register** on September 12, 2017. 82 FR 42754.

To find that placing a substance temporarily into Schedule I of the CSA is necessary to avoid an imminent hazard to the public safety, the Administrator is required to consider three of the eight factors set forth in section 201(c) of the CSA, 21 U.S.C. 811(c): The substance's history and current pattern of abuse; the scope, duration and significance of abuse; and what, if any, risk there is to the public health. 21 U.S.C. 811(h)(3). Consideration of these factors includes actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution. 21 U.S.C. 811(h)(3).

A substance meeting the statutory requirements for temporary scheduling may only be placed into Schedule I. 21 U.S.C. 811(h)(1). Substances in Schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. 21 U.S.C. 812(b)(1).

Available data and information for *ortho*-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl, summarized below, indicate that these synthetic opioids have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. The DEA's three-factor analysis, and the Assistant Secretary's June 9, 2017 and July 14, 2017 letters are available in their entirety under the tab ''Supporting Documents'' of the public docket of this action at *www.regulations.gov* under FDMS Docket ID: DEA–2017–0005 (Docket Number DEA–473).

**Factor 4. History and Current Pattern of Abuse**

The recreational abuse of fentanyl-like substances continues to be a significant concern. These substances are distributed to users, often with unpredictable outcomes. *ortho*-Fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl have recently been encountered by law enforcement and public health officials. Adverse health effects and outcomes are demonstrated by fatal overdose cases involving these substances. The documented adverse health effects of *ortho*-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl are consistent with those of other opioids.

On October 1, 2014, the DEA implemented STARLiMS (a web-based, commercial laboratory information management system) to replace the System to Retrieve Information from Drug Evidence (STRIDE) as its laboratory drug evidence data system of record. DEA laboratory data submitted after September 30, 2014, are reposited in STARLiMS. Data from STRIDE and STARLiMS were queried on June 19, 2017. STARLiMS registered four reports containing *ortho*-fluorofentanyl from California and five reports containing tetrahydrofuranyl fentanyl from Florida and Missouri. According to STARLiMS, the first laboratory submissions of *ortho*-fluorofentanyl and tetrahydrofuranyl fentanyl occurred in April 2016, and March 2017, respectively.

The National Forensic Laboratory Information System (NFLIS) is a national drug forensic laboratory reporting system that systematically collects results from drug chemistry analyses conducted by other federal, state, and local forensic laboratories across the country. Data from NFLIS was queried on June 20, 2017. NFLIS registered three reports containing *ortho*-fluorofentanyl from state or local forensic laboratories in Virginia.[3] According to NFLIS, the first report of *ortho*-fluorofentanyl was reported in September 2016. NFLIS registered two reports containing tetrahydrofuranyl fentanyl from state or local forensic laboratories in New Jersey and was first reported in January 2017. The identification of methoxyacetyl fentanyl in drug evidence submitted in April 2017 was reported to DEA from a local laboratory in Ohio.[4] The DEA is not aware of any laboratory identifications of *ortho*-fluorofentanyl prior to 2016 or identifications of tetrahydrofuranyl fentanyl or methoxyacetyl fentanyl prior to 2017.

Evidence suggests that the pattern of abuse of fentanyl analogues, including *ortho*-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl, parallels that of heroin and prescription opioid analgesics. Seizures of *ortho*-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl have been encountered in powder form similar to fentanyl and heroin and have been connected to fatal overdoses.

**Factor 5. Scope, Duration and Significance of Abuse**

Reports collected by the DEA demonstrate *ortho*-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl are being abused for their opioid properties. Abuse of *ortho*-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl have resulted in mortality (*see* DEA 3-Factor Analysis for full discussion). The DEA collected post-mortem toxicology and medical examiner reports on 13 confirmed fatalities associated with *ortho*-fluorofentanyl which occurred in Georgia (1), North Carolina (11), and Texas (1), two confirmed fatalities associated with tetrahydrofuranyl fentanyl which occurred in New Jersey (1) and Wisconsin (1), and two confirmed fatalities associated with methoxyacetyl fentanyl which occurred in Pennsylvania. It is likely that the prevalence of these substances in opioid related emergency room admissions and deaths is underreported as standard immunoassays may not differentiate fentanyl analogues from fentanyl.

*ortho*-Fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl have been identified in drug evidence collected by law enforcement. NFLIS and STARLiMS have a total of seven drug reports in which *ortho*-fluorofentanyl was identified in drug exhibits submitted to forensic laboratories in 2016 from law enforcement encounters in California and Virginia and seven drug reports in which tetrahydrofuranyl fentanyl was identified in drug exhibits submitted to forensic laboratories in 2017 from law

[3] Data are still being collected for March 2017–June 2017 due to the normal lag period for labs reporting to NFLIS.

[4] Email from Cuyahoga County Medical Examiner's Office, to DEA (May 8, 2017 02:29 p.m. EST) (on file with DEA).

enforcement encounters in Florida, Missouri, and New Jersey. The identification of methoxyacetyl fentanyl in drug evidence submitted in April 2017 was reported to DEA from Ohio.

The population likely to abuse *ortho*-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl overlaps with the population abusing prescription opioid analgesics, heroin, fentanyl, and other fentanyl-related substances. This is evidenced by the routes of drug administration and drug use history documented in *ortho*-fluorofentanyl and tetrahydrofuranyl fentanyl fatal overdose cases. Because abusers of *ortho*-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl are likely to obtain these substances through unregulated sources, the identity, purity, and quantity are uncertain and inconsistent, thus posing significant adverse health risks to the end user. Individuals who initiate (*i.e.* use a drug for the first time) *ortho*-fluorofentanyl, tetrahydrofuranyl fentanyl, or methoxyacetyl fentanyl abuse are likely to be at risk of developing substance use disorder, overdose, and death similar to that of other opioid analgesics (*e.g.,* fentanyl, morphine, etc.).

**Factor 6. What, if Any, Risk There Is to the Public Health**

*ortho*-Fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl exhibit pharmacological profiles similar to that of fentanyl and other μ-opioid receptor agonists. The toxic effects of *ortho*-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl in humans are demonstrated by overdose fatalities involving these substances. Abusers of *ortho*-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl may not know the origin, identity, or purity of these substances, thus posing significant adverse health risks when compared to abuse of pharmaceutical preparations of opioid analgesics, such as morphine and oxycodone.

Based on information received by the DEA, the misuse and abuse of *ortho*-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl lead to the same qualitative public health risks as heroin, fentanyl and other opioid analgesic substances. As with any non-medically approved opioid, the health and safety risks for users are high. The public health risks attendant to the abuse of heroin and opioid analgesics are well established and have resulted in large numbers of drug treatment admissions, emergency department visits, and fatal overdoses.

*ortho*-Fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl have been associated with numerous fatalities. At least 13 confirmed overdose deaths involving *ortho*-fluorofentanyl abuse have been reported from Georgia (1), North Carolina (11), and Texas (1). At least two confirmed overdose deaths involving tetrahydrofuranyl fentanyl have been reported from New Jersey (1) and Wisconsin (1). At least two confirmed overdose deaths involving methoxyacetyl fentanyl have been repored from Pennsylvania. As the data demonstrate, the potential for fatal and non-fatal overdoses exists for *ortho*-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl and these substances pose an imminent hazard to the public safety.

**Finding of Necessity of Schedule I Placement To Avoid Imminent Hazard to Public Safety**

In accordance with 21 U.S.C. 811(h)(3), based on the available data and information, summarized above, the continued uncontrolled manufacture, distribution, reverse distribution, importation, exportation, conduct of research and chemical analysis, possession, and abuse of *ortho*-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl poses an imminent hazard to the public safety. The DEA is not aware of any currently accepted medical uses for *ortho*-fluorofentanyl, tetrahydrofuranyl fentanyl, or methoxyacetyl fentanyl in the United States. A substance meeting the statutory requirements for temporary scheduling, 21 U.S.C. 811(h)(1), may only be placed in Schedule I. Substances in Schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. Available data and information for *ortho*-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl indicate that these substances have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. As required by section 201(h)(4) of the CSA, 21 U.S.C. 811(h)(4), the Administrator, through letters dated May 19, 2017 (*ortho*-fluorofentanyl) and July 5, 2017 (tetrahydrofuranyl fentanyl and methoxyacetyl fentanyl), notified the Assistant Secretary of the DEA's intention to temporarily place these substances in Schedule I. A notice of intent was subsequently published in the **Federal Register** on September 12, 2017. 82 FR 42754.

**Conclusion**

In accordance with the provisions of section 201(h) of the CSA, 21 U.S.C. 811(h), the Administrator considered available data and information, herein sets forth the grounds for his determination that it is necessary to temporarily schedule *ortho*-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl into Schedule I of the CSA, and finds that placement of these synthetic opioids into Schedule I of the CSA is necessary to avoid an imminent hazard to the public safety.

Because the Administrator hereby finds it necessary to temporarily place these synthetic opioids into Schedule I to avoid an imminent hazard to the public safety, this temporary order scheduling *ortho*-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl is effective on the date of publication in the **Federal Register**, and is in effect for a period of two years, with a possible extension of one additional year, pending completion of the regular (permanent) scheduling process. 21 U.S.C. 811(h)(1) and (2).

The CSA sets forth specific criteria for scheduling a drug or other substance. Permanent scheduling actions in accordance with 21 U.S.C. 811(a) are subject to formal rulemaking procedures done ''on the record after opportunity for a hearing'' conducted pursuant to the provisions of 5 U.S.C. 556 and 557. 21 U.S.C. 811. The permanent scheduling process of formal rulemaking affords interested parties with appropriate process and the government with any additional relevant information needed to make a determination. Final decisions that conclude the permanent scheduling process of formal rulemaking are subject to judicial review. 21 U.S.C. 877. Temporary scheduling orders are not subject to judicial review. 21 U.S.C. 811(h)(6).

**Requirements for Handling**

Upon the effective date of this temporary order, *ortho*-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl will become subject to the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, importation, exportation, engagement in research, and conduct of instructional activities or chemical analysis with, and possession of Schedule I controlled substances including the following:

1. *Registration.* Any person who handles (manufactures, distributes, reverse distributes, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses), or who desires to handle, *ortho*-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl must be registered with the DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958 and in accordance with 21 CFR parts 1301 and 1312, as of October 26, 2017. Any person who currently handles *ortho*-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl, and is not registered with the DEA, must submit an application for registration and may not continue to handle *ortho*-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl as of October 26, 2017, unless the DEA has approved that application for registration pursuant to 21 U.S.C. 822, 823, 957, 958, and in accordance with 21 CFR parts 1301 and 1312. Retail sales of Schedule I controlled substances to the general public are not allowed under the CSA. Possession of any quantity of these substances in a manner not authorized by the CSA on or after October 26, 2017 is unlawful and those in possession of any quantity of these substances may be subject to prosecution pursuant to the CSA.

2. *Disposal of stocks.* Any person who does not desire or is not able to obtain a Schedule I registration to handle *ortho*-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl, must surrender all quantities of currently held *ortho*-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl.

3. *Security. ortho*-Fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl are subject to Schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 821, 823, 871(b), and in accordance with 21 CFR 1301.71–1301.93, as of October 26, 2017.

4. *Labeling and packaging.* All labels, labeling, and packaging for commercial containers of *ortho*-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl must be in compliance with 21 U.S.C. 825, 958(e), and be in accordance with 21 CFR part 1302. Current DEA registrants shall have 30 calendar days from October 26, 2017, to comply with all labeling and packaging requirements.

5. *Inventory.* Every DEA registrant who possesses any quantity of *ortho*-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl on the effective date of this order must take an inventory of all stocks of these substances on hand, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11. Current DEA registrants shall have 30 calendar days from the effective date of this order to be in compliance with all inventory requirements. After the initial inventory, every DEA registrant must take an inventory of all controlled substances (including *ortho*-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl) on hand on a biennial basis, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

6. *Records.* All DEA registrants must maintain records with respect to *ortho*-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR parts 1304, and 1312, 1317 and § 1307.11. Current DEA registrants shall have 30 calendar days from the effective date of this order to be in compliance with all recordkeeping requirements.

7. *Reports.* All DEA registrants who manufacture or distribute *ortho*-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl must submit reports pursuant to 21 U.S.C. 827 and in accordance with 21 CFR parts 1304 and 1312 as of October 26, 2017.

8. *Order Forms.* All DEA registrants who distribute *ortho*-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl must comply with order form requirements pursuant to 21 U.S.C. 828 and in accordance with 21 CFR part 1305 as of October 26, 2017.

9. *Importation and Exportation.* All importation and exportation of *ortho*-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl must be in compliance with 21 U.S.C. 952, 953, 957, 958, and in accordance with 21 CFR part 1312 as of October 26, 2017.

10. *Quota.* Only DEA registered manufacturers may manufacture *ortho*-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303 as of October 26, 2017.

11. *Liability.* Any activity involving *ortho*-fluorofentanyl, tetrahydrofuranyl fentanyl, and methoxyacetyl fentanyl not authorized by, or in violation of the CSA, occurring as of October 26, 2017, is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

**Regulatory Matters**

Section 201(h) of the CSA, 21 U.S.C. 811(h), provides for a temporary scheduling action where such action is necessary to avoid an imminent hazard to the public safety. As provided in this subsection, the Attorney General may, by order, schedule a substance in Schedule I on a temporary basis. Such an order may not be issued before the expiration of 30 days from (1) the publication of a notice in the **Federal Register** of the intention to issue such order and the grounds upon which such order is to be issued, and (2) the date that notice of the proposed temporary scheduling order is transmitted to the Assistant Secretary. 21 U.S.C. 811(h)(1).

Inasmuch as section 201(h) of the CSA directs that temporary scheduling actions be issued by order and sets forth the procedures by which such orders are to be issued, the DEA believes that the notice and comment requirements of the Administrative Procedure Act (APA) at 5 U.S.C. 553, do not apply to this temporary scheduling action. In the alternative, even assuming that this action might be subject to 5 U.S.C. 553, the Administrator finds that there is good cause to forgo the notice and comment requirements of 5 U.S.C. 553, as any further delays in the process for issuance of temporary scheduling orders would be impracticable and contrary to the public interest in view of the manifest urgency to avoid an imminent hazard to the public safety.

Further, the DEA believes that this temporary scheduling action is not a ''rule'' as defined by 5 U.S.C. 601(2), and, accordingly, is not subject to the requirements of the Regulatory Flexibility Act. The requirements for the preparation of an initial regulatory flexibility analysis in 5 U.S.C. 603(a) are not applicable where, as here, the DEA is not required by the APA or any other law to publish a general notice of proposed rulemaking.

Additionally, this action is not a significant regulatory action as defined by Executive Order 12866 (Regulatory Planning and Review), section 3(f), and, accordingly, this action has not been reviewed by the Office of Management and Budget.

This action will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132 (Federalism) it is determined that this action does not have sufficient

federalism implications to warrant the preparation of a Federalism Assessment.

As noted above, this action is an order, not a rule. Accordingly, the Congressional Review Act (CRA) is inapplicable, as it applies only to rules. However, if this were a rule, pursuant to the Congressional Review Act, ''any rule for which an agency for good cause finds that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest, shall take effect at such time as the federal agency promulgating the rule determines.'' 5 U.S.C. 808(2). It is in the public interest to schedule these substances immediately to avoid an imminent hazard to the public safety. This temporary scheduling action is taken pursuant to 21 U.S.C. 811(h), which is specifically designed to enable the DEA to act in an expeditious manner to avoid an imminent hazard to the public safety. 21 U.S.C. 811(h) exempts the temporary scheduling order from standard notice and comment rulemaking procedures to ensure that the process moves swiftly. For the same reasons that underlie 21 U.S.C. 811(h), that is, the DEA's need to move quickly to place these substances into Schedule I because it poses an imminent hazard to the public safety, it would be contrary to the public interest to delay implementation of the temporary scheduling order. Therefore, this order shall take effect immediately upon its publication. The DEA has submitted a copy of this temporary order to both Houses of Congress and to the Comptroller General, although such filing is not required under the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act), 5 U.S.C. 801–808 because, as noted above, this action is an order, not a rule.

**List of Subjects in 21 CFR Part 1308**

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, the DEA amends 21 CFR part 1308 as follows:

## PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

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

**Authority:** 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

■ 2. In § 1308.11, add reserved paragraphs (h)(15) through (18) and paragraphs (h)(19), (20), and (21) to read as follows:

**§ 1308.11 Schedule I.**

* * * * *

(h) * * *

| | |
|---|---|
| (19) *N*-(2-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)propionamide, its isomers, esters, ethers, salts and salts of isomers, esters and ethers (Other names: *ortho*-fluorofentanyl, 2-fluorofentanyl) | (9816) |
| (20) *N*-(1-phenethylpiperidin-4-yl)-*N*-phenyltetrahydrofuran-2-carboxamide, its isomers, esters, ethers, salts and salts of isomers, esters and ethers (Other name: tetrahydrofuranyl fentanyl) | (9843) |
| (21) 2-methoxy-*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylacetamide, its isomers, esters, ethers, salts and salts of isomers, esters and ethers (Other name: methoxyacetyl fentanyl) | (9825) |

Dated: October 17, 2017.

**Robert W. Patterson,**

*Acting Administrator.*

[FR Doc. 2017–23206 Filed 10–25–17; 8:45 am]

**BILLING CODE 4410–09–P**

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

### 26 CFR Part 1

**[TD 9815]**

**RIN 1545–BM33**

## Dividend Equivalents From Sources Within the United States; Correction

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Final regulations and temporary regulations; Correcting amendments.

**SUMMARY:** This document contains corrections to final and temporary regulations (TD TD 9815), which were published in the **Federal Register** on Tuesday, January 24, 2017.

**DATES:** *Effective Date:* These corrections are effective October 26, 2017.

*Applicability Date:* The corrections to §§ 1.1.871–15, 1.871–15T, 1.1441–1(e)(5)(v)(B)(*4*), (e)(6), and (f)(5), 1.1441–2, 1.1441–7, and 1.1461–1 are applicable on January 19, 2017.

**FOR FURTHER INFORMATION CONTACT:** D. Peter Merkel or Karen Walny at 202–317–6938 (not a toll-free number).

**SUPPLEMENTARY INFORMATION:**

### Background

The final and temporary regulations that are the subject of these corrections are §§ 1.871–15, 1.871–15T, 1.1441–1, 1.1441–2, 1.1441–7, and 1.1461–1, promulgated under sections 871(m) and 7805 of the Internal Revenue Code. These regulations affect foreign persons that hold certain financial products providing for payments that are contingent upon or determined by reference to U.S. source dividends, as well withholding agents with respect to dividend equivalents and certain other parties to section 871(m) transactions and their agents.

### Need for Correction

As published, TD 9815 contains errors that may prove to be misleading and are in need of clarification.

**List of Subjects in 26 CFR Part 1**

Income taxes, Reporting and recordkeeping requirements.

### Correction of Publication

Accordingly, 26 CFR part 1 is corrected by making the following correcting amendments:

## PART 1—INCOME TAXES

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

**Authority:** 26 U.S.C. 7805 * * *

**§ 1.871–15 [Amended]**

■ **Par. 2.** Section 1.871–15 is amended by:

■ 1. Removing paragraph (r)(2).

■ 2. Redesignating paragraphs (r)(3), (4), and (5), as (r)(2), (3), and (4), respectively.

**§ 1.871–15 [Amended]**

■ **Par. 3.** For each section listed in the table, remove the language in the ''Remove'' column and add in its place the language in the ''Add'' column as set forth below:

| Section | Remove | Add |
|---|---|---|
| § 1.871–15(a)(14)(ii)(B) | ELI.More | ELI. More |
| § 1.871–15(l)(1), second sentence | described in this paragraph (l) | described in this paragraph (l)(1) |
| § 1.871–15(q)(1) | qualified intermediary agreement | qualified intermediary withholding agreement |

| Section | Remove | Add |
|---|---|---|
| § 1.871–15(q)(4) | ordinary | ordinarily |
| § 1.871–15(q)(5), Example (3), paragraph (ii) | country that provides withholding | country with a treaty that provides withholding |
| § 1.871–15(q)(5), Example (3), paragraph (ii) | paid by qualified derivatives dealer | paid by the qualified derivatives dealer |
| § 1.871–15(r)(1) | September 18, 2015 | January 19, 2017 |

**§ 1.871–15T [Amended]**

■ **Par. 4.** Section 1.871–15T is amended by redesignating paragraph (r)(5) as (r)(4).

**§ 1.871–15T [Amended]**

■ **Par. 5.** For each section listed in the table, remove the language in the ''Remove'' column and add in its place the language in the ''Add'' column as set forth below:

| Section | Remove | Add |
|---|---|---|
| § 1.871–15T(p)(5) | *Example 1.* | *Example.* |
| § 1.871–15T(q) through (r)(4) [Reserved] | (q) through (r)(4) [Reserved]. For further guidance, see § 1.871–15(r)(1) through (4). | (q) through (r)(3) [Reserved]. For further guidance, see § 1.871–15(q) through (r)(3) |
| § 1.871–15T(r)(4) newly redesignated | after on January | after January |

**§ 1.1441–1 [Amended]**

■ **Par. 6.** For each section listed in the table, remove the language in the ''Remove'' column and add in its place the language in the ''Add'' column as set forth below:

| Section | Remove | Add |
|---|---|---|
| § 1.1441–1(e)(5)(v)(B)(*4*)(*iv*) | U.S. income tax | U.S. federal income tax |
| § 1.1441–1(e)(6)(i)(B) | and other withholding provisions | and other provisions |
| § 1.1441–1(e)(6)(i)(C) | underlying securities (including | underlying securities as defined in § 1.871–15(a)(15) (including |
| § 1.1441–1(e)(6)(i)(C) | received in the equity | received in its equity |
| § 1.1441–1(e)(6)(i)(D)(*3*) | U.S. tax return | U.S. federal tax return |
| § 1.1441–1(e)(6)(i)(F) | QDD | qualified derivatives dealer |
| § 1.1441–1(e)(6)(ii)(B) introductory text | organized, or operates | organized or operates |
| § 1.1441–1(e)(6)(ii)(B)(*2*) | pursuant to | with respect to |
| § 1.1441–1(f)(5) | Paragraphs (e)(5)(ii)(D) | Paragraphs (e)(5)(ii)(C) |

■ **Par. 7.** Section 1.1441–2 is amended by removing the last two sentences of paragraph (f)(1) and adding a sentence at the end of the paragraph to read as follows:

**§ 1.1441–2 Amounts subject to withholding.**

* * * * *

(f) * * *

(1) * * * Paragraph (e)(7) of this section applies on or after January 19, 2017.

* * * * *

**§ 1.1441–2 [Amended]**

■ **Par. 8.** For each section listed in the table, remove the language in the ''Remove'' column and add in its place the language in the ''Add'' column as set forth below:

| Section | Remove | Add |
|---|---|---|
| § 1.1441–2(e)(7)(ii)(A) | § 1.871–15(i)(3), | § 1.871–15(i)(3)(i), |
| § 1.1441–2(e)(7)(iv) | type (securities | type (for example, securities |
| § 1.1441–2(e)(7)(v) | the types of section 871(m) transaction | the type of section 871(m) transaction |
| § 1.1441–2(e)(7)(v) | certifying that has notified | certifying that it has notified |

**§ 1.1441–7 [Amended]**

■ **Par. 9.** Section 1.1441–7 is amended by removing the second sentence of paragraph (a)(4).

**§ 1.1441–7 [Amended]**

■ **Par. 10.** For each section listed in the table, remove the language in the ''Remove'' column and add in its place the language in the ''Add'' column as set forth below:

| Section | Remove | Add |
|---|---|---|
| § 1.1441–7(a)(3), Example 9 | not required withhold | not required to withhold |
| § 1.1441–7(a)(4) | *Example 8* and | *Example 7, Example 8,* and |
| § 1.1441–7(a)(4) | apply to payments made on or after January 19 | apply beginning January 19 |

■ **Par. 11.** Section 1.1461–1 is amended by revising paragraph (c)(2)(iii) to read as follows:

**§ 1.1461–1 Payment and returns of tax withheld.**

* * * * *

(c) * * *

(2) * * *

(iii) *Applicability date.* Paragraph (c)(2) of this section applies beginning January 19, 2017.

* * * * *

**Martin V. Franks,**

*Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedure and Administration).*

[FR Doc. 2017–22830 Filed 10–25–17; 8:45 am]

**BILLING CODE 4830–01–P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

### 33 CFR Part 117

**[Docket No. USCG–2017–0936]**

**RIN 1625–AA09**

## Drawbridge Operation Regulation; Snake Creek; Islamorada, FL

**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 Snake Creek Bridge across Snake Creek, at Islamorada, FL. The deviation is necessary to alleviate the increased traffic congestion on US 1 Highway resulting from relief efforts after the passing of Hurricane Irma. This deviation allows the bridge to open once every two hours verses the current operating regulation. Local officials are requesting this action to assist in reducing the long line of traffic backups caused by the bridge openings.

**DATES:** This deviation is effective without actual notice from October 26, 2017, through 7 a.m. on November 1, 2017. For the purposes of enforcement, actual notice will be used from 7 a.m. on September 29, 2017, until October 26, 2017.

**ADDRESSES:** The docket for this deviation, USCG–2017–0936 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 LT Scott Ledee, Chief Waterways Management Division, U.S. Coast Guard Sector Key West, Coast Guard; telephone (305) 292–8768, email; *Scott.G.Ledee@uscg.mil.*

**SUPPLEMENTARY INFORMATION:** The Village of Islamorada Florida with concurrence of Florida Department of Transportation, the bridge owner, has requested a temporary change in the operating regulation for the Snake Creek Bridge on US Highway 1 crossing Snake Creek in Islamorada, Florida. The bridge has a vertical clearance of 27 feet in the closed position. With the passing of Hurricane Irma, the lower Keys have been devastated. With this increased time between openings, this deviation will allow a more uninterrupted flow of vehicle traffic carrying restorative supplies into the lower Keys without severely hindering vessel traffic. The Snake Creek Drawbridge currently operates under 33 CFR 117.331.

The deviation period is from 7 a.m. on September 29, 2017 to 7 a.m. on November 1, 2017. During this period, the bridge will open on signal, except that from 7 a.m. to 7 p.m. the draw need only open every two hours, on the hour.

Vessels able to pass through the bridge in the closed position may do so at anytime. The bridge will be able to open for emergencies and there is no immediate alternate route for vessels to pass. The Coast Guard will also inform the users of the waterways through our Local and Broadcast Notices to Mariners of the change in operating schedule for the bridge so that vessel operators can arrange their transits to minimize any impact caused by the temporary deviation.

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.

Dated: October 2, 2017.

**Barry L. Dragon,**

*Director, Bridge Branch, Seventh Coast Guard District.*

[FR Doc. 2017–23320 Filed 10–25–17; 8:45 am]

**BILLING CODE 9110–04–P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

### 33 CFR Part 117

**[Docket No. USCG–2017–0778]**

## Drawbridge Operation Regulation; Atlantic Intracoastal Waterway, Indian River, Titusville, FL

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of deviation from drawbridge regulation; modification.

**SUMMARY:** The Coast Guard has modified a temporary deviation from the operating schedule that governs the NASA Railroad Bridge (Jay Jay Bridge) across the Atlantic Intracoastal Waterway (Indian River), mile 876.6, Titusville, Florida. This modified deviation is necessary to allow the bridge owner, National Aeronautics and Space Administration (NASA) to continue repairs to the bridge. Due to delays and damage caused by Hurricane Irma, additional repairs will be required causing the bridge to remain closed to navigation periodically throughout the day. This deviation is deemed necessary for the continued safe operation of the bridge.

**DATES:** This modified deviation is effective without actual notice from October 26, 2017 through 4 p.m. on October 31, 2017. For the purposes of enforcement, actual notice will be used from 8 a.m. on September 27, 2017 until October 26, 2017.

**ADDRESSES:** The docket for this deviation, USCG–2017–0778 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 modified temporary deviation, call or email LT Allan Storm, U.S. Coast Guard Sector Jacksonville, Waterways Management Division; telephone 904–714–7616, email *Allan.H.Storm@uscg.mil.*

**SUPPLEMENTARY INFORMATION:** On August 22, 2017, the Coast Guard published a temporary deviation entitled, ''Drawbridge Operation Regulation; Atlantic Intracoastal Waterway, Indian River, Titusville, FL'' in the **Federal Register** (82 FR 39665). Under that temporary deviation, from 8 a.m. on August 17, 2017 to 4 p.m. on September 26, 2017, the bridge would remain closed to navigation from 8 a.m. to noon and from 1 p.m. to 4 p.m., Monday through Friday. The bridge owner,

NASA, has requested an extension of time for the temporary deviation from the operating schedule that governs the NASA Railroad Bridge (Jay Jay Bridge) to complete bridge repairs, due to delays and storm damage related to Hurricane Irma. The bridge is a single leaf bascule railroad bridge with a seven foot vertical clearance in the closed position. The normal operating schedule for the bridge is found in 33 CFR 117.261(j).

The deviation period is from 8 a.m. on September 27, 2017 to 4 p.m. on October 31, 2017. During this period, the bridge is allowed to remain closed to navigation from 8 a.m. to noon and from 1 p.m. to 4 p.m., Monday through Friday.

Vessels able to pass through the bridge in the closed position may do so at anytime. The bridge will be able to open for emergencies and there is no immediate alternate route for vessels to pass. The Coast Guard will also inform the users of the waterways through our Local and Broadcast Notices to Mariners of the change in operating schedule for the bridge so that vessel operators can arrange their transits to minimize any impact caused by the temporary deviation.

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.

Dated: September 27, 2017.

**Barry L. Dragon,**

*Director, Bridge Branch, Seventh Coast Guard District.*

[FR Doc. 2017–23322 Filed 10–25–17; 8:45 am]

**BILLING CODE 9110–04–P**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 62

**[EPA–R03–OAR–2017–0509; FRL–9969–92–Region 3]**

## Approval and Promulgation of State Air Quality Plans for Designated Facilities and Pollutants; City of Philadelphia; Control of Emissions From Existing Sewage Sludge Incineration Units

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Direct final rule.

**SUMMARY:** The Environmental Protection Agency (EPA) is taking direct final action to notify the public that it has received a negative declaration for sewage sludge incineration (SSI) units within the City of Philadelphia. This negative declaration certifies that SSI units subject to the requirements of sections 111(d) and 129 of the Clean Air Act (CAA) do not exist within the jurisdictional boundaries of the Philadelphia Air Management Service (AMS). EPA is accepting the negative declaration in accordance with the requirements of the CAA.

**DATES:** This rule is effective on December 26, 2017 without further notice, unless EPA receives adverse written comment by November 27, 2017. If EPA receives such comments, it will publish a timely withdrawal of the direct final rule in the **Federal Register** and inform the public that the rule will not take effect.

**ADDRESSES:** Submit your comments, identified by Docket ID Number EPA–R03–OAR–2017–0509 at *http://www.regulations.gov,* or via email to *aquino.marcos@epa.gov.* For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. For either manner of submission, EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be confidential business information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the Web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

**FOR FURTHER INFORMATION CONTACT:** Mike Gordon, (215) 814–2039, or by email at *gordon.mike@epa.gov.*

**SUPPLEMENTARY INFORMATION:**

### I. Background

Sections 111(d) and 129 of the CAA require states to submit plans to control certain pollutants (designated pollutants) at existing solid waste combustor facilities (designated facilities) whenever standards of performance have been established under section 111(b) for new sources of the same type, and EPA has established emission guidelines (EG) for such existing sources. A designated pollutant is any pollutant for which no air quality criteria have been issued, and which is not included on a list published under section 108(a) or section 112(b)(1)(A) of the CAA, but emissions of which are subject to a standard of performance for new stationary sources. On March 21, 2011 (76 FR 15372), EPA promulgated SSI unit new source performance standards, 40 CFR part 60, subpart LLLL, and emission guidelines, subpart MMMM. The designated facilities to which the EG apply are existing SSI units that: (1) Commenced construction on or before October 14, 2010; (2) that meet the definition of a SSI unit as defined in § 60.5250; and (3) are not exempt under § 60.5065.

Subpart B of 40 CFR part 60 establishes procedures to be followed and requirements to be met in the development and submission of state plans for controlling designated pollutants. Also, 40 CFR part 62 provides the procedural framework for the submission of these plans. When designated facilities are located in a state, the state must then develop and submit a plan for the control of the designated pollutant. However, 40 CFR 60.23(b) and 62.06 provide that if there are no existing sources of the designated pollutant in the state, the state may submit a letter of certification to that effect (*i.e.,* negative declaration) in lieu of a plan. The negative declaration exempts the state from the requirements of subpart B that require the submittal of a 111(d)/129 plan.

### II. State Submittal and EPA Analysis

Philadelphia AMS has determined that there are no SSI units subject to the requirements of Sections CAA 111(d) and 129 of the CAA in their respective air pollution control jurisdiction. Accordingly, Philadelphia AMS submitted a negative declaration letter to EPA certifying this fact on March 28, 2012. The negative declaration letter and EPA's technical support document for this action are available in the docket for this the docket for this rulemaking and available online at *www.regulations.gov.*

### III. Final Action

In this direct final action, EPA is amending part 62 to reflect receipt of the negative declaration letter from Philadelphia AMS. EPA is publishing this rule without prior proposal because EPA views this as a noncontroversial amendment and anticipates no adverse

comment. However, in the ''Proposed Rules'' section of today's **Federal Register**, EPA is publishing a separate document that will serve as the proposal to approve the revision if adverse comments are filed. This rule will be effective on December 26, 2017 without further notice unless EPA receives adverse comment by November 27, 2017. If EPA receives adverse comment, EPA will publish a timely withdrawal in the **Federal Register** informing the public that the rule will not take effect. EPA will address all public comments in a subsequent final rule based on the proposed rule. EPA will not institute a second comment period on this action. Any parties interested in commenting must do so at this time.

## IV. Statutory and Executive Order Reviews

### *A. General Requirements*

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and therefore is not subject to review by the Office of Management and Budget. For this reason, this action is also not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001). This action merely notifies the public of EPA receipt of a negative declaration from an air pollution control agency without any existing SSI units in their jurisdiction. This action imposes no requirements. Accordingly, EPA certifies that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this action does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). This action also does not have tribal implications because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action also does not have Federalism implications because it does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely approves the negative declaration for existing SSI units from the Philadelphia AMS and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. This action also is not subject to Executive Order 13045 ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), because it is not economically significant.

With regard to negative declarations for designated facilities received by EPA from states, EPA's role is to notify the public of the receipt of such negative declarations and revise 40 CFR part 62 accordingly. In this context, in the absence of a prior existing requirement for the State to use voluntary consensus standards (VCS), EPA has no authority to approve or disapprove a CAA section 111(d)/129 plan negative declaration submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a CAA section 111(d)/129 negative declaration, to use VCS in place of a section 111(d)/129 negative declaration that otherwise satisfies the provisions of the Clean Air Act. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. This action does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

### *B. Submission to Congress and the Comptroller General*

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

### *C. Petitions for Judicial Review*

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by December 26, 2017. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. Parties with objections to this direct final rule are encouraged to file a comment in response to the parallel notice of proposed rulemaking for this action published in the proposed rules section of today's **Federal Register**, rather than file an immediate petition for judicial review of this direct final rule, so that EPA can withdraw this direct final rule and address the comment in the proposed rulemaking.

This action approving a negative declaration submitted by Philadelphia AMS for SSI units may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

### List of Subjects in 40 CFR Part 62

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Reporting and recordkeeping requirements, Waste treatment and disposal.

Dated: October 11, 2017.

**Cecil Rodrigues,**

*Acting Regional Administrator, Region III.*

40 CFR part 62 is amended as follows:

## PART 62—APPROVAL AND PROMULGATION OF STATE PLANS FOR DESIGNATED FACILITIES AND POLLUTANTS

■ 1. The authority citation for part 62 continues to read as follows:

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

## Subpart NN—Pennsylvania

■ 2. Add an undesignated heading and § 62.9665 to subpart NN to read as follows:

### Emissions From Existing Sewage Sludge Incineration Units

#### § 62.9665 Identification of plan—negative declaration.

Letter from the City of Philadelphia, Department of Public Health, submitted March 28, 2012, certifying that there are no existing sewage sludge incineration units within the City of Philadelphia, Pennsylvania that are subject to 40 CFR part 60, subpart Ce.

[FR Doc. 2017–23229 Filed 10–25–17; 8:45 am]

BILLING CODE 6560–50–P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 63

**[EPA–HQ–OAR–2016–0490; FRL–9969–95–OAR]**

**RIN 2060–AS85**

## National Emission Standards for Hazardous Air Pollutants: Publicly Owned Treatment Works Residual Risk and Technology Review

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This action finalizes the residual risk and technology review (RTR) conducted for the Publicly Owned Treatment Works (POTW) source category regulated under national emission standards for hazardous air pollutants (NESHAP). In addition, we are taking final action addressing revised names and definitions of the subcategories, revisions to the applicability criteria, revised regulatory provisions pertaining to emissions during periods of startup, shutdown, and malfunction (SSM), initial notification requirements for existing Group 1 and Group 2 POTW, revisions to the requirements for new Group 1 POTW, requirements for electronic reporting, and other miscellaneous edits and technical corrections. While we do not anticipate any emission reductions as a result of these revisions, the changes should provide clarity for sources determining applicability and ensuring compliance.

**DATES:** This final rule is effective on October 26, 2017.

**ADDRESSES:** The Environmental Protection Agency (EPA) has established a docket for this action under Docket ID No. EPA–HQ–OAR–2016–0490. All documents in the docket are listed on the *http://www.regulations.gov* Web site. Although listed in the index, some information is not publicly available, *e.g.,* confidential business information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *http://www.regulations.gov,* or in hard copy at the EPA Docket Center, EPA WJC West Building, Room Number 3334, 1301 Constitution Ave. NW., Washington, DC. The Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m. Eastern Standard Time (EST), Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the EPA Docket Center is (202) 566–1742.

**FOR FURTHER INFORMATION CONTACT:** For questions about this final action, contact Katie Hanks, Sector Policies and Programs Division (E143–03), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina, 27711; telephone number: (919) 541–2159; fax number: (919) 541–0516; and email address: *hanks.katie@epa.gov.* For specific information regarding the risk modeling methodology, contact Terri Hollingsworth, Health and Environmental Impacts Division (C539–02), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–5623; fax number: (919) 541–0840; and email address: *hollingsworth.terri@epa.gov.* For information about the applicability of the NESHAP to a particular entity, contact Sara Ayres, Office of Enforcement and Compliance Assurance, U.S. Environmental Protection Agency, 77 West Jackson Boulevard (E–19J), Chicago, Illinois 60604; telephone number: (312) 353–6266; and email address: *ayres.sara@epa.gov.*

**SUPPLEMENTARY INFORMATION:**

Preamble acronyms and abbreviations. We use multiple acronyms and terms in this preamble. While this list may not be exhaustive, to ease the reading of this preamble and for reference purposes, the EPA defines the following terms and acronyms here:

CAA Clean Air Act
CBI confidential business information
CDX Central Data Exchange
CEDRI Compliance and Emissions Data Reporting Interface
ERT Electronic Reporting Tool
HAP hazardous air pollutants(s)
HQ hazard quotient
$H_2S$ hydrogen sulfide
ICR Information Collection Request
MACT maximum achievable control technology
MGD million gallons per day
MIR maximum individual risk
NESHAP national emission standards for hazardous air pollutants
NPDES National Pollutant Discharge Elimination System
NTTAA National Technology Transfer and Advancement Act
PB–HAP Hazardous air pollutants known to be persistent and bio-accumulative in the environment
POTW Publicly Owned Treatment Works
RFA Regulatory Flexibility Act
RIN Regulatory Information Number
RTR Risk and Technology Review
SSM startup, shutdown and malfunction
TOSHI Target Organ Specific Hazard Index
UMRA Unfunded Mandates Reform Act

*Background information.* On December 27, 2016, the EPA proposed revisions to the POTW NESHAP based on our RTR. In this action, we are finalizing decisions and revisions for the rule. We summarize some of the more significant comments we timely received regarding the proposed rule and provide our responses in this preamble. A summary of all other public comments on the proposal and the EPA's responses to those comments is available in *Response to Public Comments on the EPA's Residual Risk and Technology Review for the Publicly Owned Treatment Works Source Category* in Docket ID No. EPA–HQ–OAR–2016–0490. A ''track changes'' version of the regulatory language that incorporates the changes in this action is available in the docket.

*Organization of this document.* The information in this preamble is organized as follows:

## I. General Information

### *A. Does this action apply to me?*

*Regulated entities.* Categories and entities potentially regulated by this action are shown in Table 1 of this preamble.

TABLE 1—NESHAP AND INDUSTRIAL SOURCE CATEGORIES AFFECTED BY THIS FINAL ACTION

| NESHAP and source category | NESHAP | NAICS [1] code |
|---|---|---|
| Sewage Treatment Facilities. | Subpart VVV ..... | 221320 |

[1] North American Industry Classification System.

Table 1 of this preamble is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by the final action for the source category listed. The standards are directly applicable to the affected sources. Federal, state, local, and tribal governments are affected as discussed below. By definition, a POTW is owned by a municipality, state, intermunicipal or interstate agency, or any department, agency, or instrumentality of the federal government (see 40 CFR 63.1595 of subpart VVV). To determine whether your facility is affected, you should examine the applicability criteria in the POTW NESHAP. Specifically, if a POTW is a Group 2 POTW [1] that is a major source of hazardous air pollutant (HAP) emissions or a Group 1 POTW regardless of the HAP emissions, and the POTW meets the criteria for development and implementation of a pretreatment program according to 40 CFR 403.8, then the POTW is affected by these standards. If you have any questions regarding the applicability of any aspect of this NESHAP, please contact the appropriate person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section of this preamble.

### *B. Where can I get a copy of this document and other related information?*

In addition to being available in the docket, an electronic copy of this final action will also be available on the Internet. Following signature by the EPA Administrator, the EPA will post a copy of this final action at *http://www.epa.gov/stationary-sources-air-pollution/publicly-owned-treatment-works-potw-national-emission-standards.* Following publication in the **Federal Register**, the EPA will post the **Federal Register** version and key technical documents at this same Web site.

Additional information is available on the RTR Web site at *http://www.epa.gov/ttn/atw/rrisk/rtrpg.html.* This information includes an overview of the RTR program, links to project Web sites for the RTR source categories, and detailed emissions and other data we used as inputs to the risk assessments.

### *C. Judicial Review and Administrative Reconsideration*

Under Clean Air Act (CAA) section 307(b)(1), judicial review of this final action is available only by filing a petition for review in the United States Court of Appeals for the District of Columbia Circuit by December 26, 2017. Under CAA section 307(b)(2), the requirements established by this final rule may not be challenged separately in any civil or criminal proceedings brought by the EPA to enforce the requirements.

Section 307(d)(7)(B) of the CAA further provides that only an objection to a rule or procedure which was raised with reasonable specificity during the period for public comment (including any public hearing) may be raised during judicial review. This section also provides a mechanism for the EPA to reconsider the rule if the person raising an objection can demonstrate to the Administrator that it was impracticable to raise such objection within the period for public comment or if the grounds for such objection arose after the period for public comment (but within the time specified for judicial review) and if such objection is of central relevance to the outcome of the rule. Any person seeking to make such a demonstration should submit a Petition for Reconsideration to the Office of the Administrator, U.S. EPA, Room 3000, EPA WJC South Building, 1200 Pennsylvania Ave. NW., Washington, DC 20460, with a copy to both the person(s) listed in the preceding **FOR FURTHER INFORMATION CONTACT** section, and the Associate General Counsel for the Air and Radiation Law Office, Office of General Counsel (Mail Code 2344A), U.S. EPA, 1200 Pennsylvania Ave. NW., Washington, DC 20460.

## II. Background

### *A. What is the statutory authority for this action?*

Section 112 of the CAA establishes a two-stage regulatory process to address emissions of HAP from stationary sources. In the first stage, we must identify categories of sources emitting one or more of the HAP listed in CAA section 112(b) and then promulgate technology-based NESHAP for those sources. ''Major sources'' are those that emit, or have the potential to emit, any single HAP at a rate of 10 tons per year (tpy) or more, or 25 tpy or more of any combination of HAP. For major sources, these standards are commonly referred to as maximum achievable control technology (MACT) standards and must reflect the maximum degree of emission reductions of HAP achievable (after considering cost, energy requirements, and non-air quality health and environmental impacts). In developing MACT standards, CAA section 112(d)(2) directs the EPA to consider the application of measures, processes, methods, systems, or techniques, including but not limited to those that reduce the volume of or eliminate HAP emissions through process changes, substitution of materials, or other modifications; enclose systems or

[1] As discussed below in section III.D of this preamble, the terms ''Group 1 POTW'' and ''Group 2 POTW'' are replacing the previous terms ''industrial POTW'' and ''nonindustrial POTW. The ''Group 1'' and ''Group 2'' subcategories are described in the regulatory text at 40 CFR 63.1581.

processes to eliminate emissions; collect, capture, or treat HAP when released from a process, stack, storage, or fugitive emissions point; are design, equipment, work practice, or operational standards; or any combination of the above.

For these MACT standards, the statute specifies certain minimum stringency requirements, which are referred to as MACT floor requirements, and which may not be based on cost considerations. *See* CAA section 112(d)(3). For new sources, the MACT floor cannot be less stringent than the emission control achieved in practice by the best-controlled similar source. The MACT standards for existing sources can be less stringent than floors for new sources, but they cannot be less stringent than the average emission limitation achieved by the best-performing 12 percent of existing sources in the category or subcategory (or the best-performing five sources for categories or subcategories with fewer than 30 sources). In developing MACT standards, we must also consider control options that are more stringent than the floor under CAA section 112(d)(2). We may establish standards more stringent than the floor, based on the consideration of the cost of achieving the emissions reductions, any non-air quality health and environmental impacts, and energy requirements.

In the second stage of the regulatory process, the CAA requires the EPA to undertake two different analyses, which we refer to as the technology review and the residual risk review. Under the technology review, we must review the technology-based standards and revise them ''as necessary (taking into account developments in practices, processes, and control technologies)'' no less frequently than every 8 years, pursuant to CAA section 112(d)(6). Under the residual risk review, we must evaluate the risk to public health remaining after application of the technology-based standards and revise the standards, if necessary, to provide an ample margin of safety to protect public health or to prevent, taking into consideration costs, energy, safety, and other relevant factors, an adverse environmental effect. The residual risk review is required within 8 years after promulgation of the technology-based standards, pursuant to CAA section 112(f). In conducting the residual risk review, if the EPA determines that the current standards provide an ample margin of safety to protect public health, it is not necessary to revise the MACT standards pursuant to CAA section 112(f).[2] For more information on the statutory authority for this rule, see the proposed rule published on December 27, 2016 (81 FR 95352).

*B. What is the POTW source category and how does the NESHAP regulate HAP emissions from the source category?*

1. Definition of the POTW Source Category and the Affected Source

The EPA promulgated the NESHAP for the POTW source category (henceforth referred to as the ''POTW NESHAP'') on October 26, 1999 (64 FR 57572). The standards are codified at 40 CFR part 63, subpart VVV. The POTW NESHAP was amended on October 21, 2002 (67 FR 64742). As amended in 2002, the POTW source category consists of new and existing POTW treatment plants that are located at a POTW that is a major source of HAP emissions and that meets the criteria for development and implementation of a pretreatment program as defined by 40 CFR 403.8 under the Clean Water Act (CWA). Additional information about the National Pretreatment Program can be found in the December 27, 2016, RTR proposal (81 FR 95374). The source category covered by this MACT standard currently includes thirteen facilities.

As used in this regulation, the term POTW refers to both any POTW that is owned by a state, municipality, or intermunicipal or interstate agency and, therefore, eligible to receive grant assistance under the Subchapter II of the CWA, and any federally owned treatment works as that term is described in section 3023 of the Solid Waste Disposal Act. For more information see the December 27, 2016, RTR proposal (81 FR 95352). The source category includes any intercepting sewers, outfall sewers, sewage collection systems, pumping, power, and other equipment. The wastewater treated by these facilities is generated by industrial, commercial, and domestic sources.

2. Applicability of the 2002 POTW NESHAP

The 2002 POTW NESHAP is subcategorized based on whether the POTW is providing treatment for wastewaters received from an industrial user as the means by which that industrial user complies with another NESHAP. The 2002 POTW NESHAP defined an ''industrial POTW'' as ''a POTW that accepts a waste stream regulated by another NESHAP and provides treatment and controls as an agent for the industrial discharger. The industrial discharger complies with its NESHAP by using the treatment and controls located at the POTW. For example, an industry discharges its benzene-containing waste stream to the POTW for treatment to comply with 40 CFR part 61, subpart FF—National Emission Standards for Benzene Waste Operations. This definition does not include POTW treating waste streams not specifically regulated under another NESHAP.'' An ''industrial POTW'' is subject to the 2002 POTW NESHAP regardless of the HAP emissions (*i.e.,* the POTW does not have to be a major source). In contrast, a ''non-industrial POTW'' was defined in the 2002 POTW NESHAP as ''a POTW that does not meet the definition of an industrial POTW as defined above.'' A ''non-industrial POTW'' must be a major source to be subject to the 2002 POTW NESHAP. For more information, see the December 27, 2016, RTR proposal (81 FR 95357).

3. HAP Emitted and HAP Emission Points

The amount and type of HAP emitted from a POTW is dependent on the composition of the wastewater streams discharged to a POTW by industrial users. The primary HAP emitted from the POTW that were identified as subject to the POTW NESHAP include acetaldehyde, acetonitrile, chloroform, ethylene glycol, formaldehyde, methanol, methylene chloride, tetratchloroethylene, toluene, and xylenes. The HAP present in the wastewater entering a POTW can biodegrade, adhere to sewage sludge, volatilize to the air, or pass through (remain in the wastewater discharge) to receiving waters. Emissions can occur at any point at the POTW, including collection systems and wastewater treatment units located at the POTW treatment plant.

4. Regulation of HAP Emissions in the 2002 POTW NESHAP

The POTW NESHAP specifies requirements for the industial and non-industrial POTW subcategories. Under the 2002 POTW NESHAP, an existing ''industrial POTW'' must meet the requirements of the industrial user's NESHAP. A new or reconstructed ''industrial POTW'' must meet the requirements of the industrial user's

[2] The U.S. Court of Appeals for the District of Columbia Circuit has affirmed this approach of implementing CAA section 112(f)(2)(A): *NRDC* v. *EPA,* 529 F.3d 1077, 1083 (D.C. Cir. 2008) (''If EPA determines that the existing technology-based standards provide an 'ample margin of safety,' then the Agency is free to readopt those standards during the residual risk rulemaking.'').

NESHAP or the requirements for new or reconstructed non-industrial POTW, whichever is more stringent.

There are no control requirements in the 2002 POTW NESHAP for existing ''non-industrial POTW.'' However, new or reconstructed ''non-industrial POTW'' must equip each treatment unit up to, but not including, the secondary influent pumping station, with a cover. In addition, all covered units, except the primary clarifier, must route the air in the headspace above the surface of the wastewater to a control device that meets the requirements for closed-vent systems and control devices found in the NESHAP from Off-Site Waste and Recovery Operations (40 CFR part 63, subpart DD). As an alternative, a new or reconstructed ''non-industrial POTW'' can demonstrate that all units up to, but not including, the secondary influent pumping station emit a HAP fraction of 0.014 or less. The HAP fraction emitted is the fraction of HAP in the wastewater entering the POTW that is emitted to the atmosphere. For additional information, see the December 27, 2016, RTR proposal (81 FR 95357).

*C. What changes did we propose for the POTW source category in our December 27, 2016, RTR proposal?*

On December 27, 2016, the EPA published a proposed rule in the **Federal Register** for the POTW NESHAP, 40 CFR part 63, subpart VVV, that took into consideration the RTR analyses. In the proposed rule, we proposed that the risks are acceptable and the current standards provide an ample margin of safety to protect public health. Additionally, we did not identify any developments in practices, processes, and control technologies for the POTW source category as part of the technology review. During this rulemaking, we evaluated other revisions to the 2002 POTW NESHAP outside of the RTR. We proposed to revise the names and definitions of the industrial and non-industrial subcategories to be called Group 1 and Group 2 POTW. We also proposed to include requirements to limit emissions from collection systems and the POTW treatment plant; requirements for existing, new, or reconstructed Group 1 POTW to comply with both the requirements in the POTW NESHAP and those in the applicable NESHAP for which the POTW acts as a control agent; and HAP emission limits for existing Group 2 POTW. In addition, we proposed to clarify the applicability criteria; require initial notification for existing Group 1 and Group 2 POTW; revise regulatory provisions pertaining to emissions during periods of SSM; add requirements for electronic reporting; and make other miscellaneous edits and technical corrections.

**III. What is included in this final rule?**

This action finalizes the EPA's determinations pursuant to the RTR provisions of CAA section 112 for the POTW source category. This action also finalizes other changes to the NESHAP, including revised names and definitions of the subcategories, clarified applicability criteria, revised regulatory provisions pertaining to emissions during periods or SSM, initial notification requirements for existing Group 1 and Group 2 POTW, requirements for new or reconstructed Group 1 POTW to comply with both the requirements in the POTW NESHAP and those in the applicable NESHAP for which the POTW acts as a control agent, requirements for electronic reporting, and other miscellaneous edits and technical corrections. As explained in section IV of this preamble, we are not taking final action at this time on several provisions that were proposed, including standards for pretreatment, the inclusion of collection systems in the major source determination, and the HAP fraction emission limit for existing Group 1 and Group 2 POTW.

*A. What are the final rule amendments based on the risk review for the POTW source category?*

We determined that risks resulting from emissions from the POTW source category are acceptable. Specifically, the maximum individual cancer risk (MIR) is 2-in-1 million based on allowable emissions and 1-in-1 million based on actual emissions, well below the presumptive limit of acceptability (100-in-1 million), and other health information indicates there is no appreciable risk of adverse chronic or acute non-cancer health effects due to HAP emissions from the source category. Additionally, emissions of 2-methylnaphthalene, the only HAP emitted from the POTW source category that is known to be persistent and bio-accumulative in the environment (PB–HAP), did not exceed the worst-case Tier I screening emission rate or any ecological benchmarks. Therefore, revisions to the standards are not necessary to reduce risk to an acceptable level or to prevent an adverse environmental effect. Further, considering risk and non-risk factors, we determined that the 2002 POTW NESHAP requirements provide an ample margin of safety to protect public health. Therefore, we are not finalizing revisions to the standards under CAA section 112(f)(2).

*B. What are the final rule amendments based on the technology review for the POTW source category?*

We determined that there are no developments in practices, processes, and control technologies that warrant revisions to the MACT standards for this source category. Therefore, we are not finalizing revisions to the MACT standards under CAA section 112(d)(6).

*C. What are the final rule amendments addressing emissions during periods of startup, shutdown, and malfunction?*

Consistent with *Sierra Club* v. *EPA,* 552 F.3d 1019 (D.C. Cir. 2008), the EPA has established standards in this rule that apply at all times. We have revised Table 1 to Subpart VVV of Part 63 (the General Provisions applicability table) in several respects to eliminate the incorporation of those General Provisions that stated or were tied to the SSM exemption. These revisions to Table 1 are explained in detail in the proposed rule preamble at 81 FR 95780–95782. Further, in conjunction with the elimination of the incorporation of these General Provisions requirements, we have (1) added a general duty to minimize emissions in 40 CFR 63.1582(e) and 63.1586(e), see 81 FR at 95380 (col. 2–3); (2) incorporated performance testing requirements for control devices in 40 CFR 63.694, see 81 FR at 95781 (col. 1); (3) added language to Table 1 related to monitoring that is identical to 40 CFR 63.8(d)(3) (which is no longer incorporated) but with certain revisions to reflect the ending of the SSM plan requirement, see 81 FR at 95381 (col. 2); (4) made the recordkeeping requirements in 40 CFR 63.696(h) and 63.1589(d) applicable to periods that were previously covered by SSM-related provisions, see 81 FR 95381 (col. 2–3); and (5) amended the reporting requirements in 40 CFR 63.1590 which, in conjunction with the existing reporting requirements in 40 CFR 63.693 and 63.1590(a), will adequately provide for reporting that was previously governed by SSM-related provisions, see 81 FR at 95382.

*D. What other changes have been made to the NESHAP?*

1. Applicability Criteria

The EPA is not revising the applicability of 40 CFR part 63, subpart VVV as proposed on December 27, 2016. Instead, the EPA is finalizing minor clarifying changes to the applicability criteria that are in the 2002 POTW NESHAP. The renaming of the subcategories (from ''industrial'' to ''Group 1'' and from ''non-industrial'' to ''Group 2) and the definitions of Group

1 and Group 2 POTW are being finalized as proposed, and as discussed below. However, for clarification, the EPA has removed the statements regarding ownership and operation of POTW in regards to which POTW are required to develop and implement a pretreatment program as defined by 40 CFR 403.8. This change clarifies that any Group 1 POTW (regardless of HAP emissions) or Group 2 POTW that is a major source of HAP is subject to the POTW NESHAP if the POTW also meets the criteria for development and implementation of a pretreatment program, regardless of whether the POTW, state, or other entity implements the pretreatment program.

2. Names and Definitions of the Subcategories

As proposed, the EPA is revising the names and definitions for the subcategories identified in the POTW NESHAP. The EPA is renaming an ''industrial POTW treatment plant'' as a ''Group 1'' POTW treatment plant and a ''non-industrial POTW treatment plant'' as a ''Group 2'' POTW treatment plant. The EPA expects that this clarification will address any confusion that could have been caused by the previous subcategory names ''industrial POTW treatment plant'' and ''non-industrial treatment plant'' because POTW in both subcategories treat wastewater from industrial users. The key difference between Group 1 and Group 2 is that a Group 1 POTW acts as an agent for an industrial user by accepting and controling the industrial user's waste stream regulated under another NESHAP. By contrast, a Group 2 POTW may treat the waste stream from an industrial user, but does not act as the industrial user's agent to comply with another NESHAP.

3. Initial Notification Requirements for Existing Group 1 and Group 2 POTW

In the final rule (40 CFR 63.1586(a)), existing Group 1 and Group 2 POTW treatment plants must comply with the initial notification requirements in 40 CFR 63.1591(a) of subpart VVV. This notification requirement was not required for these existing sources in the 2002 POTW NESHAP, but was proposed in the December 27, 2016, proposal, and is consistent with notification requirements that were applicable to new or reconstructed Group 2 sources under the 2002 POTW NESHAP.

4. Requirements for New Group 1 POTW

The EPA is finalizing, as proposed, the requirement that new Group 1 POTW comply with both the requirements of the other NESHAP for which they act as an agent of control for an industrial user and the requirements for new Group 2 POTW in this final rule. The requirements for new Group 2 POTW are unchanged from the 2002 POTW NESHAP and provide the option of complying with either (a) cover all primary treatment units and route emissions through a closed vent system to a control device or (b) meet a HAP fraction emission limit of 0.014 for emissions from all primary treatment units.

5. Requirements for Electronic Reporting

The EPA is finalizing electronic reporting requirements for new POTW consistent with the proposed rule. Specifically, new POTW must electroncally submit all annual reports and certain performance test reports. The EPA believes that the electronic submittal of these reports will increase the usefulness of data contained in those reports, is in keeping with current trends in data availability, will further assist in the protection of public health and the environment, and will ultimately result in less burden on the regulated community.

6. Other Miscellaneous Edits and Technical Corrections

The EPA is finalizing the following technical corrections as proposed:

- Revising all references to ''new or reconstructed POTW'' to refer to ''new POTW'' because the definition of ''new'' includes reconstructed POTW.
- Combining text from 40 CFR 63.1581 and 63.1582 because the language was redundant and confusing. This includes revising 40 CFR 63.1581 to include all combined text and revising 40 CFR 63.1583(c) to include the text from the current 40 CR 63.1582(c).
- Revising 40 CFR 63.1586(b)(1) to require covers ''designed and operated to prevent exposure of the wastewater to the atmosphere'' instead of ''designed and operated to minimize exposure of the wastewater to the atmosphere.'' This clarification has also been made to the definition of ''cover'' in 40 CFR 63.1595.
- Revising 40 CFR 63.1587 to include compliance requirements that are currently found in 40 CFR 64.1584 and 63.1587, and deleting 40 CFR 63.1584.
- Clarifying the method for calculating the HAP fraction emitted and moving the detailed instructions for calculating the HAP fraction emitted from 40 CFR 63.1588(c)(4) to 40 CFR 63.1588(c)(3). The requirements remaining in 40 CFR 63.1588(c)(4) address monitoring for continuous compliance.
- Revising 40 CFR 63.1588(a)(3) to clarify that a cover defect must be repaired within 45 ''calendar'' days; currently the paragraph says ''45 days.''
- Adding definitions of existing source/POTW and new source/POTW to 40 CFR 63.1595 to clarify the date that determines whether a POTW is existing or new.
- Renaming the title of 40 CFR 63.1588 to ''How do Group 1 and Group 2 POTW treatment plants demonstrate compliance?'' from ''What inspections must I conduct?'' The new title better reflects the contents of this section.
- Removing the details on how to calculate the HAP fraction emitted from the definition of HAP fraction emitted. The procedure for how to calculate the HAP fraction emitted is provided within the text of the rule. Having a summarized version of this procedure in the definition could cause confusion.
- Revising two references to dates to insert the actual dates. The phrase ''six months after October 26, 1999'' was replaced with ''April 26, 2000''; and the phrase ''60 days after October 26, 1999'' was replaced with ''December 27, 1999.'' These changes do not result in a change in the date, but only clarify the specific dates being referenced.
- Clarifying that the reports required in 40 CFR 63.1589(b)(1) include the records associated with the HAP loading and not just the records associated with the HAP emissions determination.
- Removing the definition of ''Reconstruction'' in 40 CFR 63.1595 as ''Reconstruction'' is already defined in the General Provisions of 40 CFR 63.2.

*E. What are the effective and compliance dates of the standards?*

The revisions to the MACT standards being promulgated in this action are effective on October 26, 2017.

The compliance date for existing Group 1 POTW is found in the applicable NESHAP for which the industrial user is subject to wastewater requirements. The compliance date for existing Group 2 POTW constructed or reconstructed on or before December 1, 1998, remains April 26, 2000. While we do not expect any additional existing Group 1 or Group 2 POTW beyond the 13 identified, we have chosen to include an additional compliance date of October 26, 2018 for existing Group 1 and Group 2 sources to submit their initial notification. We understand from public comments that POTW are evaluating their potential emissions and additional POTW may find they are subject to the rule. These POTW are only required to submit a notification that they are subject to the rule, and the additional time given for compliance of

this notification submittal will provide time for completion of the necessary emission calculations. The 13 existing sources that are subject to the rule and were previously identified have already met this notification requirement and do not need to resubmit a notification. New sources constructed or reconstructed after December 27, 2016, must comply with all of the standards immediately upon the effective date of the standard, October 26, 2017, or upon startup, whichever is later. While we did not identify any new sources that are subject to the rule since the original rule was published in 1999, we are including a transition period until October 26, 2020 for any new sources constructed or reconstructed between December 1, 1998, and December 27, 2016, to comply with the revisions in this rule.

*F. What are the requirements for submission of annual reports and performance test data to the EPA?*

As we proposed, the EPA is finalizing the requirement for owners and operators of POTW to submit electronic copies of certain required performance test reports and annual reports through the EPA's Central Data Exchange (CDX) using the Compliance and Emissions Data Reporting Interface (CEDRI). The electronic submittal of the reports addressed in this rulemaking will increase the usefulness of the data contained in those reports, is in keeping with current trends in data availability and transparency, will further assist in the protection of public health and the environment, will improve compliance by facilitating the ability of regulated facilities to demonstrate compliance with requirements and by facilitating the ability of delegated state, local, tribal, and territorial air agencies and the EPA to assess and determine compliance, and will ultimately reduce burden on regulated facilities, delegated air agencies, and the EPA. Electronic reporting also eliminates paper-based, manual processes, thereby saving time and resources, simplifying data entry, eliminating redundancies, minimizing data reporting errors, and providing data quickly and accurately to the affected facilities, air agencies, the EPA, and the public.

The EPA Web site that stores the submitted electronic data, WebFIRE, is easily accessible and provides a user-friendly interface. By making records, data, and reports addressed in this rulemaking readily available, the EPA, the regulated community, and the public will benefit when the EPA conducts its CAA-required technology reviews. As a result of having reports readily accessible, our ability to carry out comprehensive reviews will increase and be achieved within a shorter period of time.

We anticipate fewer or less substantial Information Collection Requests (ICRs) in conjunction with prospective CAA-required technology reviews may be needed, which results in a decrease in time spent by industry to respond to data collection requests. We also expect the ICRs to contain less extensive stack testing provisions, as we will already have stack test data electronically. Reduced testing requirements would be a cost savings to industry. The EPA should also be able to conduct these required reviews more quickly. While the regulated community may benefit from a reduced burden of ICRs, the general public benefits from the agency's ability to provide these required reviews more quickly, resulting in increased public health and environmental protection.

Air agencies, as well as the EPA, can benefit from more streamlined and automated review of the electronically submitted data. Standardizing report formats allows air agencies to review reports and data more quickly. Having reports and associated data in electronic format facilitates review through the use of software ''search'' options, as well as the downloading and analyzing of data in spreadsheet format. Additionally, air agencies and the EPA can access reports wherever and whenever they want or need, as long as they have access to the Internet. The ability to access and review reports electronically assists air agencies in determining compliance with applicable regulations more quickly and accurately, potentially allowing a faster response to violations, which could minimize harmful air emissions. This benefits both air agencies and the general public.

For a more thorough discussion of electronic reporting required by this rule, see the discussion in the preamble of the proposal. In summary, in addition to supporting regulation development, control strategy development, and other air pollution control activities, having an electronic database populated with performance test data will save industry, air agencies, and the EPA significant time, money, and effort while improving the quality of emission inventories and air quality regulations and enhancing the public's access to this important information.

## IV. What is the rationale for our final decisions and amendments for the POTW source category?

For each decision or amendment, this section provides a description of what we proposed and what we are finalizing, the EPA's rationale for the final decisions and amendments, and a summary of key comments and responses. Comments not discussed in this preamble, comment summaries, and the EPA's responses can be found in the comment summary and response document available in the docket (Docket ID No. EPA–HQ–OAR–2016–0490).

*A. Residual Risk Review for the POTW Source Category*

Pursuant to CAA section 112(f), we conducted a residual risk review and presented the results of the review, along with our proposed decisions regarding risk acceptability and ample margin of safety, in the December 27, 2016, RTR proposal (81 FR 95372). The residual risk review for the POTW source category included assessment of cancer risk, chronic non-cancer risk, and acute non-cancer risk due to inhalation exposure, as well as multipathway exposure risk and environmental risk. The results of the risk assessment are presented briefly in this preamble and in more detail in the residual risk document, *Residual Risk Assessment for Publicly Owned Treatment Works Source Category in Support of the October 2017 Risk and Technology Review Final Rule,*[3] which is available in the docket for this rulemaking.

The results indicated that maximum inhalation cancer risk to the individual most exposed is 2-in-1 million based on allowable emissions and 1-in-1 million based on actual emissions, which is well below the presumptive limit of acceptability (*i.e.,* 100-in-1 million). In addition, the maximum chronic noncancer target organ specific hazard index (TOSHI) due to inhalation exposures is less than 1. The evaluation of acute noncancer risk, which was conservative, showed a hazard quotient at or below 1 for all but one POTW. Based on the results of the screening analyses for human multipathway exposure to, and environmental impacts from, PB–HAP, we also concluded that the cancer risk to the individual most exposed through ingestion is below the level of concern and no ecological benchmarks are exceeded. The facility-wide cancer and noncancer risks were estimated based on the actual emissions from all sources at the identified POTW (both MACT and non-MACT sources). The results indicated the cancer risk to

[3] This report is an update to the residual risk report provided at proposal, *Residual Risk Assessment for Publicly Owned Treatment Works Source Category in Support of the December 2016 Risk and Technology Review Proposed Rule,* available in the docket.

the individual most exposed is no greater than 10-in-1 million and the noncancer TOSHI is less than 1. Considering the above information, as well as other relevant non-health factors under the Benzene NESHAP analysis codified in CAA 112(f)(2)(B), we proposed that the risk is acceptable and the requirements in the 2002 POTW NESHAP provide an ample margin of safety to protect public health and prevent an adverse environmental effect.

The risk assessment conducted for the POTW proposal estimated cancer, chronic noncancer, and acute noncancer risk for six of the 13 facilities in the source category and is summarized and referenced above. We confirmed the existence of seven additional POTW subject to the rule that were identified through public comments. For these seven POTW, we conducted a facility-wide risk assessment of potential cancer and chronic noncancer health effects. The results of this assessment indicate that all seven POTW have a facility-wide noncancer TOSHI less than 1, four of the POTW have a facility-wide cancer risk estimated less than 1-in-1 million, and three of the POTW have a facility-wide cancer risk estimated at or above 10-in-1 million. The highest facility-wide MIR was 60-in-1 million driven by formaldehyde from internal combustion engines which are covered under the NESHAP for the Stationary Reciprocating Internal Combustion Engines source category. For this POTW with the highest facility-wide MIR, the facility-wide emissions of formaldehyde are 22 tpy while the source category emissions of formaldehyde are 0.0026 tpy, which indicates that almost 100 percent of the estimated cancer risk is from emissions sources that are not part of the POTW source category. This ratio of source category emissions relative to facility-wide emissions of formaldehyde is the same for the other two POTW with facility-wide cancer risk estimated at or above 10-in-1 million. Therefore, it is reasonable to conclude that all 13 POTW have estimated cancer risk close to or below 1-in-1 million from source category emissions and we retain our proposed determination that risk is acceptable. Further, as discussed in the December 27, 2016, RTR proposal (81 FR 95373), we retain our determination that, considering the costs, economic impacts and technological feasibility of additional standards to reduce risk further, the 2002 POTW NESHAP provides an ample margin of safety to protect public health and prevents an adverse environmental effect. Details of this risk assessment are described in the *Residual Risk Assessment for the Publicly Owned Treatment Works Source Category in Support of the October 2017 Risk and Technology Review Final Rule* found in the docket for this rulemaking.

Most of the commenters on the proposed risk review supported our risk acceptability and ample margin of safety determinations for the POTW NESHAP. Some commenters requested that we make changes to our residual risk review approach. However, we evaluated the comments and determined that no changes to our risk assessment methods or conclusions are warranted. A summary of these comments and responses are in the comment summary and response document, available in the docket for this action (Docket ID No. EPA–HQ–OAR–2016–0490).

Since proposal, our risk assessment has been broadened to include additional POTW; however, the conclusions of our risk assessment and our determinations regarding risk acceptability, ample margin of safety, and adverse environmental effects have not changed. For the reasons explained in the proposed rule and discussed above, we determined that the risks from the POTW source category are acceptable, and that the current standards provide an ample margin of safety to protect public health and prevent an adverse environmental effect.

*B. Technology Review for the POTW Source Category*

As described in the December 27, 2016, RTR proposal (81 FR 95373), and as provided by CAA section 112(d)(6), our technology review focused on identifying developments in the practices, processes, and control technologies for the POTW source category. We concluded that there are two different control options that may be used at a POTW to reduce HAP emissions: pretreatment programs and add-on controls (*i.e.,* covers or covers vented to a control device). While we proposed specific revisions to the standards, none of those revisions were the result of any identified developments in practices, processes, or control technologies beyond the programs and controls already in use at the time of the promulgation of the original 40 CFR part 63, subpart VVV rulemaking.

*Comment:* We received various comments related to the information evaluated for the proposal. Two commenters stated that there is no technical basis that requires the EPA to revise the standards since there have been no technology advances since 1998 that warrant a change in the original MACT analysis. Several commenters provided additional information on specific control technologies, including biofilters, caustic scrubbers, and carbon absorbers. One of these commenters stated that biofilters are not reliable control devices in the context of a POTW because they are designed for stable operating conditions. In contrast, another commenter provided information that biofilters might have the ability to reduce HAP in addition to hydrogen sulfide ($H_2S$) and volatile organic compounds (VOC). Additional comments on the technology review can be found in section 3 of the response to comments document in the docket for this rule (EPA–HQ–OAR–2016–0490).

*Response:* The EPA conducted a literature review and evaluated available studies and publications on the use of add-on controls and process modifications that are used to reduce emissions from POTW wastewater collection and treatment operations. As noted by the commenters, these technologies include biotrickling filters, the use of covers and ducting of the headspace vent stream to caustic scrubbers and carbon adsorbers, and biofiltration/biofilters. These types of technologies have been used historically at POTW where they provide a relatively high degree of $H_2S$ control for the purpose of preventing odor. As documented in the technology review memorandum and reflected in the comments received on the proposed rule, the efficacy of these technologies to reduce HAP emissions is highly variable and dependent on site-specific operating parameters. Our conclusion is that the experience with biofilters for controlling organics at POTW is at the experimental and pilot scale and that this technology has not been demonstrated to be commercially available and effective for controlling the range of HAP emitted by POTW. Thus, we do not consider this technology to be a development in practices, processes, or control technologies for purposes of this technology review. Scrubbers are generally not used to control emissions of organic constituents, and while carbon adsorbers may be effective at HAP control in certain applications, as used in POTW, they are generally not designed for HAP control. Nevertheless, 40 CFR part 63, subpart VVV allows flexibility for POTW to develop site-specific control strategies to meet any applicable requirements, and such strategies could include the use of biologic filters and carbon adsorbers

that can achieve the required control levels.

As stated in section III.B of this preamble, we did not identify any developments in practices, processes, or control technology with respect to programs and controls already in use when the 2002 POTW NESHAP was promulgated that warrant revisions to the standards as part of the technology review of the POTW NESHAP.

*C. Applicability Criteria*

The 2002 POTW NESHAP established three criteria (40 CFR 63.1580(a)(1), (2), and (3)) for determining what POTW are subject to the rule. Specifically, the following criteria must all be true: (1) You own or operate a POTW that includes a POTW treatment plant; (2) the POTW is a major source of HAP emissions, or an industrial POTW regardless of the HAP emissions; and (3) the POTW is required to develop and implement a pretreatment program as defined by 40 CFR 403.8. The EPA proposed to revise the applicability criteria in order to clarify the original intent of the rule. Specifically, we proposed to revise the first and second criteria in 40 CFR 63.1580(a)(1) and (2) to state that your POTW is subject to the POTW NESHAP if ''(1) You own or operate a POTW that is a major source of HAP emissions; or (2) you own or operate a Group 1 POTW regardless of whether or not it is a major source of HAP.'' As stated in the proposal, we proposed this revision because we found several instances where a POTW might not realize they are subject to the standards, or where the applicability criteria could be misinterpreted to exclude facilities that are covered by the rule. See 81 FR 95377.

The third applicability criterion in the 2002 POTW NESHAP states that ''(3) Your POTW is required to develop and implement a pretreatment program as defined by 40 CFR 403.8 (for a POTW owned or operated by a municipality, state, or intermunicipal or interstate agency), or your POTW would meet the general criteria for development and implementation of a pretreatment program (for a POTW owned or operated by a department, agency, or instrumentality of the Federal government).'' We proposed revising the third criterion in 40 CFR 63.1580(a)(3) to state ''You are subject to this subpart if your POTW has a design capacity to treat at least 5 million gallons of wastewater per day (MGD) and treats wastewater from an industrial user, and either paragraph (a)(1) or (a)(2) is true.'' This proposed revision removed the requirement that a POTW must already have a pretreatment program in place in order to be subject to the rule. The proposed revisions were intended to clarify the intent of the rule, which was to limit applicability to POTW that treat at least 5 MGD and wastewater from industrial users.

*Comment:* We received numerous comments that raised specific concerns related to these proposed changes. First, commenters disagreed that the proposed changes were necessary and stated that the proposed changes created confusion and changed the scope of affected sources. One commenter stated that the applicability of 40 CFR part 63, subpart VVV has been well-defined for over 17 years, and if sources are confused, the EPA has methods to correct any confusion without making rule changes.

Several commenters specifically objected to the proposed change that removed pretreatment from the third applicability criterion and made it a requirement of the rule. These commenters stated that removing pretreatment as an applicability criterion and making it a requirement changes the source category that the EPA intended to control. One state commented that this proposed change would cause an additional 12 POTW in their state to become subject to the rule. The commenter explained that because the state (not the POTW) implements the National Pollutant Discharge Elimination System (NPDES) pretreatment program, the original rule does not apply to any POTW in that state.

*Response:* As stated in the proposal, the EPA did not intend to expand the applicability criteria from the 2002 POTW NESHAP. After consideration of the comments received, we agree that implementing the proposed changes to rule applicability could have caused confusion among the regulated community without a demonstrable environmental benefit. Therefore, at this time, we are not making any substantive change to the 2002 POTW NESHAP third applicability criterion and are not adopting the proposed applicability criterion of 5 MGD. However, it is important to note that the requirements in the National Pretreatment Program do establish a 5 MGD threshold for applicability.

In response to the apparent potential for misinterpretation of the regulatory text that is reflected in the state's comment, we are making one minor change to clarify our interpretation and the intent of 40 CFR 63.1580(a)(3). In developing the 2002 POTW NESHAP, we wrote the rule to apply to POTW that receive a significant amount of HAP-containing waste from industrial or commercial facilities. In developing the rule language, we sought to define such POTW by using a regulatory criterion that was already established and well understood in the industry. We selected the criterion that the POTW be subject to a pretreatment program under the NPDES program because this criterion would encompass industrial and commercial wastes with HAP that pass through the POTW untreated and that could present a safety or health concern to POTW workers. In adopting this criterion, we did not limit applicability based on the entity that administers the program. In other words, the criterion encompasses every POTW that receives a waste stream that is subject to pretreatment standards, regardless of whether the standards are prescribed by the POTW itself or by a state or federal regulatory body. Thus, to make sure that the regulatory text is properly read, we have revised 40 CFR 63.1581(a)(3) to make clear that a POTW is subject to this rule if either (1) the POTW is required to develop and implement a pretreatment program as defined by 40 CFR 403.8, or (2) the POTW meets the general criteria for development and implementation of a pretreatment program, even if does not develop and implement the pretreatment program itself. Specifically, we have removed the parenthetical text in 40 CFR 63.1580(a)(3) that limited the first part of the third criterion to POTW owned or operated by a municipality, state, or intermunicipal or interstate agency and limited the second part of the third criterion to POTW owned or operated by a department, agency, or instrumentality of the federal government.

*D. Emissions From Collection Systems*

In the 2016 proposal, we stated that HAP emissions from collection systems should be included when determining whether the POTW is a major source, and therefore, subject to the rule. Specifically, we stated that the 2002 applicability criteria in 40 CFR 63.1580(a)(2) provided that emissions from the entire POTW source category must be considered when determining whether the POTW is a major source of HAP emissions, and not just the emissions from the POTW treatment plant (*i.e.,* the portion of the POTW designed to provide treatment of municipal sewage or industrial waste).

*Comment:* Several commenters opposed including emissions from collection systems in the determination of whether a POTW is a major source. The commenters stated that collection systems/sewers may include hundreds or thousands of miles of sewers and other equipment, are not always under

the jurisdiction of the POTW, and are typically owned by another entity.

We also received comments that stated the inclusion of emissions from collection systems for major source determination is inconsistent with the federal definition of a major source. One commenter stated that expansion of the major source definition to include collection sewers as part of the affected source is not authorized under section 112 of the CAA. The commenter also stated that the equipment that collect and convey wastewater to a POTW treatment plant do not reasonably constitute a ''building, structure, facility, or installation'' as specified in the definition of a stationary source in section 112(a)(3) of the CAA, are clearly not within a contiguous area under common control, and should not be considered a single source. Commenters noted that the determination of a major source of HAP emissions should be limited to emission sources within the fence line of each treatment plant, which would be consistent with the fact that the emission fraction requirement of the proposed POTW NESHAP is limited to emissions within the treatment plant. Further, one commenter contended that excluding collection system emissions in POTW major source determinations is also supported by *Alabama Power Co.* v. *Costle* and EPA's response to that decision.

Commenters also noted that the emission data reviewed by the EPA in developing the proposed rule represented the HAP emissions from the POTW treatment plant only. One commenter noted that the risk assessment did not include emissions from collection systems. Several commenters disagreed with the EPA's statement in the preamble to the proposed rule that collection systems may have significant HAP emissions. Some commenters suggested that emissions from collection systems are insignificant and in some cases collection systems are operated under a vacuum to control odors. However, none of the commenters provided data to demonstrate the level of HAP emissions from collection systems.

*Response:* Considering these comments, the EPA is not taking final action at this time on any changes to the emission sources that must be considered when determining if a POTW is a major source of HAP emissions. Specifically, the EPA is not taking action on whether emissions from collection systems should be included in the total HAP emissions from a POTW. The determination of source boundaries is a site-specific and often a complex determination. Facilities work with their permitting authority to consider factors such as whether activities and equipment are in a contiguous area and whether they are under common control. In contemplating the comments, the EPA has decided that we do not have enough information on individual POTW, including information on the jurisdiction of the control of collection system equipment or information on whether this equipment should be considered contiguous with the POTW treatment plant. Also, data on HAP emissions from collection systems are not well understood, and we are not aware of accepted methods for measuring or calculating emissions from collection systems at this time. In addition, we understand that these source boundary determinations have already been made for the approximately 16,000 POTW through Title V applicability assessment. For these reasons, we are not taking final action at this time to change these determinations. We may take action in the future if we obtain additional information on source boundary issues (*i.e.,* common control, contiguous area), HAP emissions, and other information related to the issues described above.

With respect to new sources, we expect new sources to consult their permitting authorities on these matters as they plan for new construction. The EPA considers these determinations on source boundaries to be appropriately under the jurisdiction of the permitting authority. Accordingly, to avoid regulatory disruption, this final rule takes no action to change the definition of POTW. The definition of POTW remains the same as originally promulgated and continues to include ''. . . any intercepting sewers, outfall sewers, sewage collection systems, pumping, power and other equipment.'' Likewise, we are not taking final action at this time to revise the originally promulgated definition of the affected source. The definition of affected source continues to mean the ''group of all equipment that comprise the POTW treatment plant.''

*E. Pretreatment Requirements*

As stated in section IV.C of this preamble, the EPA proposed removing pretreatment from the applicability criteria and making it a control requirement for new and existing sources. We proposed adding pretreatment requirements in the rule because pretreatment would reduce HAP emissions from the entire source category (*i.e.,* collection systems and the treatment plant) by limiting the quantity of HAP in the wastewater before it is discharged to the collection system. The intent of this requirement was to reduce the pollutant loading into the POTW in order to reduce emissions throughout all stages of treatment.

*Comment:* Several commenters objected to the EPA requiring a pretreatment program for HAP emissions. Commenters disagreed with the EPA's contention that a pretreatment program will reduce emissions of HAP by reducing the presence of toxic gases. Specifically, commenters noted that a ''pretreatment program under CAA Section 112 is not the same as a pretreatment program under the Clean Water Act (CWA)'', as 40 CFR 403 authorizes POTW to set pretreatment requirements for air contaminants for worker and plant safety, and to prevent interference and pass through. One commenter contended that the proposed rule expands the CAA regulatory framework into the CWA National Pretreatment Program without a legal basis.

Additionally, several commenters opposed requiring POTW to develop local limits and expressed concerns about the way in which local limits should be determined. Instead, commenters suggested that the EPA establish wastewater concentration limits for HAP to identify pollutants that may need local limits. One commenter stated that the EPA should either ''regulate industrial users directly for HAP or provide technically-based wastewater concentrations for HAP that POTW could use for screening (where analytical methods exist under 40 CFR part 136)'' to determine the need for establishing local limits.

Commenters also expressed concerns about the costs related to requiring pretreatment programs wherein POTW evaluate and set local limits for volatile organic HAP. The commenters stated that developing local limits to identify pollutants of concern, as well as identify potential pretreatment controls, would require significant time and that the significant costs these requirements would impose on POTW have not been quantified or justified. In contrast, one commenter stated that categorical limits set by the EPA pursuant to the CWA for certain industries could merit consideration, but additional analysis is required.

*Response:* In response to these comments, we are not taking final action at this time to require pretreatment as a control requirement for the revised NESHAP. As explained in section IV.C of this preamble, we are not changing the applicability criteria for 40 CFR part 63, subpart VVV. The existence of a

pretreatment program under the CWA will continue to be one of the three rule applicability criteria.

The EPA Office of Water is responsible for administering the pretreatment program and updates the requirements of the pretreatment program based on the best available technology and taking into account cost effectiveness. As the pretreatment requirements are modified through future updates, additional HAP reductions may occur. Because all of the POTW that are subject to the rule already have pretreatment programs, specifically requiring pretreatment under the NESHAP would not reduce HAP emissions further, but could cause confusion and increase compliance costs. Thus, we are not finalizing any revisions at this time to impose additional pretreatment requirements prior to discharging a wastewater stream to a receiving POTW. Pretreatment will continue to be handled under the authority of the CWA. By retaining the existing regulatory structure of the NESHAP, the EPA avoids redundancy and confusion in having pretreatment requirements included in both air and water permits.

*F. HAP Fraction Emitted for Existing Group 1 and Group 2 Sources*

In the 2016 proposal, we proposed that existing Group 1 and Group 2 POTW operate with an annual rolling average HAP fraction emitted from primary treatment units of 0.08 or less. As stated in the proposal, we believed that the existing POTW we knew about could meet this standard without the need for additional control.

*Comment:* We received numerous comments that opposed the proposed HAP fraction emission limit, and we received additional data to suggest the proposed 0.08 HAP fraction limit was not appropriate and did not accurately account for variability in HAP loading at individual POTW.

Several commenters objected that merely doubling the single largest HAP fractions from the two available sources was not a scientifically or statistically valid method for setting the emission limit and stated that the EPA had provided no support for using the 2x factor to account for variability of emissions. For example, the commenters collectively pointed out that the two POTW on which the proposed standard was based were operating at half capacity, that the available data represent merely a snapshot in time, that other potentially regulated POTW might emit higher HAP fractions, and that the specific combination of HAP measured by the two POTW might not be representative of HAP emitted by other POTW. One commenter suggested that due to the uncertainty associated with such a small data set, the EPA should use a larger multiplier for setting a standard.

Additionally, commenters stated that the EPA had underestimated the cost of achieving compliance with the 0.08 HAP fraction emitted standard. Specifically, commenters stated that in order to comply, they would incur capital and operating costs, in addition to the recordkeeping and reporting costs that the EPA accounted for in the proposal. One commenter stated that they would potentially need to install covers and controls in order to meet the HAP fraction emitted limit, which would be an expense of $20 to $30 million with negligible emission reductions. Two commenters argued that the compliance cost for the proposed standard was not warranted given the low public health risk that the EPA estimated. Commenters further recommended that the EPA gather more complete data from the universe of affected sources, conduct statistical analysis of those data, and determine a suitable standard based on an acceptable level of risk and variability of the data.

*Response:* After reviewing public comments and re-evaluating our analysis, we are not taking final action to adopt the 0.08 HAP fraction emitted limit for existing Group 1 and Group 2 POTW at this time. The proposed HAP fraction emitted limit did not reflect the performance or application of a specific control technology. At proposal, we envisioned this limit as an enforceable numerical limit that would ensure performance consistent with that being achieved by existing sources. However, after consideration of the information provided in public comment, we now recognize that we do not have the comprehensive data on existing POTW that are necessary to conduct a sufficiently robust analysis. The HAP fraction emitted by different POTW is influenced by individual HAP vapor pressures, pollutant loadings, HAP concentrations, sample measurement and analytical techniques, and ambient conditions, which differ from POTW to POTW. Testing of influent loadings is limited by applicable test methods, by compounds identified by dischargers, and by the HAP for which air permits require sampling. Without sufficient data, we cannot determine an appropriate HAP fraction emitted limit, considering the variability in operating conditions that is likely to occur across even well-operated POTW. Moreover, at this time, we are unable to analyze the control costs for all affected sources or the emissions reductions that might be achieved. For all of these reasons, we are not taking final action on the proposed 0.08 HAP fraction at this time, but we may in the future consider promulgating a limit if we obtain further information on the issues discussed above.

*G. New and Existing Group 1 POTW*

In addition to proposing a HAP fraction for existing Group 1 POTW, we also proposed other changes to the requirements for Group 1 POTW.

The 2002 POTW NESHAP required existing Group 1 POTW to comply only with the requirements of the other NESHAP for which they are acting as an agent of control for the industrial user. We proposed that existing Group 1 POTW must meet both the requirements of the other NESHAP for which they are acting as an agent of control for an industrial user and the proposed requirements for existing Group 2 POTW in the POTW NESHAP (*i.e.,* the proposed 0.08 HAP fraction emitted limit discussed in IV.F, above).

The 2002 POTW NESHAP required new and reconstructed (which we are now referring to as ''new'') Group 1 POTW to comply with the more stringent of the following: (1) The requirements of the other NESHAP for which they are acting as an agent of control for the industrial user; or (2) the requirements applicable to new Group 2 POTW, which allowed the POTW to choose to meet either a requirement to (a) cover all equipment and route emissions through a closed vent system to a control device; or (b) meet a HAP fraction emission limit of 0.014 for emissions from all primary treatment units. We proposed that new Group 1 POTW comply with the other NESHAP for which they are acting as an agent of control for an industrial user and the requirements for new Group 2 POTW in the 2002 POTW NESHAP. (Note that we did not propose, and are not finalizing, any revisions to the requirements for new Group 2 POTW.)

1. Existing Group 1 POTW

Comment: We received comments from one of the existing Group 1 POTW that expressed concern that by imposing the HAP fraction emitted limit on the existing Group 1 POTW with no alternative compliance option, the EPA had ignored existing POTW with covers and controls already in place. The commenter stated that new Group 1 POTW have the option of either installing covers or complying with the HAP fraction limit. However, the EPA did not provide that flexibility to

existing Group 1 POTW, thereby imposing an additional HAP fraction limit without a cover option and more onerous recordkeeping and reporting requirements. The commenter stated that the EPA should provide existing Group 1 POTW that already use covers the option of adding controls in lieu of complying with a HAP fraction limit.

Response: The EPA is not taking final action on the proposed changes for existing Group 1 sources at this time. As explained in section IV.F of this preamble, we are not setting a HAP fraction limit for existing Group 1 or Group 2 POTW at this time; therefore, no additional requirements are being added for existing Group 1 POTW in the POTW NESHAP. Thus, as required by the 2002 POTW NESHAP, an existing Group 1 POTW must comply with the control requirements as specified in the appropriate NESHAP for the industrial user(s).

2. New Group 1 POTW

We did not receive any comment on our proposed revision to the requirements for new Group 1 POTW. We proposed, and are finalizing, that new Group 1 POTW must (1) meet the requirements of the other NESHAP for which they act as an agent of control for an industrial user and (2) either (a) cover all equipment and route emissions through a closed vent system to a control device or (b) meet a HAP fraction emission limit of 0.014 for emissions from all primary treatment units. See 81 FR 95375 for our rationale for this change. Because we received no adverse comment on our proposal, we are finalizing these requirements as proposed.

## V. Summary of Cost, Environmental, and Economic Impacts and Additional Analyses Conducted

### *A. What are the affected facilities?*

The EPA estimates, based on the responses to the 2015 ICR, the 2011 and 2014 National Emissions Inventory (NEI), and public comments received, that there are 13 POTW that are engaged in treatment of industrial wastewater and are currently subject to the POTW NESHAP. Two of these facilities are considered Group 1 POTW, while the remaining eleven are considered Group 2 POTW. All 13 currently subject to the POTW NESHAP have already met the notification requirements for existing Group 1 and Group 2 POTW. The EPA is not currently aware of any planned new Group 1 or Group 2 POTW that will be constructed or any existing Group 1 or Group 2 POTW that will be reconstructed.

### *B. What are the air quality impacts?*

The EPA estimates that annual organic HAP emissions from the 13 POTW subject to the rule are approximately 35 tpy. We expect no emissions of inorganic HAP from this category. The EPA does not anticipate any additional emission reductions from the final changes to the rule, and there are no anticipated new or reconstructed facilities.

### *C. What are the cost impacts?*

The 13 entities subject to this proposal will incur only minimal costs related to familiarizing themselves with this rule—estimated to be a one-time total cost of $790 for all 13 entities. For further information on the requirements of this rule, see section IV of this preamble. For further information on the costs associated with the requirements of this rule, see the document titled *Economic Impact Analysis for the National Emission Standards for Hazardous Air Pollutants: Publicly Owned Treatment Works Risk and Technology Review,* in the docket. The memorandum titled *Technology Review Memorandum for the Publicly Owned Treatment Works Source Category,* in the docket for this action, presents costs estimated associated with the regulatory options that were not selected for inclusion in this final rule (Docket ID No. EPA–HQ–OAR–2016–0490).

### *D. What are the economic impacts?*

The economic impact analysis is designed to inform decision makers about the potential economic consequences of a regulatory action. For this rule, the EPA estimated the annual cost of recordkeeping and reporting as a percentage of reported sewage fees received by the affected POTW. For the revisions promulgated in this final rule, costs are expected to be less than 0.001 percent of collected sewage fees, based on publicly available financial reports from the fiscal year ending in 2015 for the affected entities.

In addition, the EPA performed a screening analysis for impacts on small businesses by comparing estimated population served by the affected entities to the population limit set forth by the U.S. Small Business Administration. The screening analysis found that the population served for all affected entities is greater than the limit qualifying a public entity as a small business.

More information and details of the EPA's analysis of the economic impacts, including the conclusions stated above, are provided in the technical document, *Final Economic Impact Analysis for the Publicly Owned Treatment Works National Emissions Standards for Hazardous Air Pollutants Risk and Technology Review,* which is available in the docket for this final rule (Docket ID No. EPA–HQ–OAR–2016–0490).

### *E. What are the benefits?*

We do not anticipate any significant reductions in HAP emissions as a result of these final amendments. However, we think that the amendments will help to enhance the clarity of the rule, which can improve compliance and minimize emissions.

### *F. What analysis of environmental justice did we conduct?*

We examined the potential for any environmental justice concerns that might be associated with this source category by performing a demographic analysis of the population close to the six POTW that were modeled for source category risk.[4] In this analysis, we evaluated the distribution of HAP-related cancer and non-cancer risks from the POTW source category across different social, demographic, and economic groups within the populations living near facilities identified as having the highest risks. The methodology and the results of the demographic analyses are included in a technical report, *Risk and Technology Review—Analysis of Socio-Economic Factors for Populations Living Near POTW Facilities,* available in the docket for this action (Docket ID No. EPA–HQ–OAR–2016–0490). The results for various demographic groups are based on the estimated risks from actual emissions levels for the population living within 50 kilometers (km) of the facilities.

The results of the POTW source category demographic analysis indicate that actual emissions from the source category expose no person to a cancer risk at or above 1-in-1 million or to a chronic non-cancer TOSHI greater than 1. Therefore, we conclude that this final rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it does not affect the level of protection provided to human health or the environment. However, this final rule may provide additional benefits to these demographic groups by improving the compliance and implementation of the NESHAP. The demographics of the population living within 50 km of POTW can be found in Table 2 of the document titled *Risk and Technology*

[4] See section IV.A of this preamble for an explanation of the residual risk assessment.

*Review—Analysis of Socio-Economic Factors for Populations Living Near Publicly Owned Treatment Works,* available in the docket for this final rule (Docket ID No. EPA–HQ–OAR–2016–0490).

*G. What analysis of children's environmental health did we conduct?*

This action is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866, and because the EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. The results of the POTW source category demographic analysis indicate that actual emissions from the source category expose no person to a cancer risk at or above 1-in-1 million or to a chronic non-cancer TOSHI greater than 1. Therefore, the analysis shows that actual emissions from the POTW source category are not expected to have an adverse human health effect on children.

## VI. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *http://www2.epa.gov/laws-regulations/laws-and-executive-orders.*

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

This action is not a significant regulatory action and was therefore not submitted to the Office of Management and Budget (OMB) for review.

*B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs*

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

*C. Paperwork Reduction Act (PRA)*

The information collection activities in this rule have been submitted for approval to the OMB under the PRA. The ICR document that the EPA prepared has been assigned EPA ICR number 1891.08. You can find a copy of the ICR in the docket for this rule, and it is briefly summarized here. The information collection requirements are not enforceable until OMB approves them.

The information to be collected includes the initial notification that the POTW is subject to the rule. However, as stated in this preamble, the 13 sources that we already know about have already met this initial notification requirement and are not required to submit an additional notification. The information will be used to identify sources subject to the standards.

*Respondents/affected entities:* The respondents to the recordkeeping and reporting requirements are owners and operators of POTW. The NAICS code for the respondents affected by the standard is 221320 (Sewage Treatment Facilities), which corresponds to the United States Standard Industrial Classification code 4952 (Sewerage Systems).

*Respondent's obligation to respond:* Respondents are obligated to respond in accordance with the notification requirements under 40 CFR 63.1591(a).

*Estimated number of respondents:* Zero.

*Frequency of response:* One response.

*Total estimated burden:* 0 hours (per year). Burden is defined at 5 CFR 1320.3(b).

*Total estimated cost:* $0 (per year), includes $0 annualized capital or operation and maintenance costs.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA's regulations in 40 CFR are listed in 40 CFR part 9. When OMB approves this ICR, the Agency will announce that approval in the **Federal Register** and publish a technical amendment to 40 CFR part 9 to display the OMB control number for the approved information collection activities contained in this final rule.

*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. There are no small entities affected in this regulated industry. See the technical document, *Final Economic Impact Analysis for the National Emission Standards for Hazardous Air Pollutants: Publicly Owned Treatment Works Risk and Technology Review,* which is available in the docket for this final rule (Docket ID No. EPA–HQ–OAR–2016–0490) for more detail.

*E. Unfunded Mandates Reform Act (UMRA)*

This action does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local, or tribal governments or the private sector.

*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 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. As discussed in section II.B.1 of this preamble, we have identified only 13 POTW that are subject to this final rule and none of those POTW are owned or operated by tribal governments. Thus, Executive Order 13175 does not apply to this action.

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

The action is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866, and because the EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. This action's health and risk assessments are contained in sections III.A and B and sections IV.A and B of this preamble and the *Residual Risk Report* memorandum contained in the docket for this rulemaking.

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

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

*J. National Technology Transfer and Advancement Act (NTTAA)*

This rulemaking does not involve technical standards.

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

The EPA believes that this action does *not* have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations, and/or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994).

The documentation for this decision is contained in section III.A.6 of this preamble and in the corresponding

technical report, *Risk and Technology Review—Analysis of Socio-Economic Factors for Populations Living Near Publicly Owned Treatment Works,* available in the docket for this action. The proximity results indicate, for eight of the 11 demographic categories, that the population percentages within 5 km and 50 km of source category emissions are greater than the corresponding national percentage for those same demographics. However, the results of the risk analysis presented in section III.A.6 of this preamble and in the corresponding technical report indicate that actual emissions from the source category expose no person to a cancer risk at or above 1-in-1 million or to a chronic non-cancer TOSHI greater than 1.

*L. Congressional Review Act (CRA)*

This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Part 63**

Environmental protection, Administrative practice and procedures, Air pollution control, Hazardous substances, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: October 16, 2017.

**E. Scott Pruitt,**

*Administrator.*

For the reasons stated in the preamble, the Environmental Protection Agency amends part 63 of title 40, chapter I, of the Code of Federal Regulations as follows:

## PART 63—NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS FOR SOURCE CATEGORIES

■ 1. The authority citation for part 63 continues to read as follows:

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

■ 2. Part 63 is amended by revising subpart VVV to read as follows:

### Subpart VVV—National Emission Standards for Hazardous Air Pollutants: Publicly Owned Treatment Works

**Applicability**



### Subpart VVV—National Emission Standards for Hazardous Air Pollutants: Publicly Owned Treatment Works

### Applicability

#### § 63.1580 Am I subject to this subpart?

(a) You are subject to this subpart if the following are all true:

(1) You own or operate a publicly owned treatment works (POTW) that includes an affected source (§ 63.1595);

(2) The affected source is located at a Group 2 POTW which is a major source of HAP emissions, or at any Group 1 POTW regardless of whether or not it is a major source of HAP; and

(3) Your POTW is required to develop and implement a pretreatment program as defined by 40 CFR 403.8, or your POTW meets the general criteria for development and implementation of a pretreatment program.

(b) If your existing POTW treatment plant is not located at a major source as of October 26, 1999, but thereafter becomes a major source for any reason other than reconstruction, then, for the purpose of this subpart, your POTW treatment plant would be considered an existing source.

**Note to paragraph (b):** See § 63.2 of the National Emission Standards for Hazardous Air Pollutants (NESHAP) General Provisions in subpart A of this part for the definitions of major source and area source.

(c) If you commence construction or reconstruction of your POTW treatment plant after December 1, 1998, then the requirements for a new POTW apply.

#### § 63.1581 Does the subpart distinguish between different types of POTW treatment plants?

Yes, POTW treatment plants are divided into two subcategories: Group 1 POTW treatment plants and Group 2 POTW treatment plants, as described in paragraphs (a) through (c) of this section.

(a) Your POTW is a Group 1 POTW treatment plant if an industrial user complies with its NESHAP by using the treatment and controls located at your POTW treatment plant. Your POTW treatment plant accepts the regulated waste stream and provides treatment and controls as an agent for the industrial user. Group 1 POTW treatment plant is defined in § 63.1595.

(b) Your POTW is a Group 2 POTW treatment plant if your POTW treats wastewater that is not subject to control by another NESHAP or the industrial user does not comply with its NESHAP by using the treatment and controls located at your POTW treatment plant. ''Group 2 POTW treatment plant'' is defined in § 63.1595.

(c) If, in the future, an industrial user complies with its NESHAP by using the treatment and controls located at your POTW treatment plant, then your Group 2 POTW treatment plant becomes a Group 1 POTW treatment plant on the date your POTW begins treating that regulated industrial wastewater stream.

### Requirements for Group 1 POTW Treatment Plants

#### § 63.1582 [Reserved]

#### § 63.1583 What are the emission points and control requirements for a Group 1 POTW treatment plant?

(a) The emission points and control requirements for an existing Group 1 POTW treatment plant are specified in the appropriate NESHAP for the industrial user(s).

(b) The emission points and control requirements for a new Group 1 POTW treatment plant are both those specified by the appropriate NESHAP which apply to the industrial user(s) who discharge their waste for treatment to the POTW, and those emission points and control requirements set forth in § 63.1586(b) or (c), as applicable.

(c) If your existing or new Group 1 POTW treatment plant accepts one or more specific regulated industrial waste streams as part of compliance with one or more other NESHAP, then you are subject to all the requirements of each appropriate NESHAP for each waste stream.

(d) At all times, the POTW must operate and maintain any affected source, including associated air

pollution control equipment and monitoring equipment, in a manner consistent with safety and good air pollution control practices for minimizing emissions. The general duty to minimize emissions does not require the POTW to make any further efforts to reduce emissions if levels required by the applicable standard have been achieved. Determination of whether a source is operating in compliance with operation and maintenance requirements will be based on information available to the Administrator, which may include, but is not limited to, monitoring results, review of operation and maintenance procedures, review of operation and maintenance records, and inspection of the source.

**§ 63.1584 [Reserved]**

**§ 63.1585 How does a Group 1 POTW treatment plant demonstrate compliance?**

(a) An existing Group 1 POTW treatment plant demonstrates compliance by operating treatment and control devices which meet all requirements specified in the appropriate NESHAP. Requirements may include performance tests, routine monitoring, recordkeeping, and reporting.

(b) A new Group 1 POTW treatment plant demonstrates compliance by operating treatment and control devices which meet all requirements specified in the appropriate NESHAP and by meeting the requirements specified in § 63.1586, as applicable, as well as the applicable requirements in §§ 63.1588 through 63.1595.

**Requirements for Group 1 and Group 2 POTW Treatment Plants**

**§ 63.1586 What are the emission points and control requirements for a Group 1 or Group 2 POTW?**

(a) An existing Group 1 or Group 2 POTW treatment plant must comply with the initial notification requirements in § 63.1591(a).

(b) *Cover and control standard.* Except as provided in paragraph (c) of this section, new Group 1 and Group 2 POTW treatment plants must install covers on the emission points up to, but not including, the secondary influent pumping station or the secondary treatment units. These emission points are treatment units that include, but are not limited to, influent waste stream conveyance channels, bar screens, grit chambers, grinders, pump stations, aerated feeder channels, primary clarifiers, primary effluent channels, and primary screening stations. In addition, all covered units, except primary clarifiers, must have the air in the headspace underneath the cover ducted to a control device in accordance with the standards for closed-vent systems and control devices in § 63.693 of subpart DD—National Emission Standards for Hazardous Air Pollutants from Off-site Waste and Recovery Operations of this part, except you may substitute visual inspections for leak detection rather than Method 21 of appendix A–7 of part 60 of this chapter. Covers must meet the following requirements:

(1) Covers must be tightly fitted and designed and operated to prevent exposure of the wastewater to the atmosphere. This includes, but is not limited to, the absence of visible cracks, holes, or gaps in the roof sections or between the roof and the supporting wall; broken, cracked, or otherwise damaged seals or gaskets on closure devices; and broken or missing hatches, access covers, caps, or other closure devices.

(2) If wastewater is in a treatment unit, each opening in the cover must be maintained in a closed, sealed position, unless plant personnel are present and conducting wastewater or sludge sampling, or equipment inspection, maintenance, or repair.

(c) *HAP fraction emitted standard.* As an alternative to the requirements in paragraph (b) of this section, a new Group 1 and Group 2 POTW treatment plant may comply by demonstrating, for all emission points up to, but not including, the secondary influent pumping station or the secondary treatment units, that the annual rolling average HAP fraction emitted (calculated as specified in § 63.1588(c)(3)) does not exceed 0.014. You must demonstrate that for your POTW treatment plant, the sum of all HAP emissions from these units divided by the sum of all HAP mass loadings to the POTW treatment plant results in an annual rolling average of the HAP fraction emitted of no greater than 0.014. You may use any combination of pretreatment, wastewater treatment plant modifications, and control devices to achieve this performance standard.

(d) At all times, the POTW must operate and maintain any affected source, including associated air pollution control equipment and monitoring equipment, in a manner consistent with safety and good air pollution control practices for minimizing emissions. The general duty to minimize emissions does not require the POTW to make any further efforts to reduce emissions if the requirements of the applicable standard have been met. Determination of whether a source is operating in compliance with operation and maintenance requirements will be based on information available to the Administrator, which may include, but is not limited to, monitoring results, review of operation and maintenance procedures, review of operation and maintenance records, and inspection of the source.

**§ 63.1587 When do I have to comply?**

Sources subject to this subpart are required to achieve compliance on or before the dates specified in table 2 of this subpart.

**§ 63.1588 How do Group 1 and Group 2 POTW treatment plants demonstrate compliance?**

(a) If you are complying with § 63.1586(b) by using covers, you must conduct the following inspections:

(1) You must visually check the cover and its closure devices for defects that could result in air emissions. Defects include, but are not limited to, visible cracks, holes, or gaps in the roof sections or between the roof and the supporting wall; broken, cracked, or otherwise damaged seals or gaskets on closure devices; and broken or missing hatches, access covers, caps, or other closure devices.

(2) You must perform an initial visual inspection within 60 calendar days of becoming subject to this NESHAP and perform follow-up inspections at least once per year, thereafter.

(3) In the event that you find a defect on a cover on a treatment unit in use, you must repair the defect within 45 calendar days. If you cannot repair within 45 calendar days, you must notify the EPA or the delegated authority immediately and report the reason for the delay and the date you expect to complete the repair. If you find a defect on a cover on a treatment unit that is not in service, you must repair the defect prior to putting the treatment unit back in wastewater service.

(b) If you own or operate a control device used to meet the requirements for § 63.1586(b), you must comply with the inspection and monitoring requirements of § 63.695(c) of subpart DD of this part.

(c) To comply with the HAP fraction emitted standard specified in § 63.1586(c), you must develop, to the satisfaction of the Administrator, an Inspection and Monitoring Plan. This Inspection and Monitoring Plan must include, at a minimum, the following:

(1) A method to determine the influent HAP mass loading, *i.e.,* the annual mass quantity for each HAP entering the wastewater treatment plant.

(2) A method to determine your POTW treatment plant's annual HAP emissions for all units up to, but not including, the secondary influent pumping station or the secondary treatment units. The method you use to determine your HAP emissions, such as modeling or direct source measurement, must:

(i) Be approved by the Administrator for use at your POTW;

(ii) Account for all factors affecting emissions from your POTW treatment plant including, but not limited to, emissions from wastewater treatment units; emissions resulting from inspection, maintenance, and repair activities; fluctuations (*e.g.,* daily, monthly, annual, seasonal) in your influent wastewater HAP concentrations; annual industrial loading; performance of control devices; or any other factors that could affect your annual HAP emissions; and

(iii) Include documentation that the values and sources of all data, operating conditions, assumptions, etc., used in your method result in an accurate estimation of annual emissions from your POTW treatment plant.

(3) A method to demonstrate that your POTW treatment plant meets the HAP fraction emitted standard specified in § 63.1586(c), *i.e.,* the sum of all HAP emissions from paragraph (c)(2) of this section divided by the sum of all HAP mass loadings from paragraph (c)(1) of this section results in a fraction emitted of 0.014 or less to demonstrate compliance with § 63.1586(c). The Inspection and Monitoring Plan must require, at a minimum, that you perform the calculations shown in paragraphs (c)(3)(i) through (viii) of this section within 90 days of the end of each month. This calculation shall demonstrate that your annual rolling average of the HAP fraction emitted is 0.014 or less when demonstrating compliance with § 63.1586(c).

(i) Determine the average daily flow in million gallons per day (MGD) of the wastewater entering your POTW treatment plant for the month;

(ii) Determine the flow-weighted monthly concentration of each HAP listed in Table 1 to subpart DD of this part that is reasonably anticipated to be present in your influent;

(iii) Using the information in paragraphs (c)(3)(i) and (ii) of this section, determine a total annual flow-weighted loading in pounds per day (lbs/day) of each HAP entering your POTW treatment plant;

(iv) Sum up the values for each individual HAP loading in paragraph (c)(3)(iii) of this section and determine a total annual flow-weighted loading value (lbs/day) for all HAP entering your POTW treatment plant for the current month;

(v) Based on the current month's information in paragraph (c)(3)(iii) of this section along with source testing and emission modeling, for each HAP, determine the annual emissions (lbs/day) from all wastewater units up to, but not including, secondary treatment units;

(vi) Sum up the values in paragraph (c)(3)(v) of this section and calculate the total annual emissions value for the month for all HAP from all wastewater treatment units up to, but not including, secondary treatment units;

(vii) Calculate the HAP fraction emitted value for the month, using Equation 1 of this section as follows:

$$f_e\text{monthly} = \sum E / \sum L \quad \text{(Eq. 1)}$$

Where:

$f_e$monthly = HAP fraction emitted for the previous month

$\Sigma E$ = Total HAP emissions value from paragraph (c)(3)(vi) of this section

$\Sigma L$ = Total annual loading from paragraph (c)(3)(iv) of this section

(viii) Average the HAP fraction emitted value for the month determined in paragraph (c)(3)(vii) of this section, with the values determined for the previous 11 months, to calculate an annual rolling average of the HAP fraction emitted.

(4) A method to demonstrate, to the satisfaction of the Administrator, that your POTW treatment plant is in continuous compliance with the requirements of § 63.1586(c). Continuous compliance means that your emissions, when averaged over the course of a year, do not exceed the level of emissions that allows your POTW to comply with § 63.1586(c). For example, you may identify a parameter(s) that you can monitor that assures your emissions, when averaged over the entire year, will meet the requirements in § 63.1586(c). Some example parameters that may be considered for monitoring include your wastewater influent HAP concentration and flow, industrial loading from your permitted industrial users, and your control device performance criteria. Where emission reductions are due to proper operation of equipment, work practices, or other operational procedures, your demonstration must specify the frequency of inspections and the number of days to completion of repairs.

(d) Prior to receiving approval on the Inspection and Monitoring Plan, you must follow the plan submitted to the Administrator as specified in § 63.1590(f).

**§ 63.1589 What records must I keep?**

(a) To comply with the cover and control standard specified in § 63.1586(b), you must prepare and maintain the records required in paragraphs (a)(1) through (4) of this section:

(1) A record for each treatment unit inspection required by § 63.1588(a). You must include a treatment unit identification number (or other unique identification description as selected by you) and the date of inspection.

(2) For each defect detected during inspections required by § 63.1588(a), you must record the location of the defect, a description of the defect, the date of detection, the corrective action taken to repair the defect, and the date the repair to correct the defect is completed.

(3) If repair of the defect is delayed as described in § 63.1588(a)(3), you must also record the reason for the delay and the date you expect to complete the repair.

(4) If you own or operate a control device used to meet the requirements for § 63.1586(b), you must comply with the recordkeeping requirements of § 63.696(a), (b), (g), and (h).

(b) To comply with the HAP fraction emitted standard specified in § 63.1586(c), you must prepare and maintain the records required in paragraphs (b)(1) through (3) of this section:

(1) A record of the methods and data used to determine your POTW treatment plant's annual HAP loading and HAP emissions as determined in § 63.1588(c)(1) and (2) as part of your Inspection and Monitoring Plan;

(2) A record of the methods and data used to determine that your POTW treatment plant meets the HAP fraction emitted standard of 0.014 or less, as determined in § 63.1588(c)(3) as part of your Inspection and Monitoring Plan; and

(3) A record of the methods and data that demonstrates that your POTW treatment plant is in continuous compliance with the requirements of § 63.1588(c)(4) to calculate annual emissions as specified in your Inspection and Monitoring Plan.

(c) The POTW must record the malfunction information specified in paragraphs (c)(1) through (3) of this section.

(1) In the event that an affected unit fails to meet an applicable standard, record the number of failures. For each failure, record the date, time, and duration of the failure.

(2) For each failure to meet an applicable standard, record and retain a list of the affected sources or equipment,

an estimate of the tons per year of each regulated pollutant emitted over any emission limit and a description of the method used to estimate the emissions.

(3) Record actions taken to minimize emissions in accordance with § 63.1583(d) or § 63.1586(d) and any corrective actions taken to return the affected unit to its normal or usual manner of operation.

(d) Any records required to be maintained by this part that are submitted electronically via the EPA's Compliance and Emissions Data Reporting Interface (CEDRI) may be maintained in electronic format. This ability to maintain electronic copies does not affect the requirement for facilities to make records, data, and reports available upon request to a delegated air agency or the EPA as part of an on-site compliance evaluation.

**§ 63.1590 What reports must I submit?**

(a) An existing Group 1 POTW must meet the reporting requirements specified in the appropriate NESHAP for the industrial user(s).

(b) A new Group 1 or Group 2 POTW must submit annual reports containing the information specified in paragraphs (b)(1) through (4) of this section, if applicable. You must submit annual reports following the procedure specified in paragraph (b)(5) of this section. For new units, the initial annual report is due 15 months after your POTW becomes subject to the requirements in this subpart and must cover the first 12 months of operation after your POTW becomes subject to the requirements of this subpart. Subsequent annual reports are due by the same date each year as the initial annual report and must contain information for the 12-month period following the 12-month period included in the previous annual report.

(1) The general information specified in paragraphs (b)(1)(i) and (ii) of this section must be included in all reports.

(i) The company name, POTW treatment plant name, and POTW treatment plant address, including county where the POTW is located; and

(ii) Beginning and ending dates of the reporting period.

(2) If you use covers to comply with the requirements of § 63.1586(b), you must submit the following:

(i) The dates of each visual inspection conducted;

(ii) The defects found during each visual inspection; and

(iii) For each defect found during a visual inspection, how the defects were repaired, whether the repair has been completed, and either the date each repair was completed or the date each repair is expected to be completed.

(3) If you comply with the HAP fraction emitted standard in § 63.1586(c), you must submit each value of the annual rolling average HAP fraction emitted as calculated in § 63.1588(c)(3)(vii) for the period covered by the annual report. Identify each value by the final month included in the calculation.

(4) If a source fails to meet an applicable standard, report such events in the annual report. Report the number of failures to meet an applicable standard. For each instance, report the start date, start time, and duration of each failure, as well as a list of the affected sources or equipment. If you comply with the cover and control standard in § 63.1586(b), for each failure, the report must include the percent control achieved. If you comply with the HAP fraction emitted standard in § 63.1586(c), for each failure, the report must include the HAP fraction emitted. You must include an estimate of the tons per year of each regulated pollutant emitted over the emission limit and a description of the method used to estimate the emissions in the report.

(5) You must submit the report to the Administrator at the appropriate address listed in § 63.13, unless the Administrator agrees to or species an alternate reporting method. Beginning on October 28, 2019 or once the reporting form has been available in CEDRI for 1 year, whichever is later, you must submit subsequent annual reports to the EPA via CEDRI. (CEDRI can be accessed through the EPA's Central Data Exchange (CDX)(*https://cdx.epa.gov/*)). You must use the appropriate electronic report template on the CEDRI Web site for this subpart or an alternate electronic file format consistent with the extensible markup language (XML) schema listed on the CEDRI Web site (*https://www.epa.gov/electronic-reporting-air-emissions/compliance-and-emissions-data-reporting-interface-cedri*). The date report templates become available in CEDRI will be listed on the CEDRI Web site. The reports must be submitted by the deadline specified in this subpart, regardless of the method in which the reports are submitted. If you claim that some of the information required to be submitted via CEDRI is confidential business information (CBI), you shall submit a complete report generated using the appropriate form in CEDRI or an alternate electronic file consistent with the extensible markup language (XML) schema listed on the EPA's CEDRI Web site, including information claimed to be CBI, on a compact disc, flash drive, or other commonly used electronic storage medium to the EPA. The electronic medium shall be clearly marked as CBI and mailed to U.S. EPA/OAQPS/CORE CBI Office, Attention: Group Leader, Measurement Policy Group, MD C404–02, 4930 Old Page Rd., Durham, NC 27703. The same file with the CBI omitted shall be submitted to the EPA via the EPA's CDX as described earlier in this paragraph.

(c) If you own or operate a control device used to meet the cover and control standard in § 63.1586(b), you must submit the notifications and reports required by § 63.697(b), including a notification of performance tests; a performance test report; a malfunction report; and a summary report. These notifications and reports must be submitted to the Administrator, except for performance test reports. Within 60 calendar days after the date of completing each performance test (as defined in § 63.2) required by subpart DD of this part, you must submit the results of the performance test following the procedure specified in paragraphs (c)(1) through (3) of this section.

(1) For data collected using test methods supported by the EPA's Electronic Reporting Tool (ERT) as listed on the EPA's ERT Web site (*https://www.epa.gov/electronic-reporting-air-emissions/electronic-reporting-tool-ert*) at the time of the test, you must submit the results of the performance test to the EPA via CEDRI. Performance test data must be submitted in a file format generated through the use of the EPA's ERT or an alternate electronic file format consistent with the XML schema listed on the EPA's ERT Web site.

(2) For data collected using test methods that are not supported by the EPA's ERT as listed on the EPA's ERT Web site at the time of the test, you must submit the results of the performance test to the Administrator at the appropriate address listed in § 63.13 of subpart A of this part, unless the Administrator agrees to or specifies an alternate reporting method.

(3) If you claim that some of the performance test information being submitted under paragraph (b)(1) of this section is CBI, you must submit a complete file generated through the use of the EPA's ERT or an alternate electronic file consistent with the XML schema listed on the EPA's ERT Web site, including information claimed to be CBI, on a compact disc, flash drive, or other commonly used electronic storage medium to the EPA. The electronic medium must be clearly marked as CBI and mailed to U.S. EPA/

OAQPS/CORE CBI Office, Attention: Group Leader, Measurement Policy Group, MD C404–02, 4930 Old Page Rd., Durham, NC 27703. The same ERT or alternate file with the CBI omitted must be submitted to the EPA via the EPA's CDX as described in paragraph (c)(1) of this section.

(d) You must comply with the delay of repair reporting required in § 63.1588(a)(3).

(e) You may apply to the Administrator for a waiver of recordkeeping and reporting requirements by complying with the requirements of § 63.10(f). Electronic reporting to the EPA cannot be waived.

(f) To comply with the HAP fraction emitted standard specified in § 63.1586(c), you must submit, for approval by the Administrator, an Inspection and Monitoring Plan explaining your compliance approach 90 calendar days prior to beginning operation of your new POTW or by April 24, 2018, whichever is later.

(g) If you are required to electronically submit a report through the CEDRI in the EPA's CDX, and due to a planned or actual outage of either the EPA's CEDRI or CDX systems within the period of time beginning 5 business days prior to the date that the submission is due, you will be or are precluded from accessing CEDRI or CDX and submitting a required report within the time prescribed, you may assert a claim of EPA system outage for failure to timely comply with the reporting requirement. You must submit notification to the Administrator in writing as soon as possible following the date you first knew, or through due diligence should have known, that the event may cause or caused a delay in reporting. You must provide to the Administrator a written description identifying the date, time and length of the outage; a rationale for attributing the delay in reporting beyond the regulatory deadline to the EPA system outage; describe the measures taken or to be taken to minimize the delay in reporting; and identify a date by which you propose to report, or if you have already met the reporting requirement at the time of the notification, the date you reported. In any circumstance, the report must be submitted electronically as soon as possible after the outage is resolved. The decision to accept the claim of EPA system outage and allow an extension to the reporting deadline is solely within the discretion of the Administrator.

(h) If you are required to electronically submit a report through CEDRI in the EPA's CDX and a force majeure event is about to occur, occurs, or has occurred or there are lingering effects from such an event within the period of time beginning five business days prior to the date the submission is due, the owner or operator may assert a claim of force majeure for failure to timely comply with the reporting requirement. For the purposes of this section, a force majeure event is defined as an event that will be or has been caused by circumstances beyond the control of the affected facility, its contractors, or any entity controlled by the affected facility that prevents you from complying with the requirement to submit a report electronically within the time period prescribed. Examples of such events are acts of nature (*e.g.,* hurricanes, earthquakes, or floods), acts of war or terrorism, or equipment failure or safety hazard beyond the control of the affected facility (*e.g.,* large scale power outage). If you intend to assert a claim of force majeure, you must submit notification to the Administrator in writing as soon as possible following the date you first knew, or through due diligence should have known, that the event may cause or caused a delay in reporting. You must provide to the Administrator a written description of the force majeure event and a rationale for attributing the delay in reporting beyond the regulatory deadline to the force majeure event; describe the measures taken or to be taken to minimize the delay in reporting; and identify a date by which you propose to report, or if you have already met the reporting requirement at the time of the notification, the date you reported. In any circumstance, the reporting must occur as soon as possible after the force majeure event occurs. The decision to accept the claim of force majeure and allow an extension to the reporting deadline is solely within the discretion of the Administrator.

### § 63.1591 What are my notification requirements?

(a) You must submit an initial notification that your POTW treatment plant is subject to these standards as specified in paragraphs (a)(1) and (2) of this section.

(1) If you have an existing Group 1 or Group 2 POTW treatment plant, you must submit an initial notification by October 26, 2018.

(2) If you have a new Group 1 or Group 2 POTW treatment plant, you must submit an initial notification upon startup.

(b) The initial notification must include the information included in paragraphs (b)(1) through (4) of this section.

(1) Your name and address;

(2) The address (*i.e.,* physical location) of your POTW treatment plant;

(3) An identification of these standards as the basis of the notification and your POTW treatment plant's compliance date; and

(4) A brief description of the nature, size, design, and method of operation of your POTW treatment plant, including its operating design capacity and an identification of each point of emission for each HAP, or if a definitive identification is not yet possible, a preliminary identification of each point of emission for each HAP.

(c) You must submit a notification of compliance status as required in § 63.9(h), as specified below:

(1) If you comply with § 63.1586(b) and use covers on the emission points and route air in the headspace underneath the cover to a control device, you must submit a notification of compliance status as specified in § 63.9(h) that includes a description of the POTW treatment units and installed covers, as well as the information required for control devices including the performance test results.

(2) If you comply with § 63.1586(c) by meeting the HAP fraction emitted standard, submission of the Inspection and Monitoring Plan as required in § 63.1588(c) and § 63.1590(f) meets the requirement for submitting a notification of compliance status report in § 63.9(h).

(d) You must notify the Administrator, within 30 calendar days of discovering that you are out of compliance with an applicable requirement of this subpart, including the following:

(1) The requirement to route the air in the headspace underneath the cover of all units equipped with covers, except primary clarifiers, to a control device as specified in § 63.1586(b).

(2) The HAP fraction emitted standard as specified in § 63.1586(c).

(3) The requirement to operate and maintain the affected source as specified in § 63.1586(d).

(4) The requirement to inspect covers annually and repair defects as specified in § 63.1588(a).

(5) The requirement to comply with the inspection and monitoring requirements of § 63.695(c) as specified in § 63.1588(b).

(6) The procedures specified in an Inspection and Monitoring Plan prepared as specified in § 63.1588(c).

(7) The requirements specified in an appropriate NESHAP for which the Group 1 POTW treatment plan treats regulated industrial waste as specified in § 63.1583(a) or (b), as applicable.

**§ 63.1592 Which General Provisions apply to my POTW treatment plant?**

(a) Table 1 to this subpart lists the General Provisions (40 CFR part 63, subpart A) which do and do not apply to POTW treatment plants.

(b) Unless a permit is otherwise required by law, the owner or operator of a Group 1 POTW treatment plant which is not a major source is exempt from the permitting requirements established by 40 CFR part 70.

**§ 63.1593 [Reserved]**

**§ 63.1594 Who enforces this subpart?**

(a) This subpart can be implemented and enforced by the U.S. EPA, or a delegated authority such as the applicable state, local, or tribal agency. If the U.S. EPA Administrator has delegated authority to a state, local, or tribal agency, then that agency, in addition to the U.S. EPA, has the authority to implement and enforce this subpart. Contact the applicable U.S. EPA Regional Office to find out if implementation and enforcement of this subpart is delegated to a state, local, or tribal agency.

(b) In delegating implementation and enforcement authority of this subpart to a state, local, or tribal agency under subpart E of this part, the authorities contained in paragraphs (b)(1) through (5) of this section are retained by the Administrator of U.S. EPA and cannot be delegated to the state, local, or tribal agency.

(1) Approval of alternatives to the requirements in §§ 63.1580, 63.1583, and 63.1586 through 63.1588.

(2) Approval of major alternatives to test methods under § 63.7(e)(2)(ii) and (f), as defined in § 63.90, and as required in this subpart.

(3) Approval of major alternatives to monitoring under § 63.8(f), as defined in § 63.90, and as required in this subpart.

(4) Approval of major alternatives to recordkeeping and reporting under § 63.10(f), as defined in § 63.90, and as required in this subpart.

(5) Approval of an alternative to any electronic reporting to the EPA required by this subpart.

**§ 63.1595 List of definitions.**

As used in this subpart:

*Affected source* means the group of all equipment that comprise the POTW treatment plant.

*Cover* means a device that prevents or reduces air pollutant emissions to the atmosphere by forming a continuous barrier over the waste material managed in a treatment unit. A cover may have openings (such as access hatches, sampling ports, gauge wells) that are necessary for operation, inspection, maintenance, and repair of the treatment unit on which the cover is used. A cover may be a separate piece of equipment which can be detached and removed from the treatment unit, or a cover may be formed by structural features permanently integrated into the design of the treatment unit. The cover and its closure devices must be made of suitable materials that will prevent exposure of the waste material to the atmosphere and will maintain the integrity of the cover and its closure devices throughout its intended service life.

*Existing source or existing POTW* means a POTW that commenced construction on or before December 1, 1998, and has not been reconstructed after December 1, 1998.

*Fraction emitted* means the fraction of the mass of HAP entering the POTW wastewater treatment plant which is emitted prior to secondary treatment.

*Group 1 POTW* means a POTW that accepts a waste stream regulated by another NESHAP and provides treatment and controls as an agent for the industrial user. The industrial user complies with its NESHAP by using the treatment and controls located at the POTW. For example, an industry discharges its benzene-containing waste stream to the POTW for treatment to comply with 40 CFR part 61, subpart FF—National Emission Standard for Benzene Waste Operations. This definition does not include POTW treating waste streams not specifically regulated under another NESHAP.

*Group 2 POTW* means a POTW that does not meet the definition of a Group 1 POTW. A Group 2 POTW can treat a waste stream that is either:

(1) Not specifically regulated by another NESHAP, or

(2) From an industrial user that complies with the specific wastewater requirements in their applicable NESHAP prior to discharging the waste stream to the POTW.

*Industrial user* means a nondomestic source introducing any pollutant or combination of pollutants into a POTW. Industrial users can be commercial or industrial facilities whose wastes enter local sewers.

*New source or new POTW* means any POTW that commenced construction or reconstruction after December 1, 1998.

*Publicly owned treatment works (POTW)* means a treatment works, as that term is defined by section 112(e)(5) of the Clean Air Act, which is owned by a municipality (as defined by section 502(4) of the Clean Water Act), a state, an intermunicipal or interstate agency, or any department, agency, or instrumentality of the federal government. This definition includes any intercepting sewers, outfall sewers, sewage collection systems, pumping, power, and other equipment. The wastewater treated by these facilities is generated by industrial, commercial, and domestic sources. As used in this subpart, the term POTW refers to both any publicly owned treatment works which is owned by a state, municipality, or intermunicipal or interstate agency and, therefore, eligible to receive grant assistance under the Subchapter II of the Clean Water Act, and any federally owned treatment works as that term is described in section 3023 of the Solid Waste Disposal Act.

*POTW treatment plant* means that portion of the POTW which is designed to provide treatment (including recycling and reclamation) of municipal sewage and industrial waste.

*Secondary treatment* means treatment processes, typically biological, designed to reduce the concentrations of dissolved and colloidal organic matter in wastewater.

*Waste and wastewater* means a material, or spent or used water or waste, generated from residential, industrial, commercial, mining, or agricultural operations or from community activities that contain dissolved or suspended matter, and that is discarded, discharged, or is being accumulated, stored, or physically, chemically, thermally, or biologically treated in a publicly owned treatment works.

TABLE 1 TO SUBPART VVV OF PART 63—APPLICABILITY OF 40 CFR PART 63 GENERAL PROVISIONS TO SUBPART VVV

| General provisions reference | Applicable to subpart VVV | Explanation |
|---|---|---|
| § 63.1 | | Applicability. |
| § 63.1(a)(1) | Yes | Terms defined in the Clean Air Act. |
| § 63.1(a)(2) | Yes | General applicability explanation. |
| § 63.1(a)(3) | Yes | Cannot diminish a stricter NESHAP. |

TABLE 1 TO SUBPART VVV OF PART 63—APPLICABILITY OF 40 CFR PART 63 GENERAL PROVISIONS TO SUBPART VVV—Continued

| General provisions reference | Applicable to subpart VVV | Explanation |
|---|---|---|
| § 63.1(a)(4) | Yes | Not repetitive. Doesn't apply to section 112(r). |
| § 63.1(a)(5) | Yes | Section reserved. |
| § 63.1(a)(6)–(8) | Yes | Contacts and authorities. |
| § 63.1(a)(9) | Yes | Section reserved. |
| § 63.1(a)(10) | Yes | Time period definition. |
| § 63.1(a)(11) | Yes | Postmark explanation. |
| § 63.1(a)(12)–(14) | Yes | Time period changes. Regulation conflict. Force and effect of subpart A. |
| § 63.1(b)(1) | Yes | Initial applicability determination of subpart A. |
| § 63.1(b)(2) | Yes | Section reserved. |
| § 63.1(b)(3) | No | Subpart VVV specifies recordkeeping of records of applicability determination. |
| § 63.1(c)(1) | Yes | Requires compliance with both subparts A and subpart VVV. |
| § 63.1(c)(2)(i) | No | State options regarding title V permit. Unless required by the State, area sources subject to subpart VVV are exempted from permitting requirements. |
| § 63.1(c)(2)(ii)–(iii) | No | State options regarding title V permit. |
| § 63.1(c)(3) | Yes | Section reserved. |
| § 63.1(c)(4) | Yes | Extension of compliance. |
| § 63.1(c)(5) | No | Subpart VVV addresses area sources becoming major due to increase in emissions. |
| § 63.1(d) | Yes | Section reserved. |
| § 63.1(e) | Yes | Title V permit before a relevant standard is established. |
| § 63.2 | Yes | Definitions. |
| § 63.3 | Yes | Units and abbreviations. |
| § 63.4 | | Prohibited activities and circumvention. |
| § 63.4(a)(1)–(3) | Yes | Prohibits operation in violation of subpart A. |
| § 63.4(a)(4) | Yes | Section reserved. |
| § 63.4(a)(5) | Yes | Compliance dates. |
| § 63.4(b) | Yes | Circumvention. |
| § 63.4(c) | Yes | Severability. |
| § 63.5 | | Preconstruction review and notification requirements. |
| § 63.5(a)(1) | Yes | Construction and reconstruction. |
| § 63.5(a)(2) | Yes | New source—effective dates. |
| § 63.5(b)(1) | Yes | New sources subject to relevant standards. |
| § 63.5(b)(2) | Yes | Section reserved. |
| § 63.5(b)(3) | Yes | No new major sources without Administrator approval. |
| § 63.5(b)(4) | Yes | New major source notification. |
| § 63.5(b)(5) | Yes | New major sources must comply. |
| § 63.5(b)(6) | Yes | New equipment added considered part of major source. |
| § 63.5(c) | Yes | Section reserved. |
| § 63.5(d)(1) | Yes | Implementation of section 112(l)(2)—application of approval of new source construction. |
| § 63.5(d)(2) | Yes | Application for approval of construction for new sources listing and describing planned air pollution control system. |
| § 63.5(d)(3) | Yes | Application for reconstruction. |
| § 63.5(d)(4) | Yes | Administrator may request additional information. |
| § 63.5(e) | Yes | Approval of reconstruction. |
| § 63.5(f)(1) | Yes | Approval based on State review. |
| § 63.5(f)(2) | Yes | Application deadline. |
| § 63.6 | | Compliance with standards and maintenance requirements. |
| § 63.6(a) | Yes | Applicability of compliance with standards and maintenance requirements. |
| § 63.6(b) | Yes | Compliance dates for new and reconstructed sources. |
| § 63.6(c) | Yes | Compliance dates for existing sources apply to existing Group 1 POTW treatment plants. |
| § 63.6(d) | Yes | Section reserved. |
| § 63.6(e) | Yes, except as noted below | Operation and maintenance requirements apply to new sources. |
| § 63.6(e)(1)(i) | No | General duty; See § 63.1583(d) and § 63.1586(d) for general duty requirements. |
| § 63.6(e)(1)(ii) | No | Requirement to correct malfunctions. |
| § 63.6(e)(3) | No | SSM plans are not required for POTW. |
| § 63.6(f) | Yes, except as noted below | Compliance with non-opacity emission standards applies to new sources. |
| § 63.6(f)(1) | No | The POTW standards apply at all times. |
| § 63.6(g) | Yes | Use of alternative non-opacity emission standards applies to new sources. |
| § 63.6(h) | No | POTW treatment plants do not typically have visible emissions. |
| § 63.6(i) | Yes | Extension of compliance with emission standards applies to new sources. |
| § 63.6(j) | Yes | Presidential exemption from compliance with emission standards. |
| § 63.7 | | Performance testing requirements. |
| § 63.7(a) | Yes | Performance testing is required for new sources. |
| § 63.7(b) | Yes | New sources must notify the Administrator of intention to conduct performance testing. |
| § 63.7(c) | Yes | New sources must comply with quality assurance program requirements. |
| § 63.7(d) | Yes | New sources must provide performance testing facilities at the request of the Administrator. |
| § 63.7(e) | Yes, except as noted below | Requirements for conducting performance tests apply to new sources. |
| § 63.7(e)(1) | No | The performance testing provisions of § 63.694 for control devices are incorporated by reference into subpart DD of this part. |

TABLE 1 TO SUBPART VVV OF PART 63—APPLICABILITY OF 40 CFR PART 63 GENERAL PROVISIONS TO SUBPART VVV—Continued

| General provisions reference | Applicable to subpart VVV | Explanation |
|---|---|---|
| § 63.7(f) | Yes | New sources may use an alternative test method. |
| § 63.7(g) | Yes | Requirements for data analysis, recordkeeping, and reporting associated with performance testing apply to new sources. |
| § 63.7(h) | Yes | New sources may request a waiver of performance tests. |
| § 63.8 | | Monitoring requirements. |
| § 63.8(a) | Yes | Applicability of monitoring requirements. |
| § 63.8(b) | Yes | Monitoring shall be conducted by new sources. |
| § 63.8(c) | Yes, except as noted below | New sources shall operate and maintain continuous monitoring systems (CMS). |
| § 63.8(c)(1)(i) | No | See § 63.1583(d) for general duty requirement with respect to minimizing emissions and continuous monitoring requirements. |
| § 63.8(c)(1)(iii) | No | See the applicable CMS quality control requirements under § 63.8(c) and (d). |
| § 63.8(d) | Yes, except as noted below | New sources must develop and implement a CMS quality control program. |
| § 63.8(d)(3) | No | The owner or operator must keep these written procedures on record for the life of the affected source or until the affected source is no longer subject to the provisions of this part, and make them available for inspection, upon request, by the Administrator. If the performance evaluation plan is revised, the owner or operator must keep previous (*i.e.,* superseded) versions of the performance evaluation plan on record to be made available for inspection, upon request, by the Administrator, for a period of 5 years after each revision of the plan. The program of corrective action should be included in the plan required under § 63.8(d)(2). |
| § 63.8(e) | Yes | New sources may be required to conduct a performance evaluation of CMS. |
| § 63.8(f) | Yes | New sources may use an alternative monitoring method. |
| § 63.8(g) | Yes | Requirements for reduction of monitoring data. |
| § 63.9 | | Notification requirements. |
| § 63.9(a) | Yes | Applicability of notification requirements. |
| § 63.9(b) | Yes, except as noted below | Initial notification due February 23, 2000 or 60 days after becoming subject to this subpart. |
| § 63.9(c) | Yes | Request for extension of compliance with subpart VVV. |
| § 63.9(d) | Yes | Notification that source is subject to special compliance requirements as specified in § 63.6(b)(3) and (4). |
| § 63.9(e) | Yes | Notification of performance test. |
| § 63.9(f) | No | POTW treatment plants do not typically have visible emissions. |
| § 63.9(g) | Yes | Additional notification requirements for sources with continuous emission monitoring systems. |
| § 63.9(h) | Yes, except as noted | Notification of compliance status when the source becomes subject to subpart VVV. See exceptions in § 63.1591(b). |
| § 63.9(i) | Yes | Adjustments to time periods or postmark deadlines or submittal and review of required communications. |
| § 63.9(j) | Yes | Change of information already provided to the Administrator. |
| § 63.10 | | Recordkeeping and reporting requirements. |
| § 63.10(a) | Yes | Applicability of notification and reporting requirements. |
| § 63.10(b)(1)–(2) | Yes, except as noted below | General recordkeeping requirements. |
| § 63.10(b)(2)(i) | No | Recordkeeping for occurrence and duration of startup and shutdown. |
| § 63.10(b)(2)(ii) | No | Recordkeeping for failure to meet a standard, see § 63.696. |
| § 63.10(b)(2)(iii) | Yes | Maintenance records. |
| § 63.10(b)(2)(iv) | No | Actions taken to minimize emissions during SSM. |
| § 63.10(b)(2)(v) | No | Action taken to minimize emissions during SSM. |
| § 63.10(b)(2)(vi) | Yes | Recordkeeping for CMS malfunctions. |
| § 63.10(b)(2)(vii)–(ix) | Yes | Other CMS requirements. |
| § 63.10(b)(3) | No | Recording requirement for applicability determination. |
| § 63.10(c) | Yes, except as noted below | Additional recordkeeping requirements for sources with continuous monitoring systems. |
| § 63.10(c)(7) | No | See § 63.696(h) for recordkeeping of (1) date, time, and duration; (2) listing of affected source or equipment, and an estimate of the tons per year of each regulated pollutant emitted over the standard; and (3) actions to minimize emissions and correct the failure. |
| § 63.10(c)(8) | No | See § 63.696(h) for recordkeeping of (1) date, time, and duration; (2) listing of affected source or equipment, and an estimate of the tons per year of each regulated pollutant emitted over the standard; and (3) actions to minimize emissions and correct the failure. |
| § 63.10(c)(15) | No | Use of SSM plan. |
| § 63.10(d) | Yes, except as noted below | General reporting requirements. |
| § 63.10(d)(5) | No | See § 63.697(b) for malfunction reporting requirements. |
| § 63.10(e) | Yes | Additional reporting requirements for sources with continuous monitoring systems. |
| § 63.10(f) | Yes, except as noted | Waiver of recordkeeping and reporting requirements. Electronic reporting to the EPA cannot be waived. |
| § 63.11 | Yes | Control device and equipment leak work practice requirements. |
| § 63.11(a) and (b) | Yes | If a new source uses flares to comply with the requirements of subpart VVV, the requirements of § 63.11 apply. |
| § 63.11(c), (d) and (e). | Yes | Alternative work practice for equipment leaks. |

TABLE 1 TO SUBPART VVV OF PART 63—APPLICABILITY OF 40 CFR PART 63 GENERAL PROVISIONS TO SUBPART VVV—Continued

| General provisions reference | Applicable to subpart VVV | Explanation |
|---|---|---|
| § 63.12 | Yes | State authority and designation. |
| § 63.13 | Yes | Addresses of State air pollution control agencies and EPA Regional Offices. |
| § 63.14 | Yes | Incorporation by reference. |
| § 63.15 | Yes | Availability of information and confidentiality. |

TABLE 2 TO SUBPART VVV OF PART 63—COMPLIANCE DATES AND REQUIREMENTS

| If the construction/reconstruction date is | Then the owner or operator must comply with | And the owner or operator must achieve compliance |
|---|---|---|
| Group 1 POTW: | | |
| (1) After December 27, 2016 | (i) New source requirements in §§ 63.1583(b); 63.1586(b) or (c); and 63.1588 through 63.1591. | Upon initial startup. |
| (2) After December 1, 1998 but on or before December 27, 2016. | (i) New source requirements in § 63.1583(b) but instead of complying with both requirements (industrial user(s) NESHAP and the POTW standards in §§ 63.1586(b) or (c)), you must comply with the most stringent requirement[1]. | Upon initial startup through October 26, 2020. |
| | (ii) New source requirements in §§ 63.1586(b) or (c); and 63.1588 through 63.1591. | On or before October 26, 2020. |
| (3) On or before December 1, 1998 | (i) Existing source requirements in §§ 63.1583(a) | By the compliance date specified in the other applicable NESHAP. |
| | (ii) Existing source requirements in §§ 63.1588 through 63.1591 | On or before October 26, 2018. |
| Group 2 POTW: | | |
| (4) After December 27, 2016 | (i) New source requirements in §§ 63.1586(b) or (c); and 63.1588 through 63.1591. | Upon initial startup. |
| (5) After December 1, 1998 but on or before December 27, 2016. | (i) New source requirements in § 63.1586(b) or (c)[1] | Upon initial startup through October 26, 2020. |
| | (ii) New source requirements in §§ 63.1586(b) or (c); and 63.1588 through 63.1591. | On or before October 26, 2020. |
| (6) On or before December 1, 1998 | (i) Existing source requirements in §§ 63.1586(a); and 63.1591(a) | On or before October 26, 2018. |

[1] Note: This represents the new source requirements in the original 1999 NESHAP, which are applicable until October 26, 2020. Between October 26, 2017 and October 26, 2020, you must transition to the new requirements in Table 2 (2)(ii) and (5)(ii) for Group 1 and Group 2 POTW, respectively.

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 261

**[EPA–R06–RCRA–2017–0153; SW–FRL–9969–73–Region 6]**

### Hazardous Waste Management System; Identification and Listing of Hazardous Waste

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** The Environmental Protection Agency (EPA) is granting a petition submitted by ExxonMobil Oil Corporation Beaumont Refinery (ExxonMobil) to exclude from hazardous waste control (or delist) a certain solid waste. This final rule responds to the petition submitted by ExxonMobil to have the secondary impoundment basin (SIB) solids excluded, or delisted from the definition of a hazardous waste. The SIB solids are listed as F037 (primary oil/water/solids separation sludge); and F038 (secondary oil/water/solids separation sludge).

After careful analysis and evaluation of comments submitted by the public, the EPA has concluded that the petitioned wastes are not hazardous waste when disposed of in Subtitle D landfills. This exclusion applies to the surface impoundment solids generated at ExxonMobil's Beaumont, Texas facility. Accordingly, this final rule excludes the petitioned waste from the requirements of hazardous waste regulations under the Resource Conservation and Recovery Act (RCRA) when disposed of in Subtitle D landfills but imposes testing conditions to ensure that the future-generated wastes remain qualified for delisting.

**DATES:** Effective October 26, 2017.

**ADDRESSES:** The EPA has established a docket for this action under Docket ID No. EPA–R06–RCRA–2017–0153. All documents in the docket are listed on the *http://www.regulations.gov* Web site. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available electronically through *http://www.regulations.gov.*

**FOR FURTHER INFORMATION CONTACT:** For technical information regarding the ExxonMobil Beaumont Refinery petition, contact Michelle Peace at 214–665–7430 or by email at *peace.michelle@epa.gov.*

**SUPPLEMENTARY INFORMATION:** The information in this section is organized as follows:

## I. Overview Information

*A. What action is EPA finalizing?*

The EPA is finalizing:

(1) The decision to grant ExxonMobil's Beaumont Refinery's petition to have its surface impoundment basin solids excluded, or delisted, from the definition of a hazardous waste, subject to certain continued verification and monitoring conditions; and

(2) to use the Delisting Risk Assessment Software to evaluate the potential impact of the petitioned waste on human health and the environment. The Agency used this model to predict the concentration of hazardous constituents released from the petitioned waste, once it is disposed.

After evaluating the petition, EPA proposed rule, on May 31, 2017, to exclude the ExxonMobil Beaumont Refinery waste from the lists of hazardous wastes under §§ 261.31 and 261.32. The comments received on this rulemaking will be addressed as part of this decision.

*B. Why is EPA approving this delisting?*

ExxonMobil's petition requests an exclusion from the F037 and F038 waste listings pursuant to 40 CFR 260.20 and 260.22. ExxonMobil does not believe that the petitioned waste meets the criteria for which EPA listed it. ExxonMobil also believes no additional constituents or factors could cause the waste to be hazardous. EPA's review of this petition included consideration of the original listing criteria and the additional factors required by the Hazardous and Solid Waste Amendments of 1984 (HSWA). See section 3001(f) of RCRA, 42 U.S.C. 6921(f), and 40 CFR 260.22 (d)(1)–(4) (hereinafter, all sectional references are to 40 CFR unless otherwise indicated). In making the initial delisting determination, EPA evaluated the petitioned waste against the listing criteria and factors cited in §§ 261.11(a)(2) and (a)(3). Based on this review, EPA agrees with the petitioner that the waste is non-hazardous with respect to the original listing criteria. If EPA had found, based on this review, that the waste remained hazardous based on the factors for which the waste was originally listed, EPA would have proposed to deny the petition. EPA evaluated the waste with respect to other factors or criteria to assess whether there is a reasonable basis to believe that such additional factors could cause the waste to be hazardous. EPA considered whether the waste is acutely toxic, the concentration of the constituents in the waste, their tendency to migrate and to bioaccumulate, their persistence in the environment once released from the waste, plausible and specific types of management of the petitioned waste, the quantities of waste generated, and waste variability. EPA believes that the petitioned waste does not meet the listing criteria and thus should not be a listed waste. EPA's proposed decision to delist waste from ExxonMobil is based on the information submitted in support of this rule, including descriptions of the wastes and analytical data from the Beaumont, Texas facility.

*C. What are the limits of this exclusion?*

This exclusion applies to the waste described in the petition only if the requirements described in Table 1 of part 261, Appendix IX, and the conditions contained herein are satisfied. The one-time exclusion applies to 400,000 cubic yards of surface impoundment basin solids.

*D. How will Beaumont Refinery manage the waste if it is delisted?*

Storage containers with SIB solids will be transported to an authorized solid waste landfill (*e.g.* RCRA Subtitle D landfill, commercial/industrial solid waste landfill, etc.) for disposal.

*E. When is the final delisting exclusion effective?*

This rule is effective October 26, 2017. The Hazardous and Solid Waste Amendments of 1984 amended Section 3010 of RCRA to allow rules to become effective in less than six months when the regulated community does not need the six-month period to come into compliance. That is the case here because this rule reduces, rather than increases, the existing requirements for persons generating hazardous wastes. These reasons also provide a basis for making this rule effective immediately, upon publication, under the Administrative Procedure Act, pursuant to 5 U.S.C. 553(d).

*F. How does this final rule affect states?*

Because EPA is issuing this exclusion under the Federal RCRA delisting program, only states subject to Federal RCRA delisting provisions would be affected. This would exclude two categories of States: States having a dual system that includes Federal RCRA requirements and their own requirements, and States who have received our authorization to make their own delisting decisions.

*Here are the details:* We allow states to impose their own non-RCRA regulatory requirements that are more stringent than EPA's, under section 3009 of RCRA. These more stringent requirements may include a provision that prohibits a Federally issued exclusion from taking effect in the State. Because a dual system (that is, both Federal (RCRA) and State (non-RCRA) programs) may regulate a petitioner's waste, we urge petitioners to contact the State regulatory authority to establish the status of their wastes under the State law.

EPA has also authorized some States (for example, Louisiana, Georgia, Illinois) to administer a delisting program in place of the Federal program, that is, to make State delisting decisions. Therefore, this exclusion does not apply in those authorized States. If Beaumont Refinery transports the petitioned waste to or manages the waste in any State with delisting authorization, Beaumont Refinery must obtain delisting authorization from that State before they can manage the waste as nonhazardous in the State.

## II. Background

*A. What is a delisting?*

A delisting petition is a request from a generator to EPA or another agency with jurisdiction to exclude from the list of hazardous wastes, wastes the generator does not consider hazardous under RCRA.

*B. What regulations allow facilities to delist a waste?*

Under 40 CFR 260.20 and 260.22, facilities may petition the EPA to remove their wastes from hazardous waste control by excluding them from the lists of hazardous wastes contained in §§ 261.31 and 261.32. Specifically, § 260.20 allows any person to petition the Administrator to modify or revoke any provision of Parts 260 through 266, 268 and 273 of Title 40 of the Code of Federal Regulations. Section 260.22 provides generators the opportunity to petition the Administrator to exclude a waste on a ''generator-specific'' basis from the hazardous waste lists.

*C. What information must the generator supply?*

Petitioners must provide sufficient information to EPA to allow the EPA to

determine that the waste to be excluded does not meet any of the criteria under which the waste was listed as a hazardous waste. In addition, the Administrator must determine, where he/she has a reasonable basis to believe that factors (including additional constituents) other than those for which the waste was listed could cause the waste to be a hazardous waste, that such factors do not warrant retaining the waste as a hazardous waste.

## III. EPA's Evaluation of the Waste Data

### *A. What waste and how much did Beaumont Refinery petition EPA to delist?*

In August 2016, ExxonMobil petitioned EPA to exclude from the lists of hazardous wastes contained in §§ 261.31 and 261.32, SIB solids (F037, F038) generated from its facility located in Beaumont, Texas. The waste falls under the classification of listed waste pursuant to §§ 261.31 and 261.32. Specifically, in its petition, ExxonMobil requested that EPA grant a one-time exclusion for 400,000 cubic yards of SIB solids.

The 40 CFR part 261 Appendix VII hazardous constituents which are the basis for listing can be found in Table 1.

TABLE 1—EPA WASTE CODES FOR SURFACE IMPOUNDMENT BASIN SOLIDS AND THE BASIS FOR LISTING

| Waste code | Basis for listing |
|---|---|
| F037 | Benzene, benzo(a)pyrene, chrysene, lead, chromium. |
| F038 | Benzene, benzo(a)pyrene, chrysene, lead, chromium. |

### *B. How did Beaumont Refinery sample and analyze the waste data in this petition?*

To support its petition, ExxonMobil submitted:

(1) Historical information on waste generation and management practices; and

(2) analytical results from thirty-nine samples for total and TCLP concentrations of compounds of concern (COC)s;

TABLE 2—ANALYTICAL RESULTS/MAXIMUM ALLOWABLE DELISTING CONCENTRATION

[Secondary Impoundment Basin (SIB) Solids ExxonMobil Beaumont Refinery, Beaumont, Texas]

| Constituent | Maximum total concentration (mg/kg) | Maximum TCLP concentration (mg/L) | Maximum TCLP delisting level (mg/L) |
|---|---|---|---|
| Antimony | 4.84 | 0.023 | .109 |
| Arsenic | 33.6 | 0.077 | .424 |
| Barium | 455 | 1.47 | 36 |
| Beryllium | 1.38 | <0.002 | 2.0 |
| Cadmium | 2.05 | <0.002 | 0.09 |
| Chromium | 697 | 0.205 | 2.27 |
| Cobalt | 19.4 | 0.0371 | 0.214 |
| Lead | 400 | 0.656 | 0.702 |
| Mercury | 3.61 | 0.000049 | 0.068 |
| Nickel | 68.2 | 0.152 | 13.5 |
| Selenium | 28.7 | 0.0177 | 0.890 |
| Silver | 1.23 | 0.002 | 5.0 |
| Vanadium | 90.7 | 0.0815 | 3.77 |
| Zinc | 2,470 | 5.43 | 197 |
| 2,4 Dimethylphenol | 0.97 | 0.0018 | 11.3 |
| 2-Methylphenol | <0.71 | <.000033 | 28.9 |
| 3-Methylphenol | <0.64 | 0.002 | 28.9 |
| 4-Methylphenol | <0.64 | 0.00047 | 2.89 |
| Acenaphthene | 1.7 | 0.00091 | 10.6 |
| Anthracene | 2.9 | 0.00019 | 25.9 |
| Benz(a)anthracene | 7.2 | 0.000034 | 0.07 |
| Benz(a)pyrene | 5 | <0.00003 | 26.3 |
| Bis(2-ethylhexyl)phthalate | 34 | 0.0002 | 106,000 |
| Chrysene | 19 | 0.000048 | 7.01 |
| Di-n-butyl phthalate | 0.66 | 0.0013 | 24.6 |
| Fluoranthene | 2.1 | 0.000078 | 2.46 |
| Fluorene | 4.9 | 0.0016 | 4.91 |
| Indeno(1,2,3-cd)pyrene | 2.6 | <0.000051 | 73 |
| Naphthalene | 26 | 0.02 | 0.0327 |
| Phenol | <0.71 | 0.00025 | 173 |
| Pyrene | N/A | 0.00019 | 4.45 |
| Benzene | 1.1 | <0.004 | 0.077 |
| Xylenes, total | 53 | 0.18 | 9.56 |

**Notes:** These levels represent the highest constituent concentration found in any one sample and does not necessarily represent the specific level found in one sample.

## IV. Public Comments Received on the Proposed Exclusion

*A. Who submitted comments on the proposed rule?*

The EPA received four anonymous public comments on the May 31, 2017, proposed rule via *regulations.gov.* EPA also received comments from the facility regarding the conditions and nomenclature on Table 1. The comments and responses are addressed below.

*B. Comments and Responses*

*Comment 1.* ''Exxon Mobil requests that language found on Pages 24929, 24931, and 24932 be revised to reflect that the SIB solids are delisted upon final publication in the **Federal Register**. The text in Section IV (Next Steps), Items A.(2) and A.(3) is currently structured such that additional testing would have to be performed to verify that delisting limits are met. Items (2), (3), and (4) of Table 1 (Pages 24931 and 34932) also reflect these requirements. This language appears to be a ''holdover'' associated with another delisting petition request. Our sampling program included collection of over 30 samples to support the delisting petition request. As such, we believe we have already completed a rigorous sampling program in support of this request. Also, we would note in several locations that the petition volume is listed as ''400,000 wet'' cubic yards. The SIB solids will contain water upon removal from the pond. However, they will be dewatered (*e.g.* filtration, addition of cement, etc.) to pass the paint filter test prior to disposal. As such, we suggest removing the word wet in reference to the delisted volume.''

*Response 1.* The language found in Table 1 of the exclusion has been revised to remove all conditional exclusion language. The request for the delisting is a one-time exclusion which is conditioned on proper disposal of up to 400,000 cubic yards of SIB solids and contains the data submittals, reopener and disposal notification clauses for all delisting exclusions. The conditions were included in the proposed rule in error. All references regarding the wet solids have been removed because the waste will not be disposed of in this manner. The reference to wet solids was in regards to the volume of solids as generated during the removal.

*Comment 2.* ''Excuse me? ExxonMobile wants to dump their waste into the landfills where it can pollute our ground water? NO. Absolutely NOT. These waste products are toxic to the environment and need to stay listed as hazardous. We don't want this stuff seeping into our groundwater for our kids to drink. ExxonMobile needs to spend the money on research to break down this waste sludge into something that doesn't hurt the environment. They must not be allowed to put it in dumps or store it somewhere. There probably are some kind of bacteria that will break this stuff down into something useful or non toxic. This stuff should NOT end up in our ground water. If you cannot do something positive with this waste, the process whereby this waste is produced MUST BE STOPPED. We need to move away from fossil fuel use and towards renewable energy and sustainable products.''

*Response 2.* The Delisting Program requires extensive waste sampling and a risk assessment is performed to assess a wastes potential harm to human health and the environment. The program is designed to insure that the wastes which are deemed excluded will not be managed in a manner to harm human health or the environment. This waste will be managed in a Subtitle D industrial waste landfill as solid waste to prevent releases to groundwater and air pathways.

*Comment 3.* ''The EPA should feel obligated to ensure that there are no possible adverse effects to humans or the environment by approving the petition from ExxonMobile. The EPA should conduct their own investigation, take their own samples, and perform data analysis to confirm that there are no discrepancies between their findings and those provided by the Beaumont facility. In the list of constituents provided by ExxonMobile, there are known human carcinogens such as arsenic, beryllium, cadmium, chromium, nickel, and benzene, along with other harmful constituents such as lead and mercury. The EPA should conduct an environmental impact assessment before approving this petition.''

*Response 3.* The requirements of the Federal regulations defined in 40 CFR part 260.20, and 260.22, describe the process by which wastes may be removed from the list of hazardous waste. In addition to extensive quality assurance and quality control data for the samples taken, EPA performs a risk assessment using the Delisting Risk Assessment Software to ensure that our decision is protective of human health and the environment. The constituent concentrations found in the surface impoundment basin solids are below the concentrations that would pose harm to human health and the environment.

*Comment 4.* ''Although the tests that have been run by ExxonMobil's Delisting Risk Assessment Software (DRAS) to provide scientific reasoning to the EPA for the delisting of SIB solids, I believe that more research must be conducted by the EPA itself. Employees of this agency should especially check the individual components of the SIB solids and test for even greater possibilities than those proposed by the DRAS; the DRAS was not said to take into account the effects that chemical exposure would produce on surrounding populations or even employees themselves if buildups were to occur. Risk assessment should be issued for each individual chemical compound by the EPA. Assuming the EPA would like to work rather quickly on this issue considering ExxonMobil's insistence that the SIB solids are non-hazardous, benefits would include reduced regulation on the industry, as well as, one less responsibility for the EPA. However, closer examination needs to occur, especially since this test has only been conducted for Beaumont, Texas.''

*Response 4.* A waste is eligible for delisting only if that waste, as generated at a particular facility, does not meet any of the criteria under which the waste was listed as a hazardous waste. In addition, the waste may not contain any other Appendix VIII constituents that would cause the waste to be hazardous. RCRA § 3001(f) and 40 CFR 260.22. A delisting is only intended to address a specific waste stream generated at a specific site. The risk analysis is conducted specifically for each chemical constituent of the waste stream. If any constituent concentration exceeds the delisting limit, the entire waste stream remains hazardous.

The delisting risk analysis performed using the Delisting Risk Assessment Software evaluates the worst case scenario for the petitioned waste and risk pathways are evaluated. All chemical constituents detected in the waste are individually assessed for their impact on human health and the environment.

*Comment 5.* ''I believe there should be a thorough health examination of all employees in the facility who work directly with the waste proposed for delisting. Some of these chemicals can build-up in the system over time and if any de-regulations are to occur they need science based evidence to prove the decision would not pose a human safety issue. If the decision would not prove to have a high economical impact, I do not see any reason it should be considered, especially when the decision is for only a single site.''

*Response 5.* A waste is eligible for delisting only if that waste, as generated

at a particular facility, does not meet any of the criteria under which the waste was listed as a hazardous waste. In addition, the waste may not contain any other Appendix VIII constituents that would cause the waste to be hazardous. RCRA § 3001(f) and 40 CFR 260.22. A delisting is only intended to address a specific waste stream generated at a specific site. Since individual waste streams may vary depending on raw materials, industrial processes, and other factors, it may be appropriate not to list a specific waste from a specific site. Therefore, while a waste described in the regulations or resulting from the operation of the mixture or derived-from rules generally is hazardous, a specific waste from an individual facility may not be hazardous. For this reason, 40 CFR 260.20 and 260.22 provide an exclusion procedure, called delisting, which allows persons to prove that EPA should not regulate a specific waste from a particular generating facility as a hazardous waste. A risk assessment of the petitioned waste is completed and a part of the decision factors in issuing an exclusion. Specific health examinations and worker protection is covered by the facility operating plans and overseen by OSHA. Worker safety during the management of this waste to avoid contact with this material are covered by the Health and Safety plans of the petitioner.

**V. Statutory and Executive Order Reviews**

Under Executive Order 12866, ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993), this rule is not of general applicability and therefore, is not a regulatory action subject to review by the Office of Management and Budget (OMB). This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) because it applies to a particular facility only. Because this rule is of particular applicability relating to a particular facility, it is not subject to the regulatory flexibility provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), or to sections 202, 204, and 205 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). Because this rule will affect only a particular facility, it will not significantly or uniquely affect small governments, as specified in section 203 of UMRA. Because this rule will affect only a particular facility, this proposed rule does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, ''Federalism'', (64 FR 43255, August 10, 1999). Thus, Executive Order 13132 does not apply to this rule.

Similarly, because this rule will affect only a particular facility, this proposed rule does not have tribal implications, as specified in Executive Order 13175, ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000). Thus, Executive Order 13175 does not apply to this rule. This rule also is not subject to Executive Order 13045, ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), because it is not economically significant as defined in Executive Order 12866, and because the Agency does not have reason to believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. The basis for this belief is that the Agency used DRAS, which considers health and safety risks to children, to calculate the maximum allowable concentrations for this rule. This rule is not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355 (May 22, 2001)), because it is not a significant regulatory action under Executive Order 12866. This rule does not involve technical standards; thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. As required by section 3 of Executive Order 12988, ''Civil Justice Reform'', (61 FR 4729, February 7, 1996), in issuing this rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct.

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report which includes a copy of the rule to each House of the Congress and to the Comptroller General of the United States. Section 804 exempts from section 801 the following types of rules: (1) Rules of particular applicability; (2) rules relating to agency management or personnel; and (3) rules of agency organization, procedure, or practice that do not substantially affect the rights or obligations of non-agency parties (5 U.S.C. 804(3)). EPA is not required to submit a rule report regarding today's action under section 801 because this is a rule of particular applicability. Executive Order (E.O.) 12898 (59 FR 7629 (Feb. 16, 1994)) establishes Federal executive policy on environmental justice. Its main provision directs Federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA has determined that this proposed rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it does not affect the level of protection provided to human health or the environment. The Agency's risk assessment did not identify risks from management of this material in an authorized, solid waste landfill (*e.g.* RCRA Subtitle D landfill, commercial/industrial solid waste landfill, etc.). Therefore, EPA believes that any populations in proximity of the landfills used by this facility should not be adversely affected by common waste management practices for this delisted waste.

**Lists of Subjects in 40 CFR Part 261**

Environmental protection, Hazardous waste, Recycling, Reporting and recordkeeping requirements.

**Authority:** Sec. 3001(f) RCRA, 42 U.S.C. 6921(f).

Dated: October 4, 2017.

**Wren Stenger,**

*Director, Multimedia Division, Region 6.*

For the reasons set out in the preamble, 40 CFR part 261 is amended as follows:

## PART 261—IDENTIFICATION AND LISTING OF HAZARDOUS WASTE

■ 1. The authority citation for part 261 continues to read as follows:

**Authority:** 42 U.S.C. 6905, 6912(a), 6921, 6922, and 6938.

■ 2. In Table 1—Wastes Excluded From Non-Specific Sources in Appendix IX to Part 261, add the following waste stream in alphabetical order by facility to read as follows:

**Appendix IX to Part 261—Waste Excluded Under §§ 260.20 and 260.22**

TABLE 1—WASTES EXCLUDED FROM NON-SPECIFIC SOURCES

| Facility | Address | Waste description |
|---|---|---|
| * | * | * * * * * |
| ExxonMobil ..... | Beaumont, TX ..... | Secondary Impoundment Basin Solids (SIB) (EPA Hazardous Waste Numbers F037 and F038) generated at a maximum rate of 400,000 cubic yards.<br>(1) Delisting Levels: All concentrations for those constituents must not exceed the maximum allowable concentrations in mg/l specified in this paragraph.<br>Surface Impoundment Basin Solids. Leachable Concentrations (mg/l): Antimony—0.109; Arsenic—0.424; Barium—36; Beryllium—2.0; Cadmium—0.09; Chromium—2.27; Cobalt—0.214; Lead—0.702; Mercury—0.068; Nickel—13.5; Selenium—0.890; Silver—5.0; Vanadium—3.77; Zinc—197; 2,4 Dimethylphenol—11.3; 2-Methylphenol—28.9; 3-Methylphenol—28.9; 4-Methylphenol—2.89; Acenaphthene—10.6; Anthracene-—25.9; Benz(a)anthracene—0.07; Benz(a)pyrene—26.3; Bis(2-ethylhexyl) phthalate—106,000; Chrysene—7.01; Di-n-butyl phthalate—24.6; Fluoranthene—2.46; Fluorene—4.91; Indeno(1,2,3-cd) pyrene—73; Naphthalene—0.0327; Phenol—173; Pyrene—4.45; Benzene—0.077; Xylenes, total—9.56<br>(2) Reopener<br>(A) If, any time after disposal of the delisted waste ExxonMobil possesses or is otherwise made aware of any environmental data (including but not limited to underflow water data or ground water monitoring data) or any other data relevant to the delisted waste indicating that any constituent identified for the delisting verification testing is at level higher than the delisting level allowed by the Division Director in granting the petition, then the facility must report the data, in writing, to the Division Director within 10 days of first possessing or being made aware of that data.<br>(B) If verification testing (and retest, if applicable) of the waste does not meet the delisting requirements in paragraph 1, ExxonMobil must report the data, in writing, to the Division Director within 10 days of first possessing or being made aware of that data.<br>(C) If ExxonMobil fails to submit the information described in paragraphs (2),(3)(A) or (3)(B) or if any other information is received from any source, the Division Director will make a preliminary determination as to whether the reported information requires EPA action to protect human health and/or the environment. Further action may include suspending, or revoking the exclusion, or other appropriate response necessary to protect human health and the environment.<br>(D) If the Division Director determines that the reported information requires action by EPA, the Division Director will notify the facility in writing of the actions the Division Director believes are necessary to protect human health and the environment. The notice shall include a statement of the proposed action and a statement providing the facility with an opportunity to present information as to why the proposed EPA action is not necessary. The facility shall have 10 days from receipt of the Division Director's notice to present such information.<br>(E) Following the receipt of information from the facility described in paragraph (3)(D) or (if no information is presented under paragraph (3)(D)) the initial receipt of information described in paragraphs (2), (3)(A) or (3)(B), the Division Director will issue a final written determination describing EPA actions that are necessary to protect human health and/or the environment. Any required action described in the Division Director's determination shall become effective immediately, unless the Division Director provides otherwise.<br>(3) Notification Requirements:<br>ExxonMobil must do the following before transporting the delisted waste. Failure to provide this notification will result in a violation of the delisting petition and a possible revocation of the decision.<br>(A) Provide a one-time written notification to any state Regulatory Agency to which or through which it will transport the delisted waste described above for disposal, 60 days before beginning such activities.<br>(B) For onsite disposal, a notice should be submitted to the State to notify the State that disposal of the delisted materials has begun.<br>(C) Update one-time written notification, if it ships the delisted waste into a different disposal facility.<br>(D) Failure to provide this notification will result in a violation of the delisting exclusion and a possible revocation of the decision. |
| * | * | * * * * * |

[FR Doc. 2017–23239 Filed 10–25–17; 8:45 am]

**BILLING CODE 6560–50–P**

**DEPARTMENT OF COMMERCE**

**National Oceanic and Atmospheric Administration**

**50 CFR Part 679**

**[Docket No. 161020985–7181–02]**

**RIN 0648–XF767**

## Fisheries of the Exclusive Economic Zone Off Alaska; Exchange of Flatfish in the Bering Sea and Aleutian Islands Management Area

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Temporary rule; reallocation.

**SUMMARY:** NMFS is exchanging unused flathead sole and rock sole Community Development Quota (CDQ) for yellowfin sole CDQ acceptable biological catch (ABC) reserves in the Bering Sea and Aleutian Islands management area. This action is necessary to allow the 2017 total allowable catch of yellowfin sole in the Bering Sea and Aleutian Islands management area to be harvested.

**DATES:** Effective October 26, 2017 through December 31, 2017.

**FOR FURTHER INFORMATION CONTACT:** Steve Whitney, 907–586–7228.

**SUPPLEMENTARY INFORMATION:** NMFS manages the groundfish fishery in the Bering Sea and Aleutian Islands management area (BSAI) according to the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The 2017 flathead sole, rock sole, and yellowfin sole CDQ reserves specified in the BSAI are 1,288 metric tons (mt), 5,310 mt, and 16,472 mt as established by the final 2017 and 2018 harvest specifications for groundfish in the BSAI (82 FR 11826, February 27, 2017) and revised by flatfish exchange (82 FR 48460; October 18, 2017). The 2017 flathead sole, rock sole, and yellowfin sole CDQ ABC reserves are 6,018 mt, 11,286 mt and 11,434 mt as established by the final 2017 and 2018 harvest specifications for groundfish in the BSAI (82 FR 11826, February 27, 2017) and revised by flatfish exchange (82 FR 48460; October 18, 2017).

The Yukon Delta Fisheries Development Association has requested that NMFS exchange 60 mt of flathead sole CDQ reserves and 145 mt of rock sole CDQ reserves for 205 mt of yellowfin sole CDQ ABC reserves under § 679.31(d). Therefore, in accordance with § 679.31(d), NMFS exchanges 60 mt of flathead sole CDQ reserves and 145 mt of rock sole CDQ reserves for 205 mt of yellowfin sole CDQ ABC reserves in the BSAI. This action also decreases and increases the TACs and CDQ ABC reserves by the corresponding amounts. Tables 11 and 13 of the final 2017 and 2018 harvest specifications for groundfish in the BSAI (82 FR 11826, February 27, 2017), and revised by flatfish exchange (82 FR 48460; October 18, 2017) are further revised as follows:

TABLE 11—FINAL 2017 COMMUNITY DEVELOPMENT QUOTA (CDQ) RESERVES, INCIDENTAL CATCH AMOUNTS (ICAS), AND AMENDMENT 80 ALLOCATIONS OF THE ALEUTIAN ISLANDS PACIFIC OCEAN PERCH, AND BSAI FLATHEAD SOLE, ROCK SOLE, AND YELLOWFIN SOLE TACS

[Amounts are in metric tons]

| Sector | Pacific ocean perch | | | Flathead sole | Rock sole | Yellowfin sole |
|---|---|---|---|---|---|---|
| | Eastern Aleutian district | Central Aleutian district | Western Aleutian district | BSAI | BSAI | BSAI |
| TAC | 7,900 | 7,000 | 9,000 | 14,176 | 47,225 | 154,199 |
| CDQ | 845 | 749 | 963 | 1,228 | 5,165 | 16,677 |
| ICA | 100 | 60 | 10 | 4,000 | 5,000 | 4,500 |
| BSAI trawl limited access | 695 | 619 | 161 | 0 | 0 | 18,151 |
| Amendment 80 | 6,259 | 5,572 | 7,866 | 8,949 | 37,060 | 114,871 |
| Alaska Groundfish Cooperative | 3,319 | 2,954 | 4,171 | 918 | 9,168 | 45,638 |
| Alaska Seafood Cooperative | 2,940 | 2,617 | 3,695 | 8,031 | 27,893 | 69,233 |

**Note:** Sector apportionments may not total precisely due to rounding.

TABLE 13—FINAL 2017 AND 2018 ABC SURPLUS,COMMUNITY DEVELOPMENT QUOTA (CDQ) ABC RESERVES, AND AMENDMENT 80 ABC RESERVES IN THE BSAI FOR FLATHEAD SOLE, ROCK SOLE, AND YELLOWFIN SOLE

[Amounts are in metric tons]

| Sector | 2017 Flathead sole | 2017 Rock sole | 2017 Yellowfin sole | 2018 Flathead sole | 2018 Rock sole | 2018 Yellowfin sole |
|---|---|---|---|---|---|---|
| ABC | 68,278 | 155,100 | 260,800 | 66,164 | 143,100 | 250,800 |
| TAC | 14,176 | 47,225 | 154,199 | 14,500 | 47,100 | 154,000 |
| ABC surplus | 54,102 | 107,875 | 106,601 | 51,664 | 96,000 | 96,800 |
| ABC reserve | 54,102 | 107,875 | 106,601 | 51,664 | 96,000 | 96,800 |
| CDQ ABC reserve | 6,078 | 11,431 | 11,229 | 5,528 | 10,272 | 10,358 |
| Amendment 80 ABC reserve | 48,024 | 96,444 | 95,372 | 46,136 | 85,728 | 86,442 |
| Alaska Groundfish Cooperative for 2017 [1] | 4,926 | 23,857 | 37,891 | n/a | n/a | n/a |
| Alaska Seafood Cooperative for 2017 [1] | 43,098 | 72,587 | 57,481 | n/a | n/a | n/a |

[1] The 2018 allocations for Amendment 80 species between Amendment 80 cooperatives and the Amendment 80 limited access sector will not be known until eligible participants apply for participation in the program by November 1, 2017.

**Classification**

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the flatfish exchange by the Yukon Delta Fisheries Development Association in the BSAI. Since these fisheries are currently open, it is important to immediately inform the industry as to the revised allocations. Immediate notification is necessary to allow for the orderly conduct and efficient operation of this fishery, to allow the industry to plan for the fishing season, and to avoid potential disruption to the fishing fleet as well as processors. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of October 11, 2017.

The AA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

This action is required by § 679.20 and is exempt from review under Executive Order 12866.

**Authority:** 16 U.S.C. 1801 *et seq.*

Dated: October 23, 2017.

**Emily H. Menashes,**

*Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.*

[FR Doc. 2017–23340 Filed 10–25–17; 8:45 am]

**BILLING CODE 3510–22–P**

# Proposed Rules

Federal Register
Vol. 82, No. 206
Thursday, October 26, 2017

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

## DEPARTMENT OF ENERGY

## Federal Energy Regulatory Commission

## 18 CFR Part 40

**[Docket No. RM17–11–000]**

## Revised Critical Infrastructure Protection Reliability Standard CIP–003–7—Cyber Security—Security Management Controls

**AGENCY:** Federal Energy Regulatory Commission, DOE.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Federal Energy Regulatory Commission (Commission) proposes to approve Critical Infrastructure Protection (CIP) Reliability Standard CIP–003–7 (Cyber Security—Security Management Controls), submitted by the North American Electric Reliability Corporation (NERC). Proposed Reliability Standard CIP–003–7 improves upon the current Commission-approved CIP Reliability Standards by clarifying the obligations pertaining to electronic access control for low impact BES Cyber Systems; adopting mandatory security controls for transient electronic devices (*e.g.,* thumb drives, laptop computers, and other portable devices frequently connected to and disconnected from systems) used at low impact BES Cyber Systems; and requiring responsible entities to have a policy for declaring and responding to CIP Exceptional Circumstances related to low impact BES Cyber Systems. In addition, the Commission proposes to direct NERC to develop certain modifications to the NERC Reliability Standards to provide clear, objective criteria for electronic access controls for low impact BES Cyber Systems; and address the need to mitigate the risk of malicious code that could result from third-party transient electronic devices.

**DATES:** Comments are due December 26, 2017.

**ADDRESSES:** Comments, identified by docket number, may be filed in the following ways:

- *Electronic Filing through http://www.ferc.gov.* Documents created electronically using word processing software should be filed in native applications or print-to-PDF format and not in a scanned format.
- *Mail/Hand Delivery:* Those unable to file electronically may mail or hand-deliver comments to: Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE., Washington, DC 20426.

*Instructions:* For detailed instructions on submitting comments and additional information on the rulemaking process, see the Comment Procedures section of this document.

**FOR FURTHER INFORMATION CONTACT:** Matthew Dale (Technical Information), Office of Electric Reliability, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, (202) 502–6826, *matthew.dale@ferc.gov*, Kevin Ryan (Legal Information), Office of the General Counsel, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, (202) 502–6840, *kevin.ryan@ferc.gov.*

**SUPPLEMENTARY INFORMATION:**

1. Pursuant to section 215 of the Federal Power Act (FPA),[1] the Commission proposes to approve Critical Infrastructure Protection (CIP) Reliability Standard CIP–003–7 (Cyber Security—Security Management Controls). The North American Electric Reliability Corporation (NERC), the Commission-certified Electric Reliability Organization (ERO), submitted proposed Reliability Standard CIP–003–7 in response to directives in Order No. 822.[2] The Commission also proposes to approve the associated violation risk factors and violation severity levels, implementation plan and effective dates proposed by NERC. In addition, the Commission proposes to approve the modified definitions of Transient Cyber Asset and Removable Media as well as the retirement of the definitions for Low Impact External Routable Connectivity (LERC) and Low Impact Electronic Access Point (LEAP) in the NERC Glossary of Terms Used in NERC Reliability Standards (NERC Glossary). Further, the Commission proposes to approve the retirement of Reliability Standard CIP–003–6.

2. Proposed Reliability Standard CIP–003–7 is designed to mitigate the cybersecurity risks to bulk electric system facilities, systems, and equipment, which, if destroyed, degraded, or otherwise rendered unavailable as a result of a cybersecurity incident, would affect the reliable operation of the bulk electric system.[3] As discussed below, the Commission proposes to determine that proposed Reliability Standard CIP–003–7 is just, reasonable, not unduly discriminatory or preferential, and in the public interest and addresses the directives in Order No. 822 by: 1. Clarifying the obligations pertaining to electronic access control for low impact BES Cyber Systems;[4] and 2. adopting mandatory security controls for transient electronic devices (*e.g.,* thumb drives, laptop computers, and other portable devices frequently connected to and disconnected from systems) used at low impact BES Cyber Systems. In addition, by requiring responsible entities to have a policy for declaring and responding to CIP Exceptional Circumstances for low impact BES Cyber Systems, the proposed Reliability Standard aligns the treatment of low impact BES Cyber Systems with that of high and medium impact BES Cyber Systems, which currently include a requirement for declaring and responding to CIP Exceptional Circumstances. Accordingly, we propose to approve proposed Reliability Standard CIP–003–7 because the proposed modifications improve the base-line cybersecurity posture of responsible entities compared to the current Commission-approved CIP Reliability Standards.

3. In addition, pursuant to FPA section 215(d)(5), the Commission proposes to direct NERC to develop certain modifications to the CIP Reliability Standards. As discussed below, while proposed Reliability Standard CIP–003–7 improves electronic access control for low impact BES Cyber Systems and enhances security controls for transient electronic

[1] 16 U.S.C. 824o (2012).

[2] *Revised Critical Infrastructure Protection Reliability Standards,* Order No. 822, 154 FERC ¶ 61,037, *reh'g denied,* Order No. 822–A, 156 FERC ¶ 61,052 (2016).

[3] *See* NERC Petition at 2.

[4] NERC defines ''BES Cyber System'' as one or more BES Cyber Assets logically grouped by a responsible entity to perform one or more reliability tasks for a functional entity.

devices used at low impact BES Cyber Systems, we propose to direct that NERC modify Reliability Standard CIP–003–7 to: 1. Provide clear, objective criteria for electronic access controls for low impact BES Cyber Systems; and 2. address the need to mitigate the risk of malicious code that could result from third-party transient electronic devices. We believe that modifications addressing these two concerns will address potential gaps and improve the cyber security posture of responsible entities that must comply with the CIP standards.

## I. Background

### *A. Section 215 and Mandatory Reliability Standards*

4. Section 215 of the FPA requires a Commission-certified ERO to develop mandatory and enforceable Reliability Standards, subject to Commission review and approval. Reliability Standards may be enforced by the ERO, subject to Commission oversight, or by the Commission independently.[5] Pursuant to section 215 of the FPA, the Commission established a process to select and certify an ERO,[6] and subsequently certified NERC.[7]

### *B. Order No. 822*

5. The Commission approved the ''Version 1'' CIP standards in January 2008, and subsequently acted on revised versions of the CIP standards.[8] On January 21, 2016, in Order No. 822, the Commission approved seven CIP Reliability Standards: CIP–003–6 (Security Management Controls), CIP–004–6 (Personnel and Training), CIP–006–6 (Physical Security of BES Cyber Systems), CIP–007–6 (Systems Security Management), CIP–009–6 (Recovery Plans for BES Cyber Systems), CIP–010–2 (Configuration Change Management and Vulnerability Assessments), and CIP–011–2 (Information Protection). The Commission determined that the Reliability Standards under consideration at that time were an improvement over the prior iteration of the CIP Reliability Standards and addressed the directives in Order No. 791 by, among other things, addressing in an equally effective and efficient manner the need for a NERC Glossary definition for the term ''communication networks'' and providing controls to address the risks posed by transient electronic devices (*e.g.,* thumb drives and laptop computers) used at high and medium impact BES Cyber Systems.[9]

6. In addition, in Order No. 822, pursuant to section 215(d)(5) of the FPA, the Commission directed NERC, *inter alia,* to: 1. Develop modifications to the LERC definition to eliminate ambiguity surrounding the term ''direct'' as it is used in the LERC definition; and 2. develop modifications to the CIP Reliability Standards to provide mandatory protection for transient electronic devices used at low impact BES Cyber Systems.[10]

### *C. NERC Petition*

7. On March 3, 2017, NERC submitted a petition seeking approval of Reliability Standard CIP–003–7 and the associated violation risk factors and violation severity levels, implementation plan and effective dates. NERC states that proposed Reliability Standard CIP–003–7 satisfies the criteria set forth in Order No. 672 that the Commission applies when reviewing a proposed Reliability Standard.[11] NERC also sought approval of revisions to NERC Glossary definitions for the terms Removable Media and Transient Cyber Asset, as well as the retirement of the NERC Glossary definitions of LERC and LEAP. In addition, NERC proposed the retirement of Commission-approved Reliability Standard CIP–003–6.

8. NERC states that proposed Reliability Standard CIP–003–7 improves upon the existing protections that apply to low impact BES Cyber Systems. NERC avers that the proposed modifications address the Commission's directives from Order No. 822 by: 1. Clarifying electronic access control requirements applicable to low impact BES Cyber Systems; and 2. adding requirements for the protection of transient electronic devices used for low impact BES Cyber Systems. In addition, while not required by Order No. 822, NERC proposes a CIP Exceptional Circumstances policy for low impact BES Cyber Systems.

9. In response to the Commission's directive to develop modifications to eliminate ambiguity surrounding the term ''direct'' as it is used in the LERC definition, NERC proposes to: 1. Retire the terms LERC and LEAP from the NERC Glossary; and 2. modify Section 3 of Attachment 1 to proposed Reliability Standard CIP–003–7 ''to more clearly delineate the circumstances under which Responsible Entities must establish access controls for low impact BES Cyber Systems.'' [12] NERC states that the proposed revisions are designed to simplify the electronic access control requirements associated with low impact BES Cyber Systems in order to avoid ambiguities associated with the term ''direct.'' NERC explains that it recognized the ''added layer of unnecessary complexity'' introduced by distinguishing between ''direct'' and ''indirect'' access within the LERC definition and asserts that the proposed revisions will ''help ensure that Responsible Entities implement the required security controls effectively.'' [13]

10. With regard to the Commission's directive to develop modifications to the CIP Reliability Standards to provide mandatory protection for transient electronic devices used at low impact BES Cyber Systems, NERC proposes to add a new section to Attachment 1 to proposed Reliability Standard CIP–003–7 to require responsible entities to include controls in their cyber security plans to mitigate the risk of the introduction of malicious code to low impact BES Cyber Systems that could result from the use of ''Transient Cyber Assets or Removable Media.'' Specifically, proposed Section 5 of Attachment 1 lists controls to be applied to Transient Cyber Assets and Removable Media that NERC contends ''will provide enhanced protections against the propagation of malware from transient devices.'' [14]

11. NERC also proposes a modification that was not directed by the Commission in Order No. 822. Namely, NERC proposes revisions in Requirement R1 of proposed Reliability Standard CIP–003–7 to require responsible entities to have a policy for declaring and responding to CIP Exceptional Circumstances related to low impact BES Cyber Systems.[15] NERC

[5] 16 U.S.C. 824o(e) (2012).

[6] *Rules Concerning Certification of the Electric Reliability Organization; and Procedures for the Establishment, Approval, and Enforcement of Electric Reliability Standards,* Order No. 672, FERC Stats. & Regs. ¶ 31,204, *order on reh'g,* Order No. 672–A, FERC Stats. & Regs. ¶ 31,212 (2006).

[7] *North American Electric Reliability Corp.,* 116 FERC ¶ 61,062, *order on reh'g and compliance,* 117 FERC ¶ 61,126 (2006), *aff'd sub nom. Alcoa, Inc.* v. *FERC,* 564 F.3d 1342 (D.C. Cir. 2009).

[8] *Mandatory Reliability Standards for Critical Infrastructure Protection,* Order No. 706, 122 FERC ¶ 61,040, *order on reh'g,* Order No. 706–A, 123 FERC ¶ 61,174 (2008), *order on clarification,* Order No. 706–B, 126 FERC ¶ 61,229 (2009), *order on clarification,* Order No. 706–C, 127 FERC ¶ 61,273 (2009).

[9] Order No. 822, 154 FERC ¶ 61,037 at P 17; *see also Version 5 Critical Infrastructure Protection Reliability Standards,* Order No. 791, 78 FR 72755 (Dec. 3, 2013), 145 FERC ¶ 61,160 (2013), *order on clarification and reh'g,* Order No. 791–A, 146 FERC ¶ 61,188 (2014).

[10] Order No. 822, 154 FERC ¶ 61,037 at P 18.

[11] *See* NERC Petition at 2 (citing Order No. 672, FERC Stats. & Regs. ¶ 31,204 at PP 262, 321–337); *id.* at Exhibit D (Order No. 672 Criteria).

[12] *Id.* at 16.

[13] *Id.* at 16.

[14] *Id.* at 26–27.

[15] A CIP Exceptional Circumstance is defined in the NERC Glossary as a situation that involves or threatens to involve one or more of the following,

states that a number of requirements in the existing CIP Reliability Standards specify that responsible entities do not have to implement or continue implementing these requirements during a CIP Exceptional Circumstance in order to avoid hindering the entities' ability to timely and effectively respond to the CIP Exceptional Circumstance. NERC explains that since the proposed requirements relating to transient electronic devices used at low impact BES Cyber Systems include an exception for CIP Exceptional Circumstances, NERC is proposing to add a requirement for responsible entities to have a CIP Exceptional Circumstances policy that applies to low impact BES Cyber Systems, as it already requires for high and medium impact BES Cyber Systems.[16]

12. NERC requests that proposed Reliability Standard CIP–003–7 and the revised definitions of Transient Cyber Asset and Removable Media become effective the first day of the first calendar quarter that is eighteen months after the effective date of the Commission's order approving the proposed Reliability Standard.

## II. Discussion

13. Pursuant to section 215(d)(2) of the FPA, we propose to approve Reliability Standard CIP–003–7 as just, reasonable, not unduly discriminatory or preferential, and in the public interest. Proposed Reliability Standard CIP–003–7 largely addresses the Commission's directives in Order No. 822 and is an improvement over the current Commission-approved CIP Reliability Standards. Specifically, the modifications to Section 3 of Attachment 1 to Reliability Standard CIP–003–7 clarify the obligations pertaining to electronic access control for low impact BES Cyber Systems. In addition, the modifications to Attachment 1 to Reliability Standard CIP–003–7 require mandatory security controls for transient electronic devices used at low impact BES Cyber Systems. We also propose to approve the new provision in Reliability Standard CIP–003–7, Requirement R1 requiring responsible entities to have a policy for declaring and responding to CIP Exceptional Circumstances related to low impact BES Cyber Systems. While Order No. 822 did not direct NERC to expand the scope of the CIP Exceptional Circumstances policy, the revision aligns the treatment of low impact BES Cyber Systems with that of high and medium impact BES Cyber Systems if and when a CIP Exceptional Circumstance occurs.

14. We also propose to approve the revisions to the NERC Glossary definitions of Transient Cyber Asset and Removable Media, as well as the retirement of the NERC Glossary definitions for LERC and LEAP since the proposed modifications to Reliability Standard CIP–003–7 obviate the need for the two terms. We further propose to approve the violation risk factor and violation severity level assignments associated with proposed Reliability Standard CIP–003–7 as well as NERC's proposed implementation plan and effective dates.

15. In addition, as discussed below, pursuant to section 215(d)(5) of the FPA, the Commission proposes to direct NERC to develop certain modifications to the CIP Reliability Standards. While proposed Reliability Standard CIP–003–7 improves electronic access control for low impact BES Cyber Systems and enhances security controls for transient electronic devices used at low impact BES Cyber Systems, we propose to direct that NERC modify Reliability Standard CIP–003–7 to: 1. Provide clear, objective criteria for electronic access controls for low impact BES Cyber Systems; and 2. address the need to mitigate the risk of malicious code that could result from third-party transient electronic devices.

16. Below, we discuss the following issues: A. Electronic access controls for low impact BES Cyber Systems; B. protection of transient electronic devices; C. proposed retirement and modification of definitions; D. NERC's proposed implementation plan and effective dates; and E. proposed violation severity level and violation risk factor assignments.

### *A. Electronic Access Controls for Low Impact BES Cyber Systems Order No. 822*

17. In Order No. 822, the Commission directed NERC to modify the LERC definition to eliminate ambiguity surrounding the term ''direct'' as it is used in the LERC definition.[17] The Commission explained that the directive was intended to codify the clarification provided in NERC's NOPR comments, in which NERC referenced a statement in the Guidelines and Technical Basis section of Reliability Standard CIP–003–6 that electronic access controls must be applied to low impact BES Cyber Systems unless responsible entities implement a ''complete security break'' between the external host (cyber asset) and any cyber asset(s) that may be used to pass communications to the low impact BES Cyber System.[18] The Commission observed that ''a suitable means to address our concern is to modify the [LERC] definition consistent with the commentary in the Guidelines and Technical Basis section of CIP–003–6.'' [19]

18. In addition, the Commission explained that the directive was also intended to eliminate a loophole that would have allowed transitive connections to out-of-scope cyber assets (*e.g.,* serial devices) to go unprotected under the LERC definition.[20]

#### NERC Petition

19. In its Petition, NERC proposes to: 1. Retire the terms LERC and LEAP from the NERC Glossary; and 2. modify Section 3 of Attachment 1 to Reliability Standard CIP–003–7 ''to more clearly delineate the circumstances under which Responsible Entities must establish access controls for low impact BES Cyber Systems.'' [21] NERC states that the proposed revisions are designed to simplify the electronic access control requirements associated with low impact BES Cyber Systems in order to avoid ambiguities associated with the term ''direct.'' NERC states further that it recognized the ''added layer of unnecessary complexity'' introduced by distinguishing between ''direct'' and ''indirect'' access within the LERC definition and asserts that the proposed revisions will ''help ensure that Responsible Entities implement the required security controls effectively.'' [22]

20. NERC states that proposed Reliability Standard CIP–003–7 would require responsible entities to implement electronic access controls for any communication, direct or indirect (*i.e.,* communications through an intermediary device where no direct connection is present), between a low

or similar, conditions that impact safety or bulk electric system reliability: A risk of injury or death; a natural disaster; civil unrest; an imminent or existing hardware, software, or equipment failure; a Cyber Security Incident requiring emergency assistance; a response by emergency services; the enactment of a mutual assistance agreement; or an impediment of large scale workforce availability. Glossary of Terms Used in NERC Reliability Standards (August 1, 2017), *http://www.nerc.com/files/glossary_of_terms.pdf.*

[16] NERC Petition at 31–32.

[17] Order No. 822, 154 FERC ¶ 61,037 at P 73.

[18] *Id.* (citing NERC NOPR Comments at 31).

[19] *Id.*

[20] *Id.* (''NERC's clarification on this issue resolves many of the concerns raised by EnergySec, APS, and SPP RE regarding the proposed definition, as a complete security break would not appear to permit transitive connections through one or more out of scope cyber assets to go unprotected under the definition, and would appear to require the assets to maintain 'separate conversations' as suggested by SPP RE.'').

[21] NERC Petition at 16.

[22] *Id.*

impact BES Cyber System and an outside Cyber Asset that uses a routable protocol when entering or leaving the asset containing the low impact BES Cyber System. NERC asserts that the proposed revisions to Section 3 of Attachment 1 to proposed Reliability Standard CIP–003–7 improve the clarity of the electronic access requirements and focus responsible entities ''on the security objective of controlling electronic access to permit only necessary inbound and outbound electronic access to low impact BES Cyber Systems.'' [23]

21. NERC explains that Section 3.1 of Attachment 1 to proposed Reliability Standard CIP–003–7 is composed of three basic elements: 1. Identifying routable protocol communications from outside the asset containing the low impact BES Cyber System; 2. determining necessary inbound and outbound electronic access; and 3. implementing electronic access controls to permit only necessary inbound and outbound electronic access to the low impact BES Cyber System.

22. With regard to the first element, NERC states that Section 3.1 of Attachment 1 defines the circumstances where communications require electronic access controls. The three characteristics are:

1. The communication is between the low impact BES Cyber System and a Cyber Asset outside the asset containing low impact BES Cyber System(s);

2. the communication uses a routable protocol when entering or leaving the asset containing the low impact BES Cyber System(s); and

3. the communication is not used for time-sensitive protection or control functions between intelligent electronic devices.

NERC states further that each of the three characteristics were included in the original LERC definition.[24]

23. NERC asserts that the first characteristic helps to properly focus the electronic access controls in light of ''the wide array of low impact BES Cyber Systems and the risk-based approach to protecting different types of BES Cyber Systems.'' [25] NERC explains that, whether a ''Responsible Entity uses a logical border as a demarcation point or some other understanding of what is inside or outside the asset, [the responsible entity] would have to provide a reasonable justification for its determination.'' [26] On the second characteristic, NERC states that routable communications present increased risks to the security of BES Cyber Systems and require additional protections. Therefore, communications with a low impact BES Cyber System involving routable connections require protections to address the risk of uncontrolled communications. With regard to the third characteristic, NERC explains that the exclusion of communications for time-sensitive protection and control functions is intended to avoid precluding the functionality of time-sensitive reliability enhancing functions. NERC states, however, that an entity invoking this exclusion may have to demonstrate that applying electronic access controls would introduce latency that would negatively impact functionality.[27]

24. According to NERC, the second characteristic of Section 3.1 of Attachment 1 provides that responsible entities may permit only necessary inbound and outbound electronic access to low impact BES Cyber Systems as determined by the responsible entity. NERC explains that Section 3.1 does not specify a bright line as to what constitutes ''necessary inbound and outbound access'' due to ''the wide array of assets containing low impact BES Cyber Systems and the myriad of reasons a Responsible Entity may need to allow electronic access to and from a low impact BES Cyber Systems.'' [28] NERC maintains that responsible entities ''have the flexibility to identify the necessary electronic access to meet their business and operational needs.'' [29]

25. NERC explains that ''a Responsible Entity must document the necessity of its inbound and outbound electronic access permissions and provide justification of the need for such access'' in order to demonstrate compliance with Section 3.1 of Attachment 1.[30] NERC states that absent a documented, reasonable justification, the ERO may find that the responsible entity was not in compliance with Section 3.1. NERC asserts that the purpose of the phrase ''as determined by the Responsible Entity'' in Section 3.1 is to indicate that the determination whether electronic access is necessary is to be made in the first instance by the responsible entity based on the facts and circumstances of each case. NERC states further that that the phrase ''as determined by the Responsible Entity'' does not limit the ERO's ability to engage in effective compliance oversight. Specifically, NERC contends that the ERO has the authority to review the documented justification for permitting electronic access and to determine whether it represents a reasonable exercise of discretion in light of the overall reliability objective.[31]

26. In support of its position, NERC cites the draft Reliability Standard Audit Worksheet (RSAW) for proposed Reliability Standard CIP–003–7, which provides the following language in the Note to Auditor section for Requirement R2:

> The entity must document its determination as to what is necessary inbound and outbound electronic access and provide justification of the business need for such access. Once this determination has been made and documented, the audit team's professional judgment cannot override the determination made by the Responsible Entity.[32]

NERC also provides a list of Commission-approved CIP Reliability Standards where the phrase ''as determined by the Responsible Entity'' or similar language is used. NERC states that in all circumstances where the phrase ''as determined by the Responsible Entity'' or similar language is used, ''the ERO has the authority to evaluate the reasonableness of the Responsible Entity's determination when assessing compliance to ensure it is consistent with the reliability objective of the requirement. To interpret this language otherwise would be inconsistent with NERC's statutory obligation to engage in meaningful compliance oversight . . .'' [33]

## Commission Proposal

27. The Commission proposes to approve Reliability Standard CIP–003–7 because, as discussed above, the proposed Reliability Standard largely addresses the directives in Order No. 822 and is an improvement over the current Commission-approved CIP Reliability Standards. However, NERC's proposed revisions to Reliability Standard CIP–003–7 regarding the LERC

[23] *Id.* at 17.

[24] *Id.* at 18.

[25] *Id.* at 19.

[26] *Id.*

[27] *Id.* at 20.

[28] *Id.* at 21–22.

[29] *Id.* at 22.

[30] *Id.*

[31] *Id.* at 22–23.

[32] *Id.* at 22, n.42.

[33] *Id.* at 23–24. NERC also indicates, *id* at n.42, that Footnote 1 of the draft RSAW states that ''[w]hile the information included in this RSAW provides some of the methodology that NERC has elected to use to assess compliance with the requirements of the Reliability Standard, this document should not be treated as a substitute for the Reliability Standard or viewed as additional Reliability Standard requirements. In all cases, the Regional Entity should rely on the language contained in the Reliability Standard itself, and not on the language contained in the RSAW, to determine compliance with the Reliability Standard.'' Draft RSAW, *http://www.nerc.com/pa/Stand/Project%20201602%20Modifications%20to%20CIP%20Standards%20DL/RSAW_CIP-003-7(i)_v2_Clean_01202017.pdf.*

directive and electronic access controls for low impact BES Cyber Systems raise certain issues. In Order No. 822, the Commission directed NERC to develop modifications to the LERC definition to eliminate ambiguity surrounding the term ''direct'' as it is used in the definition. The directive was based on the concern that responsible entities could avoid adopting adequate electronic access protections for low impact BES Cyber Systems by simply installing a device, such as a laptop or protocol converter, in front of the BES Cyber System to ''break'' the direct routable connection. As the Commission noted in Order No. 822, the desired clarification could have been made by including the security concepts from the Guidelines and Technical Basis section of Reliability Standard CIP–003–6 in the definition.[34] Instead, NERC's proposal comprehensively revises a responsible entity's obligations under Requirement R2 through the revisions to Attachment 1 by deleting the term LERC and giving responsible entities significantly more deference in determining how they construct the electronic access protections for low impact BES Cyber Systems.

28. We are concerned that the proposed revisions may not provide adequate electronic access controls for low impact BES Cyber Systems. Specifically, proposed Reliability Standard CIP–003–7 does not provide clear, objective criteria or measures to assess compliance by independently confirming that the access control strategy adopted by a responsible entity would reasonably meet the security objective of permitting only ''necessary inbound and outbound electronic access'' to its low impact BES Cyber Systems.

29. Section 3.1 of Attachment 1 to proposed Reliability Standard CIP–003–7 does not appear to contain clear criteria or objective measures to determine whether the electronic access control strategy chosen by the responsible entity would be effective for a given low impact BES Cyber System to permit only necessary inbound and outbound connections. In order to ensure an objective and consistently-applied requirement, the electronic access control plan required in Attachment 1 should require the responsible entity to articulate its access control strategy for a particular set of low impact BES Cyber Systems and provide a technical rationale rooted in security principles explaining how that strategy will reasonably restrict electronic access. Attachment 1 should also outline basic security principles in order to provide clear, objective criteria or measures to assist in assessing compliance. Without such a requirement, auditors will not necessarily have adequate information to assess the reasonableness of the responsible entity's decision with respect to how the responsible entity identified necessary communications or restricted electronic access to specific low impact BES Cyber Systems. And absent such information, it is possible that an auditor could assess a violation where an entity adequately protected its low impact BES Cyber Systems or fail to recognize a situation where additional protections are necessary to meet the security objective of the standard.

30. As the Commission stated in Order No. 672, there ''should be a clear criterion or measure of whether an entity is in compliance with a proposed Reliability Standard. It should contain or be accompanied by an objective measure of compliance so that it can be enforced and so that enforcement can be applied in a consistent and non-preferential manner.'' [35] The Commission reiterated this point in Order No. 791, stating that ''the absence of objective criteria to evaluate the controls chosen by responsible entities for Low Impact assets introduces an unacceptable level of ambiguity and potential inconsistency into the compliance process, and creates an unnecessary gap in reliability.'' [36] The Commission also observed that ''ambiguity will make it difficult for registered entities to develop, and NERC and the regions to objectively evaluate, the effectiveness of procedures developed to implement'' the Reliability Standard.[37]

31. As a possible model, the electronic access control requirements that are applied to medium and high impact BES Cyber systems provide a number of criteria that can be used to assess the sufficiency of a responsible entity's electronic access control strategy. For medium and high impact BES Cyber Systems, auditors use the following criteria to review whether the access control strategy is reasonable: 1. Whether the electronic access was granted through an authorized and monitored electronic access point (Reliability Standard CIP–005–5, Requirement R1); 2. whether the electronic access granted to individuals/devices was evaluated based on need (Reliability Standard CIP–005–5, Requirement R1.3); 3. whether the entity has mechanisms to enforce authentication of users with electronic access (Reliability Standard CIP–007–6, Requirement R5); and 4. whether the responsible entity routinely uses strong passwords and manages password changes (Reliability Standard CIP–007–6, Requirement R5). Absent similar criteria in the low impact electronic access control plan that are appropriately tailored to the risks posed by low impact BES Cyber Systems, responsible entities may adopt electronic access controls that do not meet the overarching security objective of restricting inbound and outbound electronic access.

32. Therefore, pursuant to section 215(d)(5) of the FPA, we propose to direct NERC to develop modifications to Reliability Standard CIP–003–7 to provide clear, objective criteria for electronic access controls for low impact BES Cyber Systems consistent with the above discussion. The Commission seeks comment on this proposal.

### *B. Protection of Transient Electronic Devices*

#### Order No. 822

33. In Order No. 822, the Commission directed NERC to develop modifications to provide mandatory protection for transient electronic devices used at low impact BES Cyber Systems based on the risk posed to bulk electric system reliability. The Commission stated that such modifications ''will provide an important enhancement to the security posture of the bulk electric system by reinforcing the defense-in-depth nature of the CIP Reliability Standards at *all* impact levels.'' [38] The Commission also stated that the proposed modifications should be designed to effectively address the risks posed by transient electronic devices used at low impact BES Cyber Systems ''in a manner that is consistent with the risk-based approach reflected in the CIP version 5 Standards.'' [39]

#### NERC Petition

34. In its Petition, NERC proposes to add a new section to Attachment 1 to proposed Reliability Standard CIP–003–7 to require responsible entities to include controls in their cyber security plans to mitigate the risk of the introduction of malicious code to low impact BES Cyber Systems through the

[34] *See* Order No. 822, 154 FERC ¶ 61,037 at P 73.

[35] *Rules Concerning Certification of the Electric Reliability Organization and Procedures for the Establishment, Approval, and Enforcement of Electric Reliability Standards,* Order No. 672, FERC Stats. & Regs. ¶ 31,204, at P 327 (2006).

[36] Order No. 791, 145 FERC ¶ 61,160 at P 108.

[37] *Id.*

[38] Order No. 822, 154 FERC ¶ 61,037 at P 32 (emphasis in original).

[39] *Id.*

use of ''Transient Cyber Assets or Removable Media.'' Specifically, proposed Section 5 of Attachment 1 lists controls to be applied to Transient Cyber Assets and Removable Media that NERC states ''will provide enhanced protections against the propagation of malware from transient devices.'' [40]

35. NERC states that the language in proposed Section 5 to Attachment 1 parallels the language in Attachment 1 to Reliability Standard CIP–010–2, which addresses mitigation of the risks of the introduction of malicious code to high and medium impact BES Cyber Systems through the use of Transient Cyber Assets or Removable Media. NERC states further that, as in Reliability Standard CIP–010–2, proposed Section 5 distinguishes between Transient Cyber Assets managed by a responsible entity and those managed by a third-party; the distinction arising because of a responsible entity's lack of control over Transient Cyber Assets managed by a third-party. NERC explains that the proposed controls for Removable Media do not distinguish between the responsible entity-managed assets and third-party managed assets due to the functionality of Removable Media. NERC provides the example of a thumb drive that can be scanned prior to use regardless of which party manages the asset.[41]

36. NERC explains that proposed Section 5 of Attachment 1 requires responsible entities to meet the security objectives ''by implementing the controls that the Responsible Entity determines necessary to meet its affirmative obligation to mitigate the risks of the introduction of malicious code.'' [42] NERC states that the approach reflected in Section 5 provides the flexibility to implement the controls that best suit the needs and characteristics of a responsible entity's organization. NERC explains further that ''the Responsible Entity must demonstrate that its selected controls were designed to meet the security objective to mitigate the risk of the introduction of malicious code.'' [43]

37. NERC outlines certain distinctions between proposed Section 5 of Attachment 1 to proposed Reliability Standard CIP–003–7 and Attachment 1 to Reliability Standard CIP–010–2. Specifically, NERC states that proposed Section 5 does not include requirements relating to authorization or software vulnerabilities, as are contained in Attachment 1 to Reliability Standard CIP–010–2. NERC explains that this difference is consistent with the risk-based approach of the CIP Reliability Standards and ''the underlying principle of concentrating limited industry resources on protecting those BES Cyber Systems with greater risk to the BES.'' NERC states that Section 5 focuses on the risk associated with the introduction of malicious code.[44]

38. In addition, NERC states that proposed Section 5 to Attachment 1 does not include language requiring a responsible entity to determine whether additional mitigation actions are necessary where a third party manages a Transient Cyber Asset, nor does it include language requiring a responsible entity to implement additional mitigation actions in such situations. NERC states that it nonetheless expects ''that if another party's processes and practices for protecting its Transient Cyber Assets do not provide reasonable assurance that they are designed to effectively meet the security objective of mitigating the introduction of malicious code, the Responsible Entity must take additional steps to meet the stated objective.'' [45] NERC explains that if a third party's practices and policies do not provide reasonable assurance that the Transient Cyber Assets would be protected from malicious code, ''simply reviewing those policies and procedures without taking other steps to mitigate the risks of introduction of malicious code may not constitute compliance.'' [46]

Commission Proposal

39. NERC's proposed modifications in Reliability Standard CIP–003–7, Requirement R2, Attachment 1, Section 5 that include malware detection and prevention controls for responsible entity-managed Transient Cyber Assets and Removable Media should improve the cybersecurity posture of responsibility entities compared to currently-effective Reliability Standard CIP–003–6. The revisions in Section 5.2, however, do not address one aspect of the reliability gap identified in Order No. 822 regarding low impact BES Cyber Systems. Specifically, as noted above, proposed Reliability Standard CIP–003–7 does not explicitly require mitigation of the introduction of malicious code from third-party managed Transient Cyber Assets, even if the responsible entity determines that the third-party's policies and procedures are inadequate.[47] While the proposed Reliability Standard does not explicitly require mitigation of the introduction of malicious code from third-party managed Transient Cyber Assets, NERC states that the failure to mitigate this risk ''may not constitute compliance.'' [48] NERC's statement suggests that, with regard to low impact BES Cyber Systems, the proposed requirement lacks an obligation for a responsible entity to correct any deficiencies that are discovered during a review of third-party Transient Cyber Asset management practices. Indeed, the parallel provision for high and medium impact BES Cyber Systems specifies that ''Responsible Entities shall determine whether any additional mitigation actions are necessary and implement such actions prior to connecting the Transient Cyber Asset.'' [49] Yet, such language obligating mitigation action is not proposed for low impact BES Cyber Assets.

40. The proposed Reliability Standard may, therefore, contain a reliability gap where a responsible entity contracts with a third-party but fails to mitigate potential deficiencies discovered in the third-party's malicious code detection and prevention practices prior to a Transient Cyber Asset being connected to a low impact BES Cyber System. That is because the proposed Reliability Standard does not contain: 1. A requirement for the responsible entity to mitigate any malicious code found during the third-party review(s); or 2. a requirement that the responsible entity take reasonable steps to mitigate the risks of third party malicious code on their systems, if an arrangement cannot be made for the third-party to do so. Without these obligations, we are concerned that responsible entities could, without compliance consequences, simply accept the risk of deficient third-party transient electronic device management practices.[50] Moreover, the requirement to ''review'' methods used by third-parties to detect and prevent malware may fail to convey the necessary next steps that a responsible entity should take.[51]

[40] *Id.* at 26–27.

[41] *Id.* at 28.

[42] *Id.*

[43] *Id.* at 29.

[44] NERC Petition at 29.

[45] *Id.* at 29–30.

[46] *Id.* at 30.

[47] *See* NERC Petition at 29–30.

[48] *Id.* at 30.

[49] Reliability Standard CIP–010–2 (Cyber Security—Configuration Change Management and Vulnerability Assessments), Requirement R4, Attachment 1, Section 2.3. In contrast, the obligations to ''review'' methods used by third-parties to detect and prevent malware are similar for lower, medium and high impact BES Cyber Assets. *Cf.* CIP–010–2, Attachment 1, Sections 2.1 and 2.2; and proposed CIP–010–3, Attachment 1, Section 3.2.

[50] *See* Order No. 706, 122 FERC ¶ 61,040 at P 150 (rejecting the concept of acceptance of risk in the CIP Reliability Standards).

[51] *See* Order No. 791, 145 FERC ¶ 61,160 at P 108.

41. Therefore, pursuant to section 215(d)(5) of the FPA, we propose to direct that NERC develop modifications to proposed Reliability Standard CIP–003–7 to address the need to mitigate the risk of malicious code that could result from third-party Transient Cyber Assets consistent with the above discussion. The Commission seeks comment on this proposal.

*C. Proposed NERC Glossary Definitions*

42. Proposed Reliability Standard CIP–003–7 includes two revised definitions for inclusion in the NERC Glossary. Specifically, NERC proposes to revise the definitions of Transient Cyber Asset and Removable Media in order to accommodate the use of the terms at all impact levels. NERC explains that the original definitions include references to concepts or requirements associated only with high and medium impact BES Cyber Systems and the definitions were modified to avoid confusion because protections for Transient Electronic Devices will now be extended to low impact BES Cyber Systems.[52]

43. In addition, NERC proposes to retire the definitions of LERC and LEAP. NERC states that the proposed retirement of the NERC Glossary terms LERC and LEAP accords with the proposed modifications to Section 3 of Attachment 1 to proposed Reliability Standard CIP–003–7 and is intended to simplify the electronic access control requirements for low impact BES Cyber Systems by avoiding the ambiguities associated with the term ''direct.'' NERC explains further that it ''recognized that distinguishing between 'direct' and 'indirect' electronic access within the LERC definition added a layer of unnecessary complexity.'' [53]

44. We propose to approve the revised definitions of Transient Cyber Asset and Removable Media, as well as the retirement of the definitions of LERC and LEAP.

*D. Implementation Plan and Effective Dates*

45. NERC requests an effective date for proposed Reliability Standard CIP–003–7 and the revised definitions of Transient Cyber Asset and Removable Media on the first day of the first calendar quarter that is eighteen months after the effective date of the Commission's order approving the proposed Reliability Standard. NERC explains that the proposed implementation plan does not alter the previously-approved compliance dates for Reliability Standard CIP–003–6 other than the compliance date for Reliability Standard CIP–003–6, Requirement R2, Attachment 1, Sections 2 and 3, which would be replaced with the effective date for proposed Reliability Standard CIP–003–7. NERC also proposes that the retirement of Reliability Standard CIP–003–6 and the associated definitions become effective on the effective date of proposed Reliability Standard CIP–003–7.[54]

46. We propose to approve NERC's implementation plan for proposed Reliability Standard CIP–003–7, as described above.

*E. Violation Risk Factor/Violation Severity Level Assignments*

47. NERC requests approval of two violation risk factors and violation severity levels assigned to proposed Reliability Standard CIP–003–7. Specifically, NERC requests approval of violation risk factor and violation severity level assignments associated with Requirements R1 and R2 of Reliability Standard CIP–003–7.[55] We propose to accept these violation risk factors and violation severity levels.

**III. Information Collection Statement**

48. The FERC–725B information collection requirements contained in this proposed rule are subject to review by the Office of Management and Budget (OMB) under section 3507(d) of the Paperwork Reduction Act of 1995.[56] OMB's regulations require approval of certain information collection requirements imposed by agency rules.[57] Upon approval of a collection of information, OMB will assign an OMB control number and expiration date. Respondents subject to the filing requirements of this rule will not be penalized for failing to respond to these collections of information unless the collections of information display a valid OMB control number. The Commission solicits comments on the Commission's need for this information, whether the information will have practical utility, the accuracy of the burden estimates, ways to enhance the quality, utility, and clarity of the information to be collected or retained, and any suggested methods for minimizing respondents' burden, including the use of automated information techniques.

49. The Commission bases its paperwork burden estimates on the changes in paperwork burden presented by the proposed revision to CIP Reliability Standard CIP–003–7 as compared to the current Commission-approved Reliability Standard CIP–003–6. The Commission has already addressed the burden of implementing Reliability Standard CIP–003–6.[58] As discussed above, the immediate rulemaking addresses three areas of modification to the CIP Reliability Standards: 1. Clarifying the obligations pertaining to electronic access control for low impact BES Cyber Systems; 2. adopting mandatory security controls for transient electronic devices (*e.g.,* thumb drives, laptop computers, and other portable devices frequently connected to and disconnected from systems) used at low impact BES Cyber Systems; and 3. requiring responsible entities to have a policy for declaring and responding to CIP Exceptional Circumstances related to low impact BES Cyber Systems.

50. The NERC Compliance Registry, as of September 2017, identifies approximately 1,320 U.S. entities that are subject to mandatory compliance with Reliability Standards. Of this total, we estimate that 1,100 entities will face an increased paperwork burden under proposed Reliability Standard CIP 003–7, estimating that a majority of these entities will have one or more low impact BES Cyber Systems. Based on these assumptions, we estimate the following reporting burden:

[52] NERC Petition at 30.

[53] *Id.* at 16.

[54] *Id.,* Exhibit C (Implementation Plan).

[55] *Id.,* Exhibit F (Analysis of Violation Risk Factors and Violation Severity Levels).

[56] 44 U.S.C. 3507(d) (2012).

[57] 5 CFR 1320.11 (2017).

[58] *See* Order No. 822, 154 FERC ¶ 61,037 at PP 84–88.

RM17–11–000 NOPR

[Mandatory Reliability Standards for Critical Infrastructure Protection Reliability Standards]

| | Number of respondents (1) | Annual number of responses per respondent (2) | Total number of responses (1) * (2) = (3) | Average burden & cost per response [59] (4) | Total annual burden hours & total annual cost (3) * (4) = (5) | Cost per respondent ($) (5) ÷ (1) |
|---|---|---|---|---|---|---|
| Create low impact TCA assets plan (one-time) [60] ... | 1,100 | 1 | 1,100 | 20 hrs.; $1,680 ..... | 6,875 hrs.; $1,848,000 ... | $1,680 |
| Updates and reviews of low impact TCA assets (ongoing) [61]. | 1,100 | [62] 300 | 330,000 | 1.5 hrs. [63]; $126 ..... | 495,000 hrs.; $41,580,000. | 37,800 |
| Update/modify documentation to remove LERC and LEAP (one-time) [60]. | 1,100 | 1 | 1,100 | 20 hrs.; $1,680 ..... | 6,875 hrs.; $1,848,000 ... | 1,680 |
| Update paperwork for access control implementation in Section 2 [64] and Section 3 [65] (ongoing) [61]. | 1,100 | 1 | 1,100 | 20 hrs.; $1,680 ..... | 6,875 hrs.; $1,848,000 ... | 1,680 |
| Total (one-time) [60] ..... | ..... | ..... | 2,200 | ..... | 13,750 hrs.; $3,696,000 | ..... |
| Total (ongoing) [61] ..... | ..... | ..... | 331,100 | ..... | 501,875 hrs.; $43,428,000. | ..... |

51. The following shows the annual cost burden for each group, based on the burden hours in the table above:

- Year 1: $3,696,000.
- Years 2 and 3: $43,428,000.
- The paperwork burden estimate includes costs associated with the initial development of a policy to address requirements relating to: 1. Clarifying the obligations pertaining to electronic access control for low impact BES Cyber Systems; 2. adopting mandatory security controls for transient electronic devices (*e.g.,* thumb drives, laptop computers, and other portable devices frequently connected to and disconnected from systems) used at low impact BES Cyber Systems; and 3. requiring responsible entities to have a policy for declaring and responding to CIP Exceptional Circumstances related to low impact BES Cyber Systems. Further, the estimate reflects the assumption that costs incurred in year 1 will pertain to policy development, while costs in years 2 and 3 will reflect the burden associated with maintaining logs and other records to demonstrate ongoing compliance.

52. *Title:* Mandatory Reliability Standards, Revised Critical Infrastructure Protection Reliability Standards

*Action:* Proposed Collection FERC–725B.

*OMB Control No.:* 1902–0248.

*Respondents:* Businesses or other for-profit institutions; not-for-profit institutions.

*Frequency of Responses:* On Occasion.

*Necessity of the Information:* This proposed rule proposes to approve the requested modifications to Reliability Standards pertaining to critical infrastructure protection. As discussed above, the Commission proposes to approve NERC's proposed revised CIP Reliability Standard CIP–003–7 pursuant to section 215(d)(2) of the FPA because it improves upon the currently-effective suite of cyber security CIP Reliability Standards.

*Internal Review:* The Commission has reviewed the proposed Reliability Standards and made a determination that its action is necessary to implement section 215 of the FPA.

53. Interested persons may obtain information on the reporting requirements by contacting the following: Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426 [Attention: Ellen Brown, Office of the Executive Director, email: *DataClearance@ferc.gov,* phone: (202) 502–8663, fax: (202) 273–0873].

54. For submitting comments concerning the collection(s) of information and the associated burden estimate(s), please send your comments to the Commission, and to the Office of Management and Budget, Office of Information and Regulatory Affairs, Washington, DC 20503 [Attention: Desk Officer for the Federal Energy Regulatory Commission, phone: (202) 395–4638, fax: (202) 395–7285]. For security reasons, comments to OMB should be submitted by email to: *oira_submission@omb.eop.gov.* Comments submitted to OMB should include Docket Number RM17–11–000 and OMB Control Number 1902–0248.

## IV. Regulatory Flexibility Act Analysis

55. The Regulatory Flexibility Act of 1980 (RFA) generally requires a description and analysis of proposed rules that will have significant economic impact on a substantial number of small entities.[66] The Small Business Administration's (SBA) Office of Size Standards develops the numerical definition of a small business.[67] The SBA revised its size standard for electric utilities (effective January 22, 2014) to a standard based on the number of employees, including affiliates (from the prior standard based on megawatt hour sales).[68] Proposed Reliability Standard CIP–003–7 is expected to impose an additional burden on 1,100 entities [69] (reliability coordinators, generator operators, generator owners, interchange coordinators or authorities, transmission operators, balancing authorities,

[59] The loaded hourly wage figure (includes benefits) is based on the average of three occupational categories for 2016 found on the Bureau of Labor Statistics Web site (*http://www.bls.gov/oes/current/naics2_22.htm):*

Legal (Occupation Code: 23–0000): $143.68.

Electrical Engineer (Occupation Code: 17–2071): $68.12.

Office and Administrative Support (Occupation Code: 43–0000): $40.89 ($143.68 + $68.12 + $40.89) ÷ 3 = $84.23. The figure is rounded to $84.00 for use in calculating wage figures in this NOPR.

[60] This one-time burden applies in Year One only.

[61] This ongoing burden applies in Year 2 and beyond.

[62] We estimate that each entity will perform 25 updates per month. 25 updates *12 months = 300 updates (*i.e.* responses) per year.

[63] The 1.5 hours of burden per response is comprised of three sub-categories:

Updates to managed low TCA assets: 15 minutes (0.25 hours) per response.

Updates to unmanaged low TCA assets: 60 minutes (1 hour) per response.

Reviews of low TCA applicable controls: 15 minutes (0.25 hours) per response.

[64] Physical Security Controls.

[65] Electronic Access Controls.

[66] 5 U.S.C. 601–12 (2012).

[67] 13 CFR 121.101 (2017).

[68] SBA Final Rule on ''Small Business Size Standards: Utilities,'' 78 FR 77343 (Dec. 23, 2013).

[69] Public utilities may fall under one of several different categories, each with a size threshold based on the company's number of employees, including affiliates, the parent company, and subsidiaries. For the analysis in this NOPR, we are using a 500 employee threshold due to each affected entity falling within the role of Electric Bulk Power Transmission and Control (NAISC Code: 221121).

transmission owners, and certain distribution providers).

56. Of the 1,100 affected entities discussed above, we estimate that approximately 857 or 78 percent [70] of the affected entities are small. As discussed above, proposed Reliability Standard CIP–003–7 enhances reliability by providing criteria against which NERC and the Commission can evaluate the sufficiency of an entity's electronic access controls for low impact BES Cyber systems, as well as improved security controls for transient electronic devices (*e.g.,* thumb drives, laptop computers, and other portable devices frequently connected to and disconnected from systems). We estimate that each of the 857 small entities to whom the proposed modifications to Reliability Standard CIP–003–7 applies will incur one-time costs of approximately $3,360 per entity to implement this standard, as well as the ongoing paperwork burden reflected in the Information Collection Statement (approximately $39,480 per year per entity). We do not consider the estimated costs for these 857 small entities to be a significant economic impact.

57. Based on the above analysis, we propose to certify that the proposed Reliability Standard will not have a significant economic impact on a substantial number of small entities.

## V. Environmental Analysis

58. The Commission is required to prepare an Environmental Assessment or an Environmental Impact Statement for any action that may have a significant adverse effect on the human environment.[71] The Commission has categorically excluded certain actions from this requirement as not having a significant effect on the human environment. Included in the exclusion are rules that are clarifying, corrective, or procedural or that do not substantially change the effect of the regulations being amended.[72] The actions proposed herein fall within this categorical exclusion in the Commission's regulations.

## VI. Comment Procedures

59. The Commission invites interested persons to submit comments on the matters and issues proposed in this notice to be adopted, including any related matters or alternative proposals that commenters may wish to discuss. Comments are due December 26, 2017. Comments must refer to Docket No. RM17–11–000, and must include the commenter's name, the organization they represent, if applicable, and address.

60. The Commission encourages comments to be filed electronically via the eFiling link on the Commission's Web site at *http://www.ferc.gov.* The Commission accepts most standard word processing formats. Documents created electronically using word processing software should be filed in native applications or print-to-PDF format and not in a scanned format. Commenters filing electronically do not need to make a paper filing.

61. Commenters that are not able to file comments electronically must send an original of their comments to: Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE., Washington, DC 20426.

62. All comments will be placed in the Commission's public files and may be viewed, printed, or downloaded remotely as described in the Document Availability section below. Commenters on this proposal are not required to serve copies of their comments on other commenters.

## VII. Document Availability

63. In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the Internet through the Commission's Home Page (*http://www.ferc.gov*) and in the Commission's Public Reference Room during normal business hours (8:30 a.m. to 5:00 p.m. Eastern time) at 888 First Street NE., Room 2A, Washington, DC 20426.

64. From the Commission's Home Page on the Internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number of this document, excluding the last three digits, in the docket number field.

65. User assistance is available for eLibrary and the Commission's Web site during normal business hours from the Commission's Online Support at 202–502–6652 (toll free at 1–866–208–3676) or email at *ferconlinesupport@ferc.gov,* or the Public Reference Room at (202) 502–8371, TTY (202) 502–8659. Email the Public Reference Room at *public.referenceroom@ferc.gov.*

By direction of the Commission.

Issued October 19, 2017.

**Nathaniel J. Davis, Sr.,**

*Deputy Secretary.*

[FR Doc. 2017–23287 Filed 10–25–17; 8:45 am]

**BILLING CODE 6717–01–P**

[70] 77.95 percent.

[71] *Regulations Implementing the National Environmental Policy Act of 1969,* Order No. 486, FERC Stats. & Regs. ¶ 30,783 (1987).

[72] 18 CFR 380.4(a)(2)(ii) (2017).

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## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

### 26 CFR Part 1

**[REG–134247–16]**

**RIN 1545–BN73**

## Revision of Regulations Under Chapter 3 Regarding Withholding of Tax on Certain U.S. Source Income Paid to Foreign Persons; Correction

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Notice of proposed rulemaking; correction.

**SUMMARY:** This document corrects a correction to a notice of proposed rulemaking (REG–134247–16) that was published in the **Federal Register** on Friday, September 15, 2017. The notice of proposed rulemaking, published on January 6, 2017, under section 1441 of the Internal Revenue Code of 1986 (Code), relates to withholding of tax on certain U.S. source income paid to foreign persons and requirements for certain claims for refund or credit of income tax made by foreign persons.

**DATES:** The correction published on September 15, 2017 (82 FR 43314), is corrected as of October 26, 2017 and is applicable beginning January 6, 2017.

**FOR FURTHER INFORMATION CONTACT:** Kamela Nelan at (202) 317- 6942 (not a toll-free number).

**SUPPLEMENTARY INFORMATION:**

### Background

The notice of proposed rulemaking (REG–134247–16) that is the subject of this correction is under section 1441 of the Code.

### Need for Correction

As published, the notice of proposed rulemaking (REG–134247–16) contains an error which may prove to be misleading and needs to be corrected.

### Correction of Publication

Accordingly, the notice of proposed rulemaking published at 82 FR 43314, September 15, 2017, is corrected as follows:

On page 43314, in the third column, under the heading ''Correction of Publication'', in the fourth line, the

language ''On page 1636, '' is corrected to read ''On page 1646, ''.

**Martin V. Franks,**

*Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedure and Administration).*

[FR Doc. 2017–22815 Filed 10–25–17; 8:45 am]

**BILLING CODE 4830–01–P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

### 33 CFR Part 117

**[Docket No. USCG–2016–0723]**

**RIN 1625–AA09**

## Drawbridge Operation Regulation; Atlantic Intracoastal Waterway, St. Augustine, FL

**AGENCY:** Coast Guard, DHS.

**ACTION:** Advance notice of proposed rulemaking; withdrawal.

**SUMMARY:** The Coast Guard is withdrawing its advance notice of proposed rulemaking (ANPRM) concerning the Bridge of Lions (SR A1A) across the Atlantic Intracoastal Waterway, mile 777.9, at St. Augustine, Florida. The City of St. Augustine proposed to modify the bridge operating schedule to alleviate vehicle traffic congestion. However, the Coast Guard has determined it would be inappropriate to move forward with a notice of proposed rulemaking. The Coast Guard believes placing additional restrictions to the bridge would add additional hazards to mariners and effect the safe navigation of vessels awaiting bridge openings.

**DATES:** The notice of proposed rulemaking published on March 15, 2017 (82 FR 13785), is withdrawn on October 26, 2017.

**ADDRESSES:** The docket for this document, USCG–2016–0723 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 document.

**FOR FURTHER INFORMATION CONTACT:** If you have questions about this document, call or email LT Allan Storm, Sector Jacksonville, Waterways Management Division, U.S. Coast Guard; telephone 904–714–7616, email *Allan.H.Storm@uscg.mil.*

**SUPPLEMENTARY INFORMATION:**

### Background Information and Regulatory History

On March 15, 2017, the Coast Guard published an ANPRM entitled ''Drawbridge Operation Regulation; Atlantic Intracoastal Waterway, St. Augustine, FL'' in the **Federal Register** (82 FR 13785). The advance notice of proposed rulemaking sought comments and information concerning a request from the City of St. Augustine to change the operating schedule for the Bridge of Lions across the Atlantic Intracoastal Waterway, St. Augustine, Florida amending the twice an hour operating schedule to a 7 a.m. to 9 p.m. period. The City of St. Augustine was concerned that vehicle traffic was becoming exponentially worse with each passing season and that the current operating schedule was contributing to vehicle traffic backups.

### Withdrawal

The Coast Guard received 386 comments, of those, 62 comments were duplicate entries, 204 comments were in favor for the requested change and 120 were against the requested change. The comments in favor of the change generally felt the additional restrictions to the bridge would help alleviate vehicular traffic on or around the bridge and the surrounding area. For the comments that opposed the change, by and large, the main concern was safety of mariners due to strong tidal currents and the high level of vessel activities occurring in the waters near the bridge. Strong currents, the close proximity of mooring fields and marinas would hamper the ability to ''keep on station'' while waiting for a bridge opening. Also, sailing vessels waiting for bridge opening would be required to be moving constantly all the while avoiding other waiting vessel traffic. The requested change to the operating schedule would extend the twice an hour draw opening schedule by an additional three hours into the evening. Concern was expressed by having to wait for an opening in darkness, stating this would cause additional hazards due to vessels already underway, traffic lights against the city and vehicular lights adjacent to the waterway. The Coast Guard acknowledges all of the above safety concerns, and for that reason, we find that any benefits of the possible additional restrictions to the Bridge of Lions do not outweigh the additional hazards to vessels and mariners transiting the area around the bridge. The current regulation as written in 33 CFR 117.261(d) will remain in effect.

Dated: October 5, 2017.

**Peter J. Brown,**

*Rear Admiral, U.S. Coast Guard, Commander, Seventh Coast Guard District.*

[FR Doc. 2017–23321 Filed 10–25–17; 8:45 am]

**BILLING CODE 9110–04–P**

## LIBRARY OF CONGRESS

### Copyright Office

### 37 CFR Part 201

**[Docket No. 2017–10]**

## Exemptions To Permit Circumvention of Access Controls on Copyrighted Works

**AGENCY:** U.S. Copyright Office, Library of Congress.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The United States Copyright Office (''Copyright Office'' or ''Office'') is conducting the seventh triennial rulemaking proceeding under the Digital Millennium Copyright Act (''DMCA''), concerning possible temporary exemptions to the DMCA's prohibition against circumvention of technological measures that control access to copyrighted works. In this proceeding, the Copyright Office has established a new, streamlined procedure for the renewal of exemptions that were granted during the sixth triennial rulemaking. It is also considering petitions for new exemptions to engage in activities not currently permitted by existing exemptions. On June 30, 2017, the Office published a Notice of Inquiry requesting petitions to renew existing exemptions and comments in response to those petitions, as well as petitions for new exemptions to engage in activities not currently permitted by existing exemptions. The Office has carefully considered the comments received in response to that Notice. With this Notice of Proposed Rulemaking (''NPRM''), the Office intends to recommend each of the existing exemptions for readoption. This NPRM also initiates three rounds of public comment on the newly-proposed exemptions. Interested parties are invited to make full legal and evidentiary submissions in support of or in opposition to the proposed exemptions, in accordance with the requirements set forth below.

**DATES:** Initial written comments (including documentary evidence) and multimedia evidence from proponents and other members of the public who support the adoption of a proposed exemption, as well as parties that

neither support nor oppose an exemption but seek to share pertinent information about a proposal, are due December 18, 2017. Written response comments (including documentary evidence) and multimedia evidence from those who oppose the adoption of a proposed exemption are due February 12, 2018. Written reply comments from supporters of particular proposals and parties that neither support nor oppose a proposal are due March 14, 2018. Commenting parties should be aware that rather than reserving time for potential extensions of time to file comments, the Office has already established what it believes to be the most generous possible deadlines consistent with the goal of concluding the triennial proceeding in a timely fashion.

**ADDRESSES:** The Copyright Office is using the *regulations.gov* system for the submission and posting of comments in this proceeding. All comments are therefore to be submitted electronically through *regulations.gov*. The Office is accepting two types of comments. First, commenters who wish briefly to express general support for or opposition to a proposed exemption may submit such comments electronically by typing into the comment field on *regulations.gov*. Second, commenters who wish to provide a fuller legal and evidentiary basis for their position may upload a Word or PDF document, but such longer submissions must be completed using the long-comment form provided on the Office's Web site at *https://www.copyright.gov/1201/2018.* Specific instructions for submitting comments, including multimedia evidence that cannot be uploaded through *regulations.gov*, are also available on that Web page. If a commenter cannot meet a particular submission requirement, please contact the Office using the contact information below for special instructions.

**FOR FURTHER INFORMATION CONTACT:** Sarang Vijay Damle, General Counsel and Associate Register of Copyrights, by email at *sdam@loc.gov,* Regan A. Smith, Deputy General Counsel, by email at *resm@loc.gov,* Anna Chauvet, Assistant General Counsel, by email at *achau@loc.gov,* or Jason E. Sloan, Attorney-Advisor, by email at *jslo@loc.gov*. Each can be contacted by telephone by calling (202) 707–8350.

**SUPPLEMENTARY INFORMATION:** On June 30, 2017, the Office published a Notice of Inquiry requesting petitions to renew current exemptions, oppositions to the renewal petitions, and petitions for newly proposed exemptions (the ''Notice of Inquiry'') in connection with the seventh triennial section 1201 rulemaking.[1] In response, the Office received thirty-nine renewal petitions, five comments regarding the scope of the renewal petitions, and one comment in opposition to renewal of a current exemption.[2] These comments are discussed further below. In addition, the Office received twenty-three petitions for new exemptions, many of which seek to expand upon a current exemption.

With this NPRM, the Office sets forth the exemptions the Register of Copyrights intends to recommend for readoption without the need for further development of the administrative record, and outlines the proposed classes for new exemptions for which the Office initiates three rounds of public comment.

## I. Standard for Evaluating Proposed Exemptions

As the Notice of Inquiry explained, for a temporary exemption from the prohibition on circumvention to be granted through the triennial rulemaking, it must be established that ''persons who are users of a copyrighted work are, or are likely to be in the succeeding 3-year period, adversely affected by the prohibition . . . in their ability to make noninfringing uses under [title 17] of a particular class of copyrighted works.'' [3] To devise an appropriate class of copyrighted works, the Office begins with the broad categories of works identified in 17 U.S.C. 102 and then refines them by other criteria, such as the technological protection measures (''TPMs'') used, distribution platforms, and/or types of uses or users.[4]

In evaluating the evidence, the Register must consider the following statutory factors: 1. The availability for use of copyrighted works; 2. the availability for use of works for nonprofit archival, preservation, and educational purposes; 3. the impact that the prohibition on the circumvention of technological measures applied to copyrighted works has on criticism, comment, news reporting, teaching, scholarship, or research; 4. the effect of circumvention of technological measures on the market for or value of copyrighted works; and 5. such other factors as the Librarian considers appropriate.'' [5] After developing a comprehensive administrative record, the Register makes a recommendation to the Librarian of Congress concerning whether exemptions are warranted based on that record.

The Office has previously articulated the substantive legal and evidentiary standard for the granting of an exemption under section 1201(a)(1) multiple times, including in its recently-issued video and PowerPoint tutorials, the 1201 Study, and in prior recommendations of the Register concerning proposed classes of exemptions, each of which is accessible from the Office's 1201 rulemaking Web page at *https://www.copyright.gov/1201/*. At bottom, in considering whether to recommend an exemption, the Office must inquire: ''*Are users of a copyrighted work adversely affected by the prohibition on circumvention in their ability to make noninfringing uses of a class of copyrighted works, or are users likely to be so adversely affected in the next three years?*'' [6] This inquiry breaks into the following elements:

- The proposed class includes at least some works protected by copyright.
- The uses at issue are noninfringing under title 17.
- Users are adversely affected in their ability to make such noninfringing uses or, alternatively, users are likely to be adversely affected in their ability to make such noninfringing uses during the next three years. This element is analyzed in reference to section 1201(a)(1)(C)'s five statutory factors.
- The statutory prohibition on circumventing access controls is the cause of the adverse effects.[7]

The Register will consider the Copyright Act and relevant judicial precedents when analyzing whether a proposed use is likely to be noninfringing.[8] When considering whether such uses are being adversely impacted by the prohibition on circumvention, the rulemaking focuses

[1] 82 FR 29804 (June 30, 2017).

[2] The comments received in response to the Notice of Inquiry are available online at *https://www.regulations.gov/docketBrowser?rpp=25&so=DESC&sb=commentDueDate&po=0&dct=PS&D=COLC-2017-0007*. References to these comments are by party name (abbreviated where appropriate) followed by either ''Renewal Pet.,'' ''Pet.,'' or ''Renewal Comment,'' as appropriate.

[3] 17 U.S.C. 1201(a)(1)(C).

[4] *See* H.R. Rep. No. 105–551, pt. 2, at 38 (1998) (''Commerce Comm. Report''); Register of Copyrights, Section 1201 Rulemaking: Sixth Triennial Proceeding to Determine Exemptions to the Prohibition on Circumvention, Recommendation of the Register of Copyrights 17–18 (2015) (''2015 Recommendation''); U.S. Copyright Office, *Section 1201 of Title 17,* at 26, 108–10 (2017), *https://www.copyright.gov/policy/1201/section-1201-full-report.pdf* (''1201 Study'').

[5] 17 U.S.C. 1201(a)(1)(C).

[6] 1201 Study at 114.

[7] *Id.* at 115; *see also id.* at 115–27.

[8] *Id.* at 115–17. While controlling precedent directly on point is not required to justify an exemption, there is no ''rule of doubt'' favoring an exemption when it is unclear that a particular use is fair or otherwise noninfringing. *See* 2015 Recommendation at 15.

on ''distinct, verifiable, and measurable impacts'' compared to ''*de minimis* impacts.'' [9] Taking the administrative record together, the Office will consider whether the preponderance of the evidence in the record shows that the conditions for granting an exemption have been met.[10]

## II. Review of Petitions To Renew Existing Exemptions

During this rulemaking, the Office initiated a new streamlined process for recommending readoption of previously-adopted exemptions to the Librarian. As the Office explained in its recent 1201 Study, the ''Register must apply the same evidentiary standards in recommending the renewal of exemptions as for first-time exemption requests,'' and the statute requires that ''a determination must be made specifically for each triennial period.'' [11] The Office further determined that ''the statutory language appears to be broad enough to permit determinations to be based upon evidence drawn from prior proceedings, but only upon a conclusion that this evidence remains reliable to support granting an exemption in the current proceeding.'' [12]

Based on this understanding of the statutory scheme, the Office solicited petitions for the renewal of exemptions as they are currently formulated, without modification. Thus, if a proponent sought to engage in any activities not currently permitted by an existing exemption, a petition for a new exemption had to have been submitted. This is because streamlined renewal is based upon a determination that, due to a lack of legal, marketplace, or technological changes, the factors that led the Register to recommend adoption of the exemption in the prior rulemaking will continue into the forthcoming triennial period.[13] That is, the same facts and circumstances underlying the previously-adopted regulatory exemption may be relied on to renew the exemption. Accordingly, to the extent that any renewal petition proposed uses beyond the current exemption, the Office disregarded those portions of the petition for purposes of considering the renewal of the exemption, and instead focused on whether it provided sufficient information to warrant readoption of the exemption in its current form.[14]

The Office received thirty-nine petitions to renew existing exemptions, including at least one petition to renew each currently-adopted exemption. Each petition to renew an existing exemption included an explanation summarizing the basis for claiming a continuing need and justification for the exemption. In each case, petitioners also signed a declaration stating that, to the best of their personal knowledge, there has not been any material change in the facts, law, or other circumstances set forth in the prior rulemaking record such that renewal of the exemption would not be justified.

The Office also received six comments in response to the renewal petitions; five did not oppose renewal, but offered more general comments, and one was styled as an opposition to renewal. One general comment filed by the Entertainment Software Association, the Motion Picture Association of America, Inc., and the Recording Industry Association of America, Inc. (collectively, ''Joint Creators'') raised some overarching issues with the renewal petitions. Specifically, Joint Creators expressed concern that many of the renewal petitions ''were based on what the petitioners attest they have been told by others, rather than on their own personal knowledge.'' [15] But as the Office explained in its Notice of Inquiry, it expected that ''a broad range of individuals have a sufficient level of knowledge and experience'' regarding the continued need for an exemption. For instance, the Notice of Inquiry noted that a renewal petition could be filed by a relevant employee or volunteer at an organization—like the American Foundation for the Blind, which advocates for the blind, visually impaired, and print disabled—who is familiar with the needs of the community, and is well-versed specifically in the e-book accessibility issue, to make the declaration with regard to the current e-book assistive technology exemption.[16] Consistent with that direction, the Office received petitions from some individuals who may not themselves have engaged in circumvention, but attested to their personal knowledge of others who have a continuing need for an exemption. Those petitions were signed by individuals at associations that had actively participated in the past rulemaking and described specific continued needs for the exemption.[17] Accordingly, the Office finds that these petitions are formally and substantively sufficient for the Office to consider in evaluating whether renewal of the existing exemptions exemption is appropriate.[18]

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[9] Commerce Comm. Report at 37; *see also* Staff of H. Comm. on the Judiciary, 105th Cong., Section-by-Section Analysis of H.R. 2281 as Passed by the United States House of Representatives on August 4th, 1998, at 6 (Comm. Print 1998) (using the equivalent phrase ''substantial adverse impact'') (''House Manager's Report''); *see also, e.g.,* 1201 Study at 119–21 (discussing same and citing application of this standard in five prior rulemakings).

[10] *See* 17 U.S.C. 1201(a)(1)(C) (asking whether users ''*are, or are likely to be* in the succeeding 3-year period, adversely affected by the prohibition [on circumvention] in their ability to make noninfringing uses'') (emphasis added); 1201 Study at 111–12; *see also Sea Island Broad. Corp.* v. *FCC,* 627 F.2d 240, 243 (D.C. Cir. 1980) (noting that ''[t]he use of the 'preponderance of evidence' standard is the traditional standard in civil and administrative proceedings''); 70 FR 57526, 57528 (Oct. 3, 2005); 2015 Recommendation at 15; Register of Copyrights, Section 1201 Rulemaking: Fifth Triennial Proceeding to Determine Exemptions to the Prohibition on Circumvention, Recommendation of the Register of Copyrights 6 (2012) (''2012 Recommendation''); Register of Copyrights, Section 1201 Rulemaking: Second Triennial Proceeding to Determine Exemptions to the Prohibition on Circumvention, Recommendation of the Register of Copyrights 19–20 (2003) (''2003 Recommendation'').

[11] 1201 Study at 142, 145.

[12] *Id.* at 143.

[13] *Id.* at 143–44.

[14] This suffices to address concerns raised that some renewal petitions sought exemptions broader than currently formulated. *See* Entertainment Software Association, the Motion Picture Association of America, Inc. & the Recording Industry of America, Inc. (collectively, ''Joint Creators'') Renewal Comment at 2; DVD Copy Control Association (''DVD CCA'') & The Advanced Access Content System Licensing Administrator (''AACS LA'') AV Noncom. Videos Renewal Comment at 1–2, 4–5; DVD CCA & AACS LA AV Univ. Renewal Comment at 1–2, 5; Alliance of Automobile Manufacturers (''Auto Alliance'') Renewal Comment at 1–2.

[15] Joint Creators Renewal Comment at 2 n.4.

[16] 82 FR at 29806. The Office did suggest that it would be improper for a member of the general public to petition for renewal if he or she knew nothing more about matters concerning e-book accessibility other than what he or she might have read in a brief newspaper article, or simply opposed the use of digital rights management tools as a matter of general principle—but none of the renewal petitions raise that issue.

[17] *See, e.g.,* The Intellectual Property & Technology Law Clinic of the University of Southern California Gould School of Law (''IPTC U.S.C.'') Renewal Pet. at 3 (''We have personally heard from a number of farmers and farm bureaus that farmers need this exemption and anticipate needing to use it in the future.''); Electronic Frontier Foundation (''EFF'') Repair Renewal Pet. at 3 (describing groups of users with continued need to engage in circumvention of motorized land vehicles and conversation with individual who modifies motorized wheelchairs and mobility scooters to tailor to the individual needs of users). The Office notes that parties demonstrated personal knowledge in multiple ways. One particularly helpful example was the petition submitted by Professors Bellovin, Blaze, and Heninger, which described how they rely on the exemption for their own security research and will continue to do so, discussed reliance on the exemption by other security researchers, and provided a recent example illustrating reliance on the exemption by security researchers. Bellovin, Blaze & Heninger Renewal Pet. at 3.

[18] Joint Creators also urged that petitions that ''expressly base their justification . . . on a need to provide circumvention assistance that would likely be prohibited by [the anti-trafficking provision of section 1201] should not be considered supportive of actual renewal.'' Joint Creators Renewal Comment at 3 (referencing Auto Care Association

As detailed below, after reviewing the petitions for renewal and comments in response, the Office concludes that it has received a sufficient petition to renew each existing exemption and it does not find any meaningful opposition to renewal. Accordingly, the Register intends to recommend readoption of all existing exemptions in their current form.[19]

*A. Literary Works Distributed Electronically (i.e., e-Books), for Use With Assistive Technologies for Persons Who Are Blind, Visually Impaired, or Have Print Disabilities*

Multiple organizations petitioned to renew the exemption for literary works distributed electronically (*i.e.,* e-books), for use with assistive technologies for persons who are blind, visually impaired, or have print disabilities (codified at 37 CFR 201.40(b)(2)).[20] No oppositions were filed against readoption of this exemption. The petitions demonstrated the continuing need and justification for the exemption, stating that individuals who are blind, visually impaired, or print disabled are significantly disadvantaged with respect to obtaining accessible e-book content because TPMs interfere with the use of assistive technologies such as screen readers and refreshable Braille displays.[21] Indeed, AFB, ACB, Samuelson-Glushko TLPC, and LCA noted that the record underpinning this exemption ''has stood and been re-established in the past five triennial reviews, dating back to 2003,'' and that the ''accessibility of ebooks is frequently cited as a top priority'' by its members and the patrons of LCA's member institutions.[22] In addition, the petitioners demonstrated personal knowledge and experience with regard to the assistive technology exemption; they are all organizations that advocate for the blind, visually impaired, and print disabled.

Based on the information provided in the renewal petitions and the lack of opposition, the Register believes that the conditions that led to adoption of this exemption are likely to continue during the next triennial period. Accordingly, the Register intends to recommend renewal of this exemption.

*B. Literary Works Consisting of Compilations of Data Generated by Implanted Medical Devices and Corresponding Personal Monitoring Systems, To Access Personal Data*

Hugo Campos, member of the Coalition of Medical Device Patients and Researchers, and represented by the Harvard Law School Cyberlaw Clinic, petitioned to renew the exemption covering access to patient data on networked medical devices (codified at 37 CFR 201.40(b)(10)).[23] No oppositions were filed against the petition to renew this exemption. Mr. Campos's petition demonstrated the continuing need and justification for the exemption, stating that patients continue to need access to data output from their medical devices to manage their health.[24] Mr. Campos demonstrated personal knowledge and experience with regard to this exemption, as he is a patient needing access to the data output from his medical device, and is a member of the Coalition of Medical Device Patients and Researchers, a coalition whose members research, comment on, and examine the effectiveness of networked medical devices.

Based on the information provided in the renewal petition and the lack of opposition, the Register believes that the conditions that led to adoption of this exemption are likely to continue during the next triennial period. Accordingly, the Register intends to recommend renewal of this exemption.

*C. Computer Programs That Operate Cellphones, Tablets, Mobile Hotspots, or Wearable Devices (e.g., Smartwatches), To Allow Connection of a Used Device to an Alternative Wireless Network (''Unlocking'')*

Multiple organizations petitioned to renew the exemption for computer programs that operate cellphones, tablets, mobile hotspots, or wearable devices (*e.g.,* smartwatches), to allow connection of a used device to an alternative wireless network (''unlocking'') (codified at 37 CFR 201.40(b)(3)).[25] No oppositions were filed against the petitions seeking to renew this exemption. The petitions demonstrate the continuing need and justification for the exemption, stating that consumers of the enumerated products continue to need to be able to unlock the devices so they can switch network providers. For example, ISRI stated that its members continue to purchase or acquire donated cell phones and tablets, and try to reuse them, but that wireless carriers still lock devices to prevent them from being used on other carriers.[26] In addition, the petitioners demonstrated personal knowledge and experience with regard to this exemption. CCA, ORI, and ISRI represent companies that rely on the ability to unlock cellphones. A number of the petitioners also participated in past 1201 triennial rulemakings relating to unlocking lawfully-acquired wireless devices.

Based on the information provided in the renewal petitions and the lack of opposition, the Register believes that the conditions that led to adoption of this exemption are likely to continue during the next triennial period. Accordingly, the Register intends to recommend renewal of this exemption.

*D. Computer Programs That Operate Smartphones, Smart TVs, Tablets, or Other All-Purpose Mobile Computing Devices, To Allow the Device To Interoperate With or To Remove Software Applications (''Jailbreaking'')*

Multiple organizations petitioned to renew the exemptions for computer programs that operate smartphones, smart TVs, tablets, or other all-purpose mobile computing devices, to allow the device to interoperate with or to remove software applications (''jailbreaking'') (codified at 37 CFR 201.40(b)(4)–(5)).[27] The petitions demonstrate the continuing need and justification for the exemption, and that petitioners had personal knowledge and experience with regard to this exemption. Specifically, the petitions state that, absent an exemption, TPMs applied to

(''Auto Care''), Consumer Technology Association (''CTA''), iFixit & Owners' Rights Initiative (''ORI'') Repair Renewal Pet.). The Office agrees that exemptions adopted through the triennial rulemaking cannot extend to the trafficking prohibitions in section 1201, but concludes that the petitions have sufficiently articulated a basis for renewal of the current exemptions under the statutory standard.

[19] Although the Office's Notice of Inquiry stated that this NPRM would set forth proposed regulatory language for any existing exemptions the Office intends to recommend for readoption, because many of the new petitions seek to expand existing exemptions, the Office concludes that proposing regulatory language at this time would be premature; the Register may propose altering current regulatory language to expand the scope of an existing exemption, where the record suggests such a change is appropriate.

[20] American Foundation for the Blind (''AFB''), American Council of the Blind (''ACB''), Samuelson-Glushko Technology Law & Policy Clinic at Colorado Law (''Samuelson-Glushko TLPC'') & Library Copyright Alliance (''LCA'') Renewal Pet.; University of Michigan Library Copyright Office (''UMLCO'') eBooks Renewal Pet.

[21] AFB, ACB, Samuelson-Glushko TLPC & LCA Renewal Pet. at 3; UMLCO eBooks Renewal Pet. at 3.

[22] AFB, ACB, Samuelson-Glushko TLPC & LCA Renewal Pet. at 3.

[23] Campos Compilations of Data Renewal Pet.

[24] *Id.* at 3.

[25] Competitive Carriers Association (''CCA'') Renewal Pet.; Consumers Union Renewal Pet.; Institute of Scrap Recycling Industries, Inc. (''ISRI'') Renewal Pet. (represented by Juelsgaard IP and Innovation Clinic, Mills Legal Clinic at Stanford Law School); ORI Unlocking Renewal Pet.

[26] ISRI Renewal Pet. at 3.

[27] New Media Rights (''NMR'') Jailbreaking Renewal Pet.; EFF Jailbreaking Renewal Pet.; Libiquity Jailbreaking Renewal Pet.; Software Freedom Conservancy (''SFC'') Renewal Pet.

the enumerated products would have an adverse effect on noninfringing uses, such as being able to install third-party applications on a smartphone or download third-party software on a smart TV to enable interoperability.[28] For example, EFF's petition outlined its declarant's experience searching current mobile computing device markets and technologies, working as a software engineer, and participating in four prior 1201 rulemakings.[29] Similarly, the Libiquity petition was submitted by someone who ''work[s] with the operating system and many of the system libraries that lie at the core of the firmware systems of a large majority of smartphones, portable all-purpose mobile computing devices, and smart televisions.'' [30]

In a brief two-page comment, BSA | The Software Alliance (''BSA'') opposed the readoption of this exemption, stating that ''alternatives to circumvention exist,'' and that ''jailbreaking can undermine the integrity and security of a platform's operating system in a manner than facilitates copyright infringement and exposes users to heightened risks of privacy violations.'' [31]

As the Office explained in the Notice of Inquiry, ''[o]pposition to a renewal petition must be meaningful, such that, from the evidence provided, it would be reasonable for the Register to conclude that the prior rulemaking record and any further information provided in the renewal petition are insufficient to support recommending renewal of an exemption.'' [32] In such a circumstance, the exemption would be considered pursuant to the more comprehensive rulemaking process (*i.e.,* three rounds of written comment, followed by public hearings).

The Office finds that BSA's comment largely re-articulates a general opposition to a jailbreaking exemption, and notes that the past three rulemakings have adopted some form of an exemption for jailbreaking certain types of mobile computing devices.[33] Indeed, BSA specifically raised the issue of circumvention alternatives to jailbreaking in the 2015 triennial rulemaking,[34] and does not now identify any specific alternatives that are available now but were not available during the previous rulemaking. BSA also cites the same article regarding pirated iOS apps considered by the Register during sixth triennial rulemaking.[35] Similarly, BSA references Apple's launch of its App Store in 2008 to evidence how ''access controls have increased, rather than decreased, the availability of software applications designed for use on mobile phones.'' [36] The sixth triennial rulemaking, however, considered the existence of Apple's App Store and third-party apps.[37] Nor does BSA identify changes in case law or new technological developments that might be relevant. Each of the issues raised by BSA in opposition to readoption had been considered and evaluated in granting the exemption previously. BSA provides no new evidence that demonstrates a change in circumstances.

The Office therefore concludes that BSA's opposition is not sufficiently meaningful to draw the conclusion that the past rulemaking record is no longer reliable, or that the reasoning adopted in the Register's 2015 Recommendation cannot be relied upon for the next three-year period.

Based on the information provided in the renewal petitions and the lack of meaningful opposition, the Register believes that the conditions that led to adoption of this exemption are likely to continue during the next triennial period. Accordingly, the Register intends to recommend renewal of this exemption.

*E. Computer Programs That Control Motorized Land Vehicles, Including Farm Equipment, for Purposes of Diagnosis, Repair, and Modification of the Vehicle*

Multiple organizations petitioned to renew the exemption for computer programs that control motorized land vehicles, including farm equipment, for purposes of diagnosis, repair, and modification of the vehicle (codified at 37 CFR 201.40(b)(6)).[38] The petitions demonstrated the continuing need and justification for the exemption to prevent owners of motorized land vehicles from being adversely impacted in their ability to diagnose, repair, and modify their vehicles as a result of TPMs that protect the copyrighted computer programs on the electronic control units (''ECUs'') that control the functioning of the vehicles. For example, Auto Care, CTA, iFixit, and ORI stated that ''approximately 20 percent of American consumers buy automotive parts and products to maintain and repair their own vehicles.'' [39] AFBF similarly remarked that many agricultural vehicles are now ''equipped with computers that monitor and control vehicle function,'' and many agricultural equipment manufacturers have adopted TPMs that restrict access to such computer software.[40] Indeed, MEMA, which during the sixth triennial rulemaking initially opposed any exemption that would impact the software and TPMs in vehicles, now supports renewal of this exemption because it strikes ''an appropriate balance between encouraging marketplace competition and innovation while mitigating the impact on safety, regulatory, and environmental compliance.'' [41] The petitioners demonstrated personal knowledge and experience with regard to this exemption; each either represents or gathered information from individuals conducting repairs or businesses that manufacture, distribute, and sell motor vehicle parts, and perform vehicle service and repair.

Although not opposing readoption of this exemption, in response to Auto Care, CTA, iFixit, and ORI's renewal petition, the Auto Alliance submitted comments to clarify that the Office ''should reject any part of the . . . petition that argues for expanding the current temporary exemption . . . in section 201.40(b)(6), and should only consider the petition to the extent it seeks renewal of the current exemption as it is currently formulated, without modification.'' [42] The Office agrees. As noted above, the Office's Notice of Inquiry clearly stated that renewal petitions could only seek readoption of current exemptions as they are currently formulated, without modification, and the Office disregarded sections of renewal petitions to the extent that they proposed uses beyond the current exemptions. To the extent Auto Care, CTA, iFixit, and ORI propose that repair shops should be able to ''lawfully assist[ ] customers in the maintenance, repair, and upgrade of their vehicles'' under the existing exemption,[43] the

[28] NMR Jailbreaking Renewal Pet. at 1; EFF Jailbreaking Renewal Pet. at 1; Libiquity Jailbreaking Renewal Pet. at 1; SFC Renewal Pet. at 1.

[29] EFF Jailbreaking Renewal Pet. at 3.

[30] Libquity Jailbreaking Renewal Pet. at 3.

[31] BSA Jailbreaking Renewal Comment at 1–2.

[32] 82 FR at 29807.

[33] 80 FR 65944, 65952–53 (Oct. 28, 2015); 77 FR 65260, 65263–64 (Oct. 26, 2012); 75 FR 43825, 43828–30 (July 27, 2010).

[34] 2015 Recommendation at 185–87.

[35] *Id.* at 187 n.1211.

[36] BSA Jailbreaking Renewal Comment at 2.

[37] 2015 Recommendation at 181–82.

[38] Auto Care, CTA, iFixit & ORI Repair Renewal Pet.; American Farm Bureau Federation (''AFBF'') Renewal Pet.; EFF Repair Renewal Pet.; Motor & Equipment Manufacturers Association (''MEMA'') Repair Renewal Pet.; IPTC U.S.C. Renewal Pet.

[39] Auto Care, CTA, iFixit & ORI Repair Renewal Pet. at 3.

[40] AFBF Renewal Pet. at 3.

[41] MEMA Repair Renewal Pet. at 3.

[42] Auto Alliance Renewal Comment at 2.

[43] Auto Care, CTA, iFixit & ORI Repair Renewal Pet. at 3.

Office finds this proposition to be outside the bounds of the procedure for exemption renewal. The Office notes, however, that iFixit petitioned for a new exemption that would expand the existing exemption to permit circumvention of TPMs to allow third-party repair services. The Office discusses iFixit's petition below.

Based on the information provided in the renewal petitions and the lack of opposition to the specific exemption, the Register believes that the conditions that led to adoption of this exemption are likely to continue during the next triennial period. Accordingly, the Register intends to recommend renewal of this exemption.[44]

*F. Computer Programs That Operate Devices and Machines Primarily Designed for Use by Individual Consumers (Including Voting Machines), Motorized Land Vehicles, or Medical Devices Designed for Implantation in Patients and Corresponding Personal Monitoring Systems, for Purposes of Good-Faith Security Research.*

Multiple organizations and security researchers petitioned to renew the exemption for purposes of good-faith security research (codified at 37 CFR 201.40(b)(7)).[45] The petitioners demonstrated the continuing need and justification for the exemption, and personal knowledge and experience with regard to this exemption. For example, Professors Bellovin, Blaze, and Heninger stated that they have conducted their own security research in reliance on the existing exemption, and that they ''regularly engage'' with other security researchers who have similarly relied on the exemption.[46] They provided an example of a recent computer security conference in which thousands of participants relied on the existing exemption to examine and test electronic voting devices, during which they identified ways the security of the voting devices could be manipulated to affect election outcomes—the results of which were reported to election officials to improve the security of their voting systems.[47]

No oppositions were filed against readoption of this exemption. To the contrary, MEMA, which during the sixth triennial rulemaking initially opposed any exemption that would impact the software and TPMs in vehicles, now supports renewal of this exemption because it strikes ''an appropriate balance between encouraging marketplace competition and innovation while mitigating the impact on safety, regulatory, and environmental compliance.'' [48] In addition, BSA submitted comments in support of renewal of this exemption, noting that because the circumvention must be ''carried out in a controlled environment'' and conducted primarily to ''promote safety and security,'' the exemption ''provides important clarity to good-faith security researchers while maintaining important safeguards that protect the safety, privacy and property interests of rights holders and the public.'' [49]

Based on the information provided in the renewal petitions and the lack of opposition, the Register believes that the conditions that led to adoption of this exemption are likely to continue during the next triennial period. Accordingly, the Register intends to recommend renewal of this exemption.[50]

*G. Computer Programs That Operate 3D Printers, To Allow Use of Alternative Feedstock*

Michael Weinberg and ORI jointly petitioned to renew the exemption for computer programs that operate 3D printers to allow use of alternative feedstock (codified at 37 CFR 201.40(b)(9)).[51] No oppositions were filed against readoption of this exemption. The petition demonstrated the continuing need and justification for the exemption, and the petitioner demonstrated personal knowledge and experience. Specifically, Mr. Weinberg petitioned for the existing exemption, and ''continued to participate in the review of that exemption . . . in his personal capacity.'' [52] In addition, the petition states that printers continue to restrict the use of third-party feedstock, thereby requiring renewal of the exemption.

Based on the information provided in the renewal petition and the lack of opposition, the Register believes that the conditions that led to adoption of this exemption are likely to continue during the next triennial period. Accordingly, the Register intends to recommend renewal of this exemption.

*H. Video Games for Which Outside Server Support Has Been Discontinued, To Allow Individual Play by Gamers and Preservation of Games by Libraries, Archives, and Museums (as Well as Necessary Jailbreaking of Console Computer Code for Preservation Uses Only)*

Multiple organizations petitioned to renew the exemption for video games for which outside server support has been discontinued (codified at 37 CFR 201.40(b)(8)).[53] The petitions state that libraries and museums continue to need the exemption to preserve and curate video games in playable form. For example, UMCLO stated that ''[m]any games still depend on connection to an external server for gameplay,'' suggesting that without a renewal of this exemption the ability of gamers to play them would be diminished.[54] In addition, the petitioners demonstrated personal knowledge and experience with regard to this exemption through past participation in the 1201 triennial rulemaking relating to access controls on video games and consoles, and/or representing major library associations with members that have relied on this exemption. Readoption of this exemption was unopposed.[55]

[44] The Office's recommendation will include removing language relating to a delayed effective date from the existing exemption. As noted in the Office's 1201 Study, during the last triennial rulemaking the Office ''implemented a twelve-month delay for certain exemptions relating to security research and automobile repair to allow other agencies to react to the new rule.'' 1201 Study at 124; *see also* 2015 Recommendation at 248, 317–18. But ''now that agencies, consumers, and businesses alike have had the opportunity to consider these issues and react to [such] exemptions,'' the Office ''does not anticipate the Register recommending additional delays for implementation of exemptions unless necessitated by a grave or unusual situation.'' 1201 Study at 125–26. Because the time delay for this exemption was intended to be a one-time delay, which has now expired, the Office considers its removal to be a technical change.

[45] Bellovin, Blaze & Heninger Renewal Pet. (represented by Professor Andrea Matwyshyn); Campos Security Research Renewal Pet.; Center for Democracy & Technology (''CDT'') Renewal Pet.; Felten, Halderman & ORI Renewal Pet. (represented by Samuelson-Glushko TLPC and Jonathan Band of policbandwidth); Libiquity Security Research Renewal Pet.

[46] Bellovin, Blaze & Heninger Renewal Pet. at 3.

[47] *Id.*

[48] MEMA Security Research Renewal Pet. at 3.

[49] BSA Security Research Renewal Comment at 2.

[50] The Office's recommendation will include removing language relating to a delayed effective date from the existing exemption. As noted above regarding the existing exemption for repair, because the time delay for this exemption was intended to be a one-time delay, which has now expired, the Office considers its removal to be a technical change.

[51] Weinberg & ORI Renewal Pet.

[52] *Id.* at 1.

[53] EFF Video Game Renewal Pet.; LCA Video Game Renewal Pet.; UMLCO Video Game Renewal Pet.

[54] UMCLO Video Game Renewal Pet. at 3.

[55] Joint Creators questioned whether the petitions sufficiently requested renewal of the portion of the exemption applicable to personal gameplay. Joint Creators Renewal Comment at 2, n.2. The Office notes that the declarations signed by the petitioners support readoption of the exemption in full. EFF Video Game Renewal Pet.; LCA Video Game Renewal Pet.; UMLCO Video Game Renewal Pet. Joint Creators themselves acknowledged that ''the petitions appear to implicitly request renewal of the current exemption in its entirety'' and did not

Continued

Based on the information provided in the renewal petitions and the lack of opposition, the Register believes that the conditions that led to adoption of this exemption are likely to continue during the next triennial period. Accordingly, the Register intends to recommend renewal of this exemption.

*I. Motion Pictures (Including Television Programs and Videos): For Educational Uses by College and University Instructors and Students*

Multiple individuals and organizations petitioned to renew the exemption for motion pictures for educational uses by college and university instructors and students (codified at 37 CFR 201.40(b)(1)(iv)).[56] No oppositions were filed against readoption of this exemption. The petitions demonstrated the continuing need and justification for the exemption, and personal knowledge and experience with regard to this exemption. For example, Joint Educators, AAUP, DCSUM, and LCA stated that courses on video essays (or multimedia or videographer criticism), now taught at many universities, would not be able to exist without relying on this exemption.[57] Without this exemption, Joint Educators, AAUP, DCSUM, and LCA assert that educators would be ''unable to provide an enriching and accurate description and analysis of cinematic or other audiovisual works when prevented from accessing such works due to TPM[s]'' [58]—and their declarant, Professor Decherney, has personally relied upon this exemption to teach a course on multimedia criticism.[59] Similarly, Professor Hobbs, who represents more than 17,000 digital and media literacy educators, and NAMLE, an organization devoted to media literacy with more than 3,500 members, stated that ''sometimes teachers must circumvent a DVD protected by the Content Scramble System when screen-capture software or other non-circumventing alternatives are unable to produce the required level of high-quality content.'' [60]

The DVD Copy Control Association (''DVD CCA'') and The Advanced Access Content System Licensing Administrator (''AACS LA'') submitted comments regarding readoption of this exemption. Although DVD CCA and AACS LA did not oppose readoption, they stated that the exemption is ''predicated on the need for close analysis of the film in uses that constitute criticism or comment,'' and suggested that Joint Educators, AAUP, ICA, DCSUM, SCMS, and LCA did ''not focus on the need for close analysis of the film'' in their renewal petition.[61] DVD CCA and AACS LA asked for clarification that ''renewal of this exemption is limited to those uses where close analysis is necessary in the particular circumstance.'' [62]

As noted above, the Office's Notice of Inquiry stated that renewal petitions are to seek readoption of current exemptions as they are currently formulated, without modification. Therefore, the Office focused on whether the renewal petition provided sufficient information to warrant readoption of the exemption in its current form. In this case, Joint Educators, AAUP, ICA, DCSUM, SCMS, and LCA did state that ''*close analysis* of digital media is being increasingly recognized across many disciplines as a fundamental tool for pedagogy,'' followed by examples of such uses.[63] Accordingly, the Office concludes that Joint Educators, AAUP, ICA, DCSUM, SCMS, and LCA provided sufficient information to support renewal of the existing exemption.

Based on the information provided in the renewal petitions and the lack of opposition, the Register believes that the conditions that led to adoption of this exemption are likely to continue during the next triennial period. Accordingly, the Register intends to recommend renewal of this exemption.

To the extent petitioners seek a broader exemption, the Office notes that petitions for new exemptions were filed seeking modification of the existing exemptions for educational uses of motion pictures. This NPRM initiates public comment on such modification through Proposed Class 1 described below, which combines multiple petitions for modified exemptions, including one by Joint Educators.

*J. Motion Pictures (Including Television Programs and Videos): For Educational Uses by K–12 Instructors and Students*

Multiple organizations petitioned to renew the exemption for motion pictures for educational uses by K–12 instructors and students (codified at 37 CFR 201.40(b)(1)(vi)).[64] No oppositions were filed against readoption of this exemption. The petitions demonstrated the continuing need and justification for the exemption, stating that K–12 instructors and students continue to rely on excerpts from digital media for class presentations and coursework, and must sometimes use screen-capture technology. In addition, the petitioners demonstrated personal knowledge and experience with regard to this exemption through representation of thousands of digital and literacy educators and/or members supporting K–12 instructors and students, combined with past participation in the 1201 triennial rulemaking.

Based on the information provided in the renewal petitions and the lack of opposition, the Register believes that the conditions that led to adoption of this exemption are likely to continue during the next triennial period. Accordingly, the Register intends to recommend renewal of this exemption.

*K. Motion Pictures (Including Television Programs and Videos): For Educational Uses in Massive Open Online Courses (''MOOCs'')*

Joint Educators, ICA, DCSUM, SCMS, and LCA petitioned to renew the exemption for motion pictures for educational uses in massive open online courses (''MOOCs'') (codified at 37 CFR 201.40(b)(1)(v)).[65] No oppositions were filed against readoption of this exemption. The petition demonstrated the continuing need and justification for the exemption, stating that instructors continue to rely on the exemption to develop, provide, and improve MOOCs, as well as increase the number of (and therefore access to) MOOCs in the field of film and media studies. In addition, the declarant, Professor Decherney, demonstrated personal knowledge by describing his reliance on the exemption to teach MOOCs on film and media studies, as well as his past participation in the 1201 triennial rulemaking, along with Professor Carpini, ICA, SCMS, and LCA.

Based on the information provided in the renewal petition and the lack of opposition, the Register believes that the

oppose such renewal. Joint Creators Renewal Comment at 2, n.2.

[56] Decherney, Sender & Carpini (collectively, ''Joint Educators''), American Association of University Professors (''AAUP''), the International Communication Association (''ICA''), Department of Communication Studies at the University of Michigan (''DCSUM''), the Society for Cinema and Media Studies (''SCMS'') & LCA AV Univ. Renewal Pet.; Hobbs & National Association for Media Literary Education (''NAMLE'') AV Univ. Renewal Pet.; UMLCO AV Univ. Renewal Pet.

[57] Joint Educators, AAUP, ICA, DCSUM, SCMS & LCA AV Univ. Renewal Pet. at 1.

[58] *Id.*

[59] *Id.*

[60] Hobbs & NAMLE AV Univ. Renewal Pet. at 1.

[61] DVD CCA & AACS LA AV Univ. Renewal Comment at 1–2.

[62] *Id.* at 4–5.

[63] Joint Educators, AAUP, ICA, DCSUM, SCMS & LCA AV Univ. Renewal Pet. at 3 (emphasis added).

[64] LCA K–12 Renewal Pet.; Hobbs & NAMLE K–12 Renewal Pet.

[65] Joint Educators, ICA, DCSUM, SCMS & LCA MOOCs Renewal Pet.

conditions that led to adoption of this exemption are likely to continue during the next triennial period. Accordingly, the Register intends to recommend renewal of this exemption.

*L. Motion Pictures (Including Television Programs and Videos): For Educational Uses in Digital and Literacy Programs Offered by Libraries, Museums, and Other Nonprofits*

Multiple organizations petitioned to renew the exemption for motion pictures for educational uses in digital and literacy programs offered by libraries, museums, and other nonprofits (codified at 37 CFR 201.40(b)(1)(viii)).[66] No oppositions were filed against readoption of this exemption. The petitions demonstrated the continuing need and justification for the exemption, and demonstrated personal knowledge and experience with regard to this exemption. For example, LCA stated that librarians across the country have relied on the current exemption and will continue to do so for their digital and literacy programs.[67] In addition, Professor Hobbs and NAMLE stated that librarians will continue to rely on this exemption for their digital and literacy programs, and to advance the digital media knowledge of their patrons.[68]

Based on the information provided in the renewal petitions and the lack of opposition, the Register believes that the conditions that led to adoption of this exemption are likely to continue during the next triennial period. Accordingly, the Register intends to recommend renewal of this exemption.

*M. Motion Pictures (Including Television Programs and Videos): For Multimedia e-Books Offering Film Analysis*

A professor and two organizations collectively petitioned to renew the exemption for motion pictures for multimedia e-books offering film analysis (codified at 37 CFR 201.40(b)(1)(iii)).[69] No oppositions were filed against readoption of this exemption. The petition demonstrated the continuing need and justification for the exemption, stating that the availability of video necessary for authors to undertake film analysis in e-books continues to be ''limited to formats encumbered by technological protection measures. . . .'' [70] In addition, the petitioners demonstrated personal knowledge through Professor Buster's continued work on an e-book series based on her lecture series, ''Deconstructing Master Filmmakers: The Uses of Cinematic Enchantment,'' and Authors Alliance's feedback that its members continue to desire authoring e-books that incorporate film for the purpose of analysis.[71]

Based on the information provided in the renewal petition and the lack of opposition, the Register believes that the conditions that led to adoption of this exemption are likely to continue during the next triennial period. Accordingly, the Register intends to recommend renewal of this exemption.

*N. Motion Pictures (Including Television Programs and Videos): For Uses in Documentary Films*

Multiple organizations petitioned to renew the exemption for motion pictures for uses in documentary films (codified at 37 CFR 201.40(b)(1)(i)).[72] No oppositions were filed against readoption of this exemption. The petitions summarized the continuing need and justification for the exemption, and the petitioners demonstrated personal knowledge and experience with regard to this exemption. For example, Joint Filmmakers, CID, and WIFV—which represent thousands of independent filmmakers across the nation—stated that TPMs such as encryption continue to prevent filmmakers from accessing needed material, and that this is ''especially true for the kind of high definition motion picture material filmmakers need to satisfy both distributors and viewers.'' [73] In addition, Joint Filmmakers have participated in multiple triennial rulemakings. Petitioners state that they personally know many filmmakers who have found it necessary to rely on this exemption, and will continue to do so.[74]

Based on the information provided in the renewal petitions and the lack of opposition, the Register believes that the conditions that led to adoption of this exemption are likely to continue during the next triennial period. Accordingly, the Register intends to recommend renewal of this exemption.

*O. Motion Pictures (Including Television Programs and Videos): For Uses in Noncommercial Videos*

Two organizations petitioned to renew the exemption for motion pictures for uses in noncommercial videos (codified at 37 CFR 201.40(b)(1)(ii)).[75] No oppositions were filed against readoption of this exemption. The petitions demonstrated the continuing need and justification for the exemption, and the petitioners demonstrated personal knowledge and experience with regard to this exemption. For example, OTW has advocated for the noncommercial video exemption in past triennial rulemakings, and has heard from ''a number of noncommercial remix artists'' who have used the exemption and anticipate needing to use it in the future.[76] These discussions included a report from an academic that video quality was important in facilitating classroom understanding and discussion.[77] Similarly, NMR stated that it has spoken to a number of noncommercial video creators who have relied on this exemption, and intend to do so in the future.[78]

Although no oppositions were filed against readoption of the exemption as it currently exists, Joint Creators submitted comments expressing concern that OTW's renewal petition proposed using language from the triennial rulemaking initiated in 2008 instead of readopting the exemption without modification.[79] DVD CCA and AACS LA made a similar observation.[80]

As noted above, the Office's Notice of Inquiry stated that renewal petitions are to seek readoption of current exemptions as they are currently formulated, without modification. As a result, the Office did not consider, as part of the renewal process, sections of renewal petitions to the extent that they proposed uses beyond the current exemptions. The Office concludes, however, that OTW's submission, fairly read, did sufficiently petition for renewal of the exemption as it currently exists, providing detailed information

[66] LCA AV Nonprofit Renewal Pet.; Hobbs & NAMLE AV Nonprofit Renewal Pet.

[67] LCA AV Nonprofit Renewal Pet. at 1.

[68] Hobbs & NAMLE AV Nonprofit Renewal Pet. at 3.

[69] Buster, Authors Alliance & AAUP Renewal Pet. (represented by Samuelson-Glushko TLPC).

[70] *Id.* at 3.

[71] *See id.*

[72] Film Independent, International Documentary Association, Kartemquin Educational Films, Inc. (collectively, ''Joint Filmmakers''), Center For Independent Documentary (''CID'') & Women in Film and Video (''WIFV'') Renewal Pet. (represented by Donaldson + Callif, LLP and UCI Intellectual Property Arts and Technology Clinic at University of California, Irvine (''UCI'')); NMR AV Documentary Renewal Pet.

[73] Joint Filmmakers, CID & WIFV Renewal Pet. at 3.

[74] *Id.;* NMR AV Documentary Renewal Pet. at 3.

[75] NMR Noncom. Videos Renewal Pet.; Organization for Transformative Works (''OTW'') Renewal Pet.

[76] OTW Renewal Pet. at 3.

[77] *Id.*

[78] NMR Noncom. Videos Renewal Pet. at 3.

[79] Joint Creators Renewal Comment at 2 n.1.

[80] DVD CCA & AACS LA AV Noncom. Videos Renewal Comment at 4.

supporting the continued need for an exemption for noncommercial videos.[81]

Based on the information provided in the renewal petitions and the lack of opposition, the Register believes that the conditions that led to adoption of this exemption are likely to continue during the next triennial period. Accordingly, the Register intends to recommend renewal of this exemption.

To the extent OTW seeks modification of the existing noncommercial video exemption, the Office notes that a petition for a new exemption was filed seeking such modification. This NPRM initiates public comment on that modification through the proposed class described below.

## III. Analysis and Classification of Proposed New Exemptions

Having addressed the petitions to renew existing exemptions, the Office now turns to the petitions for new or expanded exemptions. The Office received twenty-three petitions, which it has organized into twelve classes, as described below. Before turning to a description of those classes, the Office first explains the process and standards for submission of written comments.

### *A. Submission of Written Comments*

Persons wishing to address proposed exemptions in written comments should familiarize themselves with the substantive legal and evidentiary standards for the granting of an exemption under section 1201(a)(1), which are also described in more detail on the Office's form for submissions of longer comments, available on its Web site. In addressing factual matters, commenters (both proponents and opponents) should be aware that the Office favors specific, ''real-world'' examples supported by evidence over speculative, hypothetical observations. In cases where the technology at issue is not apparent from the requested exemption, it can be helpful for commenters to describe the TPM(s) that control access to the work and method of circumvention.

Commenters' legal analysis should explain why the proposal meets or fails to meet the criteria for an exemption under section 1201(a)(1), including, without limitation, why the uses sought are or are not noninfringing as a matter of law. The legal analysis should also discuss statutory or other legal provisions that could impact the necessity for or scope of the proposed exemption (for example, the Unlocking Consumer Choice and Wireless Competition Act (''Unlocking Act''), or 17 U.S.C. 117). Legal assertions should be supported by statutory citations, relevant case law, and other pertinent authority. In cases where a class proposes to expand an existing exemption, commenters should focus their comments on the legal and evidentiary bases for modifying the exemption, rather than the underlying exemption; as discussed above, the Register intends to recommend each current temporary exemption for renewal.

To ensure a clear and definite record for each of the proposals, commenters are required to provide a separate submission for each proposed class during each stage of the public comment period. Although a single comment may not address more than one proposed class, the same party may submit multiple written comments on different proposals. The Office acknowledges that the requirement of separate submissions may require commenters to repeat certain information across multiple submissions, but the Office believes that the administrative benefits of creating a self-contained, separate record for each proposal will be worth the modest amount of added effort.

The first round of public comment is limited to submissions from proponents (*i.e.,* those parties who proposed new exemptions during the petition phase) and other members of the public who support the adoption of a proposed exemption, as well as any members of the public who neither support nor oppose an exemption but seek only to share pertinent information about a specific proposal.

Proponents of exemptions should present their complete affirmative case for an exemption during the initial round of public comment, including all legal and evidentiary support for the proposal. Members of the public who oppose an exemption should present the full legal and evidentiary basis for their opposition in the second round of public comment. The third round of public comment will be limited to supporters of particular proposals and those who neither support nor oppose a proposal, who, in either case, seek to reply to points made in the earlier rounds of comments. Reply comments should not raise new issues, but should instead be limited to addressing arguments and evidence presented by others.

### *B. The Proposed Classes*

As noted above, the Office has reviewed and classified the proposed exemptions set forth in the twenty-three petitions received in response to its Notice of Inquiry. Any exemptions adopted as part of this rulemaking must be based on ''a particular class of works'' [82]; and the legislative history explains that each class is intended to ''be a narrow and focused subset of the broad categories of works . . . identified in Section 102 of the Copyright Act. . . .'' [83] As explained in the Notice of Inquiry, the Office consolidates or groups related and/or overlapping proposed exemptions where possible to simplify the rulemaking process and encourage joint participation among parties with common interests (though collaboration is not required). Accordingly, the Office has categorized the petitions into twelve proposed classes of works.

Each proposed class is briefly described below; additional information can be found in the underlying petitions posted on *regulations.gov*. As explained in the Notice of Inquiry, the proposed classes ''represent only a starting point for further consideration in the rulemaking proceeding, and will be subject to further refinement based on the record.'' [84] The Office further notes that it has not put forward precise regulatory language for the proposed classes, because any specific language for exemptions that the Register ultimately recommends to the Librarian will depend on the full record developed during this rulemaking. Indeed, in the case of proposed modifications to existing exemptions, as stated above, the Register may propose altering current regulatory language to expand the scope of an exemption, where the record suggests such a change is appropriate.

In addition, after examining the petitions, the Office has preliminarily identified some initial legal and factual areas of interest with respect to certain proposed classes. The Office stresses, however, that these areas are not exhaustive, and *commenters should consider and offer all legal argument and evidence they believe necessary to create a complete record.* These early observations are offered without prejudice to the Office's ability to raise other questions or concerns at later stages of the proceeding. Finally, ''where an exemption request resurrects legal or factual arguments that have been previously rejected, the Office will

[81] OTW Renewal Pet. at 3–4.

[82] 17 U.S.C. 1201(a)(1)(B).

[83] Commerce Comm. Report at 38; *see also* 1201 Study at 109–10 (noting that while ''in some cases, [the Office] can make a greater effort to group similar classes together, and will do so going forward,'' ''in other cases, the Office's ability to narrowly define the class is what enabled it to recommend the exemption at all, and so the Office will continue to refine classes when merited by the record'').

[84] 82 FR at 29808.

continue to rely on past reasoning to dismiss such arguments in the absence of new information.'' [85]

Proposed Class 1: Audiovisual Works—Criticism and Comment

Several petitions seek expansion of existing exemptions for circumvention of access controls protecting excerpts of motion pictures on DVDs, Blu-Ray discs, and digitally transmitted video for purposes of criticism and comment by various users, including creators of noncommercial videos, college and university faculty and students, faculty of massive open online courses (''MOOCs''), documentary filmmakers, and for multimedia e-books offering film analysis.

Because the new proposals raise some shared concerns, including the impact of TPMs on the alleged noninfringing uses of motion pictures and whether alternative methods of accessing the content could alleviate potential adverse impacts, the Office has grouped these petitions into one class. This grouping is without prejudice to further refinement of this class, including whether it should be parsed back into subclasses based on specific uses, following the approach of past rulemakings. This approach also accounts for a joint petition by EFF, NMR, and OTW, which seeks to collapse (essentially) the existing exemptions for excerpts of motion pictures to eliminate limitations on the types of user or use, instead allowing circumvention so long as the purpose is for criticism and comment.[86] Specifically, EFF, NMR, and OTW seek to retain the vast majority of existing introductory text of section 201.40(b)(1), but then eliminate the various categories of specific users such that the exemption becomes:

> Motion Pictures (including television shows and videos), as defined in 17 U.S.C. 101, where circumvention is undertaken solely in order to make use of short portions of the works for the purpose of criticism or comment, where the motion picture is lawfully made and acquired on a DVD protected by the Content Scrambling System, on a BluRay disc protected by the Advanced Access Control System, via a digital transmission protected by a technological measure, or a similar technological protection measure intended to control access to a work, where the person engaging in circumvention reasonably believes that non-circumventing alternatives are unable to produce the required level of high-quality source material.[87]

The Office notes that in the past, the Register has at times found it necessary to define a class by a use or user in order to recommend an exemption,[88] but also recognizes that for these audiovisual exemptions in particular, participants expressed concern that the current exemptions are overly complicated and confusing.[89] The Office invites comment on each aspect of these proposals, including whether this grouping is preferable, or whether the existing exemptions should be consolidated in some other manner, such as grouping just the permitted educational uses together.[90] For commenters who may be concerned that a single exemption is too broad, could an exemption be refined by specifically *excluding* types of uses or users, as opposed to enumerating permitted users in multiple exemptions?

Beyond EFF, NMR, and OTW's proposal, the other petitions seek to expand upon existing exemptions for purposes of criticism and comment, but in a more limited way. Specifically, Professor Buster, Authors Alliance, and OTW propose expanding the exemption for multimedia e-books offering film analysis (codified at 37 CFR 201.40(b)(1)(iii)) by removing the ''nonfiction'' and ''offering film analysis'' limitations, and removing references to screen-capture technology.[91] Similarly, Joint Filmmakers seek removal of the ''documentary'' limitation in the current exemption for uses in documentary films (codified at 37 CFR 201.40(b)(1)(i)).[92] The Office notes that many of these issues were previously considered by the Register during the 2015 triennial rulemaking, and encourages proponents to provide new factual or legal support for these proposed modifications.[93]

The two remaining petitions seek to expand the current exemptions for educational uses. Brigham Young University (''BYU'') and BYU—Idaho, Intellectual Property Office (''BYU IPO'') seek expansion of the exemption for educational uses by college and university students and instructors to more broadly cover ''uses where circumvention is undertaken to facilitate performance of motion pictures in the course of face-to-face teaching activities, as set forth in 17 U.S.C. 110(1)''; ''use of more than short portions of motion picture excerpts''; and ''uses beyond film studies or other courses requiring close analysis of film and media excerpts.'' [94] The Office notes that in the 2012 and 2015 triennial rulemakings, the Register found the ''short portions'' limitation was ''critical'' in deciding to recommend exemptions for the use of motion picture excerpts.[95]

Joint Educators seek to expand the exemption for motion pictures for educational uses in MOOCs; specifically, they propose removing the ''accredited non-profit educational institutions'' and ''massive open online courses'' limitations, and extending the exemption to ''*all* online educational institutions'' and ''for use by instructors of *all* online educational courses. . . .'' [96] The petition also proposes to have the exempted use ''no longer be limited'' by the TEACH Act (codified at 17 U.S.C. 110).[97] The Office notes that some of these considerations were previously addressed during the 2015 triennial rulemaking, and invites comment on changing legal or factual circumstances with respect to these provisions.[98]

In addition, two petitioners seek clarification that ''the use of screen-capture technology does not constitute circumvention,'' which presumably might result in the removal of current regulatory exemptions for screen capture technology, as they would be unnecessary.[99] Again the Office notes that in 2015, the Register noted that the then-existing record did not ''include any examples of screen-capture technology that holds itself out as non-

[85] 1201 Study at 147; *see also* 79 FR 55687, 55690 (Sept. 17, 2014).

[86] EFF, NMR & OTW Class 1 Pet. at 2.

[87] *Id.*

[88] 1201 Study at 109–10.

[89] *Id.* at 151; *see, e.g.,* EFF, NMR & OTW Class 1 Pet. at 2–3.

[90] *See* 1201 Study at 109 (''[I]n the upcoming seventh rulemaking, the Office will consider consolidating some of the separate classes related to motion pictures into broader categories, such as one related to educational uses.''); *see also* OTW Renewal Pet. at 4 (requesting adoption of an exemption for noncommercial videos based on regulatory language adopted in the 2008 rulemaking).

[91] Buster, Authors Alliance & OTW Class 1 Pet. at 3.

[92] Joint Filmmakers Class 1 Pet. at 3.

[93] 2015 Recommendation at 103.

[94] BYU & BYU IPO Class 1 Pet. at 2.

[95] 2015 Recommendation at 99; 2012 Recommendation at 138–39 (also declining to recommend that the exemption apply to ''students across all disciplines of study'').

[96] Joint Educators Class 1 Pet. at 2.

[97] *Id.*

[98] 2015 Recommendation at 102.

[99] BYU & BYU IPO Class 1 Pet. at 2; Joint Filmmakers Class 1 Pet. at 3; *see* 37 CFR 201.40(b)(1)(i) (''For use in documentary filmmaking . . . [w]here the circumvention is undertaken using screen-capture technology that appears to be offered to the public as enabling the reproduction of motion pictures after content has been lawfully acquired and decrypted . . .''); 37 CFR 201.40(b)(1)(iv) (''By college and university faculty and students, for educational purposes . . . [w]here the circumvention is undertaken using screen-capture technology that appears to be offered to the public as enabling the reproduction of motion pictures after content has been lawfully acquired and decrypted. . . .'').

circumventing.'' [100] The Office invites comment on whether users are relying upon the various screen capture exemptions for uses of motion picture excerpts and whether there is common understanding that screen-capture technology is non-circumventing.

Proposed Class 2: Audiovisual Works—Accessibility

This proposed class would permit circumvention of TPMs for motion pictures by ''disability services offices, organizations that support people with disabilities, libraries, and other units at educational institutions that are responsible for fulfilling those institutions' legal and ethical obligations to make works accessible to people with disabilities,'' ''where circumvention is undertaken for the purpose of making a motion picture accessible to people with disabilities, including through the provision of closed and open captions and audio description.'' [101] Specifically, the petition seeks to circumvent works stored on ''optical media, video cassettes with access control measures, and streaming services. . . .'' [102]

The Office seeks comment on whether this proposed exemption should be adopted, including any proposed regulatory language.

Proposed Class 3: Audiovisual Works—Space-Shifting

This proposed class would allow circumvention of access controls on lawfully made and acquired audiovisual works for the purpose of noncommercial space-shifting or format-shifting. The Office received two petitions seeking an exemption permitting circumvention of TPMs on DVDs and Blu-ray discs for space-shifting or format-shifting for personal use.[103] The Office notes that in the 2006, 2012, and 2015 triennial rulemakings, the Librarian rejected proposed exemptions for space-shifting or format-shifting, finding that the proponents had failed to establish under applicable law that space-shifting is a noninfringing use.[104] The Office seeks comment on all aspects of this proposed exemption, including whether, in the past three years, there has been a change in the legal or factual landscapes regarding whether space-shifting and format-shifting are noninfringing fair uses.

Proposed Class 4: Audiovisual Works—HDCP/HDMI

This proposed class would allow circumvention of TPMs ''to make noninfringing uses of audiovisual works that are subject to High-bandwidth Digital Content Protection (''HDCP''),'' which restricts access to audiovisual works passing over High-Definition Multimedia Interface (''HDMI'') connections, such as through an HDMI cable.[105] Andrew ''bunnie'' Huang has proposed an exemption to circumvent ''devices that play video discs and video game software'' using HDCP encoding to ''captur[e] the output for subsequent noninfringing uses, such as fair use or automated analysis of noncopyrightable elements of the content.'' [106] The Office notes that in an ongoing judicial proceeding, Huang alleged that he seeks to market a device called ''NeTVCR,'' which would circumvent HDCP technology to, among other things, allow people ''to save content for later viewing, move content to a viewing device of the user's choice, or convert content to a more useful format.'' [107] He further alleged that NeTVCR ''would allow customers to engage in new forms of protected and noninfringing expression using HDMI signals.'' [108]

The Office seeks comment on whether this proposed exemption should be adopted, including any proposed regulatory language. The Office encourages commenters, in the course of detailing whether the proposed exemption meets the requirements of section 1201(a)(1), to address the specific types of audiovisual works that would be accessed by this exemption, to provide examples of the types of noninfringing uses implicated, to address whether viable alternatives to circumvention exist, and to detail the effect circumvention might have on the market for or value of copyrighted works.

Proposed Class 5: Computer Programs—Unlocking

The proposed class would permit the circumvention of TPMs for computer programs that operate new and used ''wireless devices'' to allow connection to an alternative wireless network (a process commonly known as ''unlocking'').[109] Specifically, ISRI proposes expanding the exemption codified at 37 CFR 201.40(b)(3) by eliminating the current enumerated categories of devices on which circumvention may occur (*i.e.,* to allow the unlocking of any wireless device that connects to a wireless telecommunications network), as well as extending the exemption to new devices (*i.e.,* removing the requirement that the devices must be ''used''). The Office notes that these issues were to some extent considered in the last rulemaking.[110]

The Office seeks comment on whether this proposed exemption should be adopted, including specific examples demonstrating adverse effects stemming from a consumer's inability to choose the mobile wireless communications provider for a new wireless device.

Proposed Class 6: Computer Programs—Jailbreaking

The proposed class would allow circumvention of TPMs protecting ''general-purpose portable computing devices'' to allow the devices to interoperate with or to remove software applications (''jailbreaking'').[111] Specifically, EFF proposes to replace the ''portable all-purpose mobile computing devices'' limitation in the existing jailbreaking exemption (37 CFR 201.40(b)(4)) with the term ''general-purpose portable computing devices,'' and extend the exemption to such devices ''carried'' or ''used in a home,'' as well as the enabling and disabling of hardware features on such devices.[112]

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[100] 2015 Recommendation at 99.

[101] Association of Transcribers and Speech-to-text Providers (''ATSP''), Association of Research Libraries (''ARL''), American Library Association (''ALA'') & Association of College and Research Libraries (''ACRL'') Class 2 Pet. at 3.

[102] *Id.* at 3.

[103] OmniQ Class 3 Pet. at 2–3; De Pretis Class 3 Pet. at 2.

[104] *See* 80 FR at 65960; 77 FR at 65276–77; 71 FR 68472, 68478 (Nov. 27, 2006). The Librarian also previously declined to adopt an exemption to allow motion pictures on DVDs to be played on the Linux operating system. *See* 68 FR 62011, 62017 (Oct. 31, 2003). For previous discussion of OmniQ's technology, see 2015 Recommendation at 113.

[105] Huang Class 4 Pet.

[106] *Id.* at 2.

[107] Complaint for Declaratory & Injunctive Relief ¶¶ 90–93, *Green* v. *U.S. Dep't of Justice,* No. 16–cv–1492 (D.D.C. July 21, 2016).

[108] *Id.* ¶¶ 100, 101.

[109] ISRI Class 5 Pet. #1 at 2; ISRI Class 5 Pet. #2 at 2.

[110] 79 FR at 55689 (''The evaluation of whether an exemption would be appropriate under section 1201(a)(1)(C) is likely to be different for different types of wireless devices, requiring distinct legal and evidentiary showings. Thus, a petition proposing a general exemption for 'all wireless devices' * * * could be quite difficult to support, in contrast to a petition that focuses on specific categories of devices * * *''); 80 FR at 65952 (limiting final rule to ''used'' devices).

[111] EFF Class 6 Pet. at 2–3.

[112] *Id.* EFF's Class 6 petition proposes the following language for the exemption:

Computer programs that enable smartphones and general-purpose portable computing devices to execute lawfully obtained software applications, where circumvention is accomplished solely for one or more of the following purposes: to enable interoperability of such applications with computer programs on the smartphone or device, to enable or disable hardware features of the smartphone or device, or to permit removal of software from the smartphone or device. For purposes of this exemption, a ''general-purpose portable computing device'' is a portable device that is primarily designed or primarily used to run a wide variety of programs rather than for consumption of a particular type of media content, is equipped with

The Office notes that during the 2015 rulemaking, the Register recommended the adoption of the current exemption for ''portable all-purpose mobile computing devices,'' in part, because the record ''meaningfully defined'' such devices.[113]

The Office seeks comment on whether this proposed exemption should be adopted, including on the definitions of ''portable,'' ''carried,'' and ''used in the home'' that would govern the proposed exemption. The Office welcomes examples of specific types of devices that would be encompassed by the exemption other than those enumerated in the existing exemption codified at 37 CFR 201.40(b)(4).

Proposed Class 7: Computer Programs—Repair

Multiple organizations petitioned for exemptions relating to diagnosis, repair, and modification.[114] As noted above, the current exemption (codified at 37 CFR 201.40(b)(6)) is limited to the diagnosis, repair or lawful modification of motorized land vehicles, except for computer programs primarily designed for the control of telematics or entertainment systems.[115] Multiple petitions seek to expand upon this language. Specifically, EFF proposes to eliminate the limitation to motorized land vehicles, that is, to allow circumvention of TPMs applied to a broader range of devices including the ''Internet of Things,'' appliances, computer peripherals, computers, storage devices, and playback devices, toys, vehicles, and environment automation systems.[116] EFF asserts that its proposed exemption ''overlaps significantly'' with the Office's recommendation concerning a permanent exemption for repair in its recently concluded 1201 Study.[117] The Auto Care and CTA petition proposes keeping the limitation for motorized land vehicles, but removing the ''telematics or entertainment systems'' limitation, asserting that ''telematics systems increasingly are being designed by vehicle manufacturers as the means to access the embedded software that controls the parts and operation of the vehicle.'' [118] The Office notes that during the 2015 triennial rulemaking, the Register concluded that the record did not support extending the exemption to ECUs primarily designed for the control of telematics or entertainment systems.[119]

Three petitions seek to expand the existing exemption to allow third parties to provide services on behalf of owners of motorized land vehicles, an issue that also raises potential issues with respect to the anti-trafficking prohibitions under section 1201(a)(2) and (b).[120] As noted above, the statute only empowers the triennial rulemaking to adopt temporary exemptions to section 1201(a)(1)'s prohibition on circumvention of access controls. The Office has addressed the interplay of these provisions as part of the Register's recommendation during the 2015 triennial rulemaking, as well as its recent policy study on section 1201.[121]

Similarly, two petitions raise the question of potential interaction with anti-trafficking rules under section 1201(a)(2) and (b) by proposing to expand the exemption to allow the ''development and sale of repair tools,'' [122] and to ''permit companies with expertise in software development to develop and make circumvention and repair solutions available to servicers and customers.'' [123] As the Office noted in its recent 1201 Study, ''there are strong reasons to conclude that Congress did not intend to apply the manufacturing bar to exemption beneficiaries from producing their own circumvention tools for personal use,'' as ''such a reading would render the rulemaking process effectively meaningless for many users.'' [124] The Office did not recommend, however, that Congress ''take the additional step of allowing the *distribution* of necessary tools to exemption beneficiaries,'' noting that permitting the distribution of tools ''could significantly erode'' the ability of the anti-trafficking provisions to prevent the development of mainstream business models based around the production and sale of circumvention tools.[125]

The Office seeks comment on whether an expanded exemption to cover additional repair and related activities should be adopted, including any proposed regulatory language.

Proposed Class 8: Computer Programs—Video Game Preservation

The proposed class would expand upon the current exemption (codified at 37 CFR 201.40(b)(8)) permitting circumvention ''by an eligible library, archives, or museum,'' of TPMs protecting video games, for which outside server support has been discontinued. Specifically, The Museum of Art and Digital Entertainment (''MADE'') proposes expanding the existing exemption ''to further include multiplayer online games, video games with online multiplayer features, and massively multiplayer online games (MMOs), whether stored physically or in downloadable formats, and [to] add preservationists affiliated with archival institutions as users.'' [126] The Office notes that during the 2015 triennial rulemaking, the Register found that excluding uses that require access to or copying of copyrightable content stored or previously stored on developer game servers ''to be an important limitation.'' [127] In addition, the Register concluded that the then-existing record did not support extension of the exemption to online multiplayer play.[128]

The Office seeks comment on whether this proposed expanded exemption for abandoned video games should be adopted, including any proposed regulatory language. Specifically, the Office welcomes discussion of how the existing exemption excludes

an operating system primarily designed for use in a general purpose computing device, and is primarily designed to be carried or worn by an individual or used in a home.

*Id.* at 2.

[113] 2015 Recommendation at 189.

[114] iFixit Class 7 Pet. at 2; EFF Class 7 Pet. at 2–3; IPTC U.S.C., AFBF, National Corn Growers Association (''NCGA'') & National Farmers Union (''NFU'') Class 7 Pet. at 2; Auto Care & CTA Class 7 Pet. at 2–4.

[115] 37 CFR 201.40(b)(6).

[116] EFF Class 7 Pet. at 2–3 (proposing the exemption ''enable circumvention of access controls applied to software and compilations of data, where circumvention is for the purpose of noninfringing repair, diagnosis, or modification of a software-enabled device.''). The Office notes that during its study of software-enabled products, the consensus of stakeholders revealed that drawing a legislative distinction for ''software-enabled devices'' would be unworkable in practice. U.S. Copyright Office, *Software-Enabled Consumer Products* at 10 (2016), *https://www.copyright.gov/policy/software/software-full-report.pdf.*

[117] EFF Class 7 Pet. at 2; *see also* 1201 Study at 88–97 (discussing issues relating to obsolescence, repair and modification and recommending legislative consideration of a ''properly-tailored exemption for repair activities,'' but concluding that modification is appropriately addressed through the rulemaking process).

[118] Auto Care & CTA Class 7 Pet. at 4.

[119] 2015 Recommendation at 246.

[120] iFixit Class 7 Pet. at 2; IPTC U.S.C., AFBF, NCGA & NFU Class 7 Pet. at 2; Auto Care & CTA Class 7 Pet. at 3.

[121] 80 FR at 65954; 2015 Recommendation at 246–48 (excluded circumvention ''on behalf of'' vehicle owners, noting this phrase ''may implicate the anti-trafficking provisions set forth in section 1201(a)(2) and (b)''); 1201 Study at 61–62 (discussing third party assistance generally, stating although ''it cannot affirmatively recommend exemption language that is likely to be read to authorize unlawful trafficking activity,'' where appropriate, the Office will avoid recommending ''unduly narrow definitions of exemption beneficiaries'' in the context of 1201 rulemaking).

[122] iFixit Class 7 Pet. at 2.

[123] Auto Care & CTA Class 7 Pet. at 3.

[124] 1201 Study at 54.

[125] *Id.* at 53–56.

[126] MADE Class 8 Pet. at 2.

[127] 2015 Recommendation at 350.

[128] *Id.* at 351.

''preservationists affiliated with archival institutions,'' and evidence concerning whether an expanded exemption would impact the market for video games 1. by allowing users of unlawfully acquired video games to similarly bypass server checks, 2. by contributing to the circumvention of client-server protocols for nonabandoned video games, or 3. by impairing the market for older video games or for licensed services or products facilitating the backward compatibility of video games.

Proposed Class 9: Computer Programs—Software Preservation

The proposed class would allow circumvention of TPMs ''on lawfully acquired software'' by ''libraries, archives, museums, and other cultural heritage institutions'' ''for the purposes of preserving software and software-dependent materials.'' [129]

Unlike many of the other classes, this proposal represents an entirely new exemption. The Office seeks comment on whether this proposed exemption should be adopted, including specific examples of the types of noninfringing uses that are, or in the next three years, likely to be adversely affected by the prohibition on circumvention, whether viable alternatives to circumvention exist, discussion of the types of works sought to be accessed, and the specific TPMs implicated by the proposed exemption. The Office specifically seeks comment as to whether or how the exception in section 108 for libraries and archives is relevant to this exemption.[130] The Office further welcomes any suggested regulatory language, including eligibility requirements,[131] a definition of the proposed term ''software-dependent materials,'' and whether the exemption should be limited to preserving works that are intended for an institution's public collections (*e.g.,* compared to back-office licensed software).

Proposed Class 10: Computer Programs—Security Research

The Office received three petitions to expand the exemption for good-faith security research of computer programs that operate devices and machines primarily designed for use by individual consumers (including voting machines), motorized land vehicles, or medical devices designed for implantation in patients and corresponding personal monitoring systems (codified at 37 CFR 201.40(b)(7)).[132]

Two petitions propose removing the specific security research categories listed under section 201.40(b)(7)(i)(A)–(C), as well as the following limitations: 1. The ''lawfully acquired device or machine'' limitation; 2. the ''solely'' limitation (*i.e.,* ''solely for the purpose of good-faith security research''); 3. the ''not violate any applicable law, including without limitation the Computer Fraud and Abuse Act of 1986'' limitation; 4. the ''carried out in a controlled environment designed to avoid any harm to individuals or the public'' limitation; and 5. the requirement that ''information derived from the activity . . . is not used or maintained in a manner that facilitates copyright infringement.'' [133] Another petition by Professor Matthew Green proposes adoption of the regulatory language recommended by NTIA in the last rulemaking, with the further clarification that the existence of an ''End User License Agreement'' or similar terms does not defeat person's status as owner of copy of computer program.[134]

The Office notes that during the 2015 triennial rulemaking, the Register determined that the then-existing record did not support adopting an exemption that encompassed all computer programs on all systems and devices, and her recommendation discusses the rationale for the other current limitations.[135] For example, the Register noted that there appeared to be ''universal agreement'' among proponents that testing in ''live'' conditions was ''wholly inappropriate,'' and so recommended that the exemption require that the security research be conducted in a controlled setting to avoid harm to the public.[136]

The Office seeks comment on whether an expanded exemption for security research should be adopted, including discussion of the proposed regulatory language, contrasted with the current temporary and permanent exemptions for this activity.

Proposed Class 11: Computer Programs—Avionics

This proposed class would allow circumvention of TPMs to access data output by electronic systems used on aircraft, artificial satellites, and spacecraft; such systems are referred to as ''avionics.'' Specifically, Air Informatics LLC (''AI'') proposed an exemption to circumvent computer programs protecting ''access to aircraft flight, operations, maintenance and security data captured by computer programs or firmware.'' [137] AI asserts that access to such data currently protected by TPMs would facilitate safety, security, and compliance with Federal Aviation Administration regulations.[138]

The Office seeks comment on whether this exemption should be adopted, including 1. specific examples of the types of noninfringing uses that are, or in the next three years, likely to be adversely affected by a prohibition on circumvention; 2. a description of the specific TPMs sought to be circumvented; 3. the methods for circumvention; 4. the environment in which the circumvention would be accomplished; and 5. whether the proposed exemption could have negative repercussions with respect to safety or security with respect to the works at issue, or otherwise in a manner relevant to section 1201(a)(1)'s statutory factors (for example, by making it easier for wrongdoers to access sensitive data or databases).

Proposed Class 12: Computer Programs—3D Printing

This proposed class would expand the current exemption for computer programs that operate 3D printers (codified at 37 CFR 201.40(b)(9)) to allow use of non-manufacturer-approved feedstock in the printers, regardless of whether the 3D printers produce goods or materials for use in commerce the physical production of which is subject to legal or regulatory oversight, or where the circumvention is otherwise unlawful. Specifically, the

[129] The Software Preservation Network (''SPN'') & LCA Class 9 Pet. at 2.

[130] *See, e.g.,* 17 U.S.C. 108 (c), (h).

[131] *See, e.g.,* U.S. Copyright Office, *Section 108 of Title 17* at 17–22 (2016), *https://www.copyright.gov/policy/section108/discussion-document.pdf;* 37 CFR 201.40(b)(8)(iii)(D).

[132] Felten & Halderman Class 10 Pet. at 2–3; Green Class 10 Pet. at 2–3; CDT Class 10 Pet. at 2–3.

[133] Felten & Halderman Class 10 Pet.; CDT Class 10 Pet. The same petitioners also recommend removing the delay in the effective date of the exemption adopted in 2015; however, as addressed above, the Office notes that it has already concluded that removal of a delayed effective date would be appropriate as part of the request to renew this petition.

[134] Green Class 10 Pet. at 2. Specifically, NTIA recommended the following language: ''Computer programs, in the form of firmware or software, regardless of the device on which they are run, when circumvention is initiated by the owner of the copy of the computer program or with the permission of the owner of the copy of the computer program, in order to conduct good faith security research. This exemption does not obviate the need to comply with other applicable laws and regulations.'' Letter from Lawrence E. Strickling, Assistant Sec'y for Commc'ns & Info., Nat'l Telecomms. & Info. Admin., U.S. Dep't of Commerce, to Maria A. Pallante, Register of Copyrights and Dir., U.S. Copyright Office, at 89 (Sept. 18, 2015), *http://www.copyright.gov/1201/2015/2015_NTIA_Letter.pdf.*

[135] 2015 Recommendation at 317–18.

[136] *Id.* at 318.

[137] AI Class 11 Pet. at 2.

[138] *Id.* at 2–3.

petition proposes eliminating the following limitation in the current exemption: ''that the exemption shall not extend to any computer program on a 3D printer that produces goods or materials for use in commerce the physical production of which is subject to legal or regulatory oversight or a related certification process, or where the circumvention is otherwise unlawful.'' [139]

The Office seeks comment on whether this expanded exemption for 3D printing should be adopted.

## IV. Future Phases of the Seventh Triennial Rulemaking

As in prior rulemakings, after receipt of written comments, the Office will continue to solicit public engagement to create a comprehensive record. Described below are the future phases of the administrative process that will be employed for this rulemaking, so that parties may use this information in their planning.

### *A. Public Hearings*

The Copyright Office intends to hold public hearings following the last round of written comments. The hearings will be conducted in Washington DC during the week of April 9, 2018 and in California with a date and location to be determined. A separate notice providing details about the hearings and how to participate will be published in the **Federal Register** at a later date. The Office will identify specific items of inquiry to be addressed during the hearings. The hearings in Washington will be live streamed online, and the Office hopes to be able to offer the same for the California hearings.

### *B. Post-Hearing Questions*

As with previous rulemakings, following the hearings, the Copyright Office may request additional information with respect to particular classes from rulemaking participants. The Office may rely on this process in cases where it would be useful for participants to supply missing information for the record or otherwise resolve issues that the Office believes are material to particular exemptions. Such requests for information will take the form of a letter from the Copyright Office and will be addressed to individual parties involved in the proposal as to which more information is sought. While responding to such a request will be voluntary, any response will need to be supplied by a specified deadline. After the receipt of all responses, the Office will post the questions and responses on the Office's Web site as part of the public record.

### *C. Ex-Parte Communication*

In its 1201 Study, the Office noted that, in response to stakeholder requests, it would consider in this rulemaking whether to utilize informal meetings to discuss proposed regulatory language or address discrete issues prior to issuing a recommendation, including by establishing guidelines for *ex parte* communications.[140] In the past, the Office's communications with participants about the ongoing triennial rulemakings have not included discussions about the substance of the proceeding apart from the noticed phases of written comments and public hearings (although the Office has provided procedural guidance to participants, and has held discussions with other federal agencies, such as NTIA, to discuss matters within their subject matter expertise). The Office has determined that further informal communications with non-governmental participants might be beneficial in limited circumstances where the Office seeks specific information or follow-up regarding the public record, such as to discuss nuances of proposed regulatory language. However, any such communication will be limited to the post-hearing phase of the rulemaking. The primary means to communicate views in the course of the rulemaking will continue to be through the submission of written comments or participation in the public roundtables. In other words, this communication will supplement, not substitute for, the pre-existing record. While exact guidelines governing *ex parte* communications with the Office regarding the triennial rulemaking will be issued at a later date, they will be similar to those followed by other agencies such as the Consumer Financial Protection Bureau or Federal Communications Commission.[141] For example, the participating party or parties will be responsible for submitting a list of attendees and written summary of any oral communication to the Office, which will be made publicly available on the Office's Web site or *regulations.gov*. In sum, while the Office is establishing the option of informal meetings in response to stakeholder demand, it will require that all such communications be on the record to ensure the greatest possible transparency.

Dated: October 19, 2017.

**Sarang V. Damle,**

*General Counsel and Associate Register of Copyrights.*

[FR Doc. 2017–23038 Filed 10–25–17; 8:45 am]

**BILLING CODE 1410–30–P**

[139] Weinberg Class 12 Pet. at 2. *Compare* 2015 Recommendation at 376–77.

[140] 1201 Study at 150–51.

[141] The Office expects to continue to hold informal intra-governmental communications, which would not be included in such guidelines.

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 62

**[EPA–R03–OAR–2017–0509; FRL–9969–91–Region 3]**

## Approval and Promulgation of State Air Quality Plans for Designated Facilities and Pollutants; City of Philadelphia; Control of Emissions From Existing Sewage Sludge Incineration Units

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** The Environmental Protection Agency (EPA) is proposing to notify the public that it has received a negative declaration for the City of Philadelphia Air Management Services (Philadelphia AMS) for sewage sludge incineration (SSI) units. This negative declaration certifies that SSI units subject to the requirements of sections 111(d) and 129 of the Clean Air Act (CAA) do not exist within the City of Philadelphia in the Commonwealth of Pennsylvania. EPA is accepting the negative declaration in accordance with the requirements of the CAA. In the Final Rules section of this issue of the **Federal Register**, EPA is accepting the negative declaration as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. If no adverse comments are received in response to this action, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time.

**DATES:** Comments must be received in writing by November 27, 2017.

**ADDRESSES:** Submit your comments, identified by Docket ID No. EPA–R03–OAR–2017–0509 at *https://www.regulations.gov,* or via email to *aquino.marcos@epa.gov.* For comments submitted at *Regulations.gov*, follow the

online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. For either manner of submission, the EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be confidential business information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www2.epa.gov/dockets/commenting-epa-dockets.*

**FOR FURTHER INFORMATION CONTACT:** Michael Gordon, (215) 814–2039, or by email at *gordon.mike@epa.gov.*

**SUPPLEMENTARY INFORMATION:** For further information regarding the negative declaration submitted by Philadelphia AMS for SSI units, please see the information provided in the technical support document in the rulemaking docket and in the direct final action, with the same title, that is located in the ''Rules and Regulations'' section of this issue of the **Federal Register**. The negative declaration letter submitted by Philadelphia AMS and technical support document in support of this action are also available online at *www.regulations.gov.*

Dated: October 11, 2017.

**Cecil Rodrigues,**

*Acting Regional Administrator, Region III.*

[FR Doc. 2017–23231 Filed 10–25–17; 8:45 am]

**BILLING CODE 6560–50–P**

## ENVIRONMENTAL PROTECTION AGENCY

## 40 CFR Part 713

**[EPA–HQ–OPPT–2017–0421; FRL–9970–07]**

**RIN 2070–AK22**

## Mercury; Reporting Requirements for the TSCA Mercury Inventory

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** As required under section 8(b)(10)(D) of the Toxic Substances Control Act (TSCA), EPA is proposing reporting requirements for applicable persons to provide information to assist in the preparation of an ''inventory of mercury supply, use, and trade in the United States,'' where ''mercury'' is defined as ''elemental mercury'' and ''a mercury compound.'' The requirements would be applicable to any person who manufactures (including imports) mercury or mercury-added products, or otherwise intentionally uses mercury in a manufacturing process. Based on the inventory of information collected, the Agency is directed to ''identify any manufacturing processes or products that intentionally add mercury; and . . . recommend actions, including proposed revisions of Federal law or regulations, to achieve further reductions in mercury use.'' At this time, EPA is not making such identifications or recommendations.

**DATES:** Comments must be received on or before December 26, 2017.

**ADDRESSES:** Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2017–0421, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

**FOR FURTHER INFORMATION CONTACT:**

*For technical information contact:* Thomas Groeneveld, National Program Chemicals Division, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (202) 566–1188; email address: g*roeneveld.thomas@epa.gov.*

*For general information contact:* The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave. Rochester, NY 14620; telephone number: (202) 554–1404; email address: *TSCA-Hotline@epa.gov.*

**SUPPLEMENTARY INFORMATION:**

### I. Executive Summary

*A. Does this action apply to me?*

You may be potentially affected by this action if you manufacture (including import) mercury or mercury-added products, or if you otherwise intentionally use mercury in a manufacturing process. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Gold ore mining (NAICS code 212221)
- Lead ore and zinc ore mining (NAICS code 212231)
- All other metal ore mining (NAICS code 212299)
- Asphalt shingle and coating materials manufacturing (NAICS code 324122)
- Synthetic dye and pigment manufacturing (NAICS code 325130)
- Other basic inorganic chemical manufacturing (NAICS code 325180)
- All other basic organic chemical manufacturing (NAICS code 325199)
- Plastics material and resin manufacturing (NAICS code 325211)
- Pesticide and other agricultural chemical manufacturing (NAICS code 325320)
- Medicinal and botanical manufacturing (NAICS code 325411)
- Pharmaceutical preparation manufacturing (NAICS code 325412)
- Biological product (except diagnostic) manufacturing (NAICS code 325414)
- Paint and coating manufacturing (NAICS code 325510)
- Adhesive manufacturing (NAICS code 325520)
- Custom compounding of purchased resins (NAICS code 325991)
- Photographic film, paper, plate, and chemical manufacturing (NAICS code 325992)
- All other miscellaneous chemical product and preparation manufacturing (NAICS code 325998)
- Unlaminated plastics film and sheet (except packaging) manufacturing (NAICS code 326113)
- Unlaminated plastics profile shape manufacturing (NAICS code 326121)
- Urethane and other foam product (except polystyrene) manufacturing (NAICS code 326150)

- All other plastics product manufacturing (NAICS code 326199)
- Tire manufacturing (NAICS code 326211)
- All other rubber product manufacturing (NAICS code 326299)
- Iron and steel mills and ferroalloy manufacturing (NAICS code 331110)
- Rolled steel shape manufacturing (NAICS code 331221)
- Alumina refining and primary aluminum production (NAICS code 331313)
- Secondary smelting and alloying of aluminum (NAICS code 331314)
- Nonferrous metal (except aluminum) smelting and refining (NAICS code 331410)
- Secondary smelting, refining, and alloying of nonferrous metal (except copper and aluminum) (NAICS code 331492)
- Iron foundries (NAICS code 331511)
- Steel foundries (except investment) (NAICS code 331513)
- Fabricated structural metal manufacturing (NAICS code 332312)
- Industrial valve manufacturing (NAICS code 332911)
- Ammunition except small arms manufacturing (NAICS code 332993)
- Small arms, ordnance, and ordnance accessories manufacturing (NAICS code 332994)
- All other miscellaneous fabricated metal product manufacturing (NAICS code 332999)
- Food product machinery manufacturing (NAICS code 333294)
- Office machinery manufacturing (NAICS code 333313)
- Other commercial and service industry machinery manufacturing (NAICS code 333319)
- Heating equipment (except warm air furnaces) manufacturing (NAICS code 333414)
- Air-conditioning and warm air heating equipment and commercial and industrial refrigeration equipment manufacturing (NAICS code 333415)
- Pump and pumping equipment manufacturing (NAICS code 333911)
- Bare printed circuit board manufacturing (NAICS code 334412)
- Semiconductor and related device manufacturing (NAICS code 334413)
- Other electronic component manufacturing (NAICS code 334419)
- Electromedical and electrotherapeutic apparatus manufacturing (NAICS code 334510)
- Search, detection, navigation, guidance, aeronautical, and nautical system and instrument manufacturing (NAICS code 334511)
- Automatic environmental control manufacturing for residential, commercial, and appliance use (NAICS code 334512)
- Instruments and related products manufacturing for measuring, displaying, and controlling industrial process variables (NAICS code 334513)
- Totalizing fluid meter and counting device manufacturing (NAICS code 334514)
- Instrument manufacturing for measuring and testing electricity and electrical signals (NAICS code 334515)
- Analytical laboratory instrument manufacturing (NAICS code 334516)
- Watch, clock, and part manufacturing (NAICS code 334518)
- Other measuring and controlling device manufacturing (NAICS code 334519)
- Electric lamp bulb and part manufacturing (NAICS code 335110)
- Commercial, industrial, and institutional electric lighting fixture manufacturing (NAICS code 335122)
- Other lighting equipment manufacturing (NAICS code 335129)
- Electric house wares and household fan manufacturing (NAICS code 335211)
- Household vacuum cleaner manufacturing (NAICS code 335212)
- Household cooking appliance manufacturing (NAICS code 335221)
- Household refrigerator and home freezer manufacturing (NAICS code 335222)
- Household laundry equipment manufacturing (NAICS code 335224)
- Other major household appliance manufacturing (NAICS code 335228)
- Switchgear and switchboard apparatus manufacturing (NAICS code 335313)
- Relay and industrial control manufacturing (NAICS code 335314)
- Primary battery manufacturing (NAICS code 335912)
- Current-carrying wiring device manufacturing (NAICS code 335931)
- All other miscellaneous electrical equipment and component manufacturing (NAICS code 335999)
- Light truck and utility vehicle manufacturing (NAICS code 336112)
- Heavy duty truck manufacturing (NAICS code 336120)
- Motor home manufacturing (NAICS code 336213)
- Travel trailer and camper manufacturing (NAICS code 336214)
- Other aircraft parts and auxiliary equipment manufacturing (NAICS code 336413)
- Boat building (NAICS code 336612)
- Motorcycles and parts manufacturing (NAICS code 336991)
- Surgical and medical instrument manufacturing (NAICS code 339112)
- Costume jewelry and novelty manufacturing (NAICS code 339914)
- Game, toy, and children's vehicle manufacturing (NAICS code 339932)
- Sign manufacturing (NAICS code 339950)
- Other chemical and allied products merchant wholesalers (NAICS code 424690)
- Research and development in the physical, engineering, and life sciences (except biotechnology) (NAICS code 541712)
- Hazardous waste treatment and disposal (NAICS code 562211)
- Other nonhazardous waste treatment and disposal (NAICS code 562219)
- Materials recovery facilities (NAICS code 562920)
- National security (NAICS code 928110)

*B. What action is the Agency taking?*

EPA is issuing a proposed rule under TSCA section 8(b)(10) to require reporting to assist in the preparation of ''an inventory of mercury supply, use, and trade in the United States,'' where ''mercury'' is defined as ''elemental mercury'' and ''a mercury compound.'' Hereinafter ''mercury'' will refer to both elemental mercury and mercury compounds collectively, except where separately identified. This proposed rule would require reporting from any person who manufactures (including imports) mercury or mercury-added products, or otherwise intentionally uses mercury in a manufacturing process. EPA published its initial inventory report in the **Federal Register** on March 29, 2017 (Ref. 1), which noted data gaps and limitations encountered by the Agency in its historic reliance on publicly available data on the mercury market in the United States. As stated in the initial inventory report, ''[f]uture triennial inventories of mercury supply, use, and trade are expected to include data collected directly from persons who manufacture or import mercury or mercury-added products, or otherwise intentionally use mercury in a manufacturing process'' (Ref. 1). These proposed reporting requirements would help the Agency narrow such data gaps, as well as to prepare subsequent, triennial publications of the inventory, and to execute the mandate to ''identify any manufacturing processes or products that intentionally add mercury; and . . . recommend actions, including proposed revisions of Federal law or regulations, to achieve further reductions in mercury use'' (15 U.S.C. 2607(b)(10)(C)).

In addition, this information could be used by the U.S. Government to assist in its national reporting regarding its implementation of the Minamata

Convention on Mercury (Minamata Convention), to which the United States is a Party (Ref. 2). The Minamata Convention is an international environmental agreement that has as its objective the protection of human health and the environment from anthropogenic emissions and releases of elemental mercury and mercury compounds. Article 21 of the Convention requires Parties to include in their national reports, among other information, information demonstrating that the Party has met the requirements of Article 3 on Mercury Supply Sources and Trade and of Article 5 on Manufacturing Processes in Which Mercury or Mercury Compounds Are Used. As proposed, the reporting requirements of the proposed rule will further enhance the understanding of the use of mercury in the United States, in particular with respect to mercury supply sources and trade, mercury-added products, and manufacturing processes, thus providing a body of information that will assist the United States in its implementation of the reporting requirements of the Minamata Convention. EPA intends to use the collected information to implement TSCA and shape the Agency's efforts to reduce the use of mercury in commerce. In so doing, the Agency would conduct a timely evaluation and refinement of these reporting requirements so that they are efficient and non-duplicative for reporters.

EPA is proposing that supply, use, and trade of mercury include reporting requirements for activities comparable to established TSCA terms: Manufacture, import, distribution in commerce, storage, and export. The reporting requirements also would apply to otherwise intentional use of mercury in a manufacturing process. Persons who manufacture (including import) mercury or mercury-added products, or otherwise intentionally use mercury in a manufacturing process, would report amounts of mercury in pounds (lbs.) used in such activities during a designated reporting year. Reporters also would identify specific mercury compounds, mercury-added products, manufacturing processes, and how mercury is used in manufacturing processes, as applicable, from pre-selected lists. For certain activities, reporters would provide additional, contextual data (*e.g.,* country(ies) of origin/destination for imports/exports and NAICS codes for mercury or mercury-added products distributed in commerce).

The proposed reporting requirements would not apply to persons engaged in the generation, handling, or management of mercury-containing waste, unless that person manufactures or recovers mercury in the management of that waste with the intent to use the recovered mercury or store it for use. In addition, persons engaged in trade (*e.g.,* brokering, selling wholesale, shipping, warehousing, repackaging, or retail sale), but who do not first manufacture mercury or mercury-added products, or otherwise intentionally use mercury in a manufacturing process, are not required to report. Finally, in an effort to avoid reporting that is unnecessary or duplicative, the Agency is proposing certain exemptions for persons who already report for mercury and mercury-added products to the TSCA section 8(a) Chemical Data Reporting (CDR) rule and the Interstate Mercury Education and Reduction Clearinghouse (IMERC).

In addition to topics where EPA notes that we are seeking specific comment, the Agency also encourages comment on all aspects of this proposal.

*C. Why is the Agency taking this action?*

EPA is issuing a proposed rule under TSCA section 8(b)(10) to require reporting to assist in the preparation of the statutorily-required inventory of mercury supply, use, and trade in the United States. This proposed rule would require reporting from any person who manufactures (including imports) mercury or mercury-added products, or otherwise intentionally uses mercury in a manufacturing process. After the publication of its initial inventory report in the **Federal Register** on March 29, 2017 (Ref. 1), the Agency is proposing this rule to support future, triennial publications of the mercury inventory. In administering this mercury inventory, the Agency would ''identify any manufacturing processes or products that intentionally add mercury; and . . . recommend actions, including proposed revisions of Federal law or regulations, to achieve further reductions in mercury use'' (15 U.S.C. 2607(b)(10)(C)).

*D. What is the Agency's authority for taking this action?*

EPA is issuing this proposed rule pursuant to TSCA section 8(b)(10)(D) to implement the direction at TSCA section 8(b)(10)(B) that ''[n]ot later than April 1, 2017, and every 3 years thereafter, the Administrator shall carry out and publish in the **Federal Register** an inventory of mercury supply, use, and trade in the United States'' (15 U.S.C. 2607(b)(10)(B)). TSCA section 8(b)(10)(D) requires EPA to promulgate a final rule by June 22, 2018 that establishes reporting requirements applicable to any person who manufactures mercury or mercury-added products or otherwise intentionally uses mercury in a manufacturing process to assist in the preparation of the inventory (15 U.S.C. 2607(b)(10)(D)). However, persons ''engaged in the generation, handling, or management of mercury-containing waste, unless that person manufactures or recovers mercury in the management of that waste'' are not required to report to the mercury inventory (15 U.S.C. 2607(b)(10)(D)(iii)).

In addition, the Paperwork Reduction Act (PRA) requires Federal agencies to manage information resources to reduce information collection burdens on the public; increase program efficiency and effectiveness; and improve the integrity, quality, and utility of information to all users within and outside an agency, including capabilities for ensuring dissemination of public information, public access to Federal Government information, and protections for privacy and security (44 U.S.C. 3506).

Section 2 of TSCA expresses the intent of Congress that EPA carry out TSCA in a reasonable and prudent manner, and in consideration of the impacts that any action taken under TSCA may have on the environment, the economy, and society (15 U.S.C. 2601). EPA is proposing to manage and leverage its information resources, including information technology, to require the use of electronic reporting in order to implement the mercury inventory reporting requirements of TSCA section 8(b)(10)(D) in a reasonable and prudent manner.

*E. What are the estimated incremental impacts of the proposed rule?*

EPA has prepared an economic analysis of the potential impacts associated with this rulemaking (Ref. 3). The chief benefit of the proposed rule is the collection of detailed data on mercury, which will serve as a basis to recommend actions to further reduce mercury use in the United States, as required at TSCA section 8(b)(10)(C). Another benefit is the use of information collected under the proposed rule to help the United States implement its obligations under the Minamata Convention. There are no quantified benefits for the proposed rule. The statutory mandate specifically calls for and authorizes a rule to support an inventory of mercury supply, use, and trade in the United States, in order to identify any manufacturing processes or products that intentionally add mercury and recommend actions to achieve further reductions in mercury use. As described in the Agency's economic analysis, unquantified

benefits include providing increased information on mercury and assisting in the reduction of mercury use (Ref. 3). To the extent that the information gathered through this rule is used to reduce mercury use, benefits to society will result from a reduction in exposure. EPA seeks public comment on all aspects of the economic analysis.

TABLE 1—SUMMARY OF COSTS AND BENEFITS OF PROPOSAL

| Category | Description |
|---|---|
| Benefits | The proposed rule would provide information on mercury and mercury-added products to which the Agency (and the public) does not currently have access. To the extent that the information gathered through this proposed rule is used to reduce mercury use, benefits to society will result from a reduction in risk. |
| Costs | Estimated industry costs and burden total $5.96 million and 74,000 hours (for up to 750 respondents) for the first year of reporting, with an individual estimate of $7,900 and 99 hours. For future triennial reporting cycles, industry costs and burden would be $4.37 million and 54,300 hours, with an individual estimate of $5,800 and 72 hours. These estimates include compliance determination, rule familiarization, CBI substantiation, electronic reporting, and recordkeeping, in addition to completing reporting requirements. |
| Effects on State, Local, and Tribal Governments. | Government entities are not expected to be subject to the rule's requirements, which apply to entities that manufacture (including import) mercury or mercury-added products, or otherwise intentionally use mercury in a manufacturing process. The proposed rule does not have a significant intergovernmental mandate, significant or unique effect on small governments, or have Federalism implications. |
| Small Entity Impacts | The proposed rule would impact 211 companies that meet the U.S. Small Business Administration (SBA) definitions for their respective NAICS classifications: 4 small entities (1.85%) are expected to incur impacts of 1% percent or greater, and 1 of the small entities assessed is expected to incur impacts of greater than 3%. Furthermore, even if the entities whose status is ''undetermined'' were assumed to be impacted small entities, this would result in only 9 entities (4.17%). Therefore, EPA certifies that this action will not have a significant economic impact on a substantial number of small entities. |
| Environmental Justice and Protection of Children. | The information obtained from the reporting required by this proposed rule would be used to inform the Agency's decision-making process regarding chemicals to which minority or low-income populations or children may be disproportionately exposed. This information would also assist the Agency and others in determining whether elemental mercury and mercury compounds addressed in this proposed rule present potential risks, allowing the Agency and others to take appropriate action to investigate and mitigate those risks. |

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

1. *Submitting CBI.* Do not submit this information to EPA through *regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *http://www.epa.gov/dockets/comments.html.*

## II. Background

*A. Background on Mercury*

Mercury is a naturally occurring element that originates in the earth's crust and can be found in air, water, fish, and other biota. Mercury exists in three forms: Elemental, organic compounds, and inorganic compounds.

Elemental mercury (Chemical Abstracts Service Registry Number (CASRN) 7439–97–6) is a shiny, silver-white metal that is liquid at room temperature. Mercury compounds are formed when elemental mercury reacts with another substance, either in nature or intentionally by humans. Organic mercury compounds are formed in the environment when mercury combines with carbon. Inorganic mercury compounds take the form of mercury salts. EPA's TSCA Chemical Substance Inventory lists 69 mercury compounds (Ref. 4).

In the United States, elemental mercury and mercury compounds are used in the manufacture of mercury-added products and certain manufacturing processes. The typical lifecycle of products includes manufacture, distribution in commerce (including transport and storage), use, and waste management (landfilling or recycling). At any point in the product lifecycle, there is potential for mercury to be released. Globally, the major anthropogenic sources of released elemental mercury are the combustion of coal and use of elemental mercury in artisanal gold mining (Ref. 5). Emitted elemental mercury can be transported in the atmosphere on local, regional, and global scales as it cycles through air, land, and water (Ref. 6). Some of the emitted elemental mercury following deposition and transformation into divalent mercury can be biotransformed into methylmercury (Ref. 6).

Methylmercury is a persistent and bioaccumulative neurotoxicant. Exposure to methylmercury most commonly occurs when people eat kinds of fish and shellfish that have high levels of methylmercury in their tissues (Ref. 7). Almost all people have at least small amounts of methylmercury in their bodies, reflecting the widespread presence of methylmercury in the environment (Ref. 7). People exposed to high levels of methylmercury may experience adverse health effects (Ref. 7). Generally, the subtlest indicators of methylmercury toxicity are neurological changes (Ref. 7). Neurotoxic effects at comparatively low doses include subtle decrements in motor skills and sensory ability, while extremely high exposures can cause tremors, inability to walk, convulsions, and death (Ref. 7). Exposure to mercury can also cause adverse ecological effects

in plants, birds, fish, and mammals (Ref. 6).

*B. Recent Amendments to TSCA*

The Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg Act) (Pub. L. 114–182, 130 Stat. 448), enacted on June 22, 2016, implemented reforms to TSCA. Among other changes to TSCA, the Lautenberg Act amended TSCA section 8(b) to require EPA to establish: (1) An inventory of mercury supply, use, and trade in the United States; and (2) reporting requirements by rule applicable to any person who manufactures mercury or mercury-added products or otherwise intentionally uses mercury in a manufacturing process not later than June 22, 2018. (15 U.S.C. 2607(b)(10)). Information collected per the proposed reporting requirements would be used to periodically update the mercury inventory; identify any manufacturing processes or products that intentionally add mercury; and recommend actions, including proposed revisions of federal law or regulations, to achieve further reductions in mercury use (15 U.S.C. 2607(b)(10)). The Lautenberg Act also added certain mercury compounds to the TSCA section 12(c) ban on exporting of elemental mercury and authorized EPA to ban the export of additional mercury compounds by rule (15 U.S.C. 2611(c)). The Lautenberg Act also implemented other changes to the Mercury Export Ban Act of 2008 (MEBA) (Pub. L. 110–414, 122 Stat. 4341). Additional information on the Lautenberg Act is available on EPA's Web site at *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act.*

*C. Trends in Mercury Supply, Use, and Trade in the United States*

Humans have mined, refined, and used mercury for a wide variety of purposes over thousands of years. In the United States, mercury was mined until 1991, but today is produced only as a byproduct of metals mining or by recovering mercury from waste (Ref. 8). In recent decades, mercury served as a catalyst in the chlor-alkali industry and in a variety of industrial, commercial, and consumer products (Ref. 8). Due to its toxicity and replacement by new technologies, many uses of mercury have been discontinued in the United States, and the overall quantity used has fallen dramatically in recent decades. For example, over the past three decades there has been a strong downward trend of more than 97 percent in the use of mercury in mercury-added products sold in the United States. In 1980, the United States used more than 1,800 metric tons of mercury in mercury-added products annually (Ref. 8). As described in the initial inventory conducted by EPA in 2017, by 2013, only approximately 40 metric tons of mercury in products were sold in the United States (Ref. 1). Many of these products sold have cost-effective, non-mercury substitutes (Ref. 1). The United States also has traded elemental mercury and mercury compounds worldwide, although MEBA prohibited the export of elemental mercury as of January 1, 2013 and prohibits the export of certain mercury compounds as of January 1, 2020.

Prior to developing its initial inventory, EPA reviewed federal and state reports and databases, among other sources, in order to assemble a collection of available information on mercury, mercury-added products, and manufacturing processes involving mercury (Ref. 1). In reviewing data obtained, the Agency found that its baseline of data lacked the specificity and level of detail required to develop a mercury inventory responsive to TSCA section 8(b)(10)(D) or to be useful to inform mercury use reduction efforts for both the public and private sectors (Ref. 1). For example, in 2015, to develop its understanding of domestic mercury supply and trade, the Agency collected information on the quantity of mercury sold in the United States for the years 2010 and 2013 from five companies identified as the primary recyclers and distributors of mercury in the United States (Ref. 9). Comparing totals for mercury sold in products and the amount of bulk mercury sold in the United States in 2013 revealed a significant data gap of approximately 26 metric tons. IMERC data showed approximately 40 metric tons of mercury in mercury-added products sold in the United States in 2013. The information collected by the Agency for bulk elemental mercury manufactured and processed in the United States in the same year was approximately 66 metric tons. In this instance, EPA determined that mercury may be used in manufacturing processes, including as a reactant or formulation component, which may not be reflected in the amount of mercury reported as sold in products. An additional data gap identified was the amount of mercury in exported mercury-added products. The Agency is also seeking to be able to differentiate between the amount of mercury in imported mercury-added products and the amount in mercury-added products manufactured in the United States. For example, importation or domestic manufacture of mercury-added products may or may not be reflected in data reported as domestic sale of mercury-added products. EPA is committed to further addressing such data gaps and considers the national mercury inventory mandated by Congress to be an instrumental means to establish the requisite body of information to support achievement of that goal.

*D. Stakeholder Involvement*

In developing the proposed rule, the agency coordinated with the Northeast Waste Management Officials' Association, which administers the IMERC database, as directed by TSCA section 8(b)(10)(D)(ii), to avoid duplication.

**III. Summary of Proposed Rule**

This proposed rule, when finalized, would provide for the collection of information that allows EPA to implement statutory requirements at TSCA section 8(b)(10)(B), which directs that ''[n]ot later than April 1, 2017, and every 3 years thereafter, the Administrator shall carry out and publish in the **Federal Register** an inventory of mercury supply, use, and trade in the United States'' (15 U.S.C. 2607(b)(10)(B)). TSCA section 8(b)(10)(D) directs the Agency to promulgate this reporting rule no later than two years after the date of enactment of the June 2016 TSCA amendments. Based on the inventory, the Agency is directed to ''identify any manufacturing processes or products that intentionally add mercury; and . . . recommend actions, including proposed revisions of Federal law or regulations, to achieve further reductions in mercury use.'' At this time, EPA is not making such identifications or recommendations. EPA's proposal for fulfilling specific statutory provisions and terms are set forth by topic as follows.

*A. Definition of Mercury*

TSCA section 8(b)(10)(A) states ''notwithstanding [TSCA] section 3(2)(B), the term 'mercury' means . . . elemental mercury; and . . . a mercury compound'' (15 U.S.C. 2607(b)(10)(A)). As such, the definition for mercury at TSCA section 8(b)(10)(A) supersedes the exclusions for ''chemical substances'' described in TSCA section 3(2)(B) that would otherwise apply to mercury, mercury-added products, or otherwise intentional uses of mercury in manufacturing processes. For example, any ''drug, cosmetic, or device'' as described in TSCA section 3(2)(B)(vi),

should such items contain mercury, would not be excluded from reporting under the proposed rule.

For purposes of the proposed rule, the Agency proposes that where EPA distinguishes between elemental mercury and mercury compounds, elemental mercury be limited to elemental mercury (CASRN 7439–97–6) and mercury compounds be inclusive of all instances where elemental mercury or a mercury compound is reacted with another chemical substance. Examples of mercury compounds from the TSCA Chemical Substance Inventory are listed in Table 2.

TABLE 2—LIST OF MERCURY COMPOUNDS

| Chemical Abstracts Registry No. | Mercury compound |
|---|---|
| 10045–94–0 | Nitric acid, mercury(2+) salt (2:1). |
| 100–57–2 | Mercury, hydroxyphenyl-. |
| 10112–91–1 | Mercury chloride (Hg2Cl2). |
| 10124–48–8 | Mercury amide chloride (Hg(NH2)Cl). |
| 103–27–5 | Mercury, phenyl(propanoato-.kappa.O.)-. |
| 10415–75–5 | Nitric acid, mercury(1+) salt (1:1). |
| 104–60–9 | Mercury, (9-octadecenoato-.kappa.O)phenyl-. |
| 1191–80–6 | 9-Octadecenoic acid (9Z)-, mercury(2+) salt (2:1). |
| 12068–90–5 | Mercury telluride (HgTe). |
| 13170–76–8 | Hexanoic acid, 2-ethyl-, mercury(2+) salt (2:1). |
| 13302–00–6 | Mercury, (2-ethylhexanoato-.kappa.O)phenyl-. |
| 1335–31–5 | Mercury cyanide oxide (Hg2(CN)2O). |
| 1344–48–5 | Mercury sulfide (HgS). |
| 1345–09–1 | Cadmium mercury sulfide. |
| 13876–85–2 | Mercurate(2-), tetraiodo-, copper(1+) (1:2), (T–4)-. |
| 138–85–2 | Mercurate(1-), (4-carboxylatophenyl)hydroxy-, sodium (1:1). |
| 141–51–5 | Mercury, iodo(iodomethyl)-. |
| 14783–59–6 | Mercury, bis[(2-phenyldiazenecarbothioic acid-.kappa.S) 2-phenylhydrazidato-.kappa.N2]-, (T–4)-. |
| 15385–58–7 | Mercury, dibromodi-, (Hg-Hg). |
| 15785–93–0 | Mercury, chloro[4-[(2,4-dinitrophenyl)amino]phenyl]-. |
| 15829–53–5 | Mercury oxide (Hg2O). |
| 1600–27–7 | Acetic acid, mercury(2+) salt (2:1). |
| 1785–43–9 | Mercury, chloro(ethanethiolato)-. |
| 19447–62–2 | Mercury, (acetato-.kappa.O)[4-[2-[4-(dimethylamino)phenyl]diazenyl]phenyl]-. |
| 20582–71–2 | Mercurate(2-), tetrachloro-, potassium (1:2), (T–4)-. |
| 20601–83–6 | Mercury selenide (HgSe). |
| 21908–53–2 | Mercury oxide (HgO). |
| 22450–90–4 | Mercury(1+), amminephenyl-, acetate (1:1). |
| 24579–90–6 | Mercury, chloro(2-hydroxy-5-nitrophenyl)-. |
| 24806–32–4 | Mercury, [.mu.-[2-dodecylbutanedioato(2-)-.kappa.O1:.kappa.O4]]diphenyldi-. |
| 26545–49–3 | Mercury, (neodecanoato-.kappa.O)phenyl-. |
| 27685–51–4 | Cobaltate(2-), tetrakis(thiocyanato-.kappa.N)-, mercury(2+) (1:1), (T–4)-. |
| 29870–72–2 | Cadmium mercury telluride ((Cd,Hg)Te). |
| 3294–57–3 | Mercury, phenyl(trichloromethyl)-. |
| 33770–60–4 | Mercury, [3,6-dichloro-4,5-di(hydroxy-.kappa.O)-3,5-cyclohexadiene-1,2-dionato(2-)]-. |
| 3570–80–7 | Mercury, bis(acetato-.kappa.O)[.mu.-(3',6'-dihydroxy-3-oxospiro[isobenzofuran-1(3H),9'-[9H]xanthene]-2',7'-diyl)]di-. |
| 537–64–4 | Mercury, bis(4-methylphenyl)-. |
| 539–43–5 | Mercury, chloro(4-methylphenyl)-. |
| 54–64–8 | Mercurate(1-), ethyl[2-(mercapto-.kappa.S)benzoato(2-)-.kappa.O]-, sodium (1:1). |
| 55–68–5 | Mercury, (nitrato-.kappa.O)phenyl-. |
| 56724–82–4 | Mercury, phenyl[(2-phenyldiazenecarbothioic acid-.kappa.S) 2-phenylhydrazidato-.kappa.N2]-. |
| 587–85–9 | Mercury, diphenyl-. |
| 592–04–1 | Mercury cyanide (Hg(CN)2). |
| 592–85–8 | Thiocyanic acid, mercury(2+) salt (2:1). |
| 593–74–8 | Mercury, dimethyl-. |
| 59–85–8 | Mercurate(1-), (4-carboxylatophenyl)chloro-, hydrogen. |
| 623–07–4 | Mercury, chloro(4-hydroxyphenyl)-. |
| 62–38–4 | Mercury, (acetato-.kappa.O)phenyl-. |
| 62638–02–2 | Cyclohexanebutanoic acid, mercury(2+) salt (2:1). |
| 627–44–1 | Mercury, diethyl-. |
| 6283–24–5 | Mercury, (acetato-.kappa.O)(4-aminophenyl)-. |
| 628–86–4 | Mercury, bis(fulminato-.kappa.C)-. |
| 629–35–6 | Mercury, dibutyl-. |
| 63325–16–6 | Mercurate(2-), tetraiodo-, (T–4)-, hydrogen, compd. with 5-iodo-2-pyridinamine (1:2:2). |
| 63468–53–1 | Mercury, (acetato-.kappa.O)(2-hydroxy-5-nitrophenyl)-. |
| 63549–47–3 | Mercury, bis(acetato-.kappa.O)(benzenamine)-. |
| 68201–97–8 | Mercury, (acetato-.kappa.O)diamminephenyl-, (T–4)-. |
| 72379–35–2 | Mercurate(1-), triiodo-, hydrogen, compd. with 3-methyl-2(3H)-benzothiazolimine (1:1:1). |
| 7439–97–6 | Mercury. |
| 7487–94–7 | Mercury chloride (HgCl2). |
| 7546–30–7 | Mercury chloride (HgCl). |
| 7616–83–3 | Perchloric acid, mercury(2+) salt (2:1). |
| 7774–29–0 | Mercury iodide (HgI2). |
| 7783–33–7 | Mercurate(2-), tetraiodo-, potassium (1:2), (T–4)-. |

TABLE 2—LIST OF MERCURY COMPOUNDS—Continued

| Chemical Abstracts Registry No. | Mercury compound |
|---|---|
| 7783–35–9 | Sulfuric acid, mercury(2+) salt (1:1). |
| 7783–39–3 | Mercury fluoride (HgF2). |
| 7789–47–1 | Mercury bromide (HgBr2). |
| 90–03–9 | Mercury, chloro(2-hydroxyphenyl)-. |
| 94070–93–6 | Mercury, [.mu.-[(oxydi-2,1-ethanediyl 1,2-benzenedicarboxylato-.kappa.O2)(2-)]]diphenyldi-. |

*B. Explanation of Supply, Use, and Trade*

Pursuant to TSCA section 8(b)(10)(B), EPA interprets the scope of the mercury inventory to include activities within the domestic and global commodity mercury market that would fall under ''supply, use, and trade of mercury in the United States.'' An inventory that adequately accounts for mercury in supply, use, and trade includes activities of persons who must report as described in TSCA section 8(b)(10)(d)(i): Manufacture, import, and otherwise intentionally use mercury in a manufacturing process. In addition, the Agency proposes that persons required to report to the mercury inventory also include information on distribution in commerce, storage, and export in order to provide for the requisite inventory of mercury supply, use, and trade in the United States. EPA proposes that reporting to cover ''supply'' include manufacture and storage of mercury, reporting to cover ''use'' include use of mercury to manufacture a mercury-added product or otherwise intentional use of mercury in a manufacturing process, and reporting to cover ''trade'' include import, export, and distribution in commerce of mercury or mercury-added products. EPA proposes that obtaining information related to such activities, including reporting quantities of mercury, as well as qualitative information related to supply, use, and trade, is necessary to create the inventory described at TSCA section 8(b)(10)(B). Examples of such qualitative information include: Country of origin (for imports of mercury or mercury-added products), destination country (for exported mercury-added products or certain mercury compounds), and identification of purchasing or receiving industry sectors via NAICS codes (for mercury or mercury-added products distributed in domestic commerce).

In addition to using this information for the mercury inventory, this information would be used by the U.S. Government to assist in its implementation of the Minamata Convention (Ref. 2), in particular with respect to mercury supply sources and trade, mercury-added products, manufacturing processes in which mercury is used, and reporting. The United States is a Party to the Minamata Convention, which is a multilateral environmental agreement that addresses the supply, use, and trade in mercury by, among other actions, not allowing the introduction of new mercury mines and the phasing out of existing ones, phasing out and phasing down the use of mercury in a number of products and industrial processes, placing control measures on emissions to air and on releases to land and water, and taking action to reduce the use of mercury in the informal sector of artisanal and small-scale gold mining. EPA seeks comment on the proposed limited data collection requirements, such as the identification of countries that manufacture, import, or export mercury-added products (*i.e.,* countries of origin and destination), as well as the identification of purchasing or receiving industry sectors via NAICS codes, to inform activities under the Minamata Convention.

In regard to certain exports of mercury, the Agency notes that the export of elemental mercury has been prohibited since January 1, 2013 (15 U.S.C. 2611(c)(1)) and therefore the Agency is not proposing to require reporting on the export of elemental mercury from the United States. TSCA, as of January 1, 2020, will also prohibit the export of certain mercury compounds: Mercury (I) chloride or calomel; mercury (II) oxide; mercury (II) sulfate; mercury (II) nitrate; and cinnabar or mercury sulphide (the statute uses the term ''mercury sulphide'' which is an alternative spelling of ''mercury sulfide'' as found in the table above) (15 U.S.C. 2611(c)(7)). EPA recognizes that a complete inventory would include at least one cycle of reporting prior to the effective date of the prohibition for export of the five mercury compounds subject to 15 U.S.C. 2611(c)(7). As such, the inventory would benefit from the recent totals of at least one cycle of reporting prior to the effective date of the prohibition for export of mercury compounds subject to 15 U.S.C. 2611(c)(7) to (1) measure trends in supply, use, and trade; and (2) provide a baseline for comparison of the changes in the amounts of other mercury compounds exported after the 2020 effective date. The Agency also recognizes that the 2020 effective date of 15 U.S.C. 2611(c)(7) is such that any reporting on those five compounds will not assist the Agency in recommending further actions to achieve further reductions in mercury use because the export ban will be in effect as of 2020. Therefore, EPA requests public comment on whether to require one-time reporting for exports of the mercury compounds prohibited from export by 15 U.S.C. 2611(c)(7). It should be noted that reporting for exports of mercury compounds that are not prohibited from export by 15 U.S.C. 2611(c)(7), as well as products that contain intentionally-added elemental mercury and/or any mercury compounds (including the compounds prohibited from export) will be required.

In order to obtain information for the mercury inventory with the necessary level of detail, EPA is proposing to require reporting on activities that are subsets of defined terms. For example, ''manufacture'' is defined in TSCA section 3(9) to mean: ''import into the customs territory of the United States (as defined in general note 2 of the Harmonized Tariff Schedule of the United States), produce, or manufacture'' (15 U.S.C. 2602(9)). While both manufacture and import are described in the statutory definition of ''manufacture,'' the Agency proposes to separate reporting for these activities of the mercury market in order to capture distinct actions by persons who handle and trade mercury. As such, EPA is proposing that persons required to report specify distinct amounts, if any, of imported or otherwise manufactured mercury, as well as amounts of mercury in imported or otherwise manufactured mercury-added products.

Conversely, the activity ''otherwise intentionally uses mercury in a manufacturing process'' is not defined under TSCA. The Agency considers this activity to be similar, but not identical to the definition for ''process'' at TSCA section 3(13): ''preparation of a chemical substance or mixture, after its

manufacture, for distribution in commerce . . . in the same form or physical state as, or in a different form or physical state from, that in which it was received by the person so preparing such substance or mixture, or . . . as part of an article containing the chemical substance or mixture'' (15 U.S.C. 2602(13)). EPA proposes to require reporting on both the otherwise intentional use of mercury in a manufacturing process, as well as manufacture of mercury or a mercury-added product, distinguished by focusing on how the mercury came to be present in a final product. For manufacture of mercury or a mercury-added product, the Agency views such activities to be the intentional addition of mercury where mercury remains present in the final product for a particular purpose. For otherwise intentional use of mercury in a manufacturing process, the Agency views such activities to be the intentional use of mercury, but where no mercury remains or any mercury present in the final product exists only as an impurity.

Finally, TSCA section 8(f) states ''[f]or purposes of [TSCA section 8], the terms 'manufacture' and 'process' mean manufacture or process for commercial purposes'' (15 U.S.C. 2607(f)). Under a TSCA section 8(a) reporting rule, EPA has previously defined ''manufacture for commercial purposes'' for the purposes of other information gathering rules to include ''import, produce, or manufacture with the purpose of obtaining an immediate or eventual commercial advantage for the manufacturer'' and ''substances that are produced coincidentally during the manufacture, processing, use, or disposal of another substance or mixture, including both byproducts that are separated from that other substance or mixture and impurities that remain in that substance or mixture . . . [that] may, or may not, in themselves have commercial value'' (40 CFR 704.3). In the same rule, similarly, EPA has defined ''process for commercial purposes'' as ''the preparation of a chemical substance or mixture after its manufacture for distribution in commerce with the purpose of obtaining an immediate or eventual commercial advantage for the processor. Processing of any amount of a chemical substance or mixture is included in this definition. If a chemical substance or mixture containing impurities is processed for commercial purposes, then the impurities also are processed for commercial purposes'' (40 CFR 704.3). EPA notes that there is a separate definition for ''import for commercial purposes'' at 40 CFR 704.3, but finds it to be substantially similar to germane portions of ''manufacture for commercial purposes.''

EPA is proposing that the terms ''manufacture,'' ''import,'' and ''otherwise intentional use of mercury in a manufacturing process'' be interpreted for the purposes of mercury inventory reporting based on the aforementioned definitions in 40 CFR 704.3 and the statutory text at TSCA section 8(f). In regard to the manufacture (including import) of mercury as a byproduct, impurity, or similar occurrence, EPA considered whether such chemical substances are intentionally generated and whether such substances are used for commercial purposes. To synthesize these concepts, EPA is proposing to require reporting on mercury or mercury-containing byproducts manufactured for commercial purposes. Mercury generated as a byproduct not used for commercial purposes would not be subject to the proposed rule.

In addition, EPA is proposing that mercury that exists as an impurity would not be subject to the proposed rule, except where such impurities are present in a final product produced by persons who otherwise intentionally use mercury in a manufacturing process. EPA is distinguishing between the manufacture of mercury-added products versus the final products containing mercury that result from the intentional use of mercury in a manufacturing process. First, EPA considers the addition and presence of mercury in the final products of the former process to be intentional and, therefore, not an impurity. Conversely, EPA considers the presence of mercury in the final product resulting from the intentional use of mercury during the manufacturing processes identified in this proposed rule (see Unit III.D.5.) to be unintentional (*i.e.,* present as an impurity). Second, the Agency has less detailed institutional knowledge of this category of uses and is proposing to collect information on mercury that exists as an unintended impurity in products in such cases to better identify mercury use in manufacturing processes, as directed in TSCA section 8(b)(10)(C).

EPA determined that actions described in the definition of ''distribution in commerce'' at TSCA section 3(5): ''to sell, or the sale of, the substance, mixture, or article in commerce; to introduce or deliver for introduction into commerce, or the introduction or delivery for introduction into commerce of, the substance, mixture, or article; or to hold, or the holding of, the substance, mixture, or article after its introduction into commerce'' (15 U.S.C. 2602(5)), are adequate to describe both distribution in commerce and storage for the proposed rule. In particular, the Agency is interested in quantities of mercury sold or transferred between facilities in the United States. As such, EPA is proposing to incorporate the concept of ''domestic'' as defined at 40 CFR 704.3 to activities considered to be distribution in commerce, as opposed to international import and export, which would be covered separately. Where ''to hold'' or ''holding of'' (*i.e.,* storage) is concerned, EPA is proposing to require reporting for quantities of mercury stored, if any, by persons who manufacture (including import) mercury, as well as those who otherwise intentionally use mercury in a manufacturing process. Mercury stored by persons who only produce mercury-added products would not be required to be reported. Moreover, the Agency is not proposing to require reporting for quantities of mercury within mercury-added products that are stored after manufacture and prior to distribution in commerce. EPA assumes the quantity of mercury that manufacturers of mercury-added products store for later use or keep within product inventories is likely to be too small to help explain the information gap between sold and used mercury. The expected value of the information is likely to be low considering the burden and cost on reporters.

The Agency considered ''export'' in the context of ''exporter'' as defined in the TSCA section 12(b) export notification rule at 40 CFR part 707 Subpart D: ''determining and controlling the sending of the chemical substance or mixture to a destination out of the customs territory of the United States'' 40 CFR 707.63(b). For purposes of the proposed rule, however, the Agency believes that it is necessary to collect export data not only on certain mercury compounds, but also mercury-added products that are exported from the United States. As such, EPA would include articles in the reporting required for export.

Therefore, in summary, the Agency proposes to require reporting for the following activities:

- Import of mercury or a mercury-added product with the purpose of obtaining an immediate or eventual commercial advantage for the importer, except where such mercury is generated as a byproduct not used for commercial purposes or an impurity.

• Manufacture (other than import) of mercury or a mercury-added product with the purpose of obtaining an immediate or eventual commercial advantage for the manufacturer, except where such mercury is generated as a byproduct not used for commercial purposes or an impurity. In this context, EPA considers manufacture to be the intentional production of mercury, a mercury compound, or a mercury-added product, as opposed to the uses described for ''otherwise intentionally uses mercury in a manufacturing process.'' Incidental manufacture of mercury (*e.g.,* burning of coal or similar) would not be subject to the proposed rule.

• Otherwise intentional use of mercury in a manufacturing process, other than the manufacture of a mercury compound or a mercury-added product, with the purpose of obtaining an immediate or eventual commercial advantage for the user, except where such mercury is generated as a byproduct not used for commercial purposes.

• Distribution in commerce, including domestic sale or transfer, of mercury or a mercury-added product.

• Storage of mercury after manufacture (including import).

• Export of mercury or a mercury-added product, including the determining and controlling the sending of mercury (unless specifically prohibited) or a mercury-added product to a destination out of the customs territory of the United States.

These proposed interpretations of terms are intended to align with the structure and logical flow of reporting requirements described in Unit III.E. Nonetheless, EPA requests comment on the proposed interpretations of activities to be considered as part of supply, use, and trade of mercury in the United States.

*C. Coordination With Existing Reporting Programs*

TSCA section 8(b)(10)(D)(ii) directs the Agency to ''coordinate the reporting . . . with the Interstate Mercury Education and Reduction Clearinghouse'' to avoid duplication (15 U.S.C. 2607(b)(10)(D)(ii)). Furthermore, TSCA section 8(a)(5)(a) states ''[i]n carrying out [TSCA section 8], the Administrator shall, to the extent feasible . . . not require reporting which is unnecessary or duplicative'' (15 U.S.C. 2607(a)(5)(a)). The Agency seeks to avoid collecting data on mercury that would duplicate information already reported to existing state and federal programs, and to coordinate with and complement those reporting programs as much as possible. While developing this proposed rule, EPA reviewed four data collection systems applicable to supply, use, and trade of mercury (including mercury-added products and mercury used in manufacturing processes): IMERC, the TSCA section 8(a) Chemical Data Reporting rule, the Toxics Release Inventory (TRI) program, and the U.S. International Trade Commission Interactive Trade DataWeb (USITC DataWeb).

1. *IMERC.* IMERC is an online reporting database managed by the Northeast Waste Management Officials' Association (NEWMOA), which provides publicly available, national data on mercury used in products. Laws in certain states (Connecticut, Louisiana, Maine, Massachusetts, New Hampshire, New York, North Carolina, Rhode Island, and Vermont—hereinafter ''IMERC Notification states'') require companies that manufacture, distribute, or import mercury-added products to identify the mercury-added products they sell and the volume of mercury in them. The volume information is reported at a national level, although only companies selling mercury products within those states need to report. The IMERC database houses the information that is reported to IMERC Notification states on a triennial basis and provides a detailed picture of some aspects of the mercury product market. There are, however, some concerns about whether all nationwide sales are captured (*i.e.,* no reporting requirement for a company that sells mercury-added products exclusively outside of IMERC Notification states). Despite such concerns and given the statutory direction to coordinate both programs, EPA recognizes that the proposed rule and IMERC reporting requirements for mercury-added products should be harmonized to the greatest extent practicable.

While developing this proposed rule, the Agency coordinated with IMERC and NEWMOA to ensure that data collected in accordance with the proposed reporting requirements and existing IMERC reporting requirements would not be duplicative and that information collected would be shared to the greatest extent practicable. The Agency is designing the electronic reporting application for the mercury inventory that would automatically skip certain reporting requirement fields when users indicate they report to the IMERC Mercury-Added Products Database. Such users would automatically bypass mercury inventory reporting requirements that are comparable to those reported to IMERC. Specifically, those that report to IMERC would not be required to report the amount of mercury distributed in commerce under this proposed rule because EPA believes that information is captured by IMERC as national sales data. However, those that report to IMERC would still be required to provide qualitative data—NAICS codes related to sales data—as part of the distribution in commerce reporting requirement (see Table 4—Information to Report—Mercury-Added Products).

2. *TSCA Chemical Data Reporting Rule.* EPA also sought to avoid duplicating the mercury reporting requirements of its own CDR rule (Ref. 10) and reporting to the TRI program (Ref. 11). The CDR rule collects manufacturing, processing, and use information on certain chemical substances manufactured (including imported) in the United States. Persons required to report include those that manufacture (including import) for commercial purposes in excess of 2,500 lbs. for a specific reporting year for substances meeting certain criteria, which include elemental mercury; or in excess of 25,000 lbs. for a specific reporting year for most other substances, which include mercury compounds.

In general, CDR reporters do not report information on chemical substances in articles, unless they first import or domestically manufacture the chemical substance that they then incorporate into an article or product (Ref. 12). As discussed in regard to coordinating with IMERC to avoid duplicative reporting, the Agency's intended design for the reporting application for the mercury inventory would allow a CDR reporter to automatically skip certain reporting requirement fields that would be considered duplicative. As an example, those that report to CDR would not be required to provide the amount of mercury imported, however, they would be required to provide qualitative information—in this example the country of origin—as part of the reporting requirement (see Table 3—Information to Report—Mercury).

3. *Toxics Release Inventory.* The TRI program collects data on toxic chemical releases to air, water and land from industrial facilities and pollution prevention activities in the United States. The TRI program requires reporting when covered facilities in covered industrial sectors manufacture, process, or otherwise use more than 10 lbs. of elemental mercury and/or mercury compounds per year. However, while the TRI program requires reporters to specify whether mercury is manufactured, processed, or otherwise

used in activities comparable to the proposed rule (*e.g.,* article component, formulation component, reactant, chemical processing aid, manufacturing aid), it does not require reporting of quantitative data on amounts of mercury used for such activities or the kind of article involved.

4. *USITC DataWeb.* Additionally, EPA reviewed the USITC DataWeb, which provides U.S. international trade statistics and U.S. tariff data to the public (Ref. 13). All trade data are compiled from official data retrieved from the U.S. Bureau of the Census (Census). Data on U.S. exports of merchandise from the United States to all countries, except Canada, are compiled from the Electronic Export Information filed by the U.S. Principal Party in Interest or their agents through the Automated Export System. Published data on U.S. imports of merchandise are compiled primarily from automated data submitted through the Automated Commercial System of U.S. Customs and Border Protection (CBP). Data are also compiled from import entry summary forms, warehouse withdrawal forms and Foreign Trade Zone documents as required by law to be filed with CBP.

After reviewing these reporting programs, EPA has sought to design the proposed reporting requirements to be least burdensome for reporters already familiar with IMERC, CDR, TRI, and USITC DataWeb protocol. Therefore, the Agency is proposing to incorporate comparable reporting concepts and tools from each program, as well as propose some exemptions, in an attempt to increase the efficacy of while decreasing the burden to the greatest extent practicable for reporting to a national mercury inventory. EPA is seeking comment on the incorporation of the reporting concepts and tools from each program, as well as the proposed exemptions.

*D. Persons Who Must Report*

TSCA section 8(b)(10)(D)(i) states ''any person who manufactures mercury or mercury-added products or otherwise intentionally uses mercury in a manufacturing process shall make periodic reports to the Administrator'' (15 U.S.C. 2607(b)(10)(D)(i)). As explained in Unit III.B., EPA interprets the statutory text at TSCA sections 8(b)(10)(B), 8(b)(10)(D)(i), and 8(b)(10)(D)(iii) as applying to intentional acts that introduce mercury into supply, use, and trade in the United States. Furthermore, EPA reads TSCA section 8(b)(10)(D)(i) to narrow potential reporters to persons who first manufacture mercury or mercury-added products or otherwise intentionally use mercury in a manufacturing process. As such, EPA determined that persons who merely trade (*e.g.,* brokering, selling wholesale, shipping, warehousing, repackaging, or retail sale), but do not manufacture or import mercury or mercury-added products, should not be subject to the proposed reporting requirements. Aside from its reading of TSCA section 8(b)(10)(D)(i), the Agency is concerned that requiring reporting from such entities risks: (1) Double-counting of mercury as it moves through supply chains; and (2) undue burden or liability on entities that are not likely to be aware if or how mercury is present in products that they trade.

*1. Exemption for Persons Who Generate, Handle, or Manage Mercury-containing Waste.* Persons ''engaged in the generation, handling, or management of mercury-containing waste, unless that person manufactures or recovers mercury in the management of that waste'' are not required to report to the mercury inventory (15 U.S.C. 2607(b)(10)(D)(iii)). There are generally four sources of mercury-containing waste: (1) Industrial processes, which often generate a mixture of elemental mercury or mercury compounds combined with other substances; (2) the discard of mercury-added products such as fluorescent lamps; (3) the discard of elemental mercury (*e.g.* surplus commodity mercury); and (4) mercury-contaminated environmental media that are excavated as part of a contaminated site clean-up. Mercury-containing waste that is hazardous is regulated by the Resource Conservation and Recovery Act (RCRA).

EPA considers the following examples of persons and waste types to be exempt from reporting to the proposed rule:

- Hazardous waste treatment facilities that stabilize and landfill low-concentration mercury-containing waste.
- Manufacturing facilities that:

—Generate a mercury-containing waste and send it to a waste management facility.

—Use mercury to manufacture products or otherwise intentionally use mercury in a manufacturing process, and also generate a mercury-containing waste from that use or another process. The exemption applies to the mercury in the facility's waste but not to the quantity it uses. Under the proposed rule, the facility would report on the quantity it uses.

—Discard mercury-added products, such as fluorescent light bulbs, switches, and thermometers, unless the facility also intentionally uses mercury in a manufacturing process. In that case, the facility would report the mercury it uses, but not the mercury in the products it discards because the products and the mercury within them are waste.

- A person who uses a mercury-added product but does not manufacture mercury or mercury-added products and does not intentionally use mercury in a manufacturing process.
- Hazardous waste treatment facilities that recover elemental mercury from mercury-containing waste and manage that elemental mercury as a waste. There are currently two primary ways in which recovered elemental mercury can be managed as a waste: Placed in long-term storage at a facility with a RCRA permit as allowed under Section 5(g) of MEBA, or converted to mercury sulfide and exported for disposal.
- A generator producing mercury incidentally from the beneficiation or processing of ore or related pollution control activities, who accumulates this mercury on-site.
- A generator who temporarily stores waste elemental mercury for up to 90 or 180 days pending shipment for long-term storage or for treatment and disposal. The elemental mercury in all of these cases is not subject to the proposed rule.

EPA seeks comments on the examples provided and requests input on other relevant examples that may be useful.

The exemption at 15 U.S.C. 2607(b)(10)(D)(iii) does not apply to persons who manufacture or recover elemental mercury in the management of mercury-containing waste with the intent to use it or store it for use. For example, if a waste treatment facility retorts or distills mercury-containing waste to recover elemental mercury and then sells or stores the mercury for later sale, that person is considered to be a manufacturer of mercury and must report to the proposed rule for the amount of elemental mercury it sells or stores. If any manufacturer covered by the proposed rule decides at any time to manage the elemental mercury as a waste, that mercury is subject to the RCRA, but not to the proposed rule. Elemental mercury that is stored under MEBA or converted to a mercury compound and disposed of remains a waste, that is, its status cannot change from waste to commodity mercury.

2. *Reporting Threshold.* As discussed in Unit III.C., the Agency compared existing state and federal reporting databases applicable to the supply, use, and trade of mercury. EPA conducted this review in an attempt not only to eliminate duplicative reporting

requirements, but also to incorporate applicable features of such programs, including the consideration of respective reporting thresholds.

The statutory text at TSCA section 8(b)(10) is silent on a reporting threshold; however, TSCA section 8(b)(10)(C) directs the Agency to ''identify any manufacturing processes or products that intentionally add mercury'' (15 U.S.C. 2607(10)(b)(C)). The Agency interprets the direction to ''identify any'' to apply to any amount of mercury in a manufacturing process or product. When considered in light of the statutory text at TSCA section 8(b)(10)(C), as well as concerns related to the potential adverse effects on human health and the environment resulting from releases of mercury, the Agency finds that it would be inappropriate to propose a threshold under which reporting would not be required. Therefore, EPA proposes to apply the proposed reporting requirements to any person who manufactures (including imports) mercury, mercury-added products or otherwise intentionally uses mercury in a manufacturing process regardless of the amount of mercury at issue. EPA seeks comment on this approach.

The absence of a reporting threshold is consistent with IMERC reporting requirements, which apply to the intentional addition of mercury to a product, including where ''mercury is intentionally added for any reason or that incorporates a component to which mercury was intentionally added'' (Ref. 14). Because of the similarities in the intentional addition of mercury to manufacture a product and otherwise intentional use of mercury in a manufacturing process, EPA determined that all quantities of mercury used in both activities should be reported without a reporting threshold. EPA seeks comment on this approach.

By comparison, the CDR rule contains reporting thresholds for chemical substances, including elemental mercury and mercury compounds. EPA interprets the mandate in TSCA section 8(b)(10)(B) to call for a comprehensive inventory such that existing data gaps would be eliminated, where feasible. The Agency also seeks as much as possible to complement amounts of quantitative mercury data already collected by, but without overlapping with, reporting requirements of the CDR rule. In general, the Agency seeks to require reporting for persons who manufacture (including import) mercury in quantities less than the CDR thresholds for elemental mercury (2,500 lbs.) and mercury compounds (25,000 lbs.). The coordination between additional, proposed reporting requirements and the CDR rule are discussed in ''*Persons Who Manufacture (Including Import) Mercury.*''

3. *Persons Who Manufacture (Including Import) Mercury.* As described in Unit III.B., manufacture and import for the purpose of the proposed rule would include the manufacture (including import) of mercury. Although not exhaustive, persons who engage in the following activities would be required to report under the proposed rule (see Table 3. Information to Report—Mercury):

- Mining (including extraction and beneficiation processes) mercury;
- Generating or isolating mercury during ore, petroleum, or natural gas refining;
- Retorting, recovering, or recycling (including purifying) mercury from waste streams;
- Chemical manufacturing of mercury;
- Importing mercury; or
- Capturing mercury using methods to reduce emissions of hazardous air pollutants, unless the captured mercury is generated, handled, or managed as a waste or is identified as an impurity.

As described in Unit III.C., the Agency is seeking to decrease the burden of reporting to the greatest extent practicable by, among other things, complementing without overlapping existing reporting requirements related to mercury and mercury-added products. As such, EPA proposes that persons who manufacture (including import) for commercial purposes in excess of 2,500 lbs. for elemental mercury or in excess of 25,000 lbs. for mercury compounds for a specific reporting year would not be required to report amounts manufactured (including imported) or exported that are already reported per the CDR rule. Such persons would, however, be required to provide quantitative data on storage and distribution in commerce, as well as qualitative and contextual information related to all applicable data elements under the proposed rule. In further efforts to decrease reporting burdens, the Agency intends to provide pre-selected lists of mercury compounds to streamline reporting requirements as much as possible.

TABLE 3—INFORMATION TO REPORT—MERCURY

| Persons who must report | Potential reporting requirements |
|---|---|
| Persons who manufacture (including import) mercury in amounts greater than or equal to 2,500 lbs. for elemental mercury or greater than or equal to 25,000 lbs. for mercury compounds for a specific reporting year (i.e., current CDR reporters). | —Country(ies) of origin for imported mercury.<br>—Country(ies) of destination for exported mercury.<br>—Amount of mercury stored (lbs.).<br>—Amount of mercury distributed in commerce (lbs.).<br>—NAICS code(s) for mercury distributed in commerce.<br>—As applicable, specific mercury compound(s) from pre-selected list. |
| All other persons who manufacture (including import) mercury ..... | —Amount of mercury manufactured (lbs.).<br>—Amount of mercury imported (lbs.).<br>—Country(ies) of origin for imported mercury.<br>—Amount of mercury exported (lbs.), except mercury prohibited from export at 15 U.S.C. 2611(c)(1) and (7).<br>—Country(ies) of destination for exported mercury.<br>—Amount of mercury stored (lbs.).<br>—Amount of mercury distributed in commerce (lbs.).<br>—NAICS code(s) for mercury distributed in commerce.<br>—As applicable, specific mercury compound(s) from pre-selected list. |

4. *Persons Who Manufacture or Import Mercury-added Products.* As described in Unit III.B., EPA is proposing to require reporting for manufacture (including import) mercury-added products, except import of a product that contains mercury solely as a component that is a mercury-added product. The Agency proposes that a person who imports a product that contains a component that is a mercury-added product (*e.g.,* toy or

novelty item containing a mercury-added battery) would not be required to report under the proposed rule. EPA determined that this distinction was appropriate after reviewing the data reported to the IMERC Mercury-Added Products Database and comparing the companies that reported national sales data for individual mercury-added products (including components), as well as items that would be considered to contain a component that is a mercury-added product (Ref. 15). For example, companies that report to IMERC for sales of appliances and vehicles list lamps as a mercury-added component. The Agency is interested in collecting data on original manufacturers (including importers) and users of mercury and believes that requiring certain contextual data (*e.g.,* NAICS codes) would sufficiently describe the use of mercury-added components by companies who do not first manufacture, import, or otherwise intentionally use mercury. Based on its review of the companies who report to IMERC and the types of mercury-added products reported, the Agency is concerned that requiring reporting for products where mercury is present solely within a previously manufactured component poses risks of double-counting and thereby could negatively affect the reliability of future mercury inventory updates.

EPA also is concerned that requiring reporting for a product that contains a mercury-added component could create undue burden for certain importers. For example, the Agency concluded that it is more likely that an importer of batteries would know if the specific kind of battery contained mercury, as opposed to an importer of toys that may or may not contain a mercury-added battery. However, EPA requests comment on whether persons who manufacture (including import) items that contain components that are mercury-added products should also report under the proposed rule.

In addition, the Agency is aware of transactions where a consumer directly orders mercury-added drugs (*e.g.,* hemorrhoid ointments, lotions, contact-lens solutions, and nasal sprays) and medical devices (*e.g.,* thermometers and blood pressure devices) from foreign vendors. These parcels typically enter the United States via international mail and are processed at international mail facilities by the U.S. Postal Service, U.S. Customs and Border Protection, or the U.S. Food and Drug Administration. The addressee on the parcel is considered to be the importer of record. If an express courier is used, the express courier may assume the role of the importer of record. In the case where an individual consumer is purchasing and importing a mercury-added product for personal use, the Agency believes that the proposed rule does not apply to such persons. Furthermore, the proposed rule would not apply to persons engaged in the delivery of such mercury-added products to an individual consumer, even if the delivery service constitutes import and distribution in commerce. In both scenarios, the persons who are importing the mercury-added product are not doing so ''with the purpose of obtaining an immediate or eventual commercial advantage for the importer.'' However, if a delivery service intentionally specialized in part or whole in the import and distribution in commerce of mercury-added products, then that person (or company) would be required to report to the mercury inventory.

Although not exhaustive, persons who engage in the following activities would be required to report under the proposed rule (see Table 4. Information to Report—Mercury-Added Products):

- Importing mercury-added products (except the import of a product that contains a component that is a mercury-added product); or
- Producing mercury-added products (*e.g.,* inserting mercury into a switch or battery, or mixing a mercury compound with other substances to formulate a topical antiseptic).

Examples of persons who would not be required to report to this proposed rule include:

- Manufacturers of concrete made from coal ash that contains mercury, but where such mercury originated from coal burned as a fuel source (*i.e.,* mercury was not intentionally added to the coal ash or the concrete);
- Fuel blenders who combine materials that might contain mercury, but are not chosen for blending because they contain mercury;
- Consumers who purchase and import mercury-added products for personal use from a foreign vendor; or,
- Persons engaged in the delivery of mercury-added products to an individual consumer, unless the delivery service intentionally specializes in part or whole in the import and distribution in commerce of mercury-added products.

For mercury-added products, the Agency seeks not only to balance efforts to increase the efficacy of reporting while decreasing the burden to the greatest extent practicable, but also to fully describe applicable sectors of the mercury market. As described in Unit III.C., persons who report to IMERC identify the amount of mercury sold in mercury-added products that may be manufactured, distributed, or imported. The Agency considers the amount of mercury reported to IMERC as sold to be comparable to the amount of mercury to be reported under the proposed rule as distributed in commerce. As such, EPA proposes that persons reporting to IMERC would not need to report amounts of mercury distributed in commerce under the proposed rule. However, those persons would need to report quantitative and qualitative information for other applicable data elements. Under the proposed rule, such persons also would be required to report contextual information applicable to amounts, if any, of mercury manufactured, imported, distributed in commerce, or exported. In further efforts to decrease reporting burdens, the Agency intends to provide pre-selected lists of mercury-added product categories to streamline reporting requirements as much as possible.

TABLE 4—INFORMATION TO REPORT—MERCURY-ADDED PRODUCTS

| Persons who must report | Potential reporting requirements |
|---|---|
| Persons who manufacture (including import) mercury-added products, except a product that contains a component that is a mercury-added product, who currently report to IMERC. | —Amount of mercury in manufactured products (lbs.).<br>—Amount of mercury in imported products (lbs.).<br>—Country(ies) of origin for imported products.<br>—Amount of mercury in exported products (lbs.).<br>—Country(ies) of destination for exported products.<br>—NAICS code(s) for products distributed in commerce.<br>—As applicable, specific product category(ies) and subcategory(ies) from pre-selected list. |

TABLE 4—INFORMATION TO REPORT—MERCURY-ADDED PRODUCTS—Continued

| Persons who must report | Potential reporting requirements |
|---|---|
| All other persons who manufacture (including import) mercury-added products, except a product that contains a component that is a mercury-added product. | —Amount of mercury in manufactured products (lbs.).<br>—Amount of mercury in imported products (lbs.).<br>—Country(ies) of origin for imported products.<br>—Amount of mercury in exported products (lbs.).<br>—Country(ies) of destination for exported products.<br>—Amount of mercury in products distributed in commerce (lbs.).<br>—NAICS code(s) for products distributed in commerce.<br>—As applicable, specific product category(ies) and subcategory(ies) from pre-selected list. |

5. *Persons Who Otherwise Intentionally Use Mercury in a Manufacturing Process.* As described in Unit III.B., TSCA section 8(b)(10)(d)(i) includes persons who intentionally use mercury in a manufacturing process amongst those who must report. Examples of persons who otherwise intentionally use mercury in a manufacturing process that would be required to report under the proposed rule include, but are not limited to (see Table 5. Information to Report—Otherwise Intentional Use of Mercury in a Manufacturing Process):

- Producers of chlorine (*e.g.,* mercury-cell chlor-alkali process);
- Producers of polyurethane elastomer; or
- Producers of other commercial chemicals (except mercury compounds).

Unlike manufacturers (including importers) of mercury and mercury-added products, the Agency believes that persons who otherwise intentionally use mercury in a manufacturing process may currently report to existing data collection programs in the United States; however, the reporting requirements for those programs cover only some of the data elements that would be required of EPA for the mercury inventory. As such, the general, specific, and contextual reporting requirements proposed by EPA are intended to provide a complete picture of uses for which little information is currently available. In further efforts to decrease reporting burdens, the Agency intends to provide pre-selected lists of manufacturing processes and attendant uses of mercury to streamline reporting requirements as much as possible.

TABLE 5—INFORMATION TO REPORT—OTHERWISE INTENTIONAL USE OF MERCURY IN A MANUFACTURING PROCESS

| Persons who must report | Potential reporting requirements |
|---|---|
| Persons who otherwise intentionally use mercury in a manufacturing process, other than the manufacture of a mercury compound or a mercury-added product. | —Amount of mercury intentionally used (lbs.) in pre-selected list of manufacturing processes.<br>—Amount of mercury stored (lbs.).<br>—Amount of mercury in exported final product(s) (lbs.).<br>—Country(ies) of destination for exported final product(s).<br>—Amount of mercury in final product(s) distributed in commerce (lbs.).<br>—NAICS code(s) for mercury in final product(s) distributed in commerce.<br>—As applicable, specific manufacturing process from pre-selected list.<br>—As applicable, specific use of mercury in manufacturing process from pre-selected list. |

To the extent that the proposed persons who must report and descriptions and examples of the kinds of information to be reported can be clarified, the Agency welcomes comment on the aforementioned discussion and tables. In addition, the Agency requests comment on whether other persons should be required to report or, in the alternative, if any of the proposed persons should not report.

6. *Consideration of Small Entities.* Based on EPA's economic assessment of the proposed rule (Ref. 3), approximately 40 percent of the respondents will be small entities. However, small businesses are not exempt from reporting requirements because, unlike the exemption for small manufacturers and processors provided under TSCA 8(a)(1)(A) and (B), reporting and recordkeeping requirements associated with TSCA section 8(b) are applicable to all affected entities. EPA is striving to minimize the burden on all respondents, including small entities, as much as possible by developing the reporting application and database to be user-friendly and dynamic, consisting of straightforward questions that are to include fill-in-the-blank (numbers) fields, check boxes, and drop down menus.

In addition, the Agency is considering the development of compliance guides tailored to small entities that will be required to comply with the reporting requirements. EPA requests public comment on what kinds of information would be particularly important to address for small entities in such compliance guides. EPA expects to conduct outreach and webinars for small businesses to introduce the reporting database, explain requirements, and offer Q&A and other support. Under TSCA section 26(d), EPA also provides specialized assistance to respondents, particularly to small entities, including technical and other non-financial assistance to manufacturers and processors of chemical substances. EPA's TSCA Hotline assists small businesses complying with TSCA rules and provides various materials such as copies of **Federal Register** notices, advisories, and other information upon request. Contact information for the TSCA Hotline is listed under **FOR FURTHER INFORMATION CONTACT**.

*E. Reporting Requirements*

TSCA section 8(b)(10)(B) sets the general scope of the inventory as the ''mercury supply, use, and trade in the

United States'' (15 U.S.C. 2607(b)(10)(B)). EPA interprets the core elements to be covered in the mercury inventory to be the amount of mercury used in the activities within the mercury market described in Unit III.B. (*i.e.,* manufacture, import, export, storage, distribution in commerce, and otherwise intentional use of mercury in a manufacturing process). EPA also determined that, for certain elements, requiring reporting of more specific information would help to better contextualize reported quantities of mercury used in domestic and, where appropriate, global supply, use, and trade. The proposed general, specific, and contextual reporting requirements are described in this section.

1. *General Reporting Requirements.* EPA considers ''supply'' to include manufacture and storage, ''use'' to include otherwise intentional use of mercury in a manufacturing process, and ''trade'' to include import, export, and distribution in commerce. The Agency is proposing that accounting for such activities is necessary to fulfill statutory mandates at TSCA sections 8(b)(10)(B) and (C). Therefore, for persons required to report (as described in Unit III.D.), EPA proposes reporting quantitative data for mercury, mercury-added products, and otherwise intentional use of mercury in a manufacturing process (as qualified from existing terms as discussed in Unit III.B.) as follows:

a. *Importers of mercury:* Amount of mercury imported per year (lbs.); Amount of mercury stored per year (lbs.); Amount of mercury distributed in commerce per year (lbs.); Amount of mercury exported per year (lbs.).

b. *Manufacturers (other than importers) of mercury:* Amount of mercury manufactured (other than imported) per year (lbs.); Amount of mercury stored per year (lbs.); Amount of mercury distributed in commerce per year (lbs.).

c. *Importers of any mercury-added product other than a product that contains a component that is a mercury-added product* (NOTE—see Unit III.D.): Amount of mercury in imported products per year (lbs.); Amount of mercury in products distributed in domestic commerce per year (lbs.); Amount of mercury in exported products per year (lbs.).

d. *Manufacturers (other than importers) of any mercury-added product other than a product that contains a component that is a mercury-added product* (NOTE—see Unit III.D.): Amount of mercury in manufactured (other than imported) products per year (lbs.); Amount of mercury in products distributed in commerce per year (lbs.); Amount of mercury in exported products per year (lbs.).

e. *Persons who intentionally use mercury in manufacturing processes, other than the manufacture of a mercury compound or a mercury-added product:* Amount of mercury used in a manufacturing process per year (lbs.); Amount of mercury stored per year (lbs.); Amount of mercury distributed in commerce in final product(s) of manufacturing process per year (lbs.); Amount of mercury exported in final product(s) of manufacturing process per year (lbs.).

EPA understands that certain persons may report for multiple activities associated with supply, use, and trade of mercury. For example, a person may import mercury and manufacture mercury-added products. As such, the Agency attempted to design the proposed quantitative data elements for reporting requirements such that a person could report both as an ''importer of mercury'' and ''manufacturer of mercury-added products,'' but only report for the specific activity in which they engage. The Agency expects there may be certain persons engaged in the supply, use, and trade of mercury who might not be accounted for in the inventory, but EPA views this omission of prospective reporters as an opportunity to limit undue burden and avoid double-counting. Thus, the Agency is proposing to limit the persons who must report at TSCA section 8(b)(10)(D)(i) to only those persons described in Unit III.D. However, EPA requests comment on whether the proposed reporting requirements should apply to persons who do not manufacture or import mercury or mercury-added products, or otherwise intentionally use mercury in a manufacturing process, but engage in the supply, use, and trade of mercury in the United States.

2. *Specific Reporting Requirements.* To better understand the categories of mercury-added products and otherwise intentional use of mercury in a manufacturing process, the Agency also proposes to require reporters to identify the specific categories and subcategories of products and functional uses for which quantitative data is reported. The Agency believes this is an appropriate interpretation of the direction to ''identify any manufacturing processes or products that intentionally add mercury,'' which, in turn, could inform how to ''recommend actions, including proposed revisions of Federal law or regulations, to achieve further reductions in mercury use'' (15 U.S.C. 2607(b)(10)(C)). Persons required to report would provide the total amount of mercury used during the reporting year in pounds for general reporting activities associated with supply, use, and trade, rather than per category and subcategory. EPA based this decision on issues concerning burden and confidential business information that could be created by reporting quantitative information for increasingly specific categories and subcategories. Nonetheless, EPA requests comment on whether quantitative information should be required for such specific reporting categories and subcategories, as well as on the reporting categories and subcategories.

a. *Mercury-added products.* Based on the current knowledge of mercury-added products available in the marketplace, including skin products manufactured abroad and sold illegally in the United States (Ref. 16), EPA proposes the following list of categories and subcategories of mercury-added products:

- *Batteries:* Button cell, silver; Button cell, zinc-air; Button cell, alkaline; Stacked button cell batteries; Manganese oxide; Silver oxide; Mercuric oxide, non-button cell; Button cell, mercuric oxide; Button cell, zinc carbon; Other (specify).
- *Dental amalgam.*
- *Formulated products (includes uses in cosmetics, pesticides, and laboratory chemicals):* Skin-lightening creams; Lotions; Soaps and sanitizers; Topical antiseptics; Bath oils and salts; Preservatives (*e.g.,* for use in vaccines and eye-area cosmetics when no preservative alternatives are available); Pharmaceuticals (including prescription and over-the-counter drug products); Cleaning products (not registered as pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act); Pesticides; Paints; Dyes; Reagents (*e.g.,* catalysts, buffers, fixatives); Other (specify).
- *Lighting, lamps, bulbs:* Linear fluorescent; Compact fluorescent; U-tube and circular fluorescent; Cold cathode fluorescent; External electrode fluorescent; Mercury vapor; Metal halide; High pressure sodium; Mercury short arc; Neon; Other (specify).
- *Measuring instruments:* Barometer; Fever thermometer; Flow meter; Hydrometer; Hygrometer/psychrometer; Manometer; Non-fever thermometer; Pyrometer; Sphygmomanometer; Other (specify).
- *Pump seals.*
- *Switches, relays, sensors, valves:* Tilt switch; Vibration switch; Float switch; Pressure switch; Temperature switch; Displacement relay; Wetted reed

relay; Contact relay; Flame sensor; Thermostat; Other (specify).

• *Miscellaneous mercury-added products:* Wheel weights; Wheel rotation balancers/stabilizers; Firearm recoil suppressors; Carburetor synchronizers; Joint support/shock absorption bands; Other (specify).

b. *Intentional mercury use in manufacturing processes.* Based on the current knowledge of manufacturing processes involving the otherwise intentional use of mercury, EPA proposes the following manufacturing processes for which mercury may be intentionally used: Chlorine production (*e.g.,* mercury-cell chlor-alkali process); Acetaldehyde production; Vinyl chloride monomer production; Sodium/potassium methylate/ethylate production; Polyurethane/plastic production; Other (specify).

EPA proposes the following list of uses of mercury in the aforementioned manufacturing processes: Catalyst; Reactant; Reagent; Other (specify).

3. *Contextual Reporting Requirements.* Within certain sectors of the mercury market, the Agency determined that additional data requirements are important to provide context to the quantitative data reported. While the individual quantities and overarching, categorical sums can help to fulfill the statutory mandate to identify manufacturing processes or products that intentionally add mercury, EPA seeks to collect information to more thoroughly describe such activities and enhance efforts to recommend actions to achieve further reductions in mercury use, as mandated in TSCA section 8(b)(10)(C). Examples of such data requirements include descriptions of countries of origin or destination for reported import and export quantities, as well as NAICS codes for purchasing or receiving industries for mercury or mercury-added products distributed in commerce. In order to fully understand the supply, use, and trade or mercury in the United States, EPA proposes the following reporting requirements:

a. *For imports of mercury or mercury-added products:* Country of origin.

b. *For mercury or mercury-added products distributed in commerce:* Identify the applicable purchasing or receiving industry sectors via NAICS codes.

c. *For exported mercury or mercury-added products:* Destination country.

The Agency determined that the combination of general, specific, and contextual reporting requirements provides for the body of information required to fulfill statutory mandates of TSCA sections 8(b)(10)(B) and (C). As much as possible, the Agency would design all requirements to be answered only where a reporter engages in the specific activity from the inclusive list of options. In fact, EPA believes that it is unlikely that the typical reporter would be engaged in and, as a result, be required to answer all, or even many, of the proposed reporting requirements. Nonetheless, to the extent that the proposed reporting process can be streamlined, the Agency welcomes comment on the proposed general, specific, and contextual reporting requirements. In addition, the Agency requests comment on whether such reporting requirements should be added or eliminated.

*F. Frequency of Inventory Publication*

TSCA section 8(b)(10)(B) sets the date for publication of initial and subsequent, triennial iterations of the mercury inventory to commence on April 1, 2017 (15 U.S.C. 8(b)(10)(B)). Therefore, EPA expects to publish the first mercury inventory supported by the proposed reporting requirements by April 1, 2020 and every three years thereafter.

*G. Frequency of Data Collection and Reporting Deadline*

TSCA section 8(b)(10)(D) provides the authority to promulgate the rule being proposed here to assist in the preparation of the triennial inventory publication (15 U.S.C. 8(b)(10)(D)), but TSCA offers no guidance on the frequency of collection or reporting deadline. To attempt to minimize reporting obligations, the Agency compared the respective collection frequencies and reporting deadlines for IMERC, the CDR rule, and the TRI program to when EPA is required to publish the mercury inventory. TSCA section 8(b)(10)(B), (15 U.S.C. 8(b)(10)(B)), sets a publication date for the mercury inventory that falls on the reporting deadline for IMERC: April 1 in a triennial cycle starting in April 2017. Data collected under the CDR rule is submitted to the Agency on a quadrennial cycle; the next reporting cycle will occur in 2020, with a reporting deadline of September 2020. The TRI program collects and publishes data on an annual cycle with a reporting deadline of July 1 of each year.

EPA recognizes that the mercury inventory reporting deadline would need to allow for an appropriate amount of time for quality control and assurance to be performed by EPA staff before the inventory is published. As such, the Agency concluded that the proposed reporting deadline would need to occur at least several months in advance of the publication deadline (April 1). The Agency then considered whether it was feasible to select a date and reporting frequency that would coincide with the IMERC, CDR rule, and TRI program reporting deadlines, so as not to impose an additional date for those that might be required to report to multiple systems. Due to the incongruities of frequency of collection among the proposed rule (triennial cycle—publication date of April 1), IMERC (triennial cycle—reporting deadline of April 1), the CDR rule (quadrennial cycle—reporting deadline of September 30), and TRI program (annual cycle—reporting deadline of July 1), the Agency determined that attempting to coordinate with each program would be more confusing for reporters, would not allow for ample time to review and coordinate similar data (*e.g.,* mismatched dates for reporting deadline and inventory publication between CDR rule and the proposed rule), and could result in gaps of up to several years between the availability of most applicable information (*e.g.,* principal reporting year data for the CDR rule).

Based on such considerations, the Agency determined that coinciding with the triennial IMERC frequency of collection is appropriate given the mercury inventory publication schedule is also triennial. In addition, the Agency is proposing to set the mercury inventory reporting deadline to coincide with the TRI program deadline in an effort to align with a date with which certain, potential reporters might already be familiar. Therefore, EPA proposes to establish a July 1st reporting deadline for 2019 and every three years thereafter. Data submitted should cover only the calendar year preceding the year in which the reporting deadline occurs (*e.g.,* data for calendar year January 1 to December 31, 2018 reported on or before July 1, 2019). The Agency notes that IMERC ''Product Notification'' requirements are intended to inform consumers, recyclers, policy makers, and others about the total amount of mercury in the specific products that were sold in the United States in a given year. EPA seeks comment on the proposed timelines and reporting deadlines proposed.

EPA notes that there would be some discrepancies between the proposed rule and IMERC deadlines (*e.g.,* the Agency's inventory publishing deadline is the same day as IMERC reporting deadline). However, the Agency would look to statutory provisions calling for coordination with IMERC to reconcile such concerns. In addition, the Agency's intent to avoid duplicative reporting of quantitative data could result in reliance

on information reported to other data collection systems in differing reporting years (*i.e.,* current reporters to IMERC and the CDR rule). For the reasons described above, EPA believes the proposed reporting parameters would provide for the most convenience and least burden to potential reporters and the Agency. Nonetheless, EPA requests comment on the proposed frequency of data collection, reporting deadline, and timeline.

*H. Recordkeeping*

Consistent with the proposed triennial reporting and publication cycle for the mercury inventory, EPA proposes that each person who is subject to the reporting requirements must retain records that document any information reported to EPA. Records relevant to reporting during a submission period must be retained for a period of 3 years beginning on the last day of the submission period. Submitters are encouraged to retain their records longer than 3 years to ensure that past records are available as a reference when new submissions are being generated.

*I. Reporting Requirements and Confidential Business Information*

Reporters to the information collection of the proposed rule may claim that their submitted information is CBI. The statutory provisions for CBI under TSCA are at Section 14 of the law (15 U.S.C. 2613).

*J. Electronic Reporting*

EPA is proposing to require electronic reporting of the mercury inventory data, using an Agency-provided, web-based reporting software to submit mercury inventory reports through the Internet to EPA's Central Data Exchange (CDX). CDX provides the capability for submitters to access their data through the use of web services. For more information about CDX, go to *http://epa.gov/cdx.*

Should EPA adopt a mandatory electronic reporting requirement, submitters would be required to register with EPA's CDX, complete an electronic signature agreement, and to prepare a data file for submission. To submit electronically to EPA via CDX, individuals must first register with that system at *http://cdx.epa.gov/epa_home.asp.* To register in CDX, the CDX registrant agrees to the Terms and Conditions, provides information about the submitter and organization, selects a user name and password, and follows the procedures outlined in the guidance document for CDX available at *https://cdx.epa.gov/TSCA/eTSCA-Registration Guide.pdf.* The registrant would also select a role and complete an electronic signature agreement either through electronic validation using the LexisNexis services or through wet ink signature. Once registration and the electronic signature agreement are complete, the user would prepare a submission. EPA is proposing mandatory electronic reporting because such a requirement would streamline the reporting process and reduce the administrative costs associated with information submission and recordkeeping. The effort to eliminate paper-based submissions in favor of CDX reporting is part of broader government efforts to move to modern, electronic methods of information gathering. Electronic reporting allows for more efficient data transmittal and a reduction in errors with the built-in validation procedures. EPA determined the adoption of electronic reporting reduces the reporting burden for submitters by reducing the cost and time required to review. Nonetheless, the Agency requests comment on its proposal to require mandatory electronic reporting.

## IV. Request for Comment

In addition to the areas where EPA has specifically requested comment, EPA requests comment on all other aspects of this proposed rule.

## V. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT.**


1. EPA. Mercury; Initial Inventory Report of Supply, Use, and Trade. (82 FR. 15522; March 29, 2017).
2. UNEP. Minamata Convention on Mercury. (No date). Available at *http://www.mercuryconvention.org.* [Accessed August 4, 2017].
3. EPA. Economic Analysis for the Proposed Reporting Requirements for the TSCA Mercury Inventory. August 2, 2017.
4. EPA. TSCA Chemical Substance Inventory. (No date). Available at *https://www.epa.gov/tsca-inventory.* [Accessed August 4, 2017].
5. AMAP/UNEP. Technical Background Report for the Global Mercury Assessment 2013. 2013. Arctic Monitoring and Assessment Programme, Oslo, Norway/UNEP Chemicals Branch, Geneva, Switzerland. vi + 263 pp. Available at *http://apps.unep.org/piwik/download.php?file=/publications/pmtdocuments/-Technical%20background%20report%20for%20the%20global%20mercury%20assessment%20-2013TechBackRepGMA2013.pdf.*
6. EPA. Basic Information about Mercury. (No date). Available at *https://www.epa.gov/mercury/basic-information-about-mercury.* [Accessed August 4, 2017].
7. EPA. Health Effects of Exposures to Mercury. (No date). Available at *https://www.epa.gov/mercury/health-effects-exposures-mercury.* [Accessed August 4, 2017].
8. EPA. EPA's Roadmap for Mercury, EPA–747R–06–001. July 2006. Available at *http://www.epa.gov/hg/roadmap.htm.*
9. EPA. Subpoena and Information Request. March 20, 2015. Available at *https://www.epa.gov/mercury/2015-subpoena-and-information-request-epa-mercury-recyclers.*
10. EPA. Chemical Data Reporting under the Toxic Substances Control Act. (No date). Available at *https://www.epa.gov/chemical-data-reporting.* [Accessed August 4, 2017].
11. EPA. Toxics Release Inventory (TRI) Program. (No date). Available at *https://www.epa.gov/toxics-release-inventory-tri-program.* [Accessed August 4, 2017].
12. EPA. TSCA Chemical Data Reporting Fact Sheet: Articles. 2012. Available at *https://www.epa.gov/sites/production/files/documents/articlesfactsheetforcdr_reporting_080312.pdf.*
13. USITC. Guide to Foreign Trade Statistics—Description of the Foreign Trade Statistical Program. (No date). Available at *https://www.census.gov/foreign-trade/guide/sec2.html.* [Accessed August 4, 2017].
14. NEWMOA. Instructions—Mercury-added Product Notification Form, Version for Use by a Single Manufacturer, Distributor/Wholesaler, or Importer. August 2011. Available at *www.newmoa.org/prevention/mercury/imerc/InstructionsMultiple.doc.*
15. NEWMOA. Mercury-Added Products Database. (No date). Available at *http://www.newmoa.org/prevention/mercury/imerc/notification/.* [Accessed August 4, 2017].
16. U.S. Food and Drug Administration. Mercury Poisoning Linked to Skin Products. (July 26, 2016). Available at *https://www.fda.gov/forconsumers/consumerupdates/ucm294849.htm.* [Accessed October 3, 2017].
17. EPA. Collection of Information for Mercury Inventory Reporting Rule; EPA ICR No. 2567.01; OMB Control No.: 2070–NEW. [Month DD], 2017.

## VI. 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 under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011). Any changes made in response to OMB recommendations have been documented in the docket for this action.

### *B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs*

This action is expected to be subject to the requirements for regulatory actions specified in Executive Order 13771 (82 FR 9339, February 3, 2017). EPA prepared an analysis of the estimated costs and benefits associated with this action. This analysis, ''Economic Analysis for the Proposed Reporting Requirements for the TSCA Mercury Inventory'' (Economic Analysis, Ref. 3) is available in the docket and is summarized in Unit I.E.

### *C. Paperwork Reduction Act (PRA)*

The information collection activities in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB) under the PRA, 44 U.S.C. 3501 *et seq.* The Information Collection Request (ICR) document that the EPA prepared has been assigned EPA ICR number 2567.01 (Ref. 17). You can find a copy of the ICR in the docket for this rule, and it is briefly summarized here.

The reporting requirements identified in the proposed rule would provide EPA with information necessary to prepare and periodically update an inventory of mercury supply, use, and trade in the United States, as required by TSCA section 8(b)(10)(D). These proposed reporting requirements would help the Agency to prepare subsequent, triennial publications of the inventory, as well as to carry out the requirement of TSCA section 8(b)(10)(C) to identify any manufacturing processes or products that intentionally add mercury and recommend actions, including proposed revisions of Federal law or regulations, to achieve further reductions in mercury use. EPA intends to use information collected under the rule to assist in efforts to reduce the use of mercury in products and processes and to facilitate reporting on implementation of the Minamata Convention by the United States. Respondents may claim some of the information reported to EPA under the proposed rule as CBI under TSCA section 14. TSCA section 14(c) requires a supporting statement and certification for confidentiality claims asserted after June 22, 2016.

EPA estimated total burden and costs to industry associated with the proposed rule over the first three years of its promulgation (Ref. 3). For the 750 companies anticipated to be subject to the proposed reporting requirements, the average per respondent burden hours for Year 1 (of a triennial cycle for submitting information) was estimated to be 98.94 hours (Ref. 3). Years 2 and 3 are not data collection years, so there is no cost associated with the proposed rule during these years (Ref. 3). Therefore, the average for total burden hours per the three-year reporting cycle is 32.94 hours per year (Ref. 3).

*Respondents/affected entities:* Manufacturers, importers, and processors of mercury.

*Respondent's obligation to respond:* Mandatory (15 U.S.C. 2607(b)(10)(D)).

*Estimated number of respondents:* 750.

*Frequency of response:* Triennially.

*Total estimated annual burden:* 24,734 hours (averaged over 3 years). Burden is defined at 5 CFR 1320.3(b).

*Total estimated annual cost:* $1,985,446 (averaged over 3 years), includes $0 annualized capital or operation and maintenance costs.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA's regulations in 40 CFR are listed in 40 CFR part 9.

Submit your comments on the Agency's need for this information, the accuracy of the provided burden estimates and any suggested methods for minimizing respondent burden to the EPA using the docket identified at the beginning of this rule. You may also send your ICR-related comments to OMB's Office of Information and Regulatory Affairs via email to *oira_submissions@omb.eop.gov,* Attention: Desk Officer for the EPA. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after receipt, OMB must receive comments no later than November 27, 2017. The EPA will respond to any ICR-related comments in the final rule.

### *D. Regulatory Flexibility Act (RFA)*

Pursuant to section 605(b) of the RFA, 5 U.S.C. 601 *et seq.,* I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. The small entities subject to the requirements of this action include those that manufactures, including imports, mercury or mercury-added products (manufacturers), or otherwise intentionally uses mercury in a manufacturing process (processors). To identify the number of firms that are subject to the rule and considered small under SBA size standards, EPA compared the appropriate SBA size definition to the company's revenue or number of employees, as identified using Dun and Bradstreet or other market research Web sites. Of the 506 parent companies that are subject to the rule, 211 companies (42 percent) meet the SBA small business definitions for their respective NAICS classifications.

The small entity analysis estimated that 1 parent company (0.46 percent of total entities) would incur an impact of 3 percent or greater, and 3 parent companies (1.39 percent of total entities) would incur an impact of 1 to 3 percent. Details of this analysis are included in the accompanying Economic Analysis for this Rule (Ref. 3).

### *E. Unfunded Mandates Reform Act (UMRA)*

This action does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531 through 1538, and does not significantly or uniquely affect small governments. As such, the requirements of sections 202, 203, 204, or 205 of UMRA do not apply to this action.

### *F. Executive Order 13132: Federalism*

This action does not have federalism implications, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

### *G. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments*

This action does not have tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000). It will not have any effect on tribal governments, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in the Order. Thus, EO 13175 does not apply to this action.

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

EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997) as applying only to those regulatory actions that concern environmental health or safety risks that EPA has reason to believe may disproportionately affect children, per the definition of ''covered regulatory action'' in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk, nor is this action economically significant as the impact of this action will be less than $100 million.

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

This proposed rule is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001) because it is not expected to affect energy supply, distribution, or use.

*J. National Technology Transfer and Advancement Act (NTTAA)*

Since this action does not involve any technical standards, section 12(d) of NTTAA, 15 U.S.C. 272 note, does not apply to this section.

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

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. This action establishes an information requirement and does not affect the level of protection provided to human health or the environment.

**List of Subjects in 40 CFR Part 713**

Environmental protection, Mercury, Elemental mercury, Mercury compounds, Inventory, Supply, Use, Trade, Manufacture, Import, Export.

Dated: October 19, 2017.

**E. Scott Pruitt,**

*Administrator.*

Therefore, it is proposed that 40 CFR chapter I, subchapter R, be amended by adding a new part 713 to read as follows:

## PART 713—REPORTING REQUIREMENTS FOR THE TSCA INVENTORY OF MERCURY SUPPLY, USE, AND TRADE

Sec.



**Authority:** 15 U.S.C. 2607(b)(10)(D).

### § 713.1 Purpose, scope, and compliance.

(a) This part specifies reporting and recordkeeping procedures under section 8(b)(10) of the Toxic Substances Control Act (TSCA) (15 U.S.C. 2607(b)(10)) for certain manufacturers (including importers) and processers of mercury as defined in section 8(b)(10)(A) to include elemental mercury and mercury compounds. Section 8(b)(10)(D) of TSCA authorizes the EPA Administrator to require reporting from any person who manufactures mercury or mercury-added products or otherwise intentionally uses mercury in a manufacturing process to carry out and publish in the **Federal Register** an inventory of mercury supply, use, and trade in the United States. In administering this mercury inventory, EPA will identify any manufacturing processes or products that intentionally add mercury and recommend actions, including proposed revisions of Federal law or regulations, to achieve further reductions in mercury use. EPA intends to use the collected information to implement TSCA and shape the Agency's efforts to recommend actions, both voluntary and regulatory, to reduce the use of mercury in commerce. In so doing, the Agency will conduct timely evaluation and refinement of these reporting requirements so that they are efficient and non-duplicative for reporters.

(b) This part applies to the activities associated with the periodic publication of information on mercury supply, use, and trade in the United States.

(c) For purposes of this part, the reporting for mercury supply, use, and trade includes the following activities:

(1) Import of mercury or a mercury-added product with the purpose of obtaining an immediate or eventual commercial advantage for the importer, except:

(A) Mercury generated as a byproduct not used for commercial purposes or an impurity; or

(B) A product that contains a component that is a mercury-added product.

(2) Manufacture (other than import) of mercury or a mercury-added product with the purpose of obtaining an immediate or eventual commercial advantage for the manufacturer, except a product that contains a component that is a mercury-added product.

(3) Intentional use of mercury in a manufacturing process, other than the manufacture of a mercury compound or a mercury-added product, with the purpose of obtaining an immediate or eventual commercial advantage for the processor, except mercury generated as a byproduct not used for commercial purposes.

(4) Distribution in commerce, including domestic sale or transfer, of mercury or a mercury-added product.

(5) Storage of mercury after manufacture (including import).

(6) Export of mercury or a mercury-added product, including the determining and controlling the sending of mercury (unless specifically prohibited) or a mercury-added product to a destination out of the customs territory of the United States.

(d) Section 15(3) of TSCA makes it unlawful for any person to fail or refuse to submit information required under this part. In addition, TSCA section 15(3) makes it unlawful for any person to fail to keep, and permit access to, records required by this part. Section 16 of TSCA provides that any person who violates a provision of TSCA section 15 is liable to the United States for a civil penalty and may be criminally prosecuted. Pursuant to TSCA section 17, the Federal Government may seek judicial relief to compel submission of TSCA section 8 information and to otherwise restrain any violation of TSCA section 15.

(e) Each person who reports under this part must certify the accuracy of its information and maintain records that document information reported under this part and, in accordance with TSCA, permit access to, and the copying of, such records by EPA officials.

### § 713.5 Mercury for which information must be reported.

(a) Elemental mercury (Chemical Abstracts Registry Number 7439–97–6); or

(b) A mercury compound, including but not limited to the mercury

compounds listed in Table 1 of this part by Chemical Abstracts Registry Number:

TABLE 1—MERCURY COMPOUNDS

| Chemical abstracts registry No. | Mercury compound |
|---|---|
| 10045–94–0 | Nitric acid, mercury(2+) salt (2:1). |
| 100–57–2 | Mercury, hydroxyphenyl-. |
| 10112–91–1 | Mercury chloride (Hg2Cl2). |
| 10124–48–8 | Mercury amide chloride (Hg(NH2)Cl). |
| 103–27–5 | Mercury, phenyl(propanoato-.kappa.O)-. |
| 10415–75–5 | Nitric acid, mercury(1+) salt (1:1). |
| 104–60–9 | Mercury, (9-octadecenoato-.kappa.O)phenyl-. |
| 1191–80–6 | 9-Octadecenoic acid (9Z)-, mercury(2+) salt (2:1). |
| 12068–90–5 | Mercury telluride (HgTe). |
| 13170–76–8 | Hexanoic acid, 2-ethyl-, mercury(2+) salt (2:1). |
| 13302–00–6 | Mercury, (2-ethylhexanoato-.kappa.O)phenyl-. |
| 1335–31–5 | Mercury cyanide oxide (Hg2(CN)2O). |
| 1344–48–5 | Mercury sulfide (HgS). |
| 1345–09–1 | Cadmium mercury sulfide. |
| 13876–85–2 | Mercurate(2-), tetraiodo-, copper(1+) (1:2), (T–4)-. |
| 138–85–2 | Mercurate(1-), (4-carboxylatophenyl)hydroxy-, sodium (1:1). |
| 141–51–5 | Mercury, iodo(iodomethyl)-. |
| 14783–59–6 | Mercury, bis[(2-phenyldiazenecarbothioic acid-.kappa.S) 2-phenylhydrazidato-.kappa.N2]-, (T–4)-. |
| 15385–58–7 | Mercury, dibromodi-, (Hg-Hg). |
| 15785–93–0 | Mercury, chloro[4-[(2,4-dinitrophenyl)amino]phenyl]-. |
| 15829–53–5 | Mercury oxide (Hg2O). |
| 1600–27–7 | Acetic acid, mercury(2+) salt (2:1). |
| 1785–43–9 | Mercury, chloro(ethanethiolato)-. |
| 19447–62–2 | Mercury, (acetato-.kappa.O)[4-[2-[4-(dimethylamino)phenyl]diazenyl]phenyl]-. |
| 20582–71–2 | Mercurate(2-), tetrachloro-, potassium (1:2), (T–4)-. |
| 20601–83–6 | Mercury selenide (HgSe). |
| 21908–53–2 | Mercury oxide (HgO). |
| 22450–90–4 | Mercury(1+), amminephenyl-, acetate (1:1). |
| 24579–90–6 | Mercury, chloro(2-hydroxy-5-nitrophenyl)-. |
| 24806–32–4 | Mercury, [.mu.-[2-dodecylbutanedioato(2-)-.kappa.O1:.kappa.O4]]diphenyldi-. |
| 26545–49–3 | Mercury, (neodecanoato-.kappa.O)phenyl-. |
| 27685–51–4 | Cobaltate(2-), tetrakis(thiocyanato-.kappa.N)-, mercury(2+) (1:1), (T–4)-. |
| 29870–72–2 | Cadmium mercury telluride ((Cd,Hg)Te). |
| 3294–57–3 | Mercury, phenyl(trichloromethyl)-. |
| 33770–60–4 | Mercury, [3,6-dichloro-4,5-di(hydroxy-.kappa.O)-3,5-cyclohexadiene-1,2-dionato(2-)]-. |
| 3570–80–7 | Mercury, bis(acetato-.kappa.O)[.mu.-(3′,6′-dihydroxy-3-oxospiro[isobenzofuran-1(3H),9′-[9H]xanthene]-2′,7′-diyl)]di-. |
| 537–64–4 | Mercury, bis(4-methylphenyl)-. |
| 539–43–5 | Mercury, chloro(4-methylphenyl)-. |
| 54–64–8 | Mercurate(1-), ethyl[2-(mercapto-.kappa.S)benzoato(2-)-.kappa.O]-, sodium (1:1). |
| 55–68–5 | Mercury, (nitrato-.kappa.O)phenyl-. |
| 56724–82–4 | Mercury, phenyl[(2-phenyldiazenecarbothioic acid-.kappa.S) 2-phenylhydrazidato-.kappa.N2]-. |
| 587–85–9 | Mercury, diphenyl-. |
| 592–04–1 | Mercury cyanide (Hg(CN)2). |
| 592–85–8 | Thiocyanic acid, mercury(2+) salt (2:1). |
| 593–74–8 | Mercury, dimethyl-. |
| 59–85–8 | Mercurate(1-), (4-carboxylatophenyl)chloro-, hydrogen. |
| 623–07–4 | Mercury, chloro(4-hydroxyphenyl)-. |
| 62–38–4 | Mercury, (acetato-.kappa.O)phenyl-. |
| 62638–02–2 | Cyclohexanebutanoic acid, mercury(2+) salt (2:1). |
| 627–44–1 | Mercury, diethyl-. |
| 6283–24–5 | Mercury, (acetato-.kappa.O)(4-aminophenyl)-. |
| 628–86–4 | Mercury, bis(fulminato-.kappa.C)-. |
| 629–35–6 | Mercury, dibutyl-. |
| 63325–16–6 | Mercurate(2-), tetraiodo-, (T–4)-, hydrogen, compd. with 5-iodo-2-pyridinamine (1:2:2). |
| 63468–53–1 | Mercury, (acetato-.kappa.O)(2-hydroxy-5-nitrophenyl)-. |
| 63549–47–3 | Mercury, bis(acetato-.kappa.O)(benzenamine)-. |
| 68201–97–8 | Mercury, (acetato-.kappa.O)diamminephenyl-, (T–4)-. |
| 72379–35–2 | Mercurate(1-), triiodo-, hydrogen, compd. with 3-methyl-2(3H)-benzothiazolimine (1:1:1). |
| 7439–97–6 | Mercury. |
| 7487–94–7 | Mercury chloride (HgCl2). |
| 7546–30–7 | Mercury chloride (HgCl). |
| 7616–83–3 | Perchloric acid, mercury(2+) salt (2:1). |
| 7774–29–0 | Mercury iodide (HgI2). |
| 7783–33–7 | Mercurate(2-), tetraiodo-, potassium (1:2), (T–4)-. |
| 7783–35–9 | Sulfuric acid, mercury(2+) salt (1:1). |
| 7783–39–3 | Mercury fluoride (HgF2). |
| 7789–47–1 | Mercury bromide (HgBr2). |

TABLE 1—MERCURY COMPOUNDS—Continued

| Chemical abstracts registry No. | Mercury compound |
|---|---|
| 90–03–9 | Mercury, chloro(2-hydroxyphenyl)-. |
| 94070–93–6 | Mercury, [.mu.-[(oxydi-2,1-ethanediyl 1,2-benzenedicarboxylato-.kappa.O2)(2-)]]diphenyldi-. |

**§ 713.7 Mercury for which reporting is not required.**

(a) Mercury that is generated as a byproduct not used for commercial purposes; or

(b) Mercury-containing waste.

**§ 713.9 General requirements for which information must be reported.**

(a) Persons who manufacture (including import) mercury in amounts greater than or equal to 2,500 pounds (lbs.) for elemental mercury or greater than or equal to 25,000 lbs. for mercury compounds for a specific reporting year shall report, as applicable:

(1) Amount of mercury stored (lbs.); or

(2) Amount of mercury distributed in commerce (lbs.)

(b) All other persons who manufacture (including import) mercury shall report, as applicable:

(1) Amount of mercury manufactured (other than imported) (lbs.);

(2) Amount of mercury imported (lbs.);

(3) Amount of mercury exported (lbs.), except mercury prohibited from export at 15 U.S.C. 2611(c)(1) and (7);

(4) Amount of mercury stored (lbs.); or

(5) Amount of mercury distributed in commerce (lbs.).

(c) Persons who sell mercury-added products, except a product that contains a component that is a mercury-added product, in IMERC Notification states shall report, as applicable:

(1) Amount of mercury in manufactured (other than imported) products (lbs.);

(2) Amount of mercury in imported products (lbs.); or

(3) Amount of mercury in exported products (lbs.).

(d) All other persons who manufacture (including import) mercury-added products, except a product that contains a component that is a mercury-added product, shall report, as applicable:

(1) Amount of mercury in manufactured (other than imported) products (lbs.);

(2) Amount of mercury in imported products (lbs.);

(3) Amount of mercury in exported products (lbs.);

(4) Amount of mercury in products distributed in commerce (lbs.); or

(e) Persons who otherwise intentionally use mercury in a manufacturing process, other than the manufacture of a mercury compound or a mercury-added product, shall report, as applicable:

(1) Amount of mercury otherwise intentionally used (lbs.) in a manufacturing process;

(2) Amount of mercury stored (lbs.);

(3) Amount of mercury in exported final product(s) (lbs.); or

(4) Amount of mercury in final product(s) distributed in commerce (lbs.).

**§ 713.11 Specific requirements for which information must be reported.**

(a) Any person who manufactures (including imports) mercury shall specify, as applicable, the specific mercury compound(s) from a pre-selected list (as listed in Table 1 of this part).

(b) Any person who manufactures (including imports) a mercury-added product, except manufacture (including import) of a product that contains a component that is a mercury-added product, shall specify as applicable, the specific category(ies) and subcategory(ies) from a pre-selected list, as listed in Table 2 of this part:

TABLE 2—CATEGORIES AND SUBCATEGORIES OF MERCURY-ADDED PRODUCTS

| Category | Subcategory |
|---|---|
| Batteries | —Button cell, silver. |
| | —Button cell, zinc-air. |
| | —Button cell, alkaline. |
| | —Stacked button cell batteries. |
| | —Manganese oxide. |
| | —Silver oxide. |
| | —Mercuric oxide, non-button cell. |
| | —Button cell, mercuric oxide. |
| | —Button cell, zinc carbon. |
| | —Other (specify). |
| Dental amalgam | [No subcategories]. |
| Formulated products (includes uses in cosmetics, pesticides, and laboratory chemicals). | —Skin-lightening creams. |
| | —Lotions. |
| | —Soaps and sanitizers. |
| | —Bath oils and salts. |
| | —Topical antiseptics. |
| | —Preservatives (e.g., for use in vaccines and eye-area cosmetics when no preservative alternatives are available). |
| | —Pharmaceuticals (including prescription and over-the-counter drug products). |
| | —Cleaning products (not registered as pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act). |
| | —Pesticides. |
| | —Paints. |
| | —Dyes. |
| | —Reagents (e.g., catalysts, buffers, fixatives). |

TABLE 2—CATEGORIES AND SUBCATEGORIES OF MERCURY-ADDED PRODUCTS—Continued

| Category | Subcategory |
|---|---|
| | —Other (specify). |
| Lighting, lamps, bulbs | —Linear fluorescent. |
| | —Compact fluorescent. |
| | —U-tube and circular fluorescent. |
| | —Cold cathode fluorescent. |
| | —External electrode fluorescent. |
| | —Mercury vapor. |
| | —Metal halide. |
| | —High pressure sodium. |
| | —Mercury short arc. |
| | —Neon. |
| | —Other (specify). |
| Measuring instruments | —Barometer. |
| | —Fever thermometer. |
| | —Flow meter. |
| | —Hydrometer. |
| | —Hygrometer/psychrometer. |
| | —Manometer. |
| | —Non-fever thermometer. |
| | —Pyrometer. |
| | —Sphygmomanometer. |
| | —Other (specify). |
| Pump seals | [No subcategories]. |
| Switches, relays, sensors, valves | —Tilt switch. |
| | —Vibration switch. |
| | —Float switch. |
| | —Pressure switch. |
| | —Temperature switch. |
| | —Displacement relay. |
| | —Wetted reed relay. |
| | —Contact relay. |
| | —Flame sensor. |
| | —Thermostat. |
| | —Other (specify). |
| Miscellaneous/novelty mercury-added products | —Wheel weights. |
| | —Wheel rotation balancers/stabilizers. |
| | —Firearm recoil suppressors. |
| | —Carburetor synchronizers. |
| | —Joint support/shock absorption bands. |
| | —Other (specify). |

(c) Any person who otherwise intentionally uses mercury in a manufacturing process, other than the manufacture of a mercury compound or a mercury-added product, shall specify, as applicable:

(1) The specific manufacturing process for which mercury is otherwise intentionally added from a pre-selected list, as listed in Table 3 of this part:

TABLE 3—MANUFACTURING PROCESS FOR WHICH MERCURY IS OTHERWISE INTENTIONALLY ADDED

| |
|---|
| Chlorine production (e.g., mercury-cell chlor-alkali process). |
| Acetaldehyde production. |
| Vinyl chloride monomer production. |
| Sodium/potassium methylate/ethylate production. |
| Polyurethane/plastic production. |
| Other (specify). |

(2) The specific use of mercury in a manufacturing process from a pre-selected list, as listed in Table 4 of this part:

TABLE 4—SPECIFIC USE OF MERCURY IN A MANUFACTURING PROCESS

| |
|---|
| Catalyst. |
| Reactant. |
| Reagent. |
| Other (specify). |

**§ 713.13 Contextual requirements for which information must be reported.**

(a) Persons who manufacture (including import) mercury in amounts greater than or equal to 2,500 lbs. for elemental mercury or greater than or equal to 25,000 lbs. for mercury compounds for a specific reporting year shall report, as applicable:

(1) Country(ies) of origin for imported mercury;

(2) Country(ies) of destination for exported mercury;

(3) NAICS code(s) for mercury distributed in commerce.

(b) All other persons who manufacture (including import) mercury shall report, as applicable:

(1) Country(ies) of origin for imported mercury;

(2) Country(ies) of destination for exported mercury;

(3) NAICS code(s) for mercury distributed in commerce.

(c) Persons who sell mercury-added products, except a product that contains a component that is a mercury-added product, in IMERC Notification states shall report, as applicable:

(1) Country(ies) of origin for imported products;

(2) Country(ies) of destination for exported products; or

(3) NAICS code(s) for products distributed in commerce.

(d) All other persons who manufacture (including import) mercury-added products, except a product that contains a component that is a mercury-added product, shall report, as applicable:

(1) Country(ies) of origin for imported products;

(2) Country(ies) of destination for exported products; or

(3) NAICS code(s) for products distributed in commerce.

(e) Persons who otherwise intentionally use mercury in a manufacturing process, other than the manufacture of a mercury compound or a mercury-added product, shall report, as applicable:

(1) Country(ies) of destination for exported final product(s); or

(2) NAICS code(s) for mercury in final product(s) distributed in commerce.

**§ 713.15 Persons who must report.**

(a) Any person who manufactures (including imports) mercury;

(b) Any person who manufactures (including imports) a mercury-added product, except a product that contains a component that is a mercury-added product; or

(c) Any person who otherwise intentionally uses mercury in a manufacturing process, other than the manufacture of a mercury compound or a mercury-added product.

**§ 713.17 Persons not subject to this part.**

(a) Any person engaged in the generation, handling, or management of mercury-containing waste, unless that person manufactures or recovers mercury in the management of that waste.

(b) Any person who engaged in trade (*e.g.,* brokering, selling wholesale, shipping, warehousing, repackaging, or retail sale), but does not first manufacture (including import) mercury or mercury-added products or otherwise intentionally use mercury in a manufacturing process.

**§ 713.19 Reporting information to EPA.**

Any person who must report under this part shall report for the submission period described at § 713.21:

(a) Quantities of mercury in pounds per applicable activity listed under the general requirements for which information must be reported described at § 713.9;

(b) Specific requirements for which information must be reported described at § 713.11;

(c) Contextual requirements for which information must be reported described at § 713.13; and

(d) According to the procedures described at § 713.25.

**§ 713.21 When to report.**

(a) Any person who must report under this part shall report for the reporting year described as follows. The 2020 reporting year is from January 1 to December 31, 2018. Subsequent recurring reporting years are from January 1 to December 31 at 3-year intervals, beginning in 2021.

(b) All information reported for an applicable reporting year must be submitted on or before the first day of July following the reporting year. The 2020 submission deadline is July 1, 2019. Subsequent recurring submission deadlines are from July 1, in 3-year intervals, beginning in 2022.

**§ 713.23 Recordkeeping requirements.**

Each person who is subject to the reporting requirements of this part must retain records that document any information reported to EPA. Records relevant to a reporting year must be retained for a period of 3 years beginning on the last day of the reporting year. Submitters are encouraged to retain their records longer than 3 years to ensure that past records are available as a reference when new submissions are being generated.

**§ 713.25 Electronic filing.**

(a) You must use [xxx name of application xxx] to complete and submit [xxx form? xxx]. Submissions may only be made as set forth in this section.

(b) Submissions must be sent electronically to EPA via CDX.

(c) Access [xxx name of application xxx] and instructions, as follows:

(1) By Web site. Go to the EPA [xxx name of application xxx] homepage at *http://www.epa.gov/[xxxURLxxx]* and follow the appropriate links.

(2) By phone or email. Contact the EPA TSCA Hotline at (202) 554–1404 or *TSCA-Hotline@epa.gov* for a CD–ROM containing the instructions.

[FR Doc. 2017–23225 Filed 10–25–17; 8:45 am]

BILLING CODE 6560–50–P

# Notices

Federal Register
Vol. 82, No. 206
Thursday, October 26, 2017

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

## ARCHITECTURAL AND TRANSPORTATION BARRIERS COMPLIANCE BOARD

### Meetings

**AGENCY:** Architectural and Transportation Barriers Compliance Board.

**ACTION:** Notice of meetings.

**SUMMARY:** The Architectural and Transportation Barriers Compliance Board (Access Board) plans to hold its regular committee and Board meetings in Washington, DC, Monday through Wednesday, November 13–15, 2017 at the times and location listed below.

**DATES:** The schedule of events is as follows:

**Monday, November 13, 2017**

9:30 a.m.–4:00 p.m. Achieving Access for People with Disabilities in the Built Environment; an International Comparison

**Tuesday, November 14, 2017**

9:30 a.m.–10:30 a.m. Technical Programs
10:30 a.m.–11:30 a.m. Ad Hoc Committee on Frontier Issues
11:30 a.m.–Noon Budget

**Wednesday, November 15, 2017**

10:00 a.m.–10:30 a.m. Ad Hoc Committee on Design Guidance
10:30 a.m.–Noon Planning and Evaluation
1:30 p.m.–3:00 p.m. Board Meeting

**ADDRESSES:** Meetings will be held at the Access Board Conference Room, 1331 F Street NW., Suite 800, Washington, DC 20004.

**FOR FURTHER INFORMATION CONTACT:** For further information regarding the meetings, please contact David Capozzi, Executive Director, (202) 272–0010 (voice); (202) 272–0054 (TTY).

**SUPPLEMENTARY INFORMATION:** At the Board meeting scheduled on the afternoon of Wednesday, November 15, 2017, the Access Board will consider the following agenda items:

- Approval of draft meeting minutes (vote): March 15, 2017; July 12, 2017; September 13, 2017
- Ad Hoc Committee Reports: Design Guidance; Frontier Issues
- Technical Programs Committee
- Budget Committee
- Planning and Evaluation Committee
- Election Assistance Commission Report
- Executive Director's Report
- Public Comment (final 15 minutes of the meeting)

Members of the public can provide comments either in-person or over the telephone during the final 15 minutes of the Board meeting on Wednesday, November 15, 2017. Any individual interested in providing comment is asked to pre-register by sending an email to *bunales@access-board.gov* with the subject line ''Access Board meeting—Public Comment'' with your name, organization, state, and topic of comment included in the body of your email. All emails to register for public comment must be received by Wednesday, November 8, 2017. Commenters will be provided with a call-in number and passcode before the meeting. Commenters will be called on in the order by which they are pre-registered. Due to time constraints, each commenter is limited to two minutes. Commenters on the telephone will be in a listen-only capacity until they are called on.

All meetings are accessible to persons with disabilities. An assistive listening system, Communication Access Realtime Translation (CART), and sign language interpreters will be available at the Board meeting and committee meetings.

Persons attending Board meetings are requested to refrain from using perfume, cologne, and other fragrances for the comfort of other participants (see *www.access-board.gov/the-board/policies/fragrance-free-environment* for more information).

You may view the Wednesday, November 15, 2017 meeting through a live webcast from 1:30 p.m. to 3:00 p.m. at: *www.access-board.gov/webcast.*

**David M. Capozzi,**

*Executive Director.*

[FR Doc. 2017–23323 Filed 10–25–17; 8:45 am]

**BILLING CODE 8150–01–P**

## DEPARTMENT OF COMMERCE

### Foreign-Trade Zones Board

**[S–164–2017]**

### Foreign-Trade Zone 295—Central Pennsylvania; Application for Subzone; North American Höganäs Company; Johnstown, Hollsopple and St, Mary's, Pennsylvania

An application has been submitted to the Foreign-Trade Zones (FTZ) Board by the Pennsylvania Foreign Trade Zone Corporation, grantee of FTZ 295, requesting subzone status for the facilities of North American Höganäs Company (Höganäs), located in Johnstown, Hollsopple and St. Mary's, Pennsylvania. The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the FTZ Board (15 CFR part 400). It was formally docketed on October 19, 2017.

The proposed subzone would consist of the following sites: *Site 1* (9.38 acres) 101 Bridge Street, Johnstown, Cambria County; *Site 2* (98.98 acres) 111 Höganäs Way, Hollsopple, Somerset County; and, *Site 3* (3.42 acres) 210 Ceramic Street, St. Mary's, Elk County. No authorization for production activity has been requested at this time. The proposed subzone would be subject to the existing activation limit of FTZ 295.

In accordance with the FTZ Board's regulations, Elizabeth Whiteman of the FTZ Staff is designated examiner to review the application and make recommendations to the Executive Secretary.

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 December 5, 2017. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to December 20, 2017.

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 Web site, which is accessible via *www.trade.gov/ftz.*

For further information, contact Elizabeth Whiteman at *Elizabeth.Whiteman@trade.gov* or (202) 482–0473.

Dated: October 20, 2017.

**Andrew McGilvray,**

*Executive Secretary.*

[FR Doc. 2017–23309 Filed 10–25–17; 8:45 am]

**BILLING CODE 3510–DS–P**

## DEPARTMENT OF COMMERCE

### International Trade Administration

**[A–533–879, A–570–066]**

### Polytetrafluoroethylene Resin From India and the People's Republic of China: Initiation of Less-Than-Fair-Value Investigations

**AGENCY:** Enforcement and Compliance, International Trade Administration, Department of Commerce.

**DATES:** Applicable October 18, 2017.

**FOR FURTHER INFORMATION CONTACT:** Mark Kennedy at (202) 482–7883 (India), and Catherine Cartsos (the People's Republic of China (PRC)) at (202) 482–1757, AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230.

**SUPPLEMENTARY INFORMATION:**

#### The Petitions

On September 28, 2017, the U.S. Department of Commerce (the Department) received antidumping duty (AD) Petitions concerning imports of polytetrafluoroethylene resin (PTFE resin) from India and the PRC, filed in proper form on behalf of The Chemours Company FC LLC (the petitioner).[1] The AD Petitions were accompanied by a countervailing duty (CVD) Petition concerning imports of PTFE resin from India. The petitioner is a domestic producer of PTFE resin.[2]

On October 2, 2017, and October 3, 2017, the Department requested supplemental information pertaining to certain areas of the Petitions.[3] The petitioner filed responses to these requests on October 4, 2017, and October 5, 2017.[4] In addition, the petitioner filed revised scope language on October 13, 2017.[5]

In accordance with section 732(b) of the Tariff Act of 1930, as amended (the Act), the petitioner alleges that imports of PTFE resin from India and the PRC are being, or are likely to be, sold in the United States at less than fair value within the meaning of section 731 of the Act, and that such imports are materially injuring, or threatening material injury to, the domestic industry producing PTFE resin in the United States. Also, consistent with section 732(b)(1) of the Act, the Petitions are accompanied by information reasonably available to the petitioner supporting its allegations.

The Department finds that the petitioner is an interested party as defined in section 771(9)(C) of the Act and that the petitioner filed these Petitions on behalf of the domestic industry and demonstrated sufficient industry support with respect to the initiation of the AD investigations that the petitioner is requesting.[6]

#### Periods of Investigation

Because the Petitions were filed on September 28, 2017, the period of investigation (POI) for India is July 1, 2016, through June 30, 2017. Because the PRC is a non-market economy (NME) country, the POI for the PRC is January 1, 2017, through June 30, 2017.

#### Scope of the Investigations

The product covered by these investigations is PTFE resin from India and the PRC. For a full description of the scope of these investigations, *see* the ''Scope of the Investigations,'' in the Appendix to this notice.

#### Comments on Scope of the Investigations

During our review of the Petitions, the petitioner submitted a revised proposed scope to ensure that the scope language in the Petitions would be an accurate reflection of the products for which the domestic industry is seeking relief.[7]

As discussed in the preamble to the Department's regulations, we are setting aside a period for interested parties to raise issues regarding product coverage (scope).[8] The Department will consider all comments received from interested parties and, if necessary, will consult with interested parties prior to the issuance of the preliminary determinations. If scope comments include factual information,[9] all such factual information should be limited to public information. To facilitate preparation of its questionnaires, the Department requests all interested parties to submit such comments by 5:00 p.m. Eastern Time (ET) on Tuesday, November 7, 2017, which is 20 calendar days from the signature date of this notice. Any rebuttal comments, which may include factual information, must be filed by 5:00 p.m. ET on Friday, November 17, 2017, which is 10 calendar days from the initial comments deadline.[10]

The Department requests that any factual information the parties consider relevant to the scope of the investigations be submitted during this time period. However, if a party subsequently finds that additional factual information pertaining to the scope of the investigations may be relevant, the party may contact the Department and request permission to submit the additional information. All such comments must be filed on the records of each of the concurrent AD and CVD investigations.

#### Filing Requirements

All submissions to the Department must be filed electronically using Enforcement and Compliance's Antidumping Duty and Countervailing

[1] *See* Letter to the Secretary of Commerce re: ''Polytetrafluoroethylene (PTFE) Resin from the People's Republic of China and India: Antidumping and Countervailing Duty Petitions,'' dated September 28, 2017 (the Petitions).

[2] *See* the Petitions at 2.

[3] *See* Letter from the Department, ''Petitions for the Imposition of Antidumping and Countervailing Duties on Imports of Polytetrafluoroethylene Resin from India and the People's Republic of China: Supplemental Questions,'' dated October 2, 2017 (General Issues Questionnaire); *see also* Letter from the Department, ''Petition for the Imposition of Antidumping Duties on Imports of Polytetrafluoroethylene Resin from the People's Republic of China: Supplemental Questions,'' dated October 2, 2017 (PRC AD Supplemental Questionnaire); Letter from the Department, ''Petition for the Imposition of Antidumping Duties on Imports of Polytetrafluoroethylene Resin from India: Supplemental Questions,'' dated October 3, 2017 (India AD Supplemental Questionnaire).

[4] *See* Letter from the petitioner, ''Polytetrafluoroethylene (PTFE) Resin from the People's Republic of China and India: Responses to Supplemental Questions Regarding the Antidumping and Countervailing Duty Petitions'' (October 4, 2017) (General Issues and AD Supplement); *see also* Letter from the petitioner, ''Polytetrafluoroethylene (PTFE) Resin from the People's Republic of China and India: Additional Responses to Supplemental Questions Regarding the Antidumping and Countervailing Duty Petitions'' (October 5, 2017); Letter from the petitioner, ''Polytetrafluoroethylene (PTFE) Resin from India: Exhibit III–12'' (October 5, 2017).

[5] *See* Letter from the petitioner, ''Polytetrafluoroethylene (PTFE) Resin from the People's Republic of China and India: Amendment to the Suggested Scope of the Antidumping and Countervailing Duty Petitions'' (October 13, 2017). *See also* Memorandum to the File, dated October 11, 2017.

[6] *See* the ''Determination of Industry Support for the Petitions'' section, below.

[7] *See* Letter from the petitioner, ''Polytetrafluoroethylene (PTFE) Resin from the People's Republic of China and India: Amendment to the Suggested Scope of the Antidumping and Countervailing Duty Petitions'' (October 13, 2017). *See also* Memorandum to the File, dated October 11, 2017.

[8] *See Antidumping Duties; Countervailing Duties, Final Rule,* 62 FR 27296, 27323 (May 19, 1997).

[9] *See* 19 CFR 351.102(b)(21) (defining ''factual information'').

[10] *See* 19 CFR 351.303(b).

Duty Centralized Electronic Service System (ACCESS).[11] An electronically filed document must be received successfully in its entirety by the time and date it is due. Documents exempted from the electronic submission requirements must be filed manually (*i.e.,* in paper form) with Enforcement and Compliance's APO/Dockets Unit, Room 18022, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230, and stamped with the date and time of receipt by the applicable deadlines.

**Comments on Product Characteristics for AD Questionnaires**

The Department will provide interested parties an opportunity to comment on the appropriate physical characteristics of PTFE resin to be reported in response to the Department's AD questionnaires. This information will be used to identify the key physical characteristics of the merchandise under consideration in order to report the relevant costs of production accurately as well as to develop appropriate product-comparison criteria.

Interested parties may provide any information or comments that they feel are relevant to the development of an accurate list of physical characteristics. Specifically, they may provide comments as to which characteristics are appropriate to use as: (1) General product characteristics and (2) product-comparison criteria. We note that it is not always appropriate to use all product characteristics as product-comparison criteria. We base product-comparison criteria on meaningful commercial differences among products. In other words, although there may be some physical product characteristics utilized by manufacturers to describe PTFE resin, it may be that only a select few product characteristics take into account commercially meaningful physical characteristics. In addition, interested parties may comment on the order in which the physical characteristics should be used in matching products. Generally, the Department attempts to list the most important physical characteristics first and the least important characteristics last.

In order to consider the suggestions of interested parties in developing and issuing the AD questionnaires, all product characteristics comments must be filed by 5:00 p.m. ET on November 7, 2017. Any rebuttal comments must be filed by 5:00 p.m. ET on November 17, 2017. All comments and submissions to the Department must be filed electronically using ACCESS, as explained above, on the records of both the India and the PRC less-than-fair-value investigations.

**Determination of Industry Support for the Petitions**

Section 732(b)(1) of the Act requires that a petition be filed on behalf of the domestic industry. Section 732(c)(4)(A) of the Act provides that a petition meets this requirement if the domestic producers or workers who support the petition account for: (i) At least 25 percent of the total production of the domestic like product; and (ii) more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the petition. Moreover, section 732(c)(4)(D) of the Act provides that, if the petition does not establish support of domestic producers or workers accounting for more than 50 percent of the total production of the domestic like product, the Department shall: (i) Poll the industry or rely on other information in order to determine if there is support for the petition, as required by subparagraph (A); or (ii) determine industry support using a statistically valid sampling method to poll the ''industry.''

Section 771(4)(A) of the Act defines the ''industry'' as the producers as a whole of a domestic like product. Thus, to determine whether a petition has the requisite industry support, the statute directs the Department to look to producers and workers who produce the domestic like product. The International Trade Commission (ITC), which is responsible for determining whether ''the domestic industry'' has been injured, must also determine what constitutes a domestic like product in order to define the industry. While both the Department and the ITC must apply the same statutory definition regarding the domestic like product,[12] they do so for different purposes and pursuant to a separate and distinct authority. In addition, the Department's determination is subject to limitations of time and information. Although this may result in different definitions of the like product, such differences do not render the decision of either agency contrary to law.[13]

Section 771(10) of the Act defines the domestic like product as ''a product which is like, or in the absence of like, most similar in characteristics and uses with, the article subject to an investigation under this title.'' Thus, the reference point from which the domestic like product analysis begins is ''the article subject to an investigation'' (*i.e.,* the class or kind of merchandise to be investigated, which normally will be the scope as defined in the petition).

With regard to the domestic like product, the petitioner does not offer a definition of the domestic like product distinct from the scope of the investigations. Based on our analysis of the information submitted on the record, we have determined that PTFE resin, as defined in the scope, constitutes a single domestic like product and we have analyzed industry support in terms of that domestic like product.[14]

In determining whether the petitioner has standing under section 732(c)(4)(A) of the Act, we considered the industry support data contained in the Petitions with reference to the domestic like product as defined in the ''Scope of the Investigations,'' in Appendix I of this notice. The petitioner provided its own production of the domestic like product in 2016, as well as estimated 2016 production data of the domestic like product by the entire U.S. industry.[15] To establish industry support, the petitioner compared its production to the total 2016 production of the domestic like product for the entire domestic industry.[16] We relied on the data the petitioner provided for

[11] *See Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures,* 76 FR 39263 (July 6, 2011); *see also Enforcement and Compliance; Change of Electronic Filing System Name,* 79 FR 69046 (November 20, 2014) for details of the Department's electronic filing requirements, which went into effect on August 5, 2011. Information on help using ACCESS can be found at *https://access.trade.gov/help.aspx* and a handbook can be found at *https://access.trade.gov/help/Handbook%20on%20Electronic%20Filling%20Procedures.pdf.*

[12] *See* section 771(10) of the Act.

[13] *See USEC, Inc.* v. *United States,* 132 F. Supp. 2d 1, 8 (CIT 2001) (citing *Algoma Steel Corp., Ltd.* v. *United States,* 688 F. Supp. 639, 644 (CIT 1988), *aff'd* 865 F.2d 240 (Fed. Cir. 1989)).

[14] For a discussion of the domestic like product analysis in this case, *see* Antidumping Duty Investigation Initiation Checklist: Polytetrafluoroethylene (PTFE) Resin from the People's Republic of China (PRC AD Initiation Checklist), at Attachment II, Analysis of Industry Support for the Antidumping and Countervailing Duty Petitions Covering Polytetrafluoroethylene (PTFE) Resin from the People's Republic of China and India (Attachment II); and Antidumping Duty Investigation Initiation Checklist: Polytetrafluoroethylene (PTFE) Resin from India (India AD Initiation Checklist), at Attachment II. These checklists are dated concurrently with, and hereby adopted by, this notice and on file electronically via ACCESS. Access to documents filed via ACCESS is also available in the Central Records Unit, Room B8024 of the main Department of Commerce building.

[15] *See* the Petitions, at 2–4 and Exhibit I–2; *see also* General Issues and AD Supplement, at 3–4.

[16] *See* the Petitions, at Exhibit I–2; *see also* General Issues and AD Supplement, at 3–4.

purposes of measuring industry support.[17]

Our review of the data provided in the Petitions and other information readily available to the Department indicates that the petitioner has established industry support.[18] First, the Petitions established support from domestic producers (or workers) accounting for more than 50 percent of the total production of the domestic like product and, as such, the Department is not required to take further action in order to evaluate industry support (*e.g.,* polling).[19] Second, the domestic producers (or workers) have met the statutory criteria for industry support under section 732(c)(4)(A)(i) of the Act because the domestic producers (or workers) who support the Petitions account for at least 25 percent of the total production of the domestic like product.[20] Finally, the domestic producers (or workers) have met the statutory criteria for industry support under section 732(c)(4)(A)(ii) of the Act because the domestic producers (or workers) who support the Petitions account for more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the Petitions.[21] Accordingly, the Department determines that the Petitions were filed on behalf of the domestic industry within the meaning of section 732(b)(1) of the Act.

The Department finds that the petitioner filed the Petitions on behalf of the domestic industry because it is an interested party as defined in section 771(9)(C) of the Act and it has demonstrated sufficient industry support with respect to the AD investigations that it is requesting that the Department initiate.[22]

## Allegations and Evidence of Material Injury and Causation

The petitioner alleges that the U.S. industry producing the domestic like product is being materially injured, or is threatened with material injury, by reason of the imports of the subject merchandise sold at less than normal value (NV). In addition, the petitioner alleges that subject imports exceed the negligibility threshold provided for under section 771(24)(A) of the Act.[23]

The petitioner contends that the industry's injured condition is illustrated by a significant volume of subject imports; an increase in the volume of subject imports relative to U.S. consumption and production; reduced market share; underselling and price suppression or depression; lost sales and revenues; a negative impact on the domestic industry's capacity, capacity utilization, and employment; and a negative impact on revenues and operating profits.[24] We have assessed the allegations and supporting evidence regarding material injury, threat of material injury, and causation, and we have determined that these allegations are properly supported by adequate evidence, and meet the statutory requirements for initiation.[25]

## Allegations of Sales at Less Than Fair Value

The following is a description of the allegations of sales at less than fair value upon which the Department based its decision to initiate AD investigations of imports of PTFE resin from India and the PRC. The sources of data for the deductions and adjustments relating to U.S. price and NV are discussed in greater detail in the country-specific initiation checklists.

## Export Price

For the PRC, the petitioner based the U.S. price on export price (EP) using average unit values (AUVs) of publicly available import data and price quotes for sales of PTFE resin produced in, and exported from, the PRC and offered for sale in the United States.[26] For India, the petitioner based U.S. price on EP using AUVs of publicly available import data.[27] Where applicable, the petitioner made deductions from U.S. price for movement and other expenses, consistent with the terms of sale.[28]

## Constructed Export Price

For India, because the petitioner had reason to believe that the prices/offers for sale were made through a U.S. affiliate, the petitioner also based the U.S. price on constructed export price (CEP) using price quotes for sales and prices of actual sales of PTFE resin produced in, and exported from, India and offered for sale in the United States.[29] Where applicable, the petitioner made deductions from U.S. price for movement and other expenses, consistent with the terms of sale.[30]

## Normal Value

For India, the petitioner provided home market price information for PTFE resin produced and offered for sale in India that was obtained through market research.[31] For India, the petitioner provided a declaration from a market researcher to support the price information.[32]

With respect to the PRC, the petitioner stated that the Department has found it to be a NME country in prior administrative proceedings in which they were involved.[33] In accordance with section 771(18)(C)(i) of the Act, the presumption of NME status remains in effect until revoked by the Department. The presumption of NME status for the PRC has not been revoked by the Department and, therefore, remains in effect for purposes of the initiation of this investigation. Accordingly, NV in the PRC is appropriately based on factors of production (FOPs) valued in a surrogate market economy country, in accordance with section 773(c) of the Act.[34] In the course of this investigation, all parties, and the public, will have the opportunity to provide relevant information related to the granting of separate rates to individual exporters.

The petitioner claims that Mexico is an appropriate surrogate country for the PRC because it is a market economy country that is at a level of economic development comparable to that of the PRC, it is a significant producer of comparable merchandise, and public information from Mexico is available to value all material input factors.[35] Based on the information provided by the petitioner, we determine that it is appropriate to use Mexico as a surrogate country for initiation purposes.

Interested parties will have the opportunity to submit comments regarding surrogate country selection and, pursuant to 19 CFR

[17] *Id.* For further discussion, *see* PRC AD Initiation Checklist, at Attachment II; and India AD Initiation Checklist, at Attachment II.

[18] *See* PRC AD Initiation Checklist, at Attachment II; and India AD Initiation Checklist, at Attachment II.

[19] *See* section 732(c)(4)(D) of the Act; *see also* PRC AD Initiation Checklist, at Attachment II; and India AD Initiation Checklist, at Attachment II.

[20] *See* PRC AD Initiation Checklist, at Attachment II; and India AD Initiation Checklist, at Attachment II.

[21] *Id.*

[22] *Id.*

[23] *See* the Petitions, at 21 and Exhibit I–14.

[24] *Id.* at 24–34, Exhibit I–8, and Exhibits I–14, I–16, and I–17.

[25] *See* PRC AD Initiation Checklist, at Attachment III, Analysis of Allegations and Evidence of Material Injury and Causation for the Antidumping and Countervailing Duty Petitions Covering Polytetrafluoroethylene Resin (PTFE Resin) from India and the People's Republic of China (the PRC) (Attachment III); *see also* India AD Initiation Checklist, at Attachment III.

[26] *See* PRC AD Initiation Checklist.

[27] *See* India AD Initiation Checklist.

[28] *See* India AD Initiation Checklist and PRC AD Initiation Checklist.

[29] *See* India AD Initiation Checklist.

[30] *Id.*

[31] *Id.*

[32] *Id.*

[33] *See* the Petitions, at 38.

[34] *See* PRC AD Initiation Checklist.

[35] *See* Petitions, at 39–42 and Exhibits I–1, II–2, II–3.

351.301(c)(3)(i), will be provided an opportunity to submit publicly available information to value FOPs within 30 days before the scheduled date of the preliminary determination.

**Factors of Production**

Because information regarding the volume of inputs consumed by the PRC producers/exporters is not available, the petitioner relied on its own production experience as an estimate of Chinese manufacturers' FOPs.[36] The petitioner valued the estimated FOPs using surrogate values from Mexico and used the average POI exchange rate to convert the data to U.S. dollars.[37]

**Fair Value Comparisons**

Based on the data provided by the petitioner, there is reason to believe that imports of PTFE resin from India and the PRC are being, or are likely to be, sold in the United States at less than fair value. Based on comparisons of EP and CEP to NV for India and EP to NV for the PRC in accordance with sections 772 and 773 of the Act, the estimated dumping margins for PTFE resin for each of the countries covered by this initiation are as follows: (1) PRC—23.4 to 408.9 percent,[38] and (2) India—15.8 to 128.1 percent.[39]

**Initiation of Less-Than-Fair-Value Investigations**

Based upon the examination of the AD Petitions, we find that the Petitions meet the requirements of section 732 of the Act. Therefore, we are initiating AD investigations to determine whether imports of PTFE resin from India and the PRC are being, or are likely to be, sold in the United States at less than fair value. In accordance with section 733(b)(1)(A) of the Act and 19 CFR 351.205(b)(1), unless postponed, we intend to make our preliminary determinations no later than 140 days after the date of this initiation.

Under the Trade Preferences Extension Act of 2015, numerous amendments to the AD and CVD law were made.[40] The 2015 law does not specify dates of application for those amendments. On August 6, 2015, the Department published an interpretative rule, in which it announced the applicability dates for each amendment to the Act, except for amendments contained in section 771(7) of the Act, which relate to determinations of material injury by the ITC.[41] The amendments to sections 771(15), 773, 776, and 782 of the Act are applicable to all determinations made on or after August 6, 2015, and, therefore, apply to these AD investigations.[42]

**Respondent Selection**

The petitioner named seven companies in India as producers/exporters of PTFE resin.[43] For India, following standard practice in AD investigations involving market economy countries, in the event the Department determines that the number of producers/exporters involved in the investigation is large, the Department intends to review U.S. Customs and Border Protection (CBP) data for U.S. imports of PTFE resin during the POI under the appropriate Harmonized Tariff Schedule of the United States subheadings, and if it determines that it cannot individually examine each company based upon the Department's resources, then the Department will select respondents based on that data. We intend to release CBP data under Administrative Protective Order (APO) to all parties with access to information protected by APO within five business days of the announcement of the initiation of this investigation. Interested parties must submit applications for disclosure under APO in accordance with 19 CFR 351.305(b). Instructions for filing such applications may be found on the Department's Web site at *http://enforcement.trade.gov/apo.*

Interested parties may submit comments regarding the CBP data and respondent selection by 5:00 p.m. ET seven calendar days after the placement of the CBP data on the record of this investigation. Interested parties wishing to submit rebuttal comments should submit those comments five calendar days after the deadline for initial comments.

Comments must be filed electronically using ACCESS. An electronically-filed document must be received successfully, in its entirety, by ACCESS no later than 5:00 p.m. ET on the date noted above. If respondent selection is necessary, within 20 days of publication of this notice, we intend to make our decisions regarding respondent selection based upon comments received from interested parties and our analysis of the record information.

With respect to the PRC, the petitioner named 49 companies in the PRC as producers/exporters of PTFE resin.[44] In accordance with our standard practice for respondent selection in AD cases involving NME countries, we intend to issue quantity and value (Q&V) questionnaires to producers/exporters of merchandise subject to this NME investigation and, in the event the Department determines that the number of producers/exporters involved in the investigation is large, base respondent selection on the responses received. For this NME investigation, the Department will request Q&V information from known exporters and producers identified, with complete contact information, in the Petitions. In addition, the Department will post the Q&V questionnaire along with filing instructions on Enforcement and Compliance's Web site at *http://www.trade.gov/enforcement/news.asp.*

Producers/exporters of PTFE resin from the PRC that do not receive Q&V questionnaires by mail may still submit a response to the Q&V questionnaire and can obtain a copy of the Q&V questionnaire from Enforcement & Compliance's Web site. The Q&V response must be submitted by the relevant PRC exporters/producers no later than 5:00 p.m. ET on November 2, 2017. All Q&V responses must be filed electronically via ACCESS.

**Separate Rates**

In order to obtain separate-rate status in an NME investigation, exporters and producers must submit a separate-rate application.[45] The specific requirements for submitting a separate-rate application in the PRC investigation are outlined in detail in the application itself, which is available on the Department's Web site at *http://enforcement.trade.gov/nme/nme-sep-rate.html.* The separate-rate application will be due 30 days after publication of this initiation notice.[46] Exporters and producers who submit a separate-rate application and have been selected as mandatory respondents will be eligible for consideration for separate-rate status only if they respond to all parts of the

[36] *See* the Petitions, at 43 and Exhibit II–5.

[37] *See* the Petitions, at 43–46 and Exhibits II–6, II–7, II–8, II–9, II–10, II–11, II–12, II–13, and II–14.

[38] *See* PRC AD Initiation Checklist.

[39] *See* India AD Initiation Checklist.

[40] *See* Trade Preferences Extension Act of 2015, PubLIC LAW 114–27, 129 Stat. 362 (2015).

[41] *See Dates of Application of Amendments to the Antidumping and Countervailing Duty Laws Made by the Trade Preferences Extension Act of 2015,* 80 FR 46793 (August 6, 2015).

[42] *Id.* at 46794–95. The 2015 amendments may be found at *https://www.congress.gov/bill/114th-congress/house-bill/1295/text/pl.*

[43] *See* the Petitions, at Exhibit I–13.

[44] *See* the Petitions at Exhibit I–13.

[45] *See* Policy Bulletin 05.1: Separate-Rates Practice and Application of Combination Rates in Antidumping Investigation involving Non-Market Economy Countries (April 5, 2005), available at *http://enforcement.trade.gov/policy/bull05-1.pdf* (Policy Bulletin 05.1).

[46] Although in past investigations this deadline was 60 days, consistent with 19 CFR 351.301(a), which states that ''the Secretary may request any person to submit factual information at any time during a proceeding,'' this deadline is now 30 days.

Department's AD questionnaire as mandatory respondents. The Department requires that companies from the PRC submit a response to both the Q&V questionnaire and the separate-rate application by the respective deadlines in order to receive consideration for separate-rate status. Companies not filing a timely Q&V response will not receive separate-rate consideration.

**Use of Combination Rates**

The Department will calculate combination rates for certain respondents that are eligible for a separate rate in an NME investigation. The Separate Rates and Combination Rates Bulletin states:

{w}hile continuing the practice of assigning separate rates only to exporters, all separate rates that the Department will now assign in its NME Investigation will be specific to those producers that supplied the exporter during the period of investigation. Note, however, that one rate is calculated for the exporter and all of the producers which supplied subject merchandise to it during the period of investigation. This practice applies both to mandatory respondents receiving an individually calculated separate rate as well as the pool of non-investigated firms receiving the weighted-average of the individually calculated rates. This practice is referred to as the application of ''combination rates'' because such rates apply to specific combinations of exporters and one or more producers. The cash-deposit rate assigned to an exporter will apply only to merchandise both exported by the firm in question *and* produced by a firm that supplied the exporter during the period of investigation.[47]

**Distribution of Copies of the Petitions**

In accordance with section 732(b)(3)(A)(i) of the Act and 19 CFR 351.202(f), copies of the public version of the Petitions have been provided to the governments of India and the PRC *via* ACCESS. To the extent practicable, we will attempt to provide a copy of the public version of the Petitions to each exporter named in the Petitions, as provided under 19 CFR 351.203(c)(2).

**ITC Notification**

We will notify the ITC of our initiation, as required by section 732(d) of the Act.

**Preliminary Determinations by the ITC**

The ITC will preliminarily determine, within 45 days after the date on which the Petitions were filed, whether there is a reasonable indication that imports of PTFE resin from India and/or the PRC are materially injuring or threatening material injury to a U.S. industry.[48] A negative ITC determination for either country will result in the investigation being terminated with respect to that country.[49] Otherwise, these investigations will proceed according to statutory and regulatory time limits.

**Submission of Information**

Factual information is defined in 19 CFR 351.102(b)(21) as: (i) Evidence submitted in response to questionnaires; (ii) evidence submitted in support of allegations; (iii) publicly available information to value factors under 19 CFR 351.408(c) or to measure the adequacy of remuneration under 19 CFR 351.511(a)(2); (iv) evidence placed on the record by the Department; and (v) evidence other than factual information described in (i)–(iv). 19 CFR 351.301(b) requires any party, when submitting factual information, to specify under which subsection of 19 CFR 351.102(b)(21) the information is being submitted [50] and, if the information is submitted to rebut, clarify, or correct factual information already on the record, to provide an explanation identifying the information already on the record that the factual information seeks to rebut, clarify, or correct.[51] Time limits for the submission of factual information are addressed in 19 CFR 351.301, which provides specific time limits based on the type of factual information being submitted. Interested parties should review the regulations prior to submitting factual information in these investigations.

**Extensions of Time Limits**

Parties may request an extension of time limits before the expiration of a time limit established under 19 CFR 351.301, or as otherwise specified by the Secretary. In general, an extension request will be considered untimely if it is filed after the expiration of the time limit established under 19 CFR 351.301. For submissions that are due from multiple parties simultaneously, an extension request will be considered untimely if it is filed after 10:00 a.m. ET on the due date. Under certain circumstances, we may elect to specify a different time limit by which extension requests will be considered untimely for submissions which are due from multiple parties simultaneously. In such a case, we will inform parties in the letter or memorandum setting forth the deadline (including a specified time) by which extension requests must be filed to be considered timely. An extension request must be made in a separate, stand-alone submission; under limited circumstances we will grant untimely-filed requests for the extension of time limits. Parties should review *Extension of Time Limits; Final Rule,* 78 FR 57790 (September 20, 2013), available at *http://www.gpo.gov/fdsys/pkg/FR-2013-09-20/html/2013-22853.htm,* prior to submitting factual information in these investigations.

**Certification Requirements**

Any party submitting factual information in an AD or CVD proceeding must certify to the accuracy and completeness of that information.[52] Parties must use the certifications formats provided in 19 CFR 351.303(g).[53] The Department intends to reject factual submissions if the submitting party does not comply with applicable certification requirements.

**Notification to Interested Parties**

Interested parties must submit applications for disclosure under APO in accordance with 19 CFR 351.305. On January 22, 2008, the Department published *Antidumping and Countervailing Duty Proceedings: Documents Submission Procedures; APO Procedures,* 73 FR 3634 (January 22, 2008). Parties wishing to participate in these investigations should ensure that they meet the requirements of these procedures (*e.g.,* the filing of letters of appearance as discussed in 19 CFR 351.103(d)).

This notice is issued and published pursuant to sections 732(c)(2) and 777(i) of the Act, and 19 CFR 351.203(c).

Dated: October 18, 2017.

**Gary Taverman,**

*Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.*

## Appendix

**Scope of the Investigations**

The product covered by these investigations is polytetrafluoroethylene (PTFE) resin, including but not limited to granular, dispersion, or coagulated dispersion (also known as fine powder). PTFE is covered by the scope of these investigations whether filled or unfilled, whether or not modified, and whether or not containing co-polymer additives, pigments, or other materials. Also included is PTFE wet raw polymer. The chemical formula for PTFE

[47] *See* Policy Bulletin 05.1 at 6 (emphasis added).

[48] *See* section 733(a) of the Act.

[49] *Id.*

[50] *See* 19 CFR 351.301(b).

[51] *See* 19 CFR 351.301(b)(2).

[52] *See* section 782(b) of the Act.

[53] *See Certification of Factual Information to Import Administration during Antidumping and Countervailing Duty Proceedings,* 78 FR 42678 (July 17, 2013) (*Final Rule*); *see also* frequently asked questions regarding the *Final Rule,* available at *http://enforcement.trade.gov/tlei/notices/factual_info_final_rule_FAQ_07172013.pdf.*

is C2F4, and the Chemical Abstracts Service Registry number is 9002–84–0.

PTFE further processed into micropowder, having particle size typically ranging from 1 to 25 microns, and a melt-flow rate no less than 0.1 gram/10 minutes, is excluded from the scope of these investigations.

PTFE is classified in the Harmonized Tariff Schedule of the United States (HTSUS) under subheadings 3904.61.0010 and 3904.61.0090. Subject merchandise may also be classified under HTSUS subheading 3904.69.5000. Although the HTSUS subheadings and CAS Number are provided for convenience and Customs purposes, the written description of the scope is dispositive.

[FR Doc. 2017–23307 Filed 10–25–17; 8:45 am]

**BILLING CODE 3510–DS–P**

## DEPARTMENT OF COMMERCE

### International Trade Administration

**[C–533–880]**

### Polytetrafluoroethylene Resin From India: Initiation of Countervailing Duty Investigation

**AGENCY:** Enforcement and Compliance, International Trade Administration, Department of Commerce.

**DATES:** Applicable October 18, 2017.

**FOR FURTHER INFORMATION CONTACT:** Toby Vandall at (202) 482–1664 or Aimee Phelan at (202) 482–0697, AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230.

**SUPPLEMENTARY INFORMATION:**

#### The Petition

On September 28, 2017, the U.S. Department of Commerce (the Department) received a countervailing duty (CVD) Petition concerning imports of polytetrafluoroethylene (PTFE) resin from India, filed in proper form on behalf of the Chemours Company FC LLC (the petitioner).[1] The CVD Petition was accompanied by antidumping duty (AD) Petitions concerning imports of PTFE resin from India and the People's Republic of China. The petitioner is a domestic producer of PTFE resin.[2]

On October 3, 2017, the Department requested supplemental information pertaining to certain areas of the Petition.[3] The petitioner filed a response to this request on October 6, 2017.[4] In addition, the petitioner filed revised scope language on October 13, 2017.[5]

In accordance with section 702(b)(1) of the Tariff Act of 1930, as amended (the Act), the petitioner alleges that the Government of India is providing countervailable subsidies, within the meaning of sections 701 and 771(5) of the Act, to imports of PTFE resin from India and that such imports are materially injuring, or threatening material injury to, the domestic industry producing PTFE resin in the United States. Also, consistent with section 702(b)(1) of the Act, for those alleged programs on which we are initiating a CVD investigation, the Petition is accompanied by information reasonably available to the petitioner supporting its allegations.

The Department finds that the petitioner is an interested party as defined in section 771(9)(C) of the Act and that the petitioner filed this Petition on behalf of the domestic industry and demonstrated sufficient industry support with respect to the initiation of the CVD investigation that the petitioner is requesting.[6]

#### Period of Investigation

Because the Petition was filed on September 28, 2017, the period of investigation (POI) is January 1, 2016, through December 31, 2016.

#### Scope of the Investigation

The product covered by this investigation is PTFE resin from India. For a full description of the scope of this investigation, *see* the ''Scope of the Investigation,'' in the Appendix to this notice.

#### Comments on Scope of the Investigation

During our review of the Petition, the Department issued questions to, and received a response from, the petitioner pertaining to the proposed scope to ensure that the scope language in the Petition would be an accurate reflection of the products for which the domestic industry is seeking relief.[7]

As discussed in the preamble to the Department's regulations, we are setting aside a period for interested parties to raise issues regarding product coverage (scope).[8] The Department will consider all comments received from interested parties and, if necessary, will consult with the interested parties prior to the issuance of the preliminary determinations. If scope comments include factual information,[9] all such factual information should be limited to public information. To facilitate preparation of its questionnaires, the Department requests all interested parties to submit such comments by 5:00 p.m. Eastern Time (ET) on Tuesday, November 7, 2017, which is 20 calendar days from the signature date of this notice. Any rebuttal comments, which may include factual information, must be filed by 5:00 p.m. ET on Friday, November 17, 2017, which is 10 calendar days from the initial comments deadline.

The Department requests that any factual information the parties consider relevant to the scope of the investigation be submitted during this time period. However, if a party subsequently finds that additional factual information pertaining to the scope of the investigation may be relevant, the party may contact the Department and request permission to submit the additional information. All such comments must be filed on the records of each of the concurrent AD and CVD investigations.

#### Filing Requirements

All submissions to the Department must be filed electronically using Enforcement and Compliance's Antidumping Duty and Countervailing Duty Centralized Electronic Service System (ACCESS).[10] An electronically filed document must be received successfully in its entirety by the time and date it is due. Documents exempted from the electronic submission requirements must be filed manually (*i.e.,* in paper form) with Enforcement

[1] *See* Letter from the petitioner, ''Re: Polytetrafluoroethylene (PTFE) Resin from the People's Republic of China and India: Antidumping and Countervailing Duty Petitions'' (September 28, 2017) (the Petition).

[2] *Id.* at 2.

[3] *See* Letter from the Department, ''Petition for the Imposition of Countervailing Duties on Imports of Polytetrafluoroethylene Resin from India: Supplemental Questions'' (October 3, 2017).

[4] *See* Letter from the petitioner, ''Polytetrafluoroethylene (PTFE) Resin from India: Responses to Supplemental Questions Regarding the Countervailing Duty Petition'' (October 6, 2017).

[5] *See* Letter from the petitioner, ''Polytetrafluoroethylene (PTFE) Resin from the People's Republic of China and India: Amendment to the Suggested Scope of the Antidumping and Countervailing Duty Petitions'' (October 13, 2017).

[6] *See* ''Determination of Industry Support for the Petition'' section, below.

[7] *See* Letter from the petitioner, ''Polytetrafluoroethylene (PTFE) Resin from the People's Republic of China and India: Amendment to the Suggested Scope of the Antidumping and Countervailing Duty Petitions'' (October 13, 2017). *See also* Memorandum to the File (October 11, 2017).

[8] *See Antidumping Duties; Countervailing Duties; Final Rule,* 62 FR 27296, 27323 (May 19, 1997).

[9] *See* 19 CFR 351.102(b)(21) (defining ''factual information'').

[10] *See Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures,* 76 FR 39263 (July 6, 2011), *see also Enforcement and Compliance: Change of Electronic Filing System Name,* 79 FR 69046 (November 20, 2014) for details of the Department's electronic filing requirements, which went into effect on August 5, 2011. Information on help using ACCESS can be found at *https://access.trade.gov/help.aspx,* and a handbook can be found at *https://access.trade.gov/help/Handbook%20on%20Electronic%20Filling%20Procedures.pdf.*

and Compliance's APO/Dockets Unit, Room 18022, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230, and stamped with the date and time of receipt by the applicable deadlines.

**Consultations**

Pursuant to sections 702(b)(4)(A)(i) and (ii) of the Act, the Department notified representatives of the Government of India of the receipt of the Petition, and provided them the opportunity for consultations with respect to the CVD Petition.[11] Consultations with the GOI were held at the Department of Commerce on October 18, 2017.[12]

**Determination of Industry Support for the Petition**

Section 702(b)(1) of the Act requires that a petition be filed on behalf of the domestic industry. Section 702(c)(4)(A) of the Act provides that a petition meets this requirement if the domestic producers or workers who support the petition account for: (i) At least 25 percent of the total production of the domestic like product; and (ii) more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the petition. Moreover, section 702(c)(4)(D) of the Act provides that, if the petition does not establish support of domestic producers or workers accounting for more than 50 percent of the total production of the domestic like product, the Department shall: (i) Poll the industry or rely on other information in order to determine if there is support for the petition, as required by subparagraph (A); or (ii) determine industry support using a statistically valid sampling method to poll the ''industry.''

Section 771(4)(A) of the Act defines the ''industry'' as the producers as a whole of a domestic like product. Thus, to determine whether a petition has the requisite industry support, the statute directs the Department to look to producers and workers who produce the domestic like product. The International Trade Commission (ITC), which is responsible for determining whether ''the domestic industry'' has been injured, must also determine what constitutes a domestic like product in order to define the industry. While both the Department and the ITC must apply the same statutory definition regarding the domestic like product,[13] they do so for different purposes and pursuant to a separate and distinct authority. In addition, the Department's determination is subject to limitations of time and information. Although this may result in different definitions of the like product, such differences do not render the decision of either agency contrary to law.[14]

Section 771(10) of the Act defines the domestic like product as ''a product which is like, or in the absence of like, most similar in characteristics and uses with, the article subject to an investigation under this title.'' Thus, the reference point from which the domestic like product analysis begins is ''the article subject to an investigation'' (*i.e.,* the class or kind of merchandise to be investigated, which normally will be the scope as defined in the petition).

With regard to the domestic like product, the petitioner does not offer a definition of the domestic like product distinct from the scope of this investigation. Based on our analysis of the information submitted on the record, we have determined that PTFE resin, as defined in the scope, constitutes a single domestic like product and we have analyzed industry support in terms of that domestic like product.[15]

In determining whether the petitioner has standing under section 702(c)(4)(A) of the Act, we considered the industry support data contained in the Petition with reference to the domestic like product as defined in the ''Scope of the Investigation,'' in the Appendix to this notice. The petitioner provided its own production of the domestic like product in 2016, as well as estimated 2016 production data of the domestic like product by the entire U.S. industry.[16] To establish industry support, the petitioner compared its production to the total 2016 production of the domestic like product for the entire domestic industry.[17] We relied on the data the petitioner provided for purposes of measuring industry support.[18]

Our review of the data provided in the Petition and other information readily available to the Department indicates that the petitioner has established industry support.[19] First, the Petition established support from domestic producers (or workers) accounting for more than 50 percent of the total production of the domestic like product and, as such, the Department is not required to take further action in order to evaluate industry support (*e.g.,* polling).[20] Second, the domestic producers (or workers) have met the statutory criteria for industry support under section 702(c)(4)(A)(i) of the Act because the domestic producers (or workers) who support the Petition account for at least 25 percent of the total production of the domestic like product.[21] Finally, the domestic producers (or workers) have met the statutory criteria for industry support under section 702(c)(4)(A)(ii) of the Act because the domestic producers (or workers) who support the Petition account for more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the Petition.[22] Accordingly, the Department determines that the Petition was filed on behalf of the domestic industry within the meaning of section 702(b)(1) of the Act.

The Department finds that the petitioner filed the Petition on behalf of the domestic industry because it is an interested party as defined in section 771(9)(C) of the Act and it has demonstrated sufficient industry support with respect to the CVD investigation that it is requesting the Department initiate.[23]

**Injury Test**

Because India is a ''Subsidies Agreement Country'' within the meaning of section 701(b) of the Act, section 701(a)(2) of the Act applies to

[11] *See* Letter to the Embassy of India, ''Countervailing Duty Petition on Polytetrafluoroethylene Resin from India'' (September 28, 2017).

[12] *See* Memorandum, ''Consultations with Officials from the Government of India Regarding the Countervailing Duty Petition on Polytetrafluoroethylene (PTFE) Resin from India'' (October 18, 2017).

[13] *See* section 771(10) of the Act.

[14] *See USEC, Inc.* v. *United States,* 132 F. Supp. 2d 1, 8 (CIT 2001) (citing *Algoma Steel Corp., Ltd.* v. *United States,* 688 F. Supp. 639, 644 (CIT 1988), *aff'd* 865 F.2d 240 (Fed. Cir. 1989)).

[15] For a discussion of the domestic like product analysis in this case, *see* Countervailing Duty Investigation Initiation Checklist Polytetrafluoroethylene (PTFE) Resin from India (India CVD Initiation Checklist), at Attachment II, Analysis of Industry Support for the Antidumping and Countervailing Duty Petitions Covering Polytetrafluoroethylene (PTFE) Resin from the People's Republic of China and India (Attachment II). This checklist is dated concurrently with this notice and on file electronically via ACCESS. Access to documents filed via ACCESS is also available in the Central Records Unit, Room B8024 of the main Department of Commerce building.

[16] *See* Petition at 2–4 and Exhibit I–2; *see also* General Issues and AD Supplement at 3–4.

[17] *See* Petition at Exhibit I–2; *see also* General Issues and AD Supplement at 3–4.

[18] *Id.* For further discussion, *see* India CVD Initiation Checklist at Attachment II.

[19] *See* India CVD Initiation Checklist at Attachment II.

[20] *See* section 702(c)(4)(D) of the Act; *see also* India CVD Initiation Checklist at Attachment II.

[21] *See* India CVD Initiation Checklist at Attachment II.

[22] *Id.*

[23] *Id.*

this investigation. Accordingly, the ITC must determine whether imports of the subject merchandise from India materially injure, or threaten material injury to, a U.S. industry.

**Allegations and Evidence of Material Injury and Causation**

The petitioner alleges that the U.S. industry producing the domestic like product is being materially injured, or is threatened with material injury, by reason of the imports of the subject merchandise, which are benefitting from countervailable subsidies. In addition, the petitioner alleges that subject imports exceed the negligibility threshold provided for under section 771(24)(A) of the Act.[24] In CVD petitions, section 771(24)(B) of the Act provides that imports of subject merchandise from developing and least developed countries must exceed the negligibility threshold of four percent. The petitioner also demonstrates that subject imports from India, which has been designated as a least developed country under section 771(36)(B) of the Act, exceed the negligibility threshold of four percent.[25]

The petitioner contends that the industry's injured condition is illustrated by a significant volume of subject imports; an increase in the volume of subject imports relative to U.S. consumption and production; reduced market share; underselling and price suppression or depression; lost sales and revenues; a negative impact on the domestic industry's capacity, capacity utilization, and employment; and a negative impact on revenues and operating profits.[26] We have assessed the allegations and supporting evidence regarding material injury, threat of material injury, and causation, and we have determined that these allegations are properly supported by adequate evidence, and meet the statutory requirements for initiation.[27]

**Initiation of CVD Investigation**

Based on the examination of the CVD Petition, we find that the Petition meets the requirements of section 702 of the Act. Therefore, we are initiating a CVD investigation to determine whether imports of PTFE resin from India benefit from countervailable subsidies conferred by the government of this country. In accordance with section 703(b)(1) of the Act and 19 CFR 351.205(b)(1), unless postponed, we intend to make our preliminary determination no later than 65 days after the date of this initiation.

Under the Trade Preferences Extension Act of 2015, numerous amendments to the AD and CVD laws were made.[28] The 2015 law does not specify dates of application for those amendments. On August 6, 2015, the Department published an interpretative rule, in which it announced the applicability dates for each amendment to the Act, except for amendments contained in section 771(7) of the Act, which relate to determinations of material injury by the ITC.[29] The amendments to sections 776 and 782 of the Act are applicable to all determinations made on or after August 6, 2015, and, therefore, apply to this CVD investigation.[30]

Based on our review of the Petition, we find that there is sufficient information to initiate a CVD investigation on 18 of the 22 alleged programs in India. For a full discussion of the basis for our decision on whether to initiate on each program, *see* the India CVD Initiation Checklist. A public version of the initiation checklist for this investigation is available on ACCESS.

In accordance with section 703(b)(1) of the Act and 19 CFR 351.205(b)(1), unless postponed, we will make our preliminary determination no later than 65 days after the date of this initiation.

**Respondent Selection**

The petitioner named seven companies in India as producers/exporters of PTFE resin.[31] For India, following standard practice in CVD investigations, in the event the Department determines that the number of producers/exporters is large, the Department intends to review U.S. Customs and Border Protection (CBP) data for U.S. imports of PTFE resin during the POI under the appropriate Harmonized Tariff Schedule of the United States subheadings, and if it determines it cannot individually examine each company based upon the Department's resources, then the Department will select respondents based on that data.

On October 12, 2017, the Department released CBP data under the Administrative Protective Order (APO) to all parties with access to information protected by APO and indicated that interested parties wishing to comment regarding the CBP data and respondent selection must do so within three business days of the publication date of the notice of initiation of this CVD investigation.[32] Interested parties must submit applications for disclosure under APO in accordance with 19 CFR 351.505(b). Instructions for filing such applications may be found on the Department's Web site at *http://enforcement.trade.gov/apo.* The Department will not accept rebuttal comments regarding the CBP data or respondent selection.

Comments must be filed electronically using ACCESS. An electronically filed document must be received successfully, in its entirety, by ACCESS no later than 5:00 p.m. ET on the date noted above. If respondent selection is necessary, within 20 days of publication of this notice, we intend to make our decision regarding respondent selection based upon comments received from interested parties and our analysis of the record information.

**Distribution of Copies of the Petition**

In accordance with section 702(b)(4)(A)(i) of the Act and 19 CFR 351.202(f), a copy of the public version of the Petition has been provided to the Government of India *via* ACCESS. To the extent practicable, we will attempt to provide a copy of the public version of the Petition to each exporter named in the Petition, as provided under 19 CFR 351.203(c)(2).

**ITC Notification**

We will notify the ITC of our initiation, as required by section 702(d) of the Act.

**Preliminary Determination by the ITC**

The ITC will preliminarily determine, within 45 days after the date on which the Petition were filed, whether there is a reasonable indication that imports of PTFE resin from India is materially injuring, or threatening material injury to, a U.S. industry.[33] A negative ITC determination will result in the investigation being terminated.[34]

[24] *See* Volume I of the Petitions at 21 and Exhibit I–14.

[25] *Id.*

[26] *Id.* at 24–34, Exhibit I–8, and Exhibits I–14, I–16, and I–17.

[27] *See* India CVD Initiation Checklist at Attachment III, Analysis of Allegations and Evidence of Material Injury and Causation for the Antidumping and Countervailing Duty Petitions Covering Polytetrafluoroethylene Resin (PTFE Resin) from India and the People's Republic of China (the PRC) (Attachment III).

[28] *See* Trade Preferences Extension Act of 2015, Public Law 114–27, 129 Stat. 362 (2015).

[29] *See Dates of Application of Amendments to the Antidumping and Countervailing Duty Laws Made by the Trade Preferences Extension Act of 2015,* 80 FR 46793 (August 6, 2015) (*Applicability Notice*). The 2015 amendments may be found at *https://www.congress.gov/bill/114th-congress/house-bill/1295/text/pl.*

[30] *See Applicability Notice,* 80 FR at 46794–95.

[31] *See* Petition at Exhibit I–13.

[32] *See* Memorandum, ''Polytetrafluoroethylene (PTFE) Resin from India Countervailing Duty Petition: Release of U.S. Customs and Border Protection Data'' (October 12, 2017).

[33] *See* section 703(a)(2) of the Act.

[34] *See* section 703(a)(1) of the Act.

Otherwise, this investigation will proceed according to statutory and regulatory time limits.

**Submission of Factual Information**

Factual information is defined in 19 CFR 351.102(b)(21) as: (i) Evidence submitted in response to questionnaires; (ii) evidence submitted in support of allegations; (iii) publicly available information to value factors under 19 CFR 351.408(c) or to measure the adequacy of remuneration under 19 CFR 351.511(a)(2); (iv) evidence placed on the record by the Department; and (v) evidence other than factual information described in (i)–(iv). 19 CFR 351.301(b) requires any party, when submitting factual information, to specify under which subsection of 19 CFR 351.102(b)(21) the information is being submitted [35] and, if the information is submitted to rebut, clarify, or correct factual information already on the record, to provide an explanation identifying the information already on the record that the factual information seeks to rebut, clarify, or correct.[36] Time limits for the submission of factual information are addressed in 19 CFR 351.301, which provides specific time limits based on the type of factual information being submitted. Interested parties should review the regulations prior to submitting factual information in this investigation.

**Extensions of Time Limits**

Parties may request an extension of time limits before the expiration of a time limit established under 19 CFR 351.301, or as otherwise specified by the Secretary. In general, an extension request will be considered untimely if it is filed after the time limit established under 19 CFR 351.301 expires. For submissions that are due from multiple parties simultaneously, an extension request will be considered untimely if it is filed after 10:00 a.m. ET on the due date. Under certain circumstances, we may elect to specify a different time limit by which extension requests will be considered untimely for submissions which are due from multiple parties simultaneously. In such a case, we will inform parties in the letter or memorandum setting forth the deadline (including a specified time) by which extension requests must be filed to be considered timely. An extension request must be made in a separate, stand-alone submission; under limited circumstances we will grant untimely-filed requests for the extension of time limits. Parties should review *Extension of Time Limits; Final Rule,* 78 FR 57790 (September 20, 2013), available at *http://www.gpo.gov/fdsys/pkg/FR-2013-09-20/html/2013-22853.htm,* prior to submitting factual information in this investigation.

**Certification Requirements**

Any party submitting factual information in an AD or CVD proceeding must certify to the accuracy and completeness of that information.[37] Parties must use the certification formats provided in 19 CFR 351.303(g).[38] The Department intends to reject factual submissions if the submitting party does not comply with the applicable revised certification requirements.

**Notification to Interested Parties**

Interested parties must submit applications for disclosure under APO in accordance with 19 CFR 351.305. On January 22, 2008, the Department published *Antidumping and Countervailing Duty Proceedings: Documents Submission Procedures; APO Procedures,* 73 FR 3634 (January 22, 2008). Parties wishing to participate in this investigation should ensure that they meet the requirements of these procedures (*e.g.,* the filing of letters of appearance as discussed at 19 CFR 351.103(d)).

This notice is issued and published pursuant to sections 702 and 777(i) of the Act.

Dated: October 18, 2017.

**Gary Taverman,**

*Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.*

## Appendix

**Scope of the Investigation**

The product covered by this investigation is polytetrafluoroethylene (PTFE) resin, including but not limited to granular, dispersion, or coagulated dispersion (also known as fine powder). PTFE is covered by the scope of this investigation whether filled or unfilled, whether or not modified, and whether or not containing co-polymer additives, pigments, or other materials. Also included is PTFE wet raw polymer. The chemical formula for PTFE is C2F4, and the Chemical Abstracts Service Registry number is 9002–84–0.

PTFE further processed into micropowder, having particle size typically ranging from 1 to 25 microns, and a melt-flow rate no less than 0.1 gram/10 minutes, is excluded from the scope of this investigation.

PTFE is classified in the Harmonized Tariff Schedule of the United States (HTSUS) under subheadings 3904.61.0010 and 3904.61.0090. Subject merchandise may also be classified under HTSUS subheading 3904.69.5000. Although the HTSUS subheadings and CAS Number are provided for convenience and Customs purposes, the written description of the scope is dispositive.

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[35] *See* 19 CFR 351.301(b).

[36] *See* 19 CFR 351.301(b)(2).

[37] *See* section 782(b) of the Act.

[38] *See also Certification of Factual Information to Import Administration During Antidumping and Countervailing Duty Proceedings,* 78 FR 42678 (July 17, 2013) (''*Final Rule*''). Answers to frequently asked questions regarding the *Final Rule* are available at *http://enforcement.trade.gov/tlei/notices/factual_info_final_rule_FAQ_07172013.pdf.*

## DEPARTMENT OF COMMERCE

### National Institute of Standards and Technology

### Judges Panel of the Malcolm Baldrige National Quality Award

**AGENCY:** National Institute of Standards and Technology, Department of Commerce.

**ACTION:** Notice of closed meeting.

**SUMMARY:** The Judges Panel of the Malcolm Baldrige National Quality Award (Judges Panel) will meet in closed session Sunday, November 5, 2017 through Thursday, November 9, 2017 from 8:30 a.m. until 5:30 p.m. Eastern Time each day. The purpose of this meeting is to review recommendations from site visits, and recommend 2017 Malcolm Baldrige National Quality Award recipients. The meeting is closed to the public in order to protect the proprietary data to be examined and discussed at the meeting.

**DATES:** The meeting will be held Sunday, November 5, 2017 through Thursday, November 9, 2017, from 8:30 a.m. until 5:30 p.m. Eastern Time each day. The entire meeting will be closed to the public.

**ADDRESSES:** The meeting will be held at the National Institute of Standards and Technology, 100 Bureau Drive, Gaithersburg, MD 20899.

**FOR FURTHER INFORMATION CONTACT:** Robert Fangmeyer, Director, Baldrige Performance Excellence Program, National Institute of Standards and Technology, 100 Bureau Drive, Mail Stop 1020, Gaithersburg, MD 20899–1020, telephone number (301) 975–2360, email *robert.fangmeyer@nist.gov.*

**SUPPLEMENTARY INFORMATION:**

**Authority:** 15 U.S.C. 3711a(d)(1) and the Federal Advisory Committee Act, as amended, 5 U.S.C. App.

Pursuant to 41 CFR 102–3.150(b), this **Federal Register** notice for this meeting is being published fewer than 15 calendar days prior to the meeting as

exceptional circumstances exist. It is imperative that the Judges Panel will meet on Sunday, November 5, 2017 through Thursday, November 9, 2017, from 8:30 a.m. until 5:30 p.m. Eastern Time each day to accommodate the scheduling priorities of the key participants, who must maintain a strict schedule to review recommendations from site visits, and recommend 2017 Malcolm Baldrige National Quality Award recipients. The Judges Panel is composed of twelve members, appointed by the Secretary of Commerce, with balanced representation from U.S. service, manufacturing, nonprofit, education, and health care industries. Members are selected for their familiarity with quality improvement operations and competitiveness issues of manufacturing companies, service companies, small businesses, health care providers, and educational institutions. Members are also chosen who have broad experience in for-profit and nonprofit areas. The purpose of this meeting is to review recommendations from site visits and recommend 2017 Malcolm Baldrige National Quality Award (Award) recipients. The meeting is closed to the public in order to protect the proprietary data to be examined and discussed at the meeting.

The Chief Financial Officer and Assistant Secretary for Administration, with the concurrence of the Assistant General Counsel for Administration and Transactions, formally determined on March 21, 2017, pursuant to Section 10(d) of the Federal Advisory Committee Act, in accordance with Section 5(c) of the Government in Sunshine Act, Public Law 94–409, that the meeting of the Judges Panel may be closed to the public in accordance with 5 U.S.C. 552b(c)(4), because the meeting is likely to disclose trade secrets and commercial or financial information obtained from a person which is privileged or confidential; and 5 U.S.C. 552b(c)(9)(B) because the meeting is likely to disclose information the premature disclosure of which would, in the case of any agency, be likely to significantly frustrate implementation of a proposed agency action. The meeting, which involves examination of current Award applicant data from U.S. organizations and a discussion of these data as compared to the Award criteria in order to recommend Award recipients, will be closed to the public.

**Kevin Kimball,**

*NIST Chief of Staff.*

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**BILLING CODE 3510–13–P**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

**RIN 0648–XF750**

### Atlantic Highly Migratory Species; Exempted Fishing, Scientific Research, Display, and Shark Research Fishery; Letters of Acknowledgment

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Notice of intent; request for comments.

**SUMMARY:** NMFS announces its intent to issue exempted fishing permits (EFPs), scientific research permits (SRPs), display permits, letters of acknowledgment (LOAs), and shark research fishery permits for Atlantic highly migratory species (HMS) in 2018. EFPs and related permits would authorize collection of a limited number of tunas, swordfish, billfishes, and sharks (collectively known as HMS) from Federal waters in the Atlantic Ocean, Caribbean Sea, and Gulf of Mexico for the purposes of scientific data collection, bycatch research, public display, and to evaluate the efficacy of environmental clean-up efforts, among other things. Letters of acknowledgement acknowledge that scientific research activity aboard a scientific research vessel is being conducted. Generally, EFPs and related permits would be valid from the date of issuance through December 31, 2018, unless otherwise specified, subject to the terms and conditions of individual permits.

**DATES:** Written comments on these activities received in response to this notice will be considered by NMFS when issuing EFPs and related permits and must be received on or before *November 27, 2017.*

**ADDRESSES:** Comments may be submitted by any of the following methods:

- *Email: nmfs.hms.efp2018@noaa.gov.* Include in the subject line the following identifier: 0648–XF750
- *Mail:* Craig Cockrell, Highly Migratory Species Management Division (F/SF1), NMFS, 1315 East-West Highway, Silver Spring, MD 20910.

**FOR FURTHER INFORMATION CONTACT:** Craig Cockrell, phone: (301) 427–8503

**SUPPLEMENTARY INFORMATION:** Issuance of EFPs and related permits are necessary because HMS regulations (*e.g.,* fishing seasons, prohibited species, authorized gear, closed areas, and minimum sizes) may otherwise prohibit the collection of live animals and/or biological samples for data collection and public display purposes or may otherwise prohibit certain fishing activity. Pursuant to 50 CFR 600 and 635, a NMFS Regional Administrator or Director may authorize, for limited testing, public display, data collection, exploratory fishing, compensation fishing, conservation engineering, health and safety surveys, environmental cleanup, and/or hazard removal purposes, the target or incidental harvest of species managed under an FMP or fishery regulations that would otherwise be prohibited. These permits exempt permit holders from the specific portions of the regulations (*e.g.,* fishing seasons, prohibited species, authorized gear, closed areas, and minimum sizes) that may otherwise prohibit the collection of HMS for public education, public display, or scientific research. Permit holders are not exempted from the regulations in entirety. Collection of HMS under EFPs, SRPs, LOAs, display, and shark research fishery permits represents a small portion of the overall fishing mortality for HMS, and this mortality is counted against the quota of the species harvested, as appropriate and applicable. The terms and conditions of individual permits are unique; however, all permits will include reporting requirements, limit the number and/or species of HMS to be collected, and only authorize collection in Federal waters of the Atlantic Ocean, Gulf of Mexico, and Caribbean Sea.

EFPs and related permits are issued under the authority of the Magnuson-Stevens Fishery Conservation and Management Reauthorization Act (Magnuson-Stevens Act) (16 U.S.C. 1801 *et seq.*) and/or the Atlantic Tunas Convention Act (ATCA) (16 U.S.C. 971 *et seq.*). Regulations at 50 CFR 600.745 and 635.32 govern scientific research activity, exempted fishing, and exempted public display and educational activities with respect to Atlantic HMS. Before issuing LOAs, EFPs, or SRPs, NMFS requests, among other things, copies of scientific research plans. Because the Magnuson-Stevens Act states that scientific research activity which is conducted on a scientific research vessel is not fishing, NMFS issues LOAs and not EFPs for bona fide research activities (*e.g.,* scientific research being conducted from a research vessel and not a commercial or recreational fishing vessel) involving species that are only regulated under the Magnuson-Stevens Act (*e.g.,* most species of sharks) and not

under ATCA. NMFS generally does not consider recreational or commercial vessels to be bona fide research vessels. However, if the vessels have been contracted only to conduct research and not participate in any commercial or recreational fishing activities during that research, NMFS may consider those vessels as bona fide research platforms while conducting the specified research. For example, in the past, NMFS has determined that commercial pelagic longline vessels assisting with population surveys for sharks may be considered ''bona fide research vessels'' while engaged only in the specified research. NMFS acknowledges that the proposed activity meets the definition of scientific research under the Magnuson-Stevens Act and not ATCA by issuing an LOA to researchers. Examples of research conducted under LOAs include tagging and releasing of sharks during bottom longline surveys to understand the distribution and seasonal abundance of different shark species, and collecting and sampling sharks caught during trawl surveys for life history and bycatch studies.

While scientific research is exempt under MSA, scientific research is not exempt from regulation under ATCA. Therefore, NMFS issues SRPs that authorize researchers to collect HMS from bona fide research vessels for collection of species managed under this statute (*e.g.,* tunas, swordfish, billfish, and some species of sharks). One example of research conducted under SRPs consists of scientific surveys of HMS conducted from NOAA research vessels.

EFPs are issued to researchers collecting ATCA and Magnuson-Stevens Act-managed species while conducting research from commercial or recreational fishing vessels. Examples of research conducted under EFPs include collection of young-of-the-year bluefin tuna for genetic research; conducting billfish larval tows from private vessels to determine billfish habitat use, life history, and population structure; determining catch rates and gear characteristics of the swordfish buoy gear fishery and the green-stick tuna fishery; and tagging sharks caught on commercial or recreational fishing gear to determining post-release mortality rates.

NMFS is also seeking public comment on its intent to issue display permits for the collection of sharks and other HMS for public display in 2017. Collection of sharks and other HMS sought for public display in aquaria often involves collection when the commercial fishing seasons are closed, collection of otherwise prohibited species (*e.g.,* sand tiger sharks), and collection of fish below the regulatory minimum size. Under Amendment 2 to the 2006 Consolidated Atlantic HMS Fishery Management Plan, NMFS determined that dusky sharks cannot be collected for public display.

The majority of EFPs and related permits described in this annual notice relate to scientific sampling and tagging of Atlantic HMS within existing quotas and the impacts of the activities have been previously analyzed in various environmental assessments and environmental impact statements for Atlantic HMS. NMFS intends to issue these permits without additional opportunity for public comment beyond what is provided in this notice. Occasionally, NMFS receives applications for research activities that were not anticipated, or for research that is outside the scope of general scientific sampling and tagging of Atlantic HMS, or rarely, for research that is particularly controversial. Should NMFS receive such applications, NMFS will provide additional opportunity for public comment, consistent with the regulations at 50 CFR part 600.745.

During the comment period for the November 2016 notice of intent to issue EFPs (81 FR 80646), NMFS received numerous comments regarding previous years' white shark research in Federal waters, focusing primarily on concerns about the need for coordination among researchers regarding the potential effects of one project on another. The volume of these comments indicated that any EFPs or SRP applications involving white sharks in 2017 should be considered ''controversial'' and warranted additional opportunity for public comment. Subsequently, NMFS published a notice in the **Federal Register** (March 1, 2017, 82 FR 12340) requesting public comment on applications for exempted fishing permits and related permits for white shark research, particularly on two applications involving white shark research that had been received at that time.

During the comment period, NMFS received 722 comments related to white shark research and the applications described in the notice. The majority of the comments were in support of continuing white shark research. Other comments that were received commented on a range of issues related to white shark research including concern regarding the proper handling of white sharks and the type of gear being used for research and concern regarding tagging operations on charter and private vessels due to long fight times on light tackle rods and reels. Some of the comments also stated that NMFS should approve EFP applications for white shark research on a case-by-case basis or that NMFS should stop issuing EFPs or related permits for research on sharks. After reviewing these comments, NMFS decided to issue EFPs and related permits for white shark research as appropriate in 2017. During 2018, NMFS anticipates permits for white shark research would be undertaken with substantially the same terms and conditions and scope as last year, with no additional anticipated effects. Comments are invited specifically on these issues related to issuance of white shark permits this year.

In addition, Amendment 2 to the 2006 Consolidated HMS Fishery Management Plan (FMP) implemented a shark research fishery. This research fishery is conducted under the auspices of the exempted fishing permit program. Shark research fishery permit holders assist NMFS in collecting valuable shark life history and other scientific data required in shark stock assessments. Since the shark research fishery was established in 2008, the research fishery has allowed for: The collection of fishery dependent data for current and future stock assessments; the operation of cooperative research to meet NMFS' ongoing research objectives; the collection of updated life-history information used in the sandbar shark (and other species) stock assessment; the collection of data on habitat preferences that might help reduce fishery interactions through bycatch mitigation; the evaluation of the utility of the mid-Atlantic closed area on the recovery of dusky sharks; and the collection of hook-timer and pop-up satellite archival tag information to determine at-vessel and post-release mortality of dusky sharks. Fishermen who wish to participate must fill out an application for a shark research permit under the exempted fishing program. Shark research fishery participants are subject to 100-percent observer coverage. All non-prohibited shark species brought back to the vessel dead must be retained and will count against the appropriate quotas of the shark research fishery participant. During the 2017 shark research fishery, all participants were limited to a very small number of dusky shark mortalities on a regional basis. Once the number of mortalities occurs in a specific region all shark research fishery activities must stop within that region. Also, participants are limited to two sets per trip with, one set limited to 150 hooks and the second set limited to 300 hooks.

All participants are also limited to a maximum of 500 hooks onboard the vessel with on a shark research fishery trip. A **Federal Register** notice describing the specific objectives for the shark research fishery in 2018 and requesting applications from interested and eligible shark fishermen is expected to publish in the near future. NMFS requests public comment regarding NMFS' intent to issue shark research fishery permits in 2018 during the comment period of this notice.

The authorized number of species for 2017, as well as the number of specimens collected in 2016, is summarized in Table 1. The number of specimens collected in 2017 will be available when all 2017 interim and annual reports are submitted to NMFS. In 2016, the number of specimens collected was less than the number of authorized specimens for all permit types, other than SRPs issued for shark research.

In all cases, mortality associated with an EFPs, SRPs, or display permits (except for larvae) is counted against the appropriate quota. NMFS issued a total of 39 EFPs, SRPs, display permits, and LOAs in 2016 for the collection of HMS and a total of 5 shark research fishery permits. As of October 3, 2017, NMFS has issued a total of 33 EFPs, SRPs, display permits, and LOAs and a total of 5 shark research fishery permits.

TABLE 1—SUMMARY OF HMS EXEMPTED FISHING PERMITS ISSUED IN 2016 AND 2017, OTHER THAN SHARK RESEARCH FISHERY PERMITS

["HMS" refers to multiple species being collected under a given permit type.]

| Permit type | 2016 | | | | | 2017 | |
|---|---|---|---|---|---|---|---|
| | Permits issued** | Authorized fish (num) | Authorized larvae (num) | Fish kept/discarded dead (num) | Larvae kept (num) | Permits issued** | Authorized fish (Num)** |
| EFP | | | | | | | |
| HMS | 4 | 247 | 0 | 17 | 0 | 4 | 357 |
| Shark | 12 | 721 | 0 | 85 | 0 | 4 | 57 |
| Tuna | 4 | 530 | 0 | 0 | 0 | 2 | 350 |
| SRP | | | | | | | |
| HMS | 1 | 42 | 0 | 0 | 0 | 3 | 260 |
| Shark | 5 | 1,165 | 0 | 310 | 0 | 1 | 720 |
| Tuna | 1 | 60 | 0 | 0 | 0 | 0 | 0 |
| Display | | | | | | | |
| HMS | 0 | 0 | 0 | 0 | 0 | 2 | 88 |
| Shark | 3 | 109 | 0 | 26 | 0 | 5 | 109 |
| Total | 30 | 2,874 | 0 | | 0 | 21 | 1,941 |
| LOA* | | | | | | | |
| Shark | 9 | 2,906 | 0 | 618 | 0 | 12 | 2,275 |

*LOAs are issued for bona fide scientific research activities involving non-ATCA managed species (*e.g.,* most species of sharks). Collections made under an LOA are not authorized; rather this estimated harvest for research is acknowledged by NMFS. Permittees are encouraged to report all fishing activities in a timely manner.

**Atlantic HMS larvae were authorized for collection but no limit on the number of larvae were set.

Final decisions on the issuance of any EFPs, SRPs, display permits, and shark research fishery permits will depend on the submission of all required information about the proposed activities, NMFS' review of public comments received on this notice, an applicant's reporting history on past permits, if vessels or applicants were issued any prior violations of marine resource laws administered by NOAA, consistency with relevant NEPA documents, and any consultations with appropriate Regional Fishery Management Councils, states, or Federal agencies. NMFS does not anticipate any significant environmental impacts from the issuance of these EFPs as assessed in the 1999 FMP, the 2006 Consolidated HMS FMP and its amendments, the Environmental Assessment for the 2012 Swordfish Specifications, and the Environmental Assessment for the 2015 Final Bluefin Tuna Quota and Atlantic Tuna Fisheries Management Measures.

**Authority:** 16 U.S.C. 971 *et seq.* and 16 U.S.C. 1801 *et seq.*

Dated: October 23, 2017.

**Emily H. Menashes,**

*Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.*

[FR Doc. 2017–23312 Filed 10–25–17; 8:45 am]

**BILLING CODE 3510–22–P**

## DEPARTMENT OF DEFENSE

### Department of the Air Force

### Names of Members of the Performance Review Board for the Department of the Air Force

**AGENCY:** Department of the Air Force, DOD.

**ACTION:** Notice.

**SUMMARY:** Notice is given of the names of members of the 2017 Performance Review Board for the Department of the Air Force.

**DATES:** These appointments are effective as of November 13, 2017.

**SUPPLEMENTARY INFORMATION:** Pursuant to 5 U.S.C. 4314(c) (1–5), the Department of the Air Force (AF) announces the appointment of members to the AF's Senior Executive Service (SES) Performance Review Board (PRB). Appointments are made by the authorizing official. Each board member shall review and evaluate performance scores provided by the SES' immediate supervisor. Performance standards must be applied consistently across the AF. The board will make final recommendations to the authorizing official relative to the performance of the executive.

The members of the 2017 Performance Review Board for the Air Force are:

1. Board President—Gen Ellen M. Pawlikowski, Commander, Air Force Material Command
2. Honorable Matthew P. Donovan, Under Secretary of the Air Force

3. General Stephen W. Wilson, Vice Chief of Staff of the Air Force
4. Lt Gen Stayce D. Harris, Assistant Vice Chief of Staff and Director
5. Lt Gen Gina M. Grosso, Deputy Chief of Staff, Manpower, Personnel and Services
6. Lt Gen John F. Thompson, Commander, Space and Missile Systems Center
7. Lt Gen Bradford J. Shwedo, Chief, Information Dominance and Chief Information Officer
8. Lt Gen Jerry D. Harris, Deputy Chief of Staff, Strategic Plans and Requirements
9. Dr. Todd A. Fore, Assistant Deputy Chief of Staff, Manpower, Personnel and Services
10. Ms. Patricia M. Young, Air Force Material Command Executive Director
11. Mr. Richard K. Hartley, Principle Deputy Assistant Secretary, Installations and Environment
12. Mr. Jeffery R. Shelton, Deputy Administrative Assistant for the Secretary of the Air Force
13. Mr. Daniel R. Sitterly, Principal Deputy Assistant Secretary, Manpower and Reserve Affairs
14. Mr. Joseph M. McDade, Principal Deputy General Counsel
15. Mr. John B. Salvatori, Director, Capabilities Management Office
16. Ms. Pamela C. Schwenke, Deputy Assistant Secretary, Cost and Economics
17. Mr. James J. Brooks, Air National Guard, Executive Director
18. Mr. Craig A. Smith, Deputy General Counsel, Intelligence, International and Military Affairs

Additionally, all career status Air Force Tier 3 SES members not included in the above list are eligible to serve on the 2017 Performance Review Board and are hereby nominated for inclusion on an ad hoc basis in the event of absence(s).

**FOR FURTHER INFORMATION CONTACT:** Please direct any written comments or requests for information to Ms. Lorna Fermanis, Senior Executive Management, AF/DPS, 1040 Air Force Pentagon, Washington, DC 20330–1040 (PH: 703–697–0897; or via email at *lorna.fermanis@us.af.mil*)

**Henry Williams,**

*Acting Air Force Federal Register Liaison Officer.*

[FR Doc. 2017–23327 Filed 10–25–17; 8:45 am]

**BILLING CODE 5001–10–P**

## DEPARTMENT OF DEFENSE

### Office of the Secretary

**[Docket ID DOD–2017–OS–0035]**

### Submission for OMB Review; Comment Request

**AGENCY:** Office of the Under Secretary of Defense for Acquisition, Technology and Logistics, DoD.

**ACTION:** 30-Day information collection notice.

**SUMMARY:** The Department of Defense has submitted to OMB for clearance, the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

**DATES:** Consideration will be given to all comments received by November 27, 2017.

**ADDRESSES:** Comments and recommendations on the proposed information collection should be emailed to Ms. Jasmeet Seehra, DoD Desk Officer, at *Oira_submission@omb.eop.gov.* Please identify the proposed information collection by DoD Desk Officer and the Docket ID number and title of the information collection.

**FOR FURTHER INFORMATION CONTACT:** Fred Licari, 571–372–0493, or *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

**SUPPLEMENTARY INFORMATION:**

*Title, Associated Form and OMB Number:* Pre-embarkation Certificate of Disinsection, DD Form 3044; OMB Control Number 0704–XXXX.

*Type of Request:* New.

*Number of Respondents:* 1,000.

*Responses per Respondent:* 1.

*Annual Responses:* 1,000.

Average Burden per Response: 10 minutes.

*Annual Burden Hours:* 166.67 hours.

*Needs and Uses:* The information collection requirement is necessary to provide proof of aircraft disinsection to foreign countries that require it, before cargo and aircrew will be allowed to dis-embark in those countries.

*Affected Public:* Individuals or households.

*Frequency:* On Occasion.

*Respondent's Obligation:* Mandatory.

*OMB Desk Officer:* Ms. Jasmeet Seehra.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

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

*DOD Clearance Officer:* Mr. Frederick Licari.

Written requests for copies of the information collection proposal should be sent to Mr. Licari at WHS/ESD Directives Division, 4800 Mark Center Drive, East Tower, Suite 03F09, Alexandria, VA 22350–3100.

Dated: October 20, 2017.

**Aaron Siegel,**

*Alternate OSD Federal Register Liaison Officer, Department of Defense.*

[FR Doc. 2017–23258 Filed 10–25–17; 8:45 am]

**BILLING CODE 5001–06–P**

## DEPARTMENT OF DEFENSE

### Office of the Secretary

**[Docket ID: DOD–2017–OS–0061]**

### Submission for OMB Review; Comment Request

**AGENCY:** Office of the Under Secretary of Defense for Acquisition, Technology and Logistics, DOD.

**ACTION:** 30-day information collection notice.

**SUMMARY:** The Department of Defense has submitted to OMB for clearance, the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

**DATES:** Consideration will be given to all comments received by November 27, 2017.

**ADDRESSES:** Comments and recommendations on the proposed information collection should be emailed to Ms. Jasmeet Seehra, DoD Desk Officer, at *Oira_submission@omb.eop.gov.* Please identify the proposed information collection by DoD Desk Officer and the Docket ID number and title of the information collection.

**FOR FURTHER INFORMATION CONTACT:** Fred Licari, 571–372–0493, or *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

**SUPPLEMENTARY INFORMATION:**

*Title, Associated Form and OMB Number:* Assessing and Strengthening the Manufacturing and Defense Industrial Base Supply Chain Resiliency of the United States; OMB Control Number 0704–XXXX.

*Type of Request:* Emergency.

*Number of Respondents:* 300.

*Responses per Respondent:* 1.

*Annual Responses:* 300.

*Average Burden Per Response:* 60 minutes.

*Annual Burden Hours:* 300.

*Needs and Uses:* The information collection requirement is being submitted as an emergency. The information collection requirement is necessary to obtain information in support of Executive Order 13806: Assessing and Strengthening the United States Manufacturing and Defense Industrial Base and Supply Chain Resiliency. The questionnaire is used to identify, assess, and make recommendations in support of a more robust industrial base.

*Affected Public:* Businesses or other for-profit.

*Frequency:* One Time.

*Respondent's Obligation:* Voluntary.

*OMB Desk Officer:* Ms. Jasmeet Seehra.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

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

*DOD Clearance Officer:* Mr. Frederick Licari.

Written requests for copies of the information collection proposal should be sent to Mr. Licari at WHS/ESD Directives Division, 4800 Mark Center Drive, East Tower, Suite 03F09, Alexandria, VA 22350–3100.

Dated: October 20, 2017.

**Aaron Siegel,**

*Alternate OSD Federal Register, Liaison Officer, Department of Defense.*

[FR Doc. 2017–23262 Filed 10–25–17; 8:45 am]

**BILLING CODE 5001–06–P**

## DEPARTMENT OF DEFENSE

### Department of the Army, Corps of Engineers

### Environmental Impact Statement Withdrawal and Availability of an Environmental Assessment for the Souris River Basin Flood Risk Management Feasibility Study, Ward County, North Dakota

**AGENCY:** U.S. Army Corps of Engineers, DoD.

**ACTION:** Notice of withdrawal of an environmental impact statement; notice of availability of an environmental assessment.

**SUMMARY:** In accordance with the National Environmental Policy Act (NEPA), on September 18, 2016, the St. Paul District, U.S. Army Corps of Engineers (Corps) initiated the Environmental Impact Statement (EIS) process to identify and analyze potential impacts associated with flood risk management measures evaluated within a Federal feasibility study for the Souris River Basin within the continental United States. Currently, the Corps has identified a Tentatively Selected Plan (TSP) that includes a high-flow diversion and a 1200-ft long levee. However, preliminary analysis of the TSP indicate no significant impacts are expected, therefore the Corps is terminating the EIS process and is withdrawing the Notice of Intent published in the Thursday, September 18, 2016 issue of the **Federal Register**. In its place, a draft integrated Feasibility Report and Environmental Assessment (FR/EA) will be available for a 30-day public comment period beginning October 30, 2017.

**DATES:** Comments on the draft FR/EA may be submitted starting October 30, 2017 through November 30, 2017. If comments are provided by mail, they must be received at the address below no later than November 30, 2017.

**ADDRESSES:** The draft FR/EA can be viewed online starting October 30, 2017 at *http://www.mvp.usace.army.mil/Home/Public-Notices/*.

Comments may be submitted on the draft FR/EA using any of the following methods:

• *Mail:* Attn: David F. Potter, Regional Planning and Environment Division North, U.S. Army Corps of Engineers, 180 Fifth Street East, Suite 700, St. Paul, MN 55101–1678.

• *Email: david.f.potter@usace.army.mil.*

*Instructions:* Direct your comments to Corps of Engineers St. Paul District. Comment letters should include the commenter's physical mailing address and the project title in the subject line. Please ensure that your comments are submitted within the specified comment period. Comments received after the closing date will be marked ''late,'' and may only be considered if time permits. Please note that comments may be part of the public record.

**FOR FURTHER INFORMATION CONTACT:** Questions regarding this action can be addressed to Mr. David F. Potter, Regional Planning & Environment Division North, by phone: (651) 290–5713, by fax: (651) 290–5805, by email: *david.f.potter@usace.army.mil,* or by mail: Regional Planning and Environment Division North, U.S. Army Corps of Engineers, 180 Fifth Street East, Suite 700, St. Paul, MN 55101–1678.

**SUPPLEMENTARY INFORMATION:** The Souris River Basin Flood Risk Management Feasibility Study (Feasibility Study) is being developed by the Corps in partnership with the Souris River Joint Water Resources Board (SRJB). The purpose of this study is to collect and evaluate pertinent engineering, economic, social, and environmental information in order to assess the potential for a federal flood risk management project within the basin. The study objective is to define a feasible and implementable project to reduce flood risk which is relatively high within the basin. Due to the potentially significant environmental effects associated with the project, the Corps issued a Notice of Intent to Prepare an EIS (76 FR 336) on September 18, 2016.

The Feasibility Study is complementary to the SRJB's local plan, the Mouse River Enhanced Flood Protection Plan (MREFPP). Because of its influence on an existing federal flood project, this non-federal effort has requested permission from the Corps of Engineers to pursue actions under 33 U.S.C. 408 (frequently referred to as Section 408). A separate Notice of Intent was published (FR Doc. 2015–17670 Filed July 16, 2015) for an EIS associated with the Corps of Engineers' decision on the Section 408 request. Additional details on the local, non-federal flood MREFPP can be found at *mouseriverplan.com*. During this Feasibility Study, many of the initial flood risk management measures were screened out from further consideration. Major features of the TSP include a high-flow diversion and a 1200-ft long levee. Preliminary analysis indicate that the environmental effects of the TSP are less than significant. For this reason, an EIS is no longer being pursued in favor

of an EA in accordance with Corps regulations at 33 CFR part 230, Appendix C(2).

We are advising the public that a draft integrated FR/EA for the Feasibility Study has been prepared and is available for public review and comment. The FR/EA considers the effects of, and alternatives to, the TSP.

Dated: October 12, 2017.

**Terry J. Birkenstock,**

*Deputy Chief, Regional Planning and Environment Division North.*

[FR Doc. 2017–23318 Filed 10–25–17; 8:45 am]

**BILLING CODE 3720–58–P**

## DEPARTMENT OF DEFENSE

### Department of the Army, Corps of Engineers

### Notice of Availability of a Draft Integrated General Reevaluation Report and Environmental Assessment and Draft Finding of No Significant Impact for the Proposed Lower Pajaro River Flood Risk Management Project, Monterey and Santa Cruz Counties, CA

**AGENCY:** Department of the Army, U.S. Army Corps of Engineers, DoD.

**ACTION:** Notice of availability.

**SUMMARY:** The U.S. Army Corps of Engineers (USACE), San Francisco District, announces the availability for review and comment of the draft integrated General Reevaluation Report and Environmental Assessment (GRR/EA) and the draft Finding of No Significant Impact (FONSI) for the proposed Pajaro River Flood Risk Management Project, Monterey and Santa Cruz Counties, CA., USACE Procedures for Implementing [the National Environmental Policy Act] NEPA, notice of the availability of this draft GRR/EA and draft FONSI for review and comment is being provided to agencies, organizations, and the interested public.

**DATES:** Comments on the draft GRR/EA and draft FONSI may be submitted starting October 31, 2017, through November 30, 2017. If comments are provided by mail, they must be received at the address below no later than November 30, 2017.

**ADDRESSES:** The draft GRR/EA can be viewed online starting October 31, 2017, at: *http://www.spn.usace.army.mil/Missions/Projects-and-Programs/Projects-by-Category/Projects-for-Flood-Risk-Management/Pajaro-River-Watsonville/*. Comments may be submitted on the draft GRR/EA using any of the following methods:

- *Mail:* U.S. Army Corps of Engineers, San Francisco District, ATTN: CESPN–ET–PB-Pajaro River, 1455 Market Street, San Francisco, CA 94103–1398.
- *Email: CESPN-ET-PB@usace.army.mil.*
- Comment letters should include the commenter's physical mailing address and include ''Pajaro River'' in the subject line.

**FOR FURTHER INFORMATION CONTACT:** Mr. Christopher Eng, U.S. Army Corps of Engineers, San Francisco District, 1455 Market Street, San Francisco, CA 94103–1398. Telephone: (415) 503–6868. Email: *CESPN-ET-PB@usace.army.mil.*

**SUPPLEMENTARY INFORMATION:**

*1. Proposed Action.* USACE and the non-Federal study partners, Monterey and Santa Cruz Counties, propose to reduce flood risk to the City of Watsonville and the town of Pajaro by implementing a combination of structural measures along the lower Pajaro River, Salsipuedes Creek, and Corralitos Creek. These measures include: Improving existing levees; constructing new levees, including setback levees; and constructing new floodwalls. The draft GRR/EA presents the draft findings of the General Reevaluation Study and identifies and describes the benefits, costs, and environmental effects of alternatives plans to reduce flood risk to the city of Watsonville, town of Pajaro, and surrounding area. Based on the evaluation, USACE has identified a Federal interest in at least one alternative plan, the Tentatively Selected Plan (TSP), to reduce the risk of flooding while minimizing adverse environmental effects. The TSP is the National Economic Development Plan (NED). The environmental review conducted as part of this study has initially concluded that, with mitigation, the proposed alternatives would not result in any significant environmental effects. This review and its findings are documented in the draft GRR/EA.

2. *Alternatives.* Ten project alternatives, including the no action alternative, have been evaluated in detail in the draft GRR/EA in accordance with NEPA (33 CFR part 230 (USACE NEPA Regulations) and 33 CFR part 325, Appendix B (NEPA Implementation Procedures for USACE Regulatory Projects).

3. *Changes Since Publication of the Notice of Intent (NOI).* An NOI was published in the **Federal Register** on June 8, 2001, (66 FR 30894) to advise the interested public and agencies that USACE planned to prepare a combined EIS/EIR for the Pajaro River Flood Risk Management Study. Since publication of the NOI, USACE and Monterey and Santa Cruz Counties have worked with stakeholders to identify and incorporate measures to avoid, minimize, and compensate for adverse environmental effects. As a result, the environmental review conducted as part of this study has initially concluded that, with mitigation, the proposed alternatives would not result in any significant environmental effects. Therefore, an EA has been prepared instead of an EIS. Also, USACE now requires water resources planning and NEPA documents to be integrated into a single document, in this case, an integrated GRR/EA. The California Environmental Quality Act (CEQA) document for the study is being prepared separately by Santa Cruz and Monterey Counties as the CEQA lead agencies.

*c.* USACE is consulting with the State Historic Preservation Officer and with Native American Tribes to comply with the National Historic Preservation Act, and with the U.S. Fish and Wildlife Service and National Marine Fisheries Service to comply with the Endangered Species Act. USACE is also coordinating with the U.S. Fish and Wildlife Service to comply with the Fish and Wildlife Coordination Act.

4. *Availability of the Draft EA.* The draft GRR/EA and draft FONSI are available for public review and comment 30 days beginning October 31, 2017 and ending November 30, 2017.

5. A public meeting to discuss the status of the study, present the draft results of the GRR/EA, and receive questions and comments will be held on November 8, 2017, from 6:00 p.m. to 8:00 p.m. at the Watsonville Civic Plaza Community Room, 275 Main Street, 4th Floor, Watsonville, California 95076–5133.

Dated: October 18, 2017.

**Travis J. Rayfield,**

*Lieutenant Colonel, U.S. Army, District Commander.*

[FR Doc. 2017–23276 Filed 10–25–17; 8:45 am]

**BILLING CODE 3720–58–P**

## DEPARTMENT OF EDUCATION

**[Docket No.: ED–2017–ICCD–0130]**

### Agency Information Collection Activities; Comment Request; State Educational Agency and Local Educational Agency—School Data Collection and Reporting Under ESEA, Title I, Part A

**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 an extension of an existing information collection.

**DATES:** Interested persons are invited to submit comments on or before December 26, 2017.

**ADDRESSES:** To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2017–ICCD–0130. 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 216–44, Washington, DC 20202–4537.

**FOR FURTHER INFORMATION CONTACT:** For specific questions related to collection activities, please contact Hannah Hodel, 202–453–6448.

**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:* State Educational Agency and Local Educational Agency—School Data Collection and Reporting under ESEA, Title I, Part A.

*OMB Control Number:* 1810–0622.

*Type of Review:* An extension of an existing information collection.

*Respondents/Affected Public:* State, Local, and Tribal Governments.

*Total Estimated Number of Annual Responses:* 52.

*Total Estimated Number of Annual Burden Hours:* 2,080.

*Abstract:* Although the U.S. Department of Education (ED) determines Title I, Part A allocations for Local Educational Agencies (LEAs), State Educational Agencies (SEAs) must adjust ED-determined Title I, Part A LEA allocations to account for newly created LEAs and LEA boundary changes, to redistribute Title I, Part A funds to small LEAs (under 20,000 total population) using alternative poverty data, and to reserve funds for school improvement, State administration, and the State academic achievement awards program. This control number covers only the burden associated with the actual procedures an SEA must follow when adjusting ED-determined LEA allocations.

Dated: October 20, 2017.

**Tomakie Washington,**

*Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.*

[FR Doc. 2017–23222 Filed 10–25–17; 8:45 am]

**BILLING CODE 4000–01–P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

### Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

*Docket Numbers:* EC17–126–000.

*Applicants:* South Central MCN LLC.

*Description:* Response to Deficiency Letter and Update to June 1, 2017 Application of South Central MCN LLC for Authorization to Acquire Transmission Facilities.

*Filed Date:* 10/19/17.

*Accession Number:* 20171019–5135.

*Comments Due:* 5 p.m. ET 11/9/17.

Take notice that the Commission received the following electric rate filings:

*Docket Numbers:* ER17–1769–001.

*Applicants:* Solar Star Oregon II, LLC.

*Description:* Notice of Change in Status of Solar Star Oregon II, LLC.

*Filed Date:* 10/20/17.

*Accession Number:* 20171020–5107.

*Comments Due:* 5 p.m. ET 11/13/17.

*Docket Numbers:* ER17–399–002.

*Applicants:* Midcontinent Independent System Operator, Inc., Duke Energy Indiana, LLC.

*Description:* Compliance filing: 2017–10–20_SA 2285 Duke Energy-AEP WDS (Hagerstown) to be effective 3/1/2017.

*Filed Date:* 10/20/17.

*Accession Number:* 20171020–5075.

*Comments Due:* 5 p.m. ET 11/13/17.

*Docket Numbers:* ER17–772–003.

*Applicants:* Southwest Power Pool, Inc.

*Description:* Compliance filing: Compliance Filing in ER17–772—Order No. 825 Compliance Filing to be effective 5/11/2017.

*Filed Date:* 10/20/17.

*Accession Number:* 20171020–5088.

*Comments Due:* 5 p.m. ET 11/17/17.

*Docket Numbers:* ER18–112–000.

*Applicants:* Southwestern Public Service Company.

*Description:* § 205(d) Rate Filing: SPS–GSEC–DSEC-Intecon Agrmt-Sub 25–692–0.0.0 to be effective 10/21/2017.

*Filed Date:* 10/20/17.

*Accession Number:* 20171020–5071.

*Comments Due:* 5 p.m. ET 11/13/17.

*Docket Numbers:* ER18–113–000.

*Applicants:* Northern States Power Company, a Minnesota corporation.

*Description:* § 205(d) Rate Filing: 2017–10–20 CAPX-Big Stone-So Brkngs-CMA–594–0.1.0–NOC to be effective 12/20/2017.

*Filed Date:* 10/20/17.

*Accession Number:* 20171020–5080.

*Comments Due:* 5 p.m. ET 11/13/17.

*Docket Numbers:* ER18–114–000.

*Applicants:* PJM Interconnection, L.L.C.

*Description:* § 205(d) Rate Filing: Wholesale Market Participation Agreement No. 4820; Queue AC1–016 to be effective 10/12/2017.

*Filed Date:* 10/20/17.

*Accession Number:* 20171020–5084.

*Comments Due:* 5 p.m. ET 11/13/17.

*Docket Numbers:* ER18–115–000.

*Applicants:* PJM Interconnection, L.L.C.

*Description:* § 205(d) Rate Filing: Wholesale Market Participation Agreement No. 4821; Queue AC1–017 to be effective 10/12/2017.

*Filed Date:* 10/20/17.

*Accession Number:* 20171020–5085.

*Comments Due:* 5 p.m. ET 11/13/17.

*Docket Numbers:* ER18–116–000.

*Applicants:* PJM Interconnection, L.L.C.

*Description:* § 205(d) Rate Filing: Wholesale Market Participation Agreement No. 4822; Queue AC1–019 to be effective 10/12/2017.

*Filed Date:* 10/20/17.

*Accession Number:* 20171020–5086.

*Comments Due:* 5 p.m. ET 11/13/17.

*Docket Numbers:* ER18–117–000.

*Applicants:* Solar Star Oregon II, LLC.

*Description:* § 205(d) Rate Filing: Normal filing 1017 to be effective 10/21/2017.

*Filed Date:* 10/20/17.

*Accession Number:* 20171020–5087.

*Comments Due:* 5 p.m. ET 11/13/17.

*Docket Numbers:* ER18–118–000.

*Applicants:* Public Service Company of New Mexico.

*Description:* Notice of Cancellation of Interconnection Agreement (Rate Schedule No. 95) of Public Service Company of New Mexico.

*Filed Date:* 10/20/17.

*Accession Number:* 20171020–5106.

*Comments Due:* 5 p.m. ET 11/13/17.

*Docket Numbers:* ER18–119–000.

*Applicants:* Pacific Gas and Electric Company.

*Description:* § 205(d) Rate Filing: CDWR Work Performance Agreement for Wind Gap Pumping Plant #2 to be effective 10/23/2017.

*Filed Date:* 10/20/17.

*Accession Number:* 20171020–5110.

*Comments Due:* 5 p.m. ET 11/13/17.

*Docket Numbers:* ER18–120–000.

*Applicants:* Arizona Public Service Company.

*Description:* § 205(d) Rate Filing: OATT Attachment G Revision to be effective 12/20/2017.

*Filed Date:* 10/20/17.

*Accession Number:* 20171020–5115.

*Comments Due:* 5 p.m. ET 11/13/17.

*Docket Numbers:* ER18–121–000.

*Applicants:* Alabama Power Company.

*Description:* § 205(d) Rate Filing: Core Solar SPV XX LGIA Filing to be effective 10/10/2017.

*Filed Date:* 10/20/17.

*Accession Number:* 20171020–5136.

*Comments Due:* 5 p.m. ET 11/13/17.

*Docket Numbers:* ER18–122–000.

*Applicants:* New England Power Pool Participants Committee, ISO New England Inc.

*Description:* § 205(d) Rate Filing: Revisions Regarding Modeling Options for Small Generators to be effective 12/20/2017.

*Filed Date:* 10/20/17.

*Accession Number:* 20171020–5149.

*Comments Due:* 5 p.m. ET 11/13/17.

*Docket Numbers:* ER18–123–000.

*Applicants:* PJM Interconnection, L.L.C.

*Description:* § 205(d) Rate Filing: Amendment to Wholesale Market Participation Agreement No. 3499, Queue No. Y1–063 to be effective 1/30/2013.

*Filed Date:* 10/20/17.

*Accession Number:* 20171020–5160.

*Comments Due:* 5 p.m. ET 11/13/17.

*Docket Numbers:* ER18–124–000.

*Applicants:* Midcontinent Independent System Operator, Inc., Northern States Power Company, a Minnesota corporation, Great River Energy.

*Description:* § 205(d) Rate Filing: 2017–10–20_SA 3060 NSP–GRE T–T Pomerleau Lake to be effective 11/1/2017.

*Filed Date:* 10/20/17.

*Accession Number:* 20171020–5171.

*Comments Due:* 5 p.m. ET 11/13/17.

Take notice that the Commission received the following electric securities filings:

*Docket Numbers:* ES17–64–000.

*Applicants:* Monongahela Power Company.

*Description:* Amendment to September 29, 2017 Application for Authorization Under Section 204(a) of the Federal Power Act to Issue Short-Term Debt Securities of Monongahela Power Company.

*Filed Date:* 10/20/17.

*Accession Number:* 20171020–5135.

*Comments Due:* 5 p.m. ET 11/13/17.

*Docket Numbers:* ES18–4–000.

*Applicants:* Monongahela Power Company.

*Description:* Application Of Monongahela Power Company For Authorization under Section 204(A) of the FPA.

*Filed Date:* 10/20/17.

*Accession Number:* 20171020–5105.

*Comments Due:* 5 p.m. ET 11/13/17.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: October 20, 2017.

**Nathaniel J. Davis, Sr.,**

*Deputy Secretary.*

[FR Doc. 2017–23291 Filed 10–25–17; 8:45 am]

**BILLING CODE 6717–01–P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket No. EL18–18–000]**

### Midcontinent Independent System Operator, Inc.; Notice of Institution of Section 206 Proceeding and Refund Effective Date

On October 19, 2017, the Commission issued an order in Docket No. EL18–18–000, *Midcontinent Indep. Sys. Operator, Inc.,* 161 FERC 61,057 (2017) (October 2017 Order), pursuant to section 206 of the Federal Power Act (FPA), 16 U.S.C. 824e (2012), instituting an investigation to examine the Midcontinent Independent System Operator, Inc. (MISO) Transmission Owners Agreement and any other Commission-jurisdictional MISO documents that must be revised to fully implement the refund commitment concerns identified in the Commission's July 21, 2016 order in Docket No. EL16–99–000 in *Ark. Elec. Coop. Corp.* v. *ALLETE, Inc.,* 156 FERC 61,061 (2016). The October 2017 Order also consolidated Docket Nos. EL16–99–000 and EL18–18–000.

The refund effective date in Docket No. EL18–18–000, established pursuant to section 206(b) of the FPA, will be the date of publication of this notice in the **Federal Register**.

Any interested person desiring to be heard in Docket No. EL18–18–000 must file a notice of intervention or motion to intervene, as appropriate, with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rule 214 of the Commission's Rules of Practice and Procedure, 18 CFR 385.214, within 21 days of the date of issuance of the order.

Dated: October 19, 2017.

**Nathaniel J. Davis, Sr.,**

*Deputy Secretary.*

[FR Doc. 2017–23296 Filed 10–25–17; 8:45 am]

**BILLING CODE 6717–01–P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket No. EL18–12–000]**

### ATX Southwest, LLC; Notice of Institution of Section 206 Proceeding and Refund Effective Date

On October 19, 2017, the Commission issued an order in Docket No. EL18–12–000, pursuant to section 206 of the Federal Power Act (FPA), 16 U.S.C. 824e (2012), instituting an investigation into whether the formula rate protocols of ATX Southwest, LLC may be unjust, unreasonable, unduly discriminatory or preferential. *ATX Southwest, LLC,* 161 FERC 61,049 (2017).

The refund effective date in Docket No. EL18–12–000, established pursuant to section 206(b) of the FPA, will be the date of publication of this notice in the **Federal Register.**

Any interested person desiring to be heard in Docket No. EL18–12–000 must file a notice of intervention or motion to intervene, as appropriate, with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rule 214 of the Commission's Rules of Practice and Procedure, 18 CFR 385.214, within 21 days of the date of issuance of the order.

Dated: October 19, 2017.

**Nathaniel J. Davis, Sr.,**

*Deputy Secretary.*

[FR Doc. 2017–23288 Filed 10–25–17; 8:45 am]

**BILLING CODE 6717–01–P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

### Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

**Filings Instituting Proceedings**

*Docket Numbers:* RP17–1103–001.

*Applicants:* Transcontinental Gas Pipe Line Company, LLC.

*Description:* Tariff Amendment: Virginia Southside Expansion Project II Initial Rates Amended to be effective 12/1/2017.

*Filed Date:* 10/17/17.

*Accession Number:* 20171017–5178.

*Comments Due:* 5 p.m. ET 10/30/17.

*Docket Numbers:* RP18–37–000.

*Applicants:* Equitrans, L.P.

*Description:* Compliance filing Notice Regarding Non-Jurisdictional Gathering Facilities (F–1006 F–1008 F–1009).

*Filed Date:* 10/17/17.

*Accession Number:* 20171017–5127.

*Comments Due:* 5 p.m. ET 10/30/17.

*Docket Numbers:* RP18–38–000.

*Applicants:* Great Lakes Gas Transmission Limited Partnership.

*Description:* § 4(d) Rate Filing: Language Revision and Updates to be effective 11/18/2017.

*Filed Date:* 10/17/17.

*Accession Number:* 20171017–5139.

*Comments Due:* 5 p.m. ET 10/30/17.

*Docket Numbers:* RP18–39–000.

*Applicants:* Natural Gas Pipeline Company of America LLC.

*Description:* § 4(d) Rate Filing: Shell Energy North America-NRA Filing to be effective 10/18/2017.

*Filed Date:* 10/17/17.

*Accession Number:* 20171017–5163.

*Comments Due:* 5 p.m. ET 10/30/17.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and § 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: October 18, 2017.

**Nathaniel J. Davis, Sr.,**

*Deputy Secretary.*

[FR Doc. 2017–23283 Filed 10–25–17; 8:45 am]

**BILLING CODE 6717–01–P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket No. EL18–13–000]**

### Transource Kansas, LLC; Notice of Institution of Section 206 Proceeding and Refund Effective Date

On October 19, 2017, the Commission issued an order in Docket No. EL18–13–000, pursuant to section 206 of the Federal Power Act (FPA), 16 U.S.C. 824e (2012), instituting an investigation into whether the formula rate protocols of Transource Kansas, LLC may be unjust, unreasonable, unduly discriminatory or preferential. *Transource Kansas, LLC,* 161 FERC 61,050 (2017).

The refund effective date in Docket No. EL18–13–000, established pursuant to section 206(b) of the FPA, will be the date of publication of this notice in the **Federal Register.**

Any interested person desiring to be heard in Docket No. EL18–13–000 must file a notice of intervention or motion to intervene, as appropriate, with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rule 214 of the Commission's Rules of Practice and Procedure, 18 CFR 385.214, within 21 days of the date of issuance of the order.

Dated: October 19, 2017.

**Nathaniel J. Davis, Sr.,**

*Deputy Secretary.*

[FR Doc. 2017–23292 Filed 10–25–17; 8:45 am]

**BILLING CODE 6717–01–P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

### Combined Notice of Filings #2

Take notice that the Commission received the following exempt wholesale generator filings:

*Docket Numbers:* EG18–8–000.

*Applicants:* 54KR 8ME LLC.

*Description:* Notice of Self-Certification of Exempt Wholesale Generator Status of 54KR 8me LLC.

*Filed Date:* 10/19/17.

*Accession Number:* 20171019–5108.

*Comments Due:* 5 p.m. ET 11/9/17.

Take notice that the Commission received the following electric rate filings:

*Docket Numbers:* ER18–7–001.

*Applicants:* Lamarr Energy, LLC.

*Description:* Tariff Amendment: Market Based Rate Tariff to be effective 12/1/2017.

*Filed Date:* 10/19/17.

*Accession Number:* 20171019–5079.

*Comments Due:* 5 p.m. ET 11/9/17.

*Docket Numbers:* ER18–7–002.

*Applicants:* Lamarr Energy, LLC.

*Description:* Tariff Amendment: Market Based Rate Tariff to be effective 12/1/2017.

*Filed Date:* 10/19/17.

*Accession Number:* 20171019–5099.

*Comments Due:* 5 p.m. ET 11/9/17.

*Docket Numbers:* ER18–103–000.
*Applicants:* 67RK 8me LLC.
*Description:* § 205(d) Rate Filing: SFA to be effective 10/20/2017.
*Filed Date:* 10/19/17.
*Accession Number:* 20171019–5034.
*Comments Due:* 5 p.m. ET 11/9/17.

*Docket Numbers:* ER18–104–000.
*Applicants:* 67RK 8me LLC.
*Description:* § 205(d) Rate Filing: Co-Tenancy Agreement to be effective 10/20/2017.
*Filed Date:* 10/19/17.
*Accession Number:* 20171019–5035.
*Comments Due:* 5 p.m. ET 11/9/17.

*Docket Numbers:* ER18–105–000.
*Applicants:* 65HK 8me LLC.
*Description:* § 205(d) Rate Filing: 65HK 8me LLC Hayworth SFA to be effective 10/20/2017.
*Filed Date:* 10/19/17.
*Accession Number:* 20171019–5036.
*Comments Due:* 5 p.m. ET 11/9/17.

*Docket Numbers:* ER18–106–000.
*Applicants:* 87RL 8me LLC.
*Description:* § 205(d) Rate Filing: 87RL 8me LLC Woodmere SFA to be effective 10/20/2017.
*Filed Date:* 10/19/17.
*Accession Number:* 20171019–5037.
*Comments Due:* 5 p.m. ET 11/9/17.

*Docket Numbers:* ER18–107–000.
*Applicants:* 65HK 8me LLC.
*Description:* § 205(d) Rate Filing: 65HK 8me LLC Hayworth Co-Tenancy Agreement to be effective 10/20/2017.
*Filed Date:* 10/19/17.
*Accession Number:* 20171019–5038.
*Comments Due:* 5 p.m. ET 11/9/17.

*Docket Numbers:* ER18–108–000.
*Applicants:* 87RL 8me LLC.
*Description:* § 205(d) Rate Filing: 87RL 8me LLC Woodmere Co-Tenancy Agreement to be effective 10/20/2017.
*Filed Date:* 10/19/17.
*Accession Number:* 20171019–5039.
*Comments Due:* 5 p.m. ET 11/9/17.

*Docket Numbers:* ER18–109–000.
*Applicants:* Nevada Power Company.
*Description:* Tariff Cancellation: Rate Schedule No. 153 NPC/Aha Macav Termination to be effective 10/20/2017.
*Filed Date:* 10/19/17.
*Accession Number:* 20171019–5083.
*Comments Due:* 5 p.m. ET 11/9/17.

*Docket Numbers:* ER18–110–000.
*Applicants:* Duke Energy Progress, LLC.
*Description:* § 205(d) Rate Filing: DEP Five Towns Pro Forma NITSA Filing to be effective 1/1/2018.
*Filed Date:* 10/19/17.
*Accession Number:* 20171019–5098.
*Comments Due:* 5 p.m. ET 11/9/17.

*Docket Numbers:* ER18–111–000.
*Applicants:* The United Illuminating Company.
*Description:* § 205(d) Rate Filing: Pootatuck Ring Bus Expansion Agreement to be effective 10/20/2017.
*Filed Date:* 10/19/17.
*Accession Number:* 20171019–5111.
*Comments Due:* 5 p.m. ET 11/9/17.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: October 19, 2017.

**Nathaniel J. Davis, Sr.,**

*Deputy Secretary.*

[FR Doc. 2017–23285 Filed 10–25–17; 8:45 am]

**BILLING CODE 6717–01–P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket No. ER18–97–000]**

### MS Solar 3, 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 MS Solar 3, 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 November 8, 2017.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: October 19, 2017.

**Nathaniel J. Davis, Sr.,**

*Deputy Secretary.*

[FR Doc. 2017–23297 Filed 10–25–17; 8:45 am]

**BILLING CODE 6717–01–P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket No. EL18–14–000]**

### Midwest Power Transmission Arkansas, LLC; Notice of Institution of Section 206 Proceeding and Refund Effective Date

On October 19, 2017, the Commission issued an order in Docket No. EL18–14–000, pursuant to section 206 of the Federal Power Act (FPA), 16 U.S.C. 824e (2012), instituting an investigation into whether the formula rate protocols of Midwest Power Transmission Arkansas, LLC may be unjust, unreasonable, unduly discriminatory or preferential. *Midwest Power*

*Transmission Arkansas, LLC,* 161 FERC 61,051 (201X).

The refund effective date in Docket No. EL18–14–000, established pursuant to section 206(b) of the FPA, will be the date of publication of this notice in the **Federal Register**.

Any interested person desiring to be heard in Docket No. EL18–14–000 must file a notice of intervention or motion to intervene, as appropriate, with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rule 214 of the Commission's Rules of Practice and Procedure, 18 CFR 385.214, within 21 days of the date of issuance of the order.

Dated: October 19, 2017.

**Nathaniel J. Davis, Sr.,**

*Deputy Secretary.*

[FR Doc. 2017–23293 Filed 10–25–17; 8:45 am]

**BILLING CODE 6717–01–P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket No. EL18–17–000]**

### Midcontinent Independent System Operator, Inc.; Notice of Institution of Section 206 Proceeding and Refund Effective Date

On October 19, 2017, the Commission issued an order in Docket No. EL18–17–000, pursuant to section 206 of the Federal Power Act (FPA), 16 U.S.C. 824e (2012), instituting an investigation into whether the Open Access Transmission, Energy and Operating Reserve Markets Tariff of Midcontinent Independent System Operator, Inc. may be unjust, unreasonable, unduly discriminatory or preferential. *Midcontinent Indep. Sys. Operator, Inc.,* 161 FERC 61,076 (2017).

The refund effective date in Docket No. EL18–17–000, established pursuant to section 206(b) of the FPA, will be the date of publication of this notice in the **Federal Register**.

Any interested person desiring to be heard in Docket No. EL18–17–000 must file a notice of intervention or motion to intervene, as appropriate, with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rule 214 of the Commission's Rules of Practice and Procedure, 18 CFR 385.214, within 21 days of the date of issuance of the order.

Dated: October 19, 2017.

**Nathaniel J. Davis, Sr.,**

*Deputy Secretary.*

[FR Doc. 2017–23295 Filed 10–25–17; 8:45 am]

**BILLING CODE 6717–01–P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

### Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

*Docket Numbers:* EC18–6–000.

*Applicants:* V3 Commodities Group, LLC.

*Description:* Application for Authorization under Section 203 of the Federal Power Act, and Requests for Waivers of Filing Requirements, Expedited Review and Confidential Treatment of V3 Commodities Group, LLC.

*Filed Date:* 10/18/17.

*Accession Number:* 20171018–5191.

*Comments Due:* 5 p.m. ET 11/8/17.

Take notice that the Commission received the following electric rate filings:

*Docket Numbers:* ER13–343–008*; ER13–342–012; ER16–700–001; ER16–701–001*.

*Applicants:* CPV Shore, LLC, CPV Maryland, LLC, CPV Towantic, LLC, CPV Valley, LLC.

*Description:* Supplement to June 30, 2017 Market Power Update of CPV Maryland, LLC, *et. al.*

*Filed Date:* 10/18/17.

*Accession Number:* 20171018–5183.

*Comments Due:* 5 p.m. ET 11/1/17.

*Docket Numbers:* ER15–2735–001.

*Applicants:* Garrison Energy Center LLC.

*Description:* Report Filing: Refund Report—Informational Filing to be effective N/A.

*Filed Date:* 10/18/17.

*Accession Number:* 20171018–5145.

*Comments Due:* 5 p.m. ET 11/8/17.

*Docket Numbers:* ER17–2210–000.

*Applicants:* Duke Energy Carolinas, LLC.

*Description:* Report Filing: DEC–SCEG Refund Report to be effective N/A.

*Filed Date:* 10/18/17.

*Accession Number:* 20171018–5158.

*Comments Due:* 5 p.m. ET 11/8/17.

*Docket Numbers:* ER18–99–000.

*Applicants:* Southwest Power Pool, Inc.

*Description:* § 205(d) Rate Filing: South Central MCN LLC Formula Rate to be effective 12/31/9998.

*Filed Date:* 10/18/17.

*Accession Number:* 20171018–5171.

*Comments Due:* 5 p.m. ET 11/8/17.

*Docket Numbers:* ER18–100–000.

*Applicants:* Wisconsin Power and Light Company.

*Description:* § 205(d) Rate Filing: WPL—ACEC Wholesale Power Agreement to be effective 6/1/2020.

*Filed Date:* 10/18/17.

*Accession Number:* 20171018–5173.

*Comments Due:* 5 p.m. ET 11/8/17.

*Docket Numbers:* ER18–101–000.

*Applicants:* Wisconsin Power and Light Company.

*Description:* § 205(d) Rate Filing: WPL—CWEC Wholesale Power Agreement to be effective 6/1/2020.

*Filed Date:* 10/18/17.

*Accession Number:* 20171018–5174.

*Comments Due:* 5 p.m. ET 11/8/17.

*Docket Numbers:* ER18–102–000.

*Applicants:* Wisconsin Power and Light Company.

*Description:* § 205(d) Rate Filing: WPL—REC Wholesale Power Agreement to be effective 6/1/2020.

*Filed Date:* 10/18/17.

*Accession Number:* 20171018–5175.

*Comments Due:* 5 p.m. ET 11/8/17.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf*. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: October 19, 2017.

**Nathaniel J. Davis, Sr.,**

*Deputy Secretary.*

[FR Doc. 2017–23284 Filed 10–25–17; 8:45 am]

**BILLING CODE 6717–01–P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket No. ER18–95–000]**

### Buchanan Energy Services Company, 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 Buchanan Energy Services Company, 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 November 8, 2017.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: October 19, 2017.

**Nathaniel J. Davis, Sr.,**

*Deputy Secretary.*

[FR Doc. 2017–23290 Filed 10–25–17; 8:45 am]

**BILLING CODE 6717–01–P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket No. EL18–15–000]**

### Kanstar Transmission, LLC; Notice of Institution of Section 206 Proceeding and Refund Effective Date

On October 19, 2017, the Commission issued an order in Docket No. EL18–15–000, pursuant to section 206 of the Federal Power Act (FPA), 16 U.S.C. 824e (2012), instituting an investigation into whether the formula rate protocols of Kanstar Transmission, LLC may be unjust, unreasonable, unduly discriminatory or preferential. *Kanstar Transmission, LLC,* 161 FERC 61,052 (2017).

The refund effective date in Docket No. EL18–15–000, established pursuant to section 206(b) of the FPA, will be the date of publication of this notice in the **Federal Register**.

Any interested person desiring to be heard in Docket No. EL18–15–000 must file a notice of intervention or motion to intervene, as appropriate, with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rule 214 of the Commission's Rules of Practice and Procedure, 18 CFR 385.214, within 21 days of the date of issuance of the order.

Dated: October 19, 2017.

**Nathaniel J. Davis, Sr.,**

*Deputy Secretary.*

[FR Doc. 2017–23289 Filed 10–25–17; 8:45 am]

**BILLING CODE 6717–01–P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket No. EL18–16–000]**

### South Central MCN LLC; Notice of Institution of Section 206 Proceeding and Refund Effective Date

On October 19, 2017, the Commission issued an order in Docket No. EL18–16–000, pursuant to section 206 of the Federal Power Act (FPA), 16 U.S.C. 824e (2012), instituting an investigation into whether the formula rate protocols of South Central MCN LLC may be unjust, unreasonable, unduly discriminatory or preferential. *South Central MCN LLC,* 161 FERC 61,053 (2017).

The refund effective date in Docket No. EL18–16–000, established pursuant to section 206(b) of the FPA, will be the date of publication of this notice in the **Federal Register**.

Any interested person desiring to be heard in Docket No. EL18–16–000 must file a notice of intervention or motion to intervene, as appropriate, with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rule 214 of the Commission's Rules of Practice and Procedure, 18 CFR 385.214, within 21 days of the date of issuance of the order.

Dated: October 19, 2017.

**Nathaniel J. Davis, Sr.,**

*Deputy Secretary.*

[FR Doc. 2017–23294 Filed 10–25–17; 8:45 am]

**BILLING CODE 6717–01–P**

## ENVIRONMENTAL PROTECTION AGENCY

**[FRL–9969–90–Region 1]**

### 2017 Fall Joint Meeting of the Ozone Transport Commission and the Mid-Atlantic Northeast Visibility Union

**AGENCY:** Environmental Protection Agency.

**ACTION:** Notice of meeting.

**SUMMARY:** The United States Environmental Protection Agency is announcing the joint 2017 Fall Meeting of the Ozone Transport Commission (OTC) and the Mid-Atlantic Northeast Visibility Union (MANE–VU). The meeting agenda will include topics regarding reducing ground-level ozone precursors and matters relative to Regional Haze and visibility improvement in Federal Class I areas in a multi-pollutant context.

**DATES:** The meeting will be held on November 15, 2017 starting at 9:15 a.m. and ending at 4:00 p.m.

**ADDRESSES:** Location: Melrose Georgetown Hotel, 2430 Pennsylvania Avenue NW., Washington, DC 20037, 202–955–6400.

**FOR FURTHER INFORMATION CONTACT:** For documents and press inquiries contact: Ozone Transport Commission, 444 North Capitol Street NW., Suite 322, Washington, DC 20001; (202) 508–3840; email: *ozone@otcair.org;* Web site: *http://www.otcair.org.*

**SUPPLEMENTARY INFORMATION:** The Clean Air Act Amendments of 1990 contain at Section 184 provisions for the Control of Interstate Ozone Air Pollution. Section 184(a) establishes an Ozone Transport Region (OTR) comprised of the States of Connecticut, Delaware, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont, parts of Virginia and the District of Columbia. The purpose of the OTC is to

deal with ground-level ozone formation, transport, and control within the OTR.

The Mid-Atlantic/Northeast Visibility Union (MANE–VU) was formed at in 2001, in response to EPA's issuance of the Regional Haze rule. MANE–VU's members include: Connecticut, Delaware, the District of Columbia, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont, the Penobscot Indian Nation, the St. Regis Mohawk Tribe along with EPA and Federal Land Managers.

*Type of Meeting:* Open.

*Agenda:* Copies of the final agenda will be available from the OTC office (202) 508–3840; by email: *ozone@otcair.org* or via the OTC Web site at *http://www.otcair.org.*

Dated: October 4, 2017.

**Deborah Szaro,**

*Acting Regional Administrator, Region I.*

[FR Doc. 2017–23242 Filed 10–25–17; 8:45 am]

**BILLING CODE 6560–50–P**

## FEDERAL COMMUNICATIONS COMMISSION

**[OMB 3060–0848]**

### Information Collection Being Reviewed by the Federal Communications Commission

**AGENCY:** Federal Communications Commission.

**ACTION:** Notice and request for comments.

**SUMMARY:** As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid Office of Management and Budget (OMB) control number.

**DATES:** Written PRA comments should be submitted on or before December 26, 2017. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

**ADDRESSES:** Direct all PRA comments to Nicole Ongele, FCC, via email *PRA@fcc.gov* and to *Nicole.Ongele@fcc.gov*.

**FOR FURTHER INFORMATION CONTACT:** For additional information about the information collection, contact Nicole Ongele at (202) 418–2991.

**SUPPLEMENTARY INFORMATION:** As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

*OMB Control Number:* 3060–0848.

*Title:* Deployment of Wireline Services Offering Advanced Telecommunications Capability, CC Docket No. 98–147.

*Form Number:* N/A.

*Type of Review:* Extension of a currently approved collection.

*Respondents:* Business or other for-profit.

*Number of Respondents and Responses:* 750 respondents; 9,270 responses.

*Estimated Time per Response:* 3.54 hours (average burden per response).

*Frequency of Response:* On occasion reporting requirement, recordkeeping requirement and third-party disclosure requirement.

*Obligation to Respond:* Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. 201 and 251 of the Communications Act of 1934, as amended.

*Total Annual Burden:* 32,845 hours.

*Total Annual Cost:* No cost.

*Privacy Act Impact Assessment:* No impact(s).

*Nature and Extent of Confidentiality:* The Commission is not requesting respondents to submit confidential information. Any respondent that submits information to the Commission that they believe is confidential may request confidential treatment of such information under 47 CFR 0.459 of the Commission's rules.

*Needs and Uses:* The information collection requirements implement sections 201 and 251 of the Communications Act of 1934, as amended, to provide for physical collocation on rates, terms and conditions that are just, reasonable and nondiscriminatory, and to promote deployment of advanced telecommunications services without significantly degrading the performance of other services. All of the requirements will be used by the Commission and competitive local exchange carriers (LECs) to facilitate the deployment of telecommunications services, including advanced telecommunications services.

Federal Communications Commission.

**Katura Jackson,**

*Federal Register Liaison Officer, Office of the Secretary.*

[FR Doc. 2017–23216 Filed 10–25–17; 8:45 am]

**BILLING CODE 6712–01–P**

## FEDERAL RESERVE SYSTEM

### Proposed Agency Information Collection Activities; Comment Request

**AGENCY:** Board of Governors of the Federal Reserve System.

**ACTION:** Revision to proposal.

**SUMMARY:** The Board of Governors of the Federal Reserve System (Board or Federal Reserve) is modifying its proposal to extend for three years, with revision, the Banking Organization Systemic Risk Report (FR Y–15; OMB No. 7100–0352). The Board is extending the proposed implementation date for the proposed revisions to the FR Y–15 from December 31, 2017, to March 31, 2018. The Board is also reopening the

public comment period for the proposal by 30 days, so that the comment period ends on November 23, 2017.

**DATES:** The proposed collection of information is amended effective October 18, 2017 and the public comment period shall terminate on November 23, 2017.

**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 Board's public Web site 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 Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC 20551, (202) 452–3829. Telecommunications Device for the Deaf (TDD) users may contact (202) 263–4869, Board of Governors of the Federal Reserve System, Washington, DC 20551.

**SUPPLEMENTARY INFORMATION:** On August 24, 2017, the Board invited public comment on a proposal that would extend for three years the FR Y–15 and make certain revisions to the report (FR Y–15 proposal). As revised, the report would include Mexican pesos in total payments activity rather than as a memorandum item; add securities brokers to the definition of financial institutions; expressly include derivative transactions where a clearing member bank guarantees the performance of a client to a central counterparty; and, specify how certain cleared derivatives transactions are reported.[1] As initially proposed, these revisions to the FR Y–15 would have been effective for reports reflecting a December 31, 2017, as-of date. The comment period for the FR Y–15 proposal was previously scheduled to end on October 23, 2017.

The Board has received feedback that additional time may be required for affected banking organizations to analyze the impact of, and to provide comments on, the FR Y–15 changes being proposed.

In response to the feedback, this notice hereby reopens the public comment period for the FR Y–15 proposal by 30 days, with comments due November 23, 2017, to provide additional time for comment.

[1] *See* 82 FR 40154 (August 24, 2017).

This notice also amends the proposed implementation date of the FR Y–15 proposal such that the proposed changes would be effective for reports reflecting the March 31, 2018, as-of date. This revision would provide respondents with an additional 90 days to prepare their systems to reflect any changes to the FR Y–15 that the Board may adopt after reviewing the comments received.

Board of Governors of the Federal Reserve System, October 23, 2017.

**Ann E. Misback,**

*Secretary of the Board.*

[FR Doc. 2017–23271 Filed 10–25–17; 8:45 am]

**BILLING CODE 6210–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

### Advisory Council for the Elimination of Tuberculosis Meeting

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice of meeting.

**SUMMARY:** In accordance with the Federal Advisory Committee Act, the Centers for Disease Control and Prevention (CDC) announces the following meeting of the Advisory Council for the Elimination of Tuberculosis (ACET). This meeting is open to the public, limited only by 100 room seating and 100 ports for audio phone lines. Time will be available for public comment. Comments should be submitted in writing by email to the contact person listed below. The deadline for receipt is Monday, December 4, 2017. Persons who desire to make an oral statement, may request it at the time of the public comment period on December 12, 2017 at 11:40 a.m. EST. This meeting is also accessible by teleconference: 1–877–927–1433 and participant passcode: 12016435.

**DATES:** The meeting will be held on December 11, 2017, 8:30 a.m. to 4:30 p.m., EST and December 12, 2017, 8:30 a.m. to 12:00 p.m., EST.

**ADDRESSES:** CDC Corporate Square Campus, 8 Corporate Square Boulevard, Atlanta, Georgia 30329.

**FOR FURTHER INFORMATION CONTACT:** Margie Scott-Cseh, Committee Management Specialist, CDC, 1600 Clifton Road NE., Mailstop: E–07, Atlanta, Georgia 30329, telephone (404) 639–8317; *zkr7@cdc.gov.*

**SUPPLEMENTARY INFORMATION:**

*Purpose:* This Council advises and makes recommendations to the Secretary of Health and Human Services, the Assistant Secretary for Health, and the Director, CDC, regarding the elimination of tuberculosis. Specifically, the Council makes recommendations regarding policies, strategies, objectives, and priorities; addresses the development and application of new technologies; and reviews the extent to which progress has been made toward eliminating tuberculosis.

*Matters To Be Considered:* The agenda will include discussions on (1) Update on preliminary tuberculosis funding formula; (2) Update on whole genome sequencing data sharing plan; (3) Update on three-month Isoniazid/Rifapentine Regimen (3HP) guidelines; and (4) Updates from ACET workgroups. Agenda items are subject to change as priorities dictate.

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.

**Claudette Grant,**

*Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. 2017–23335 Filed 10–25–17; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

### Board of Scientific Counselors, Office of Infectious Diseases (BSC, OID)

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice of meeting.

**SUMMARY:** In accordance with the Federal Advisory Committee Act, the Centers for Disease Control and Prevention (CDC), announces the following meeting for the Board of Scientific Counselors, Office of Infectious Diseases (BSC, OID). This meeting is open to the public, limited only by the space available; the meeting room will accommodate up to 100 people. The public is also welcome to listen to the meeting by telephone, limited only by the number of ports

available (50); the toll-free dial-in number is 1–877–951–7311, with a pass code of 2208740.

**DATES:** The meeting will be held on December 6, 2017, 8:30 a.m. to 5:00 p.m., EST, and December 7, 2017, 8:30 a.m. to 12:00 p.m., EST.

**ADDRESSES:** CDC, Global Communications Center, 1600 Clifton Road NE., Building 19, Auditorium B3, Atlanta, Georgia 30329; also 1–877–951–7311, with a pass code of 2208740.

**FOR FURTHER INFORMATION CONTACT:** Robin Moseley, MAT, Designated Federal Officer, OID, CDC, 1600 Clifton Road NE., Mailstop D10, Atlanta, Georgia 30329, Telephone (404) 639–4461; *rrm1@cdc.gov.*

**SUPPLEMENTARY INFORMATION:**

*Purpose:* The BSC, OID, provides advice and guidance to the Secretary, Department of Health and Human Services; the Director, CDC; the Director, OID; and the Directors of the National Center for Immunization and Respiratory Diseases, the National Center for Emerging and Zoonotic Infectious Diseases, and the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, CDC, in the following areas: Strategies, goals, and priorities for programs; research within the national centers; and overall strategic direction and focus of OID and the national centers.

*Matters To Be Considered:* The agenda will include discussions on priority issues for the national centers, including foodborne infections, advanced molecular detection, antimicrobial resistance, sexually transmitted diseases, and vaccination coverage. A report back from the Board's Food Safety Modernization Act Surveillance Working Group will also be given. Agenda items are subject to change as priorities dictate.

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.

**Claudette Grant**

*Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention .*

[FR Doc. 2017–23336 Filed 10–25–17; 8:45 am]

**BILLING CODE 4163–19–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

### Advisory Board on Radiation and Worker Health (ABRWH or the Advisory Board), National Institute for Occupational Safety and Health (NIOSH); Meeting

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice of meeting.

**SUMMARY:** In accordance with section 10(a)(2) of the Federal Advisory Committee Act, the Centers for Disease Control and Prevention (CDC), announces the following meeting of the Advisory Board on Radiation and Worker Health (ABRWH). This meeting is open to the public, limited only by the space available. The meeting space accommodates approximately 150 people. The public is welcome to submit written comments in advance of the meeting, to the contact person below. Written comments received in advance of the meeting will be included in the official record of the meeting. The public is also welcome to listen to the meeting by joining the teleconference at the USA toll-free, dial-in number at 1–866–659–0537; the pass code is 9933701. The conference line has 150 ports for callers. The Web conference by which the public can view presentations as they are presented is *https://webconf.cdc.gov/zab6/yzdq02pl?sl=1.*

**DATES:** The meeting will be held on December 13 from 8:15 to 6:00 p.m. Mountain Time and December 14, 2017, 8:15 a.m. to 11:00 a.m. Mountain Time. A public comment session will begin on December 13 at 6:00 p.m. Mountain Time and conclude at 7:00 p.m. or following the final call for public comment, whichever comes first.

**ADDRESSES:** Doubletree by Hilton Albuquerque, 201 Marquette Avenue Northwest, Albuquerque, New Mexico 87102; Phone: (505) 247–7057, Fax: (505) 247–7017. Audio conference call via FTS Conferencing. The USA toll-free dial-in number is 1–866–659–0537; the pass code is 9933701. Web conference by Skype: Meeting CONNECTION: *https://webconf.cdc.gov/zab6/yzdq02pl?sl=1.*

**FOR FURTHER INFORMATION CONTACT:** Theodore Katz, MPA, Designated Federal Officer, NIOSH, CDC, 1600 Clifton Road, Mailstop E–20, Atlanta, Georgia 30333, Telephone (513) 533–6800, Toll Free 1 (800) CDC–INFO, Email *ocas@cdc.gov.*

**SUPPLEMENTARY INFORMATION:**

*Background:* The Advisory Board was established under the Energy Employees Occupational Illness Compensation Program Act of 2000 to advise the President on a variety of policy and technical functions required to implement and effectively manage the new compensation program. Key functions of the Advisory Board include providing advice on the development of probability of causation guidelines which have been promulgated by the Department of Health and Human Services (HHS) as a final rule, advice on methods of dose reconstruction which have also been promulgated by HHS as a final rule, advice on the scientific validity and quality of dose estimation and reconstruction efforts being performed for purposes of the compensation program, and advice on petitions to add classes of workers to the Special Exposure Cohort (SEC). In December 2000, the President delegated responsibility for funding, staffing, and operating the Advisory Board to HHS, which subsequently delegated this authority to the CDC. NIOSH implements this responsibility for CDC. The charter was issued on August 3, 2001, renewed at appropriate intervals, rechartered on March 22, 2016 pursuant to Executive Order 13708, and will expire on September 30, 2019.

*Purpose:* This Advisory Board is charged with (a) providing advice to the Secretary, HHS, on the development of guidelines under Executive Order 13179; (b) providing advice to the Secretary, HHS, on the scientific validity and quality of dose reconstruction efforts performed for this program; and (c) upon request by the Secretary, HHS, advising the Secretary on whether there is a class of employees at any Department of Energy facility who were exposed to radiation but for whom it is not feasible to estimate their radiation dose, and on whether there is reasonable likelihood that such radiation doses may have endangered the health of members of this class.

*Matters to be Considered:* The agenda will include discussions on: NIOSH Program Update; Department of Labor Program Update; Department of Energy Program Update; SEC Petitions Update; dose reconstruction review methods; review of methods for estimating co-worker radiation doses; possible discussions of Site Profile reviews for Weldon Spring Plant (Weldon Spring, Missouri) and Pacific Proving Grounds (Marshall Islands); the SEC petition for Savannah River Site (1973–2007; Aiken, South Carolina), and possibly one or more of the following SEC petitions: Idaho National Laboratory (1963–1970;

Scoville, Idaho), Area IV of Santa Susanna Field Laboratory (1991–1993; Ventura County, California), Ames Laboratory (1971—undetermined ending date; Ames, Iowa); and Board Work Sessions. Agenda items are subject to change as priorities dictate.

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.

**Claudette Grant,**

*Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. 2017–23333 Filed 10–25–17; 8:45 am]

**BILLING CODE 4163–19–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

### Advisory Committee to the Director (ACD), Centers for Disease Control and Prevention (CDC)—State, Tribal, Local and Territorial (STLT) Subcommittee

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice of meeting.

**SUMMARY:** In accordance with the Federal Advisory Committee Act, the Centers for Disease Control and Prevention (CDC), announces the following meeting for the State, Tribal, Local and Territorial Subcommittee, Centers for Disease Control and Prevention (STLT, CDC). This meeting is open to the public, limited only by 100 ports for audio phone lines access available. The public is also welcome to listen to the meeting by (866) 917–2712, passcode 9418625. The public comment period is from 03:50 p.m.–03:55 p.m. EST. Please register for public comment by December 8, 2017 via email to *acdirector@cdc.gov.*

**DATES:** The meeting will be held on December 18, 2017, 2:30 p.m. to 4:00 p.m., EST.

**ADDRESSES:** Audio Line Access Only (866) 917–2712, passcode 9418625.

**FOR FURTHER INFORMATION CONTACT:** Jose Montero, MD, MPH, Director, Office for State, Tribal, Local and Territorial Support, CDC, 4770 Buford Highway, Mailstop E70, Atlanta, Georgia 30341, (404) 498–0300, *ostltsdirector@cdc.gov.*

**SUPPLEMENTARY INFORMATION:**

*Purpose:* The Subcommittee will provide counsel to the ACD, CDC on strategies, future needs, and challenges faced by State, Tribal, Local and Territorial health agencies, and will provide guidance on opportunities for CDC through the ACD.

*Matters To Be Considered:* The agenda will include discussions on implementation of ACD-adopted recommendations related to the health department of the future, additional developments that may expand these recommendations, and how CDC can best support STLT health departments. Agenda items are subject to change as priorities dictate.

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.

**Claudette Grant,**

*Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. 2017–23334 Filed 10–25–17; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

**[Document Identifiers: CMS–10114 and CMS–417]**

### 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 November 27, 2017.

**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) 395–5806 *OR*, Email: *OIRA_submission@omb.eop.gov.*

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:

1. Access CMS' Web site address at Web site address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

**FOR FURTHER INFORMATION CONTACT:** William Parham at (410) 786–4669.

**SUPPLEMENTARY INFORMATION:** Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes

the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Extension of a currently approved collection;

*Title of Information Collection:* National Provider Identifier (NPI) Application and Update Form and Supporting Regulations in 45 CFR 142.408, 45 CFR 162.406, 45 CFR 162.408; *Use:* The National Provider Identifier Application and Update Form is used by health care providers to apply for NPIs and furnish updates to the information they supplied on their initial applications. The form is also used to deactivate their NPIs if necessary. The original application form was approved in February 2005 and has been in use since May 23, 2005. The form is available on paper or can be completed via a web-based process. Health care providers can mail a paper application, complete the application via the web-based process via the National Plan and Provider Enumeration System (NPPES), or have a trusted organization submit the application on their behalf via the Electronic File Interchange (EFI) process. The Enumerator uses the NPPES to process the application and generate the NPI. NPPES is the Medicare contractor tasked with issuing NPIs, and maintaining and storing NPI data. *Form Number:* CMS–10114 (OMB control number: 0938–0931); *Frequency:* On occasion; *Affected Public:* Business or other for-profit, Not-for-profit institutions, and Federal government; *Number of Respondents:* 1,473,185; *Total Annual Responses:* 1,473,185; *Total Annual Hours:* 250,442. (For policy questions regarding this collection contact Kimberly McPhillips at 410–786–5374).

2. *Type of Information Collection Request:* Reinstatement without change of a previously approved collection; *Title of Information Collection:* Hospice Request for Certification and Supporting Regulations; *Use:* The Hospice Request for Certification Form is the identification and screening form used to initiate the certification process and to determine if the provider has sufficient personnel to participate in the Medicare program. *Form Number:* CMS–417 (OMB Control number: 0938–0313); *Frequency:* Annually; *Affected Public:* Private Sector—Business or other for-profits; *Number of Respondents:* 851; Total *Annual Responses:* 851; *Total Annual Hours:* 213. (For policy questions regarding this collection contact Thomas Pryor at 410–786–1332.)

Dated: October 23, 2017.

**William N. Parham, III,**

*Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2017–23341 Filed 10–25–17; 8:45 am]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2016–N–1486]**

### Authorizations of Emergency Use of In Vitro Diagnostic Devices for Detection of Zika Virus; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the issuance of two Emergency Use Authorizations (EUAs) (the Authorizations) for in vitro diagnostic devices for detection of the Zika virus in response to the Zika virus outbreak in the Americas. FDA issued these Authorizations under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as requested by Thermo Fisher Scientific and The Center for Infection and Immunity, Columbia University. The Authorizations contain, among other things, conditions on the emergency use of the authorized in vitro diagnostic devices. The Authorizations follow the February 26, 2016, determination by the Secretary of Health and Human Services (HHS) that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad and that involves Zika virus. On the basis of such determination, the Secretary of HHS declared on February 26, 2016, that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection, subject to the terms of any authorization issued under the FD&C Act. The Authorizations, which include an explanation of the reasons for issuance, are reprinted in this document.

**DATES:** The Authorization for Thermo Fisher Scientific is applicable as of August 2, 2017; the Authorization for The Center for Infection and Immunity, Columbia University is effective as of August 11, 2017.

**ADDRESSES:** Submit written requests for single copies of the EUAs to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the Authorizations may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorizations.

**FOR FURTHER INFORMATION CONTACT:** Carmen Maher, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4347, Silver Spring, MD 20993–0002, 301–796–8510 (this is not a toll free number).

**SUPPLEMENTARY INFORMATION:**

#### I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb–3) as amended by the Project BioShield Act of 2004 (Pub. L. 108–276) and the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (Pub. L. 113–5) allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. With this EUA authority, FDA can help assure that medical countermeasures may be used in emergencies to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by biological, chemical, nuclear, or radiological agents when there are no adequate, approved, and available alternatives.

Section 564(b)(1) of the FD&C Act provides that, before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of the following grounds: (1) A determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear agent or agents; (2) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to U.S. military forces of attack with a biological, chemical, radiological, or nuclear agent or agents; (3) a determination by the Secretary of HHS that there is a public health emergency, or a significant potential for

a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad, and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents; or (4) the identification of a material threat by the Secretary of Homeland Security under section 319F–2 of the Public Health Service (PHS) Act (42 U.S.C. 247d–6b) sufficient to affect national security or the health and security of U.S. citizens living abroad.

Once the Secretary of HHS has declared that circumstances exist justifying an authorization under section 564 of the FD&C Act, FDA may authorize the emergency use of a drug, device, or biological product if the Agency concludes that the statutory criteria are satisfied. Under section 564(h)(1) of the FD&C Act, FDA is required to publish in the **Federal Register** a notice of each authorization, and each termination or revocation of an authorization, and an explanation of the reasons for the action. Section 564 of the FD&C Act permits FDA to authorize the introduction into interstate commerce of a drug, device, or biological product intended for use when the Secretary of HHS has declared that circumstances exist justifying the authorization of emergency use. Products appropriate for emergency use may include products and uses that are not approved, cleared, or licensed under sections 505, 510(k), or 515 of the FD&C Act (21 U.S.C. 355, 360(k), and 360(e) or section 351 of the PHS Act (42 U.S.C. 262). FDA may issue an EUA only if, after consultation with the HHS Assistant Secretary for Preparedness and Response, the Director of the National Institutes of Health, and the Director of the Centers for Disease Control and Prevention (to the extent feasible and appropriate given the applicable circumstances), FDA [1] concludes: (1) That an agent referred to in a declaration of emergency or threat can cause a serious or life-threatening disease or condition; (2) that, based on the totality of scientific evidence available to FDA, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that: (A) The product may be effective in diagnosing, treating, or preventing (i) such disease or condition; or (ii) a serious or life-threatening disease or condition caused by a product authorized under section 564, approved or cleared under the FD&C Act, or licensed under section 351 of the PHS Act, for diagnosing, treating, or preventing such a disease or condition caused by such an agent; and (B) the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product, taking into consideration the material threat posed by the agent or agents identified in a declaration under section 564(b)(1)(D) of the FD&C Act, if applicable; (3) that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition; and (4) that such other criteria as may be prescribed by regulation are satisfied.

No other criteria for issuance have been prescribed by regulation under section 564(c)(4) of the FD&C Act. Because the statute is self-executing, regulations or guidance are not required for FDA to implement the EUA authority.

## II. EUA Requests for In Vitro Diagnostic Devices for Detection of the Zika Virus

On February 26, 2016, the Secretary of HHS determined that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad and that involves Zika virus. On February 26, 2016, under section 564(b)(1) of the FD&C Act, and on the basis of such determination, the Secretary of HHS declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection, subject to the terms of any authorization issued under section 564 of the FD&C Act. Notice of the determination and declaration of the Secretary was published in the **Federal Register** on March 2, 2016 (81 FR 10878). On June 5, 2017, Thermo Fisher Scientific requested, and on August 2, 2017, FDA issued, an EUA for the TaqPath Zika Virus Kit (ZIKV), subject to the terms of the Authorization. On July 31, 2017, The Center for Infection and Immunity, Columbia University requested, and on August 11, 2017, FDA issued, an EUA for the CII-ArboViroPlex rRT-PCR assay, subject to the terms of the Authorization.

## III. Electronic Access

An electronic version of this document and the full text of the Authorizations are available on the internet at *https://www.regulations.gov*.

## IV. The Authorizations

Having concluded that the criteria for issuance of the Authorizations under section 564(c) of the FD&C Act are met, FDA has authorized the emergency use of two in vitro diagnostic devices for detection of Zika virus subject to the terms of the Authorizations. The Authorizations in their entirety (not including the authorized versions of the fact sheets and other written materials) follows and provides an explanation of the reasons for issuance, as required by section 564(h)(1) of the FD&C Act.

BILLING CODE 4164–01–P

[1] The Secretary of HHS has delegated the authority to issue an EUA under section 564 of the FD&C Act to the Commissioner of Food and Drugs.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

August 2, 2017

Faith Du
Regulatory Analyst
Thermo Fisher Scientific
6055 Sunol Blvd.
Pleasanton, CA 94566

Dear Ms. Du:

This letter is in response to your request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of Thermo Fisher Scientific's ("Thermo Fisher") TaqPath Zika Virus Kit (ZIKV) for the qualitative detection of RNA from Zika virus in human serum and urine (collected alongside a patient-matched serum specimen) from individuals meeting Centers for Disease Control and Prevention (CDC) Zika virus clinical criteria (e.g., clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active Zika transmission at the time of travel, or other epidemiological criteria for which Zika virus testing may be indicated), by laboratories in the United States (U.S.) that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests, or by similarly qualified non-U.S. laboratories, pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 360bbb-3).[1] Test results are for the identification of Zika virus RNA. Zika virus RNA is generally detectable in serum during the acute phase of infection and, according to the updated CDC Guidance for U.S. Laboratories Testing for Zika Virus Infection,[2] up to 14 days in serum and urine (possibly longer in urine), following onset of symptoms, if present. Positive results are indicative of current infection.

On February 26, 2016, pursuant to section 564(b)(1)(C) of the Act (21 U.S.C. § 360bbb-3(b)(1)(C)), the Secretary of Health and Human Services (HHS) determined that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad and that involves Zika virus.[3] Pursuant to section 564(b)(1) of the Act (21 U.S.C. § 360bbb-3(b)(1)), and on the basis

[1] For ease of reference, this letter will refer to "laboratories in the United States (U.S.) that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests, or...similarly qualified non-U.S. laboratories" as "authorized laboratories."
[2] Available at http://www.cdc.gov/zika/laboratories/lab-guidance.html (last updated on July 24, 2017).
[3] As amended by the Pandemic and All-Hazards Preparedness Reauthorization Act, Pub. L. No. 113-5, under section

of such determination, the Secretary of HHS then declared that circumstances exist justifying the authorization of the emergency use of *in vitro* diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection, subject to the terms of any authorization issued under 21 U.S.C. § 360bbb-3(a).[4]

Having concluded that the criteria for issuance of this authorization under section 564(c) of the Act (21 U.S.C. § 360bbb-3(c)) are met, I am authorizing the emergency use of the TaqPath Zika Virus Kit (ZIKV) (as described in the Scope of Authorization section of this letter (Section II)) in individuals meeting CDC Zika virus clinical criteria (e.g., clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active Zika transmission at the time of travel, or other epidemiological criteria for which Zika virus testing may be indicated) (as described in the Scope of Authorization section of this letter (Section II)) for the detection of Zika virus infection by authorized laboratories, subject to the terms of this authorization.

**I. Criteria for Issuance of Authorization**

I have concluded that the emergency use of the TaqPath Zika Virus Kit (ZIKV) for the detection of Zika virus and diagnosis of Zika virus infection in the specified population meets the criteria for issuance of an authorization under section 564(c) of the Act, because I have concluded that:

1. The Zika virus can cause Zika virus infection, a serious or life-threatening disease or condition to humans infected with the virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the TaqPath Zika Virus Kit (ZIKV), when used with the specified instrument(s) and in accordance with the Scope of Authorization, may be effective in detecting Zika virus and diagnosing Zika virus infection, and that the known and potential benefits of the TaqPath Zika Virus Kit (ZIKV) for detecting Zika virus and diagnosing Zika virus infection outweigh the known and potential risks of such product; and

3. There is no adequate, approved, and available alternative to the emergency use of the TaqPath Zika Virus Kit (ZIKV) for detecting Zika virus and diagnosing Zika virus infection.[5]

**II. Scope of Authorization**

I have concluded, pursuant to section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of the authorized TaqPath Zika Virus Kit (ZIKV) by authorized laboratories for the detection of RNA from Zika virus and diagnosis of Zika virus infection in individuals

564(b)(1)(C) of the Act, the Secretary may make a determination of a public health emergency, or of a significant potential for a public health emergency.

[4] HHS. *Determination and Declaration Regarding Emergency Use of in Vitro Diagnostic Tests for Detection of Zika Virus and/or Diagnosis of Zika Virus Infection*. 81 Fed. Reg. 10878 (March 2, 2016).

[5] No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.

meeting CDC Zika virus clinical criteria (e.g., clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active Zika transmission at the time of travel, or other epidemiological criteria for which Zika virus testing may be indicated).

**The Authorized TaqPath Zika Virus Kit (ZIKV)**

The TaqPath Zika Virus Kit (ZIKV) is a lyophilized real-time reverse transcription polymerase chain reaction (rRT-PCR) assay for the qualitative detection of RNA from Zika virus in human serum, urine (collected alongside a patient-matched serum specimen), and other authorized specimen types.

To perform the TaqPath Zika Virus Kit (ZIKV), the RNA is first extracted and purified from the patient specimen. The RNA is then reverse transcribed into cDNA which is amplified using the primer set and detected using the specific probe. The rRT-PCR is performed on the Applied Biosystems QuantStudio Dx Real-time PCR instrument, or other authorized instruments.

The TaqPath Zika Virus Kit (ZIKV) includes the following materials or other authorized materials: Twelve (12) lyophilized strip tubes with each strip comprised of eight (8) assay tubes containing lyophilized one-step RT- PCR reagents: primers, probes, reverse transcription and amplification reagents, reverse transcriptase and Human Peptidylprolyl Isomerase A (PPIA) endogenous control. The kit also contains twelve (12) flat cap strips for sealing the assay tubes following sample addition, and a desiccant pouch to adsorb moisture. The TaqPath Zika Virus Kit (ZIKV) also requires the use of additional materials and ancillary reagents that are not included with the test but are commonly used in clinical laboratories and are described in the authorized TaqPath Zika Virus Kit (ZIKV) Instructions for Use.

The TaqPath Zika Virus Kit (ZIKV) requires the following control materials, or other authorized control materials; all controls listed below must generate expected results in order for a test to be considered valid, as outlined in the TaqPath Zika Virus Kit (ZIKV) Instructions for Use:

- Zika Virus Positive Control: Live or inactivated Zika virus – run with each batch of patient specimens. Monitors for failures of in nucleic acid extraction and isolation, rRT-PCR reagents and reaction conditions.
- Negative Control: DNase and RNase-free water – run with each batch of patient specimens. Monitors for reagent and system contamination.
- Endogenous Internal Control: All clinical samples are tested for the Human Peptidylprolyl Isomerase A (PPIA) gene (using the PPIA primer and probe set included in the TaqPath Zika Virus Kit (ZIKV)) to control for specimen quality and as an indicator that nucleic acid resulted from the extraction process.

The above described TaqPath Zika Virus Kit (ZIKV), when labeled consistently with the labeling authorized by FDA entitled "TaqPath Zika Virus Kit (ZIKV) Instructions for Use" (available at http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm), which may be revised by Thermo Fisher in consultation with, and with concurrence of, the Division of Microbiology Devices (DMD)/Office of In Vitro Diagnostics and Radiological Health (OIR)/Center for Devices and Radiological Health (CDRH), is authorized to be

distributed to and used by authorized laboratories under this EUA, despite the fact that it does not meet certain requirements otherwise required by federal law.

The above described TaqPath Zika Virus Kit (ZIKV) is authorized to be accompanied by the following information pertaining to the emergency use, which is authorized to be made available to healthcare providers and patients, including pregnant women:

- Fact Sheet for Healthcare Providers: Interpreting TaqPath Zika Virus Kit (ZIKV) Test Results
- Fact Sheet for Patients: Understanding Results from the TaqPath Zika Virus Kit (ZIKV)

As described in Section IV below, Thermo Fisher and its authorized distributors are also authorized to make available additional information relating to the emergency use of the authorized TaqPath Zika Virus Kit (ZIKV) that is consistent with, and does not exceed, the terms of this letter of authorization.

I have concluded, pursuant to section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of the authorized TaqPath Zika Virus Kit (ZIKV) in the specified population, when used for detection of Zika virus and to diagnose Zika virus infection and used consistently with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of such a product.

I have concluded, pursuant to section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that the authorized TaqPath Zika Virus Kit (ZIKV) may be effective in the detection of Zika virus and diagnosis of Zika virus infection, when used consistently with the Scope of Authorization of this letter (Section II), pursuant to section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, and concludes that the authorized TaqPath Zika Virus Kit (ZIKV), when used for detection of Zika virus and to diagnose Zika virus infection in the specified population (as described in the Scope of Authorization of this letter (Section II)), meets the criteria set forth in section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of the authorized TaqPath Zika Virus Kit (ZIKV) under this EUA must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination described above and the Secretary of HHS's corresponding declaration under section 564(b)(1), the TaqPath Zika Virus Kit (ZIKV) described above is authorized to detect Zika virus and diagnose Zika virus infection in individuals meeting CDC Zika virus clinical criteria (e.g., clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active Zika virus transmissions at the time of travel, or other epidemiological criteria for which Zika virus testing may be indicated).

This EUA will cease to be effective when the HHS declaration that circumstances exist to justify the EUA is terminated under section 564(b)(2) of the Act or when the EUA is revoked under section 564(g) of the Act.

**III. Waiver of Certain Requirements**

I am waiving the following requirements for the TaqPath Zika Virus Kit (ZIKV) during the duration of this EUA:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of the TaqPath Zika Virus Kit (ZIKV).

- Labeling requirements for cleared, approved, or investigational devices, including labeling requirements under 21 CFR 809.10 and 21 CFR 809.30, except for the intended use statement (21 CFR 809.10(a)(2), (b)(2)), adequate directions for use (21 U.S.C. 352(f)), (21 CFR 809.10(b)(5), (7), and (8)), any appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4), and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

**IV. Conditions of Authorization**

Pursuant to section 564 of the Act, I am establishing the following conditions on this authorization:

**Thermo Fisher and Its Authorized Distributor(s)**

A. Thermo Fisher and its authorized distributor(s) will distribute the authorized TaqPath Zika Virus Kit (ZIKV) with the authorized labeling only to authorized laboratories. Changes to the authorized labeling may be made by Thermo Fisher in consultation with, and require concurrence of, DMD/OIR/CDRH.

B. Thermo Fisher and its authorized distributor(s) will provide to authorized laboratories the authorized TaqPath Zika Virus Kit (ZIKV) Fact Sheet for Healthcare Providers and the authorized TaqPath Zika Virus Kit (ZIKV) Fact Sheet for Patients.

C. Thermo Fisher and its authorized distributor(s) will make available on their websites the authorized TaqPath Zika Virus Kit (ZIKV) Fact Sheet for Healthcare Providers and the authorized TaqPath Zika Virus Kit (ZIKV) Fact Sheet for Patients.

D. Thermo Fisher and its authorized distributor(s) will inform authorized laboratories and relevant public health authority(ies) of this EUA, including the terms and conditions herein.

E. Thermo Fisher and its authorized distributor(s) will ensure that the authorized

laboratories using the authorized TaqPath Zika Virus Kit (ZIKV) have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.[6]

F. Through a process of inventory control, Thermo Fisher and its authorized distributor(s) will maintain records of device usage.

G. Thermo Fisher and its authorized distributor(s) will collect information on the performance of the test. Thermo Fisher will report to FDA any suspected occurrence of false positive and false negative results and significant deviations from the established performance characteristics of the test of which Thermo Fisher becomes aware.

H. Thermo Fisher and its authorized distributor(s) are authorized to make available additional information relating to the emergency use of the authorized TaqPath Zika Virus Kit (ZIKV) that is consistent with, and does not exceed, the terms of this letter of authorization.

**Thermo Fisher**

I. Thermo Fisher will notify FDA of any authorized distributor(s) of the TaqPath Zika Virus Kit (ZIKV), including the name, address, and phone number of any authorized distributor(s).

J. Thermo Fisher will provide its authorized distributor(s) with a copy of this EUA, and communicate to its authorized distributor(s) any subsequent amendments that might be made to this EUA and its authorized accompanying materials (e.g., Fact Sheets, Instructions for Use).

K. Thermo Fisher may request changes to the authorized TaqPath Zika Virus Kit (ZIKV) Fact Sheet for Healthcare Providers and the authorized TaqPath Zika Virus Kit (ZIKV) Fact Sheet for Patients. Such requests will be made by Thermo Fisher in consultation with, and require concurrence of, DMD/OIR/CDRH.

L. Thermo Fisher may request the addition of other instruments for use with the authorized TaqPath Zika Virus Kit (ZIKV). Such requests will be made by Thermo Fisher in consultation with, and require concurrence of, DMD/OIR/CDRH.

M. Thermo Fisher may request the addition of other extraction methods for use with the authorized TaqPath Zika Virus Kit (ZIKV). Such requests will be made by Thermo Fisher in consultation with, and require concurrence of, DMD/OIR/CDRH.

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[6] For questions related to reporting Zika test results to relevant public health authorities, it is recommended that Thermo Fisher, other authorized distributor(s), and authorized laboratories consult with the applicable country, state or territory health department(s). According to CDC, Zika virus disease is a nationally notifiable condition (see http://www.cdc.gov/zika/).

N. Thermo Fisher may request the addition of other specimen types for use with the authorized TaqPath Zika Virus Kit (ZIKV). Such requests will be made by Thermo Fisher in consultation with, and require concurrence of, DMD/OIR/CDRH.

O. Thermo Fisher may request the addition and/or substitution of other control materials for use with the authorized TaqPath Zika Virus Kit (ZIKV). Such requests will be made by Thermo Fisher in consultation with, and require concurrence of, DMD/OIR/CDRH.

P. Thermo Fisher may request the addition and/or substitution of other ancillary reagents and materials for use with the authorized TaqPath Zika Virus Kit (ZIKV). Such requests will be made by Thermo Fisher in consultation with, and require concurrence of, DMD/OIR/CDRH.

Q. Thermo Fisher will assess traceability[7] of the TaqPath Zika Virus Kit (ZIKV) with FDA-recommended reference material(s). After submission to FDA and DMD/OIR/CDRH's review of and concurrence with the data, Thermo Fisher will update its labeling to reflect the additional testing.

R. Thermo Fisher will track adverse events and report to FDA under 21 CFR Part 803.

**Authorized Laboratories**

S. Authorized laboratories will include with reports of the results of the TaqPath Zika Virus Kit (ZIKV) the authorized Fact Sheet for Healthcare Providers and the authorized Fact Sheet for Patients. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.

T. Authorized laboratories will perform the TaqPath Zika Virus Kit (ZIKV) using the KingFisher Flex Purification System (KingFisher) and MagMAX Pathogen RNA/DNA Kit or with other authorized extraction methods.

U. Authorized laboratories will perform the TaqPath Zika Virus Kit (ZIKV) on the Applied Biosystems QuantStudio Dx Real-time PCR instrument, or other authorized instruments.

V. Authorized laboratories will perform the TaqPath Zika Virus Kit (ZIKV) on human serum, or urine (collected with a patient-matched serum specimen), or other authorized specimen types.

W. Authorized laboratories will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.[8]

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[7] Traceability refers to tracing analytical sensitivity/reactivity back to a FDA-recommended reference material.

[8] For questions related to reporting Zika test results to relevant public health authorities, it is recommended that Thermo Fisher, other authorized distributor(s), and authorized laboratories consult with the applicable country, state or territory health department(s). According to CDC, Zika virus disease is a nationally notifiable condition. http://www.cdc.gov/zika/.

X. Authorized laboratories will collect information on the performance of the test and report to DMD/OIR/CDRH (*via* email CDRH-EUA-Reporting@fda.hhs.gov) and Thermo Fisher any suspected occurrence of false positive or false negative results of which they become aware.

Y. All laboratory personnel using the test should be appropriately trained in RT-PCR techniques and use appropriate laboratory and personal protective equipment when handling this kit, and use the test in accordance with the authorized labeling.

**Thermo Fisher, Its Authorized Distributor(s) and Authorized Laboratories**

Z. Thermo Fisher, its authorized distributor(s), and authorized laboratories will ensure that any records associated with this EUA are maintained until notified by FDA. Such records will be made available to FDA for inspection upon request.

**Conditions Related to Advertising and Promotion**

AA. All advertising and promotional descriptive printed matter relating to the use of the authorized TaqPath Zika Virus Kit (ZIKV) shall be consistent with the Fact Sheets and authorized labeling, as well as the terms set forth in this EUA and the applicable requirements set forth in the Act and FDA regulations.

BB. All advertising and promotional descriptive printed matter relating to the use of the authorized TaqPath Zika Virus Kit (ZIKV) shall clearly and conspicuously state that:

- This test has not been FDA cleared or approved;
- This test has been authorized by FDA under an EUA for use by authorized laboratories;
- This test has been authorized only for the detection of RNA from Zika virus and diagnosis of Zika virus infection, not for any other viruses or pathogens; and
- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of *in vitro* diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

No advertising or promotional descriptive printed matter relating to the use of the authorized TaqPath Zika Virus Kit (ZIKV) may represent or suggest that this test is safe or effective for the diagnosis of Zika virus infection.

The emergency use of the authorized TaqPath Zika Virus Kit (ZIKV) as described in this letter of authorization must comply with the conditions and all other terms of this authorization.

**V. Duration of Authorization**

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of *in vitro* diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Sincerely,

Scott Gottlieb, M.D.
Commissioner of Food and Drugs

Enclosures

U.S. FOOD & DRUG ADMINISTRATION

August 11, 2017

W. Ian Lipkin, MD
Director
The Center for Infection and Immunity
Columbia University
722 West 168th St., 17th Floor
New York, NY 10032

Dear Dr. Lipkin:

This letter is in response to your request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of The Center for Infection and Immunity, Columbia University's ("Columbia University") CII-ArboViroPlex rRT-PCR assay for the qualitative detection and differentiation of RNA from Zika virus, dengue virus, chikungunya virus, and West Nile virus in serum, and for the qualitative detection of Zika virus RNA in urine (collected alongside a patient-matched serum specimen). The assay is intended for use with specimens collected from individuals meeting Centers for Disease Control and Prevention (CDC) Zika virus clinical criteria (e.g., clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active Zika transmission at the time of travel, or other epidemiological criteria for which Zika virus testing may be indicated), by laboratories in the United States (U.S.) that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests, or by similarly qualified non-U.S. laboratories, pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 360bbb-3).[1] Assay results are for the identification of Zika, dengue, chikungunya, and West Nile viral RNA. Viral RNA is generally detectable in serum during the acute phase of infection and, according to the updated CDC Guidance for U.S. Laboratories Testing for Zika Virus Infection,[2] up to 14 days in serum and urine (possibly longer in urine), following onset of symptoms, if present. Positive results are indicative of current infection.

On February 26, 2016, pursuant to section 564(b)(1)(C) of the Act (21 U.S.C. § 360bbb-3(b)(1)(C)), the Secretary of Health and Human Services (HHS) determined that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad and that involves Zika virus.[3] Pursuant to section 564(b)(1) of the Act (21 U.S.C. § 360bbb-3(b)(1)), and on the basis

[1] For ease of reference, this letter will refer to "laboratories in the United States (U.S.) that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests, or…similarly qualified non-U.S. laboratories" as "authorized laboratories."
[2] Available at http://www.cdc.gov/zika/laboratories/lab-guidance.html (last updated on July 24, 2017).
[3] As amended by the Pandemic and All Hazards Preparedness Reauthorization Act, Pub. L. No. 113-5, under section

of such determination, the Secretary of HHS then declared that circumstances exist justifying the authorization of the emergency use of *in vitro* diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection, subject to the terms of any authorization issued under 21 U.S.C. § 360bbb-3(a).[4]

Having concluded that the criteria for issuance of this authorization under section 564(c) of the Act (21 U.S.C. § 360bbb-3(c)) are met, I am authorizing the emergency use of the CII-ArboViroPlex rRT-PCR assay (as described in the Scope of Authorization section of this letter (Section II)) in individuals meeting CDC Zika virus clinical criteria (e.g., clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active Zika transmission at the time of travel, or other epidemiological criteria for which Zika virus testing may be indicated) (as described in the Scope of Authorization section of this letter (Section II)) for the detection of Zika virus infection by authorized laboratories, subject to the terms of this authorization.

**I. Criteria for Issuance of Authorization**

I have concluded that the emergency use of the CII-ArboViroPlex rRT-PCR assay for the detection of Zika virus and diagnosis of Zika virus infection in the specified population meets the criteria for issuance of an authorization under section 564(c) of the Act, because I have concluded that:

1. The Zika virus can cause Zika virus infection, a serious or life-threatening disease or condition to humans infected with the virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the CII-ArboViroPlex rRT-PCR assay, when used with the specified instrument(s) and in accordance with the Scope of Authorization, may be effective in detecting Zika virus and diagnosing Zika virus infection, and that the known and potential benefits of the CII-ArboViroPlex rRT-PCR assay for detecting Zika virus and diagnosing Zika virus infection outweigh the known and potential risks of such product; and

3. There is no adequate, approved, and available alternative to the emergency use of the CII-ArboViroPlex rRT-PCR assay for detecting Zika virus and diagnosing Zika virus infection.[5]

**II. Scope of Authorization**

I have concluded, pursuant to section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of the authorized CII-ArboViroPlex rRT-PCR assay by authorized laboratories for the qualitative detection and differentiation of RNA from Zika virus, dengue virus,

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564(b)(1)(C) of the Act, the Secretary may make a determination of a public health emergency, or of a significant potential for a public health emergency.

[4] HHS. *Determination and Declaration Regarding Emergency Use of in Vitro Diagnostic Tests for Detection of Zika Virus and/or Diagnosis of Zika Virus Infection*. 81 Fed. Reg. 10878 (March 2, 2016).

[5] No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.

chikungunya virus, and West Nile virus in serum, and for the qualitative detection of Zika virus RNA in urine (collected alongside a patient-matched serum specimen) in individuals meeting CDC Zika virus clinical criteria (e.g., clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active Zika transmission at the time of travel, or other epidemiological criteria for which Zika virus testing may be indicated).

**The Authorized CII-ArboViroPlex rRT-PCR assay**

The CII-ArboViroPlex rRT-PCR assay is a multiplex one-step real-time reverse transcription polymerase chain reaction (rRT-PCR) assay for the qualitative detection and differentiation of RNA from Zika virus, dengue virus, chikungunya virus, and West Nile virus in serum, and other authorized specimen types. The CII-ArboViroPlex rRT-PCR assay can also be used for the qualitative detection of Zika virus RNA in urine when collected alongside a patient-matched serum specimen and other authorized whole blood derived specimen types.

To perform the CII-ArboViroPlex rRT-PCR assay, the RNA is first extracted and purified from the patient specimen. The RNA is then reverse transcribed into cDNA which is amplified using the primer set and detected using the specific probe. The rRT-PCR is performed on the CFX96 Real-Time PCR Detection System (Bio-Rad), or other authorized instruments.

The CII-ArboViroPlex rRT-PCR assay includes the following materials or other authorized materials:

- ZIKV-MIX, DENV-MIX, CHIKV-MIX, WNV-MIX and RP-MIX vials containing primers and probes for the assay targets and internal control
- ZPC, DPC, CP, WPC, HSC, eHSC, NTC vials containing the positive and negative controls used in the assay
- Diluent vial used to reconstitute dried vials

The CII-ArboViroPlex rRT-PCR assay also requires the use of additional materials and ancillary reagents that are not included with the test but are commonly used in clinical laboratories and are described in the authorized CII-ArboViroPlex rRT-PCR assay Instructions for Use.

The CII-ArboViroPlex rRT-PCR assay requires the following control materials, or other authorized control materials; all controls listed below must generate expected results in order for a test to be considered valid, as outlined in the CII-ArboViroPlex rRT-PCR assay Instructions for Use:

- Human Specimen Control: A human cell culture preparation used as an extraction control and positive control for the RNase P primer and probe set that is extracted and tested concurrently with the test specimens.
- Extracted Human Specimen Control (eHSC): Extracted total nucleic acid from a human cell culture preparation known to contain RNase P (eHSC), but negative for viral targets, is used as a control for performance of RNase P primer/probe set and PCR reagent function.
- Positive Controls for viruses: Run with each batch of patient specimens. Monitors for failures of rRT-PCR reagents and reaction conditions.
    - ZIKV Positive Control (ZPC), synthetic *in vitro* transcribed RNA

  - DENV Positive Control (DPC), synthetic *in vitro* transcribed RNA
  - CHIKV Positive Control (CPC), synthetic *in vitro* transcribed RNA
  - WNV Positive Control (WPC), synthetic *in vitro* transcribed RNA
- No Template Control (NTC): Sterile, nuclease-free water—two NTC run with each PCR plate. Monitors for reagent and system contamination.
- RNase P control in clinical samples: All clinical samples and HSC are tested for human RNase P, using the RP primer and probe set, to control for specimen quality and as an indicator that nucleic acid resulted from the extraction process.

The above described CII-ArboViroPlex rRT-PCR assay, when labeled consistently with the labeling authorized by FDA entitled "CII-ArboViroPlex rRT-PCR assay Instructions for Use" (available at http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm), which may be revised by Columbia University in consultation with, and with concurrence of, the Division of Microbiology Devices (DMD)/Office of In Vitro Diagnostics and Radiological Health (OIR)/Center for Devices and Radiological Health (CDRH), is authorized to be distributed to and used by authorized laboratories under this EUA, despite the fact that it does not meet certain requirements otherwise required by federal law.

The above described CII-ArboViroPlex rRT-PCR assay is authorized to be accompanied by the following information pertaining to the emergency use, which is authorized to be made available to healthcare providers and patients, including pregnant women:

- Fact Sheet for Healthcare Providers: Interpreting CII-ArboViroPlex rRT-PCR Assay Test Results
- Fact Sheet for Patients: Understanding Results from the CII-ArboViroPlex rRT-PCR Assay

As described in Section IV below, Columbia University and its authorized distributors are also authorized to make available additional information relating to the emergency use of the authorized CII-ArboViroPlex rRT-PCR assay that is consistent with, and does not exceed, the terms of this letter of authorization.

I have concluded, pursuant to section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of the authorized CII-ArboViroPlex rRT-PCR assay in the specified population, when used for detection of Zika virus and to diagnose Zika virus infection and used consistently with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of such a product.

I have concluded, pursuant to section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that the authorized CII-ArboViroPlex rRT-PCR assay may be effective in the detection of Zika virus and diagnosis of Zika virus infection, when used consistently with the Scope of Authorization of this letter (Section II), pursuant to section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, and concludes that the authorized CII-

ArboViroPlex rRT-PCR assay, when used for detection of Zika virus and to diagnose Zika virus infection in the specified population (as described in the Scope of Authorization of this letter (Section II)), meets the criteria set forth in section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of the authorized CII-ArboViroPlex rRT-PCR assay under this EUA must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination described above and the Secretary of HHS's corresponding declaration under section 564(b)(1), the CII-ArboViroPlex rRT-PCR assay described above is authorized to detect Zika virus and diagnose Zika virus infection in individuals meeting CDC Zika virus clinical criteria (e.g., clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active Zika virus transmissions at the time of travel, or other epidemiological criteria for which Zika virus testing may be indicated).

This EUA will cease to be effective when the HHS declaration that circumstances exist to justify the EUA is terminated under section 564(b)(2) of the Act or when the EUA is revoked under section 564(g) of the Act.

**III. Waiver of Certain Requirements**

I am waiving the following requirements for the CII-ArboViroPlex rRT-PCR assay during the duration of this EUA:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of the CII-ArboViroPlex rRT-PCR assay.

- Labeling requirements for cleared, approved, or investigational devices, including labeling requirements under 21 CFR 809.10 and 21 CFR 809.30, except for the intended use statement (21 CFR 809.10(a)(2), (b)(2)); adequate directions for use (21 U.S.C. 352(f)), (21 CFR 809.10(b)(5), (7), and (8)); any appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4); and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

**IV. Conditions of Authorization**

Pursuant to section 564 of the Act, I am establishing the following conditions on this authorization:

**Columbia University and Its Authorized Distributor(s)**

A. Columbia University and its authorized distributor(s) will distribute the authorized CII-ArboViroPlex rRT-PCR assay with the authorized labeling only to authorized laboratories. Changes to the authorized labeling may be made by Columbia University in consultation with, and require concurrence of, DMD/OIR/CDRH.

B. Columbia University and its authorized distributor(s) will provide to authorized laboratories the authorized CII-ArboViroPlex rRT-PCR assay Fact Sheet for Healthcare Providers and the authorized CII-ArboViroPlex rRT-PCR assay Fact Sheet for Patients.

C. Columbia University and its authorized distributor(s) will make available on their websites the authorized CII-ArboViroPlex rRT-PCR assay Fact Sheet for Healthcare Providers and the authorized CII-ArboViroPlex rRT-PCR assay Fact Sheet for Patients.

D. Columbia University and its authorized distributor(s) will inform authorized laboratories and relevant public health authority(ies) of this EUA, including the terms and conditions herein.

E. Columbia University and its authorized distributor(s) will ensure that the authorized laboratories using the authorized CII-ArboViroPlex rRT-PCR assay have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.[6]

F. Through a process of inventory control, Columbia University and its authorized distributor(s) will maintain records of device usage.

G. Columbia University and its authorized distributor(s) will collect information on the performance of the test. Columbia University will report to FDA any suspected occurrence of false positive and false negative results and significant deviations from the established performance characteristics of the test of which Columbia University becomes aware.

H. Columbia University and its authorized distributor(s) are authorized to make available additional information relating to the emergency use of the authorized CII-ArboViroPlex rRT-PCR assay that is consistent with, and does not exceed, the terms of this letter of authorization.

**Columbia University**

I. Columbia University will notify FDA of any authorized distributor(s) of the CII-

[6] For questions related to reporting Zika test results to relevant public health authorities, it is recommended that Columbia University, other authorized distributor(s), and authorized laboratories consult with the applicable country, state, or territory health department(s). According to CDC, Zika virus disease is a nationally notifiable condition (see http://www.cdc.gov/zika/).

ArboViroPlex rRT-PCR assay, including the name, address, and phone number of any authorized distributor(s).

J. Columbia University will provide its authorized distributor(s) with a copy of this EUA, and communicate to its authorized distributor(s) any subsequent amendments that might be made to this EUA and its authorized accompanying materials (e.g., Fact Sheets, Instructions for Use).

K. Columbia University may request changes to the authorized CII-ArboViroPlex rRT-PCR assay Fact Sheet for Healthcare Providers and the authorized CII-ArboViroPlex rRT-PCR assay Fact Sheet for Patients. Such requests will be made by Columbia University in consultation with, and require concurrence of, DMD/OIR/CDRH.

L. Columbia University may request the addition of other instruments for use with the authorized CII-ArboViroPlex rRT-PCR assay. Such requests will be made by Columbia University in consultation with, and require concurrence of, DMD/OIR/CDRH.

M. Columbia University may request the addition of other extraction methods for use with the authorized CII-ArboViroPlex rRT-PCR assay. Such requests will be made by Columbia University in consultation with, and require concurrence of, DMD/OIR/CDRH.

N. Columbia University may request the addition of other specimen types for use with the authorized CII-ArboViroPlex rRT-PCR assay. Such requests will be made by Columbia University in consultation with, and require concurrence of, DMD/OIR/CDRH.

O. Columbia University may request the addition and/or substitution of other control materials for use with the authorized CII-ArboViroPlex rRT-PCR assay. Such requests will be made by Columbia University in consultation with, and require concurrence of, DMD/OIR/CDRH.

P. Columbia University may request the addition and/or substitution of other ancillary reagents and materials for use with the authorized CII-ArboViroPlex rRT-PCR assay. Such requests will be made by Columbia University in consultation with, and require concurrence of, DMD/OIR/CDRH.

Q. Columbia University will assess traceability[7] of the CII-ArboViroPlex rRT-PCR assay with FDA-recommended reference material(s). After submission to FDA and DMD/OIR/CDRH's review of and concurrence with the data, Columbia University will update its labeling to reflect the additional testing.

R. Columbia University will track adverse events and report to FDA under 21 CFR Part 803.

**Authorized Laboratories**

[7] *Traceability* refers to tracing analytical sensitivity/reactivity back to a FDA-recommended reference material.

S. Authorized laboratories will include with reports of the results of the CII-ArboViroPlex rRT-PCR assay the authorized Fact Sheet for Healthcare Providers and the authorized Fact Sheet for Patients. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.

T. Authorized laboratories will perform the CII-ArboViroPlex rRT-PCR assay using the NucliSENS easyMAG automated extraction platform (bioMérieux) or with other authorized extraction methods.

U. Authorized laboratories will perform the CII-ArboViroPlex rRT-PCR assay on the CFX96 Real-Time PCR Detection System (Bio-Rad), or other authorized instruments.

V. Authorized laboratories will perform the CII-ArboViroPlex rRT-PCR assay for Zika virus, dengue virus, chikungunya virus, and West Nile virus on human serum or other authorized specimen types.

W. Authorized laboratories will perform the CII-ArboViroPlex rRT-PCR assay for Zika virus on human urine when collected alongside a patient-matched serum specimen and other authorized whole blood derived specimen types.

X. Authorized laboratories will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.[8]

Y. Authorized laboratories will collect information on the performance of the test and report to DMD/OIR/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and Columbia University any suspected occurrence of false positive or false negative results of which they become aware.

Z. All laboratory personnel using the test should be appropriately trained in RT-PCR techniques and use appropriate laboratory and personal protective equipment when handling this kit, and use the test in accordance with the authorized labeling.

**Columbia University, Its Authorized Distributor(s), and Authorized Laboratories**

AA. Columbia University, its authorized distributor(s), and authorized laboratories, will ensure that any records associated with this EUA are maintained until notified by FDA. Such records will be made available to FDA for inspection upon request.

**Conditions Related to Advertising and Promotion**

BB. All advertising and promotional descriptive printed matter relating to the use of the

[8] For questions related to reporting Zika test results to relevant public health authorities, it is recommended that Columbia University, other authorized distributor(s), and authorized laboratories consult with the applicable country, state, or territory health department(s). According to CDC, Zika virus disease is a nationally notifiable condition (http://www.cdc.gov/zika/).

authorized CII-ArboViroPlex rRT-PCR assay shall be consistent with the Fact Sheets and authorized labeling, as well as the terms set forth in this EUA and the applicable requirements set forth in the Act and FDA regulations.

CC. All advertising and promotional descriptive printed matter relating to the use of the authorized CII-ArboViroPlex rRT-PCR assay shall clearly and conspicuously state that:

- This test has not been FDA cleared or approved;
- This test has been authorized by FDA under an EUA for use by authorized laboratories;
- This test has been authorized only for the detection and differentiation of RNA from Zika virus, dengue virus, chikungunya virus, and West Nile virus, not for any other viruses or pathogens; and
- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of *in vitro* diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

No advertising or promotional descriptive printed matter relating to the use of the authorized CII-ArboViroPlex rRT-PCR assay may represent or suggest that this test is safe or effective for the diagnosis of Zika virus infection.

The emergency use of the authorized CII-ArboViroPlex rRT-PCR assay as described in this letter of authorization must comply with the conditions and all other terms of this authorization.

**V. Duration of Authorization**

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of *in vitro* diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Sincerely,

Scott Gottlieb, M.D.
Commissioner of Food and Drugs

Enclosures

Dated: October 20, 2017.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2017–23224 Filed 10–25–17; 8:45 am]

**BILLING CODE 4164–01–C**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2017–N–5818]**

### Pharmacy Compounding Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; establishment of a public docket; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Pharmacy Compounding Advisory Committee (PCAC). The general function of the committee is to provide advice on scientific, technical, and medical issues concerning drug compounding under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), and, as required, any other product for which FDA has regulatory responsibility, and to make appropriate recommendations to the Agency. The meeting will be open to the public.

**DATES:** The meeting will be held on November 20, 2017, from 8:30 a.m. to 5 p.m. and November 21, 2017, from 8:30 a.m. to 11:30 a.m.

**ADDRESSES:** FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Answers to commonly asked questions, including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2017–N–5818. The docket will close on November 17, 2017. Submit either electronic or written comments on this public meeting by November 17, 2017. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before November 17, 2017. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of November 17, 2017. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Comments received on or before November 3, 2017, will be provided to the committee. Comments received after that date will be taken into consideration by the Agency.

You may submit comments as follows:

*Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

*Written/Paper Submissions*

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

*Instructions:* All submissions received must include the Docket No. FDA–2017–N–5818 for ''Pharmacy Compounding Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Cindy Chee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, Fax: 301–847–8533, email: *PCAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting

cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

**SUPPLEMENTARY INFORMATION:**

*Background:* Section 503A of the FD&C Act (21 U.S.C. 353a) describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist in a State licensed pharmacy or a Federal facility, or a licensed physician, to be exempt from the following three sections of the FD&C Act: (1) Section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B)) (concerning current good manufacturing practice (CGMP)); (2) section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use); and (3) section 505 (21 U.S.C. 355) (concerning the approval of human drug products under new drug applications (NDAs) or abbreviated new drug applications (ANDAs)).

The Drug Quality and Security Act added a new section 503B to the FD&C Act (21 U.S.C. 353b), which created a new category of compounders termed ''outsourcing facilities.'' Under section 503B of the FD&C Act, outsourcing facilities are defined, in part, as facilities that meet certain conditions described in section 503B, including registration with FDA as an outsourcing facility. If these conditions are satisfied, a drug product compounded for human use by or under the direct supervision of a licensed pharmacist in an outsourcing facility is exempt from three sections of the FD&C Act: (1) Section 502(f)(1) (concerning the labeling of drugs with adequate directions for use); (2) section 505 (concerning the approval of human drug products under NDAs or ANDAs); and (3) section 582 (21 U.S.C. 360eee–1) (concerning the drug supply chain security requirements). Outsourcing facilities are not exempt from CGMP requirements in section 501(a)(2)(B) of the FD&C Act.

One of the conditions that must be satisfied to qualify for the exemptions under section 503A of the FD&C Act is that a bulk drug substance (active pharmaceutical ingredient) used in a compounded drug product must meet one of the following criteria: (1) Complies with the standards of an applicable United States Pharmacopoeia (USP) or National Formulary (NF) monograph, if a monograph exists, and the USP chapter on pharmacy compounding; (2) if an applicable monograph does not exist, is a component of a drug approved by the Secretary of Health and Human Services (the Secretary); or (3) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, appears on a list developed by the Secretary through regulations issued by the Secretary (the ''503A Bulks List'') (see section 503A(b)(1)(A)(i) of the FD&C Act).

Another condition that must be satisfied to qualify for the exemptions under section 503A of the FD&C Act is that the compounded drug product is not a drug product identified by the Secretary by regulation as a drug product that presents demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of that drug product (see section 503A(b)(3)(A) of the FD&C Act).

A condition that must be satisfied to qualify for the exemptions in section 503B of the FD&C Act is that the compounded drug is not identified (directly or as part of a category of drugs) on a list, published by the Secretary by regulation, of drugs or categories of drugs that present demonstrable difficulties for compounding that are reasonably likely to lead to an adverse effect on the safety or effectiveness of the drug or category of drugs, taking into account the risks and benefits to patients, or the drug is compounded in accordance with all applicable conditions identified on the list as conditions that are necessary to prevent the drug or category of drugs from presenting such demonstrable difficulties (see section 503B(a)(6)(A) and (B) of the FD&C Act).

FDA intends to discuss with the committee bulk drug substances nominated for inclusion on the 503A Bulks List and drug products nominated for inclusion on the list of drug products that present demonstrable difficulties for compounding under sections 503A and 503B (''Difficult to Compound List'').

*Agenda:* The committee intends to discuss six bulk drug substances nominated for inclusion on the section 503A Bulks List. FDA will discuss the following nominated bulk drug substances: astragalus, L-citrulline, pregnenolone, 7-keto dehydroepiandrosterone (DHEA), epigallocatechin gallate (EGCg), and resveratrol. The chart below identifies the use(s) FDA reviewed for each of the six bulk drug substances being discussed at this advisory committee meeting. The nominators of these substances will be invited to make a short presentation supporting the nomination.

| Drug | Uses reviewed |
|---|---|
| Astragalus | Allergic rhinitis, asthma, diabetes, herpes simplex keratitis, wound healing. |
| L-citrulline | Hyperammonaemia due to cycle disorders. |
| Pregnenolone | Rheumatoid arthritis, hypercholesterolemia, manic and depressive symptoms of bipolar disorder and bipolar disorder with substance abuse (dual diagnosis), positive and negative symptoms of schizophrenia. |
| 7-keto dehydroepiandrosterone | Weight loss, Raynaud's phenomena. |
| Epigallocatechin gallate | Treatment of obesity, wound healing, corneal neovascularization, non-alcoholic fatty liver disease, cardiac hypertrophy, diabetes (type 1 & 2), Parkinson's disease. |
| Resveratrol | Treatment of older adults with impaired glucose tolerance, pain. |

The committee also intends to discuss liposome drug products and drug products produced using hot melt extrusion technology for inclusion on the Difficult to Compound List. Drug products produced ''by extrusion or nanotechnology'' were nominated for inclusion on the Difficult to Compound List. The nominators will be invited to make a short presentation supporting the nomination.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the

appropriate advisory committee meeting link.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. All electronic and written submissions submitted to the Docket (see the **ADDRESSES** section) on or before November 3, 2017, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 9:35 a.m. and 9:45 a.m., 10:55 a.m. and 11:05 a.m., 12 noon and 12:10 p.m., 2:05 p.m. and 2:15 p.m., 3:25 p.m. and 3:35 p.m., and 4:30 p.m. and 4:40 p.m. on November 20, 2017, and between approximately 9:40 a.m. and 9:50 a.m. and 11:10 a.m. and 11:20 a.m. on November 21, 2017. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before October 26, 2017. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 27, 2017.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Cindy Chee at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 20, 2017.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2017–23223 Filed 10–25–17; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2013–N–0961]**

### Matthew Schroeder; Denial of Hearing; Final Debarment Order

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is denying Matthew Schroeder's (Schroeder's) request for a hearing and is issuing an order under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) permanently debarring Schroeder from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Schroeder was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. Schroeder failed to file with the Agency information and analyses sufficient to create a basis for a hearing concerning this action.

**DATES:** This order is applicable October 26, 2017.

**ADDRESSES:** Any application by Schroeder for special termination of debarment under section 306(d) of the FD&C Act (application) may be submitted as follows:

*Electronic Submissions*

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. An application submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your application will be made public, you are solely responsible for ensuring that your application does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your application, that information will be posted on *https://www.regulations.gov.*
- If you want to submit an application with confidential information that you do not wish to be made available to the public, submit the application as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

*Written/Paper Submissions*

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For a written/paper application submitted to the Dockets Management Staff, FDA will post your application, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

*Instructions:* Your application must include the Docket No. FDA–2013–N–0961. An application will be placed in the docket and, unless submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions*—To submit an application with confidential information that you do not wish to be made publicly available, submit your application only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of your application. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your application and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

*Docket:* For access to the docket, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852 between 9 a.m.

and 4 p.m., Monday through Friday. Publicly available submissions may be seen in the docket.

**FOR FURTHER INFORMATION CONTACT:** Julie Finegan, Office of Scientific Integrity, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4218, Silver Spring, Maryland 20993, 301–796–8618.

**SUPPLEMENTARY INFORMATION:**

## I. Background

On October 11, 2012, the U.S. District Court for the Northern District of Georgia entered a criminal judgment against Matthew Schroeder under his guilty plea. Schroeder pled guilty to a felony under the FD&C Act, namely aiding and abetting, with the intent to defraud or mislead, in the dispensing of phenazepam without a prescription, resulting in the phenazapam being misbranded while held for sale after shipment in interstate commerce in violation of sections 301(k), 503(b)(1), 303(a)(2) of the FD&C Act (21 U.S.C. 331(k), 353(b)(1) and 333(a)(2)) and 18 U.S.C. 2. Specifically, Schroeder, through his company, Novel Research Supply, and eBay ID, ''finemineralsfossilssio2'' sold phenazepam and methylenedioxypyrovalerone. Both are unapproved drugs and are used by drug users for recreational purposes. According to FDA's September 24, 2014, letter to Schroeder, in August 2010, Kevin Lewis purchased phenazepam on eBay from ''finemineralsfossilssio2'' and later died after ingesting phenazepam through an injection.

Schroeder is subject to debarment based on a finding, under section 306(a)(2) of the FD&C Act (21 U.S.C. 335a(a)(2)), that he was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. By the letter dated September 24, 2014, FDA notified Schroeder of a proposal to permanently debar him from providing services in any capacity to a person having an approved or pending drug product application. Schroeder requested a hearing on the proposal and special termination of debarment. Schroeder acknowledges his conviction under Federal law, but argues that multiple mitigating factors merit a hearing or special termination of debarment.

Under the authority delegated to him by the Commissioner of Food and Drugs, the Director of the Office of Scientific Integrity (OSI) has considered Schroeder's request for a hearing. Hearings will not be granted on issues of policy or law, on mere allegations, denials, or general descriptions of positions and contentions, or on data and information insufficient to justify the factual determination urged (see 21 CFR 21.24(b)).

The Director of OSI considered Schroeder's arguments and concludes that they are unpersuasive and fail to raise a genuine issue of fact requiring a hearing.

## II. Arguments

In his request for hearing, Schroeder first argues that he took voluntary steps to mitigate the dangers posed by the drugs by putting warnings against human consumption on the sales packaging and Web site. Schroeder states that he discontinued drug sales after an FDA investigator contacted him and that he fully disclosed all of his wrongdoing. Schroeder next argues that he cooperated with investigations and provided testimony against the drug suppliers. Third, Schroeder argues that he ended all his activities concerning drug sales and has not violated the FD&C Act since September 2010. He also states that his phenazepam sales only spanned two months. Fourth, Schroeder addresses Kevin Lewis' death and purchases. Schroeder states that in the case against another drug supplier, the prosecutor determined that Kevin Lewis died from long-term IV drug use, rather than the phenazepam purchased from Schroeder's eBay account. Schroeder also clarifies that Kevin Lewis purchased the phenazepam by using his mother's eBay account. Finally, Schroeder alleges that he does not pose a recidivism risk.

Section 306(a)(2) of the FD&C Act provides FDA with the authority to debar an individual who has been convicted of certain Federal felonies. The only relevant factual issue is whether Schroeder was actually convicted of a felony under Federal law for conduct relating to the development or approval of a drug product or otherwise relating to the regulation of a drug product under the FD&C Act. Schroeder does not dispute that he pled guilty to a felony under the FD&C Act, specifically aiding and abetting, with the intent to defraud and mislead, in the dispensing of phenazepam without a prescription, resulting in the phenazepam being misbranded while held for sale after shipment in interstate commerce. Accordingly, Schroeder's arguments fail to raise a genuine and substantial issue of fact as to whether he was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act.

Along with his request for a hearing, Schroeder also requested a special termination of debarment. Under section 306(d), a debarred individual may apply for special termination of debarment. While the debarment period can be limited to less than permanent, the individual must be debarred for at least 1 year. Schroeder is not yet debarred, so his request for special termination of debarment is not appropriate for consideration at this time.

## III. Findings and Order

Therefore, the Director of OSI, under section 306(a)(2) of the FD&C Act and under the authority delegated to him, finds that Matthew Schroeder has been convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act.

As a result of the foregoing findings, Matthew Schroeder is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under section 505, 512, or 802 of the FD&C Act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective (see **DATES**) (21 U.S.C. 335a(c)(1)(B) and (c)(2)(A)(ii) and 21 U.S.C. 321(dd)). Any person with an approved or pending drug product application who knowingly uses the services of Schroeder, in any capacity during his period of debarment, will be subject to civil money penalties. See section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6)). If Schroeder, during his period of debarment, provides services in any capacity to a person with an approved or pending drug product application, he will be subject to civil money penalties. See section 307(a)(7) of the FD&C Act (21 U.S.C. 335b(a)(7)). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Schroeder during his period of debarment.

Dated: October 20, 2017.

**G. Matthew Warren,**

*Director, Office of Scientific Integrity.*

[FR Doc. 2017–23275 Filed 10–25–17; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

**[Docket No. USCG–2017–0953]**

### Information Collection Request to Office of Management and Budget; OMB Control Number: 1625–0029

**AGENCY:** Coast Guard, DHS.

**ACTION:** Sixty-day notice requesting comments.

**SUMMARY:** In compliance with the Paperwork Reduction Act of 1995, the U.S. Coast Guard intends to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting an extension of its approval for the following collection of information: 1625–0029, Self-propelled Liquefied Gas Vessels; without change. Our ICR describes the information we seek to collect from the public. Before submitting this ICR to OIRA, the Coast Guard is inviting comments as described below.

**DATES:** Comments must reach the Coast Guard on or before December 26, 2017.

**ADDRESSES:** You may submit comments identified by Coast Guard docket number [USCG–2017–0953] to the Coast Guard using the Federal eRulemaking Portal at *http://www.regulations.gov.* See the ''Public participation and request for comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

A copy of the ICR is available through the docket on the Internet at *http://www.regulations.gov.* Additionally, copies are available from: Commandant (CG–612), Attn: Paperwork Reduction Act Manager, U.S. Coast Guard, 2703 Martin Luther King, Jr. Ave. SE., STOP 7710, Washington, DC 20593–7710.

**FOR FURTHER INFORMATION CONTACT:** Mr. Anthony Smith, Office of Information Management, telephone 202–475–3532, or fax 202–372–8405, for questions on these documents.

**SUPPLEMENTARY INFORMATION:**

#### Public participation and Request for Comments

This Notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology. In response to your comments, we may revise this ICR or decide not to seek an extension of approval for the Collection. We will consider all comments and material received during the comment period.

We encourage you to respond to this request by submitting comments and related materials. Comments must contain the OMB Control Number of the ICR and the docket number of this request, [USCG–2017–0953], and must be received by December 26, 2017.

#### Submitting Comments

We encourage you to submit comments through the Federal eRulemaking Portal at *http://www.regulations.gov.* If your material cannot be submitted using *http://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at *http://www.regulations.gov* and can be viewed by following that Web site's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

We accept anonymous comments. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided. For more about privacy and the docket, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

#### Information Collection Request

*Title:* Self-propelled Liquefied Gas Vessels.

*OMB Control Number:* 1625–0029.

*Summary:* The information is needed to ensure compliance with our rules for the design and operation of liquefied gas carriers.

*Need:* Title 46 U.S.C. 3703 and 9101 authorizes the Coast Guard to establish regulations to protect life, property, and the environment from the hazards associated with the carriage of dangerous liquid cargo in bulk. Title 46 CFR part 154 prescribes the rules for the carriage of liquefied gases in bulk on self-propelled vessels by governing the design, construction, equipment, and operation of these vessels and the safety of personnel aboard them.

*Forms:* None.

*Respondents:* Owners and operators of self-propelled vessels carrying liquefied gas.

*Frequency:* On occasion.

*Hour Burden Estimate:* The estimated burden has increased from 7,890 hours to 8,169 hours a year due to an increase in the estimated number of respondents.

**Authority:** The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended.

Dated: October 16, 2017.

**James D. Roppel,**

*U.S. Coast Guard, Acting Chief, Office of Information Management.*

[FR Doc. 2017–23302 Filed 10–25–17; 8:45 am]

**BILLING CODE 9110–04–P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

**[Docket No. USCG–2017–0902]**

### Information Collection Request to Office of Management and Budget; OMB Control Number: 1625–0020

**AGENCY:** Coast Guard, DHS.

**ACTION:** Sixty-day notice requesting comments.

**SUMMARY:** In compliance with the Paperwork Reduction Act of 1995, the U.S. Coast Guard intends to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting an extension of its approval for the following collection of information: 1625–0020, Security Zones, Regulated Navigation Areas, and Safety Zones; without change. Our ICR describes the information we seek to collect from the public. Before submitting this ICR to OIRA, the Coast Guard is inviting comments as described below.

**DATES:** Comments must reach the Coast Guard on or before December 26, 2017.

**ADDRESSES:** You may submit comments identified by Coast Guard docket

number [USCG–2017–0902] to the Coast Guard using the Federal eRulemaking Portal at *http://www.regulations.gov.* See the ''Public participation and request for comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

A copy of the ICR is available through the docket on the Internet at *http://www.regulations.gov.* Additionally, copies are available from: Commandant (CG–612), Attn: Paperwork Reduction Act Manager, U.S. Coast Guard, 2703 Martin Luther King Jr. Ave. SE., Stop 7710, Washington, DC 20593–7710.

**FOR FURTHER INFORMATION CONTACT:** Mr. Anthony Smith, Office of Information Management, telephone 202–475–3532, or fax 202–372–8405, for questions on these documents.

**SUPPLEMENTARY INFORMATION:**

### Public Participation and Request for Comments

This Notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology. In response to your comments, we may revise this ICR or decide not to seek an extension of approval for the Collection. We will consider all comments and material received during the comment period.

We encourage you to respond to this request by submitting comments and related materials. Comments must contain the OMB Control Number of the ICR and the docket number of this request, [USCG–2017–0902], and must be received by December 26, 2017.

### Submitting Comments

We encourage you to submit comments through the Federal eRulemaking Portal at *http://www.regulations.gov.* If your material cannot be submitted using *http://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at *http://www.regulations.gov* and can be viewed by following that Web site's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

We accept anonymous comments. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided. For more about privacy and the docket, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

### Information Collection Request

*Title:* Security Zones, Regulated Navigation Areas, and Safety Zones.

*OMB Control Number:* 1625–0020.

*Summary:* The Coast Guard collects this information only when someone seeks a security zone, regulated navigation area, or safety zone. It uses the information to assess the need to establish one of these areas.

*Need:* Section 1226 and 1231 of 33 U.S.C. and 50 U.S.C. 191 and 195, and parts 6 and 165 of 33 CFR give the Coast Guard Captain of the Port (COTP) the authority to designate security zones in the U.S. for as long as the COTP deems necessary to prevent damage or injury. Section 1223 of 33 U.S.C. authorizes the Coast Guard to prescribe rules to control vessel traffic in areas he or she deems hazardous because of reduced visibility, adverse weather, or vessel congestion. Section 1225 of 33 U.S.C. authorizes the Coast Guard to establish rules to allow the designation of safety zones where access is limited to authorized persons, vehicles, or vessels to protect the public from hazardous situations.

*Forms:* Not applicable.

*Respondents:* Federal, State, and local government agencies, owners and operators of vessels and facilities.

*Frequency:* On occasion.

*Hour Burden Estimate:* The estimated burden has decreased from 413 hours to 178 hours a year due to a decrease in the estimated annual number of respondents.

**Authority:** The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended.

Dated: October 16, 2017.

**James D. Roppel,**

*Acting Chief, Office of Information Management, U.S. Coast Guard.*

[FR Doc. 2017–23304 Filed 10–25–17; 8:45 am]

**BILLING CODE 9110–04–P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

**[Docket No. USCG–2017–0904]**

### Information Collection Request to Office of Management and Budget; OMB Control Number: 1625–0022

**AGENCY:** Coast Guard, DHS.

**ACTION:** Sixty-day notice requesting comments.

**SUMMARY:** In compliance with the Paperwork Reduction Act of 1995, the U.S. Coast Guard intends to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting an extension of its approval for the following collection of information: 1625–0022, Application for Tonnage Measurement of Vessels; without change. Our ICR describes the information we seek to collect from the public. Before submitting this ICR to OIRA, the Coast Guard is inviting comments as described below.

**DATES:** Comments must reach the Coast Guard on or before December 26, 2017.

**ADDRESSES:** You may submit comments identified by Coast Guard docket number [USCG–2017–0904] to the Coast Guard using the Federal eRulemaking Portal at *http://www.regulations.gov.* See the ''Public participation and request for comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

A copy of the ICR is available through the docket on the Internet at *http://www.regulations.gov.* Additionally, copies are available from: Commandant (CG–612), Attn: Paperwork Reduction Act Manager, U.S. Coast Guard, 2703 Martin Luther King Jr. Ave. SE., Stop 7710, Washington, DC 20593–7710.

**FOR FURTHER INFORMATION CONTACT:** Mr. Anthony Smith, Office of Information Management, telephone 202–475–3532, or fax 202–372–8405, for questions on these documents.

**SUPPLEMENTARY INFORMATION:**

**Public Participation and Request for Comments**

This Notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology. In response to your comments, we may revise this ICR or decide not to seek an extension of approval for the Collection. We will consider all comments and material received during the comment period.

We encourage you to respond to this request by submitting comments and related materials. Comments must contain the OMB Control Number of the ICR and the docket number of this request, [USCG–2017–0904], and must be received by December 26, 2017.

**Submitting Comments**

We encourage you to submit comments through the Federal eRulemaking Portal at *http://www.regulations.gov.* If your material cannot be submitted using *http://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at *http://www.regulations.gov* and can be viewed by following that Web site's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

We accept anonymous comments. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided. For more about privacy and the docket, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

**Information Collection Request**

*Title:* Application for Tonnage Measurement of Vessels.

*OMB Control Number:* 1625–0022.

*Summary:* The information is used by the Coast Guard to determine a vessel's tonnage. Tonnage in turn helps to determine licensing, inspection, safety requirements, and operating fees.

*Need:* Under 46 U.S.C. 14104 certain vessels must be measured for tonnage. Coast Guard regulations for this measurement are contained in 46 CFR part 69.

*Forms:* CG–5397, Application for Simplified Measurement.

*Respondents:* Owners of vessels.

*Frequency:* On occasion.

*Hour Burden Estimate:* The estimated burden has increased from 14,610 hours to 15,094 hours a year due to an increase in the estimated annual number of responses.

**Authority:** The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended.

Dated: October 16, 2017.

**James D. Roppel,**

*U.S. Coast Guard, Acting Chief, Office of Information Management.*

[FR Doc. 2017–23298 Filed 10–25–17; 8:45 am]

**BILLING CODE 9110–04–P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

**[Docket No. USCG–2017–0899]**

### Information Collection Request to Office of Management and Budget; OMB Control Number: 1625–0058

**AGENCY:** Coast Guard, DHS.

**ACTION:** Sixty-day notice requesting comments.

**SUMMARY:** In compliance with the Paperwork Reduction Act of 1995, the U.S. Coast Guard intends to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting approval for reinstatement, without change, of the following collection of information: 1625–0058, Application for Permit to Transport Municipal and Commercial Waste. Our ICR describes the information we seek to collect from the public. Before submitting this ICR to OIRA, the Coast Guard is inviting comments as described below.

**DATES:** Comments must reach the Coast Guard on or before December 26, 2017.

**ADDRESSES:** You may submit comments identified by Coast Guard docket number [USCG–2017–0899] to the Coast Guard using the Federal eRulemaking Portal at *http://www.regulations.gov.* See the ''Public participation and request for comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

A copy of the ICR is available through the docket on the Internet at *http://www.regulations.gov.* Additionally, copies are available from: Commandant (CG–612), Attn: Paperwork Reduction Act Manager, U.S. Coast Guard, 2703 Martin Luther King Jr. Ave. SE., Stop 7710, Washington, DC 20593–7710.

**FOR FURTHER INFORMATION CONTACT:** Mr. Anthony Smith, Office of Information Management, telephone 202–475–3532, or fax 202–372–8405, for questions on these documents.

**SUPPLEMENTARY INFORMATION:**

**Public Participation and Request for Comments**

This Notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology. In response to your comments, we may revise this ICR or decide not to seek reinstatement of the Collection. We will consider all comments and material received during the comment period.

We encourage you to respond to this request by submitting comments and related materials. Comments must contain the OMB Control Number of the ICR and the docket number of this request, [USCG–2017–0899], and must be received by December 26, 2017.

**Submitting Comments**

We encourage you to submit comments through the Federal eRulemaking Portal at *http://www.regulations.gov.* If your material cannot be submitted using *http://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at *http://www.regulations.gov* and can be viewed by following that Web site's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

We accept anonymous comments. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided. For more about privacy and the docket, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

**Information Collection Request**

*Title:* Application for Permit to Transport Municipal and Commercial Waste.

*OMB Control Number:* 1625–0058.

*Summary:* This information collection provides the basis for issuing or denying a permit, required under 33 U.S.C. 2601 and 33 CFR 151.1009, for the transportation of municipal or commercial waste in the coastal waters of the United States.

*Need:* In accordance with 33 U.S.C. 2601, the U.S. Coast Guard issued regulations requiring an owner or operator of a vessel to apply for a permit to transport municipal or commercial waste in the United States and to display an identification number or other marking on their vessel.

*Forms:* None.

*Respondents:* Owners and operators of vessels.

*Frequency:* Every 18 months.

*Hour Burden Estimate:* The estimated burden remains at 13 hours a year.

**Authority:** The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended.

Dated: October 16, 2017.

**James D. Roppel,**

*U.S. Coast Guard, Acting Chief, Office of Information Management.*

[FR Doc. 2017–23300 Filed 10–25–17; 8:45 am]

**BILLING CODE 9110–04–P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

**[Docket No. USCG–2015–0694]**

### Information Collection Request to Office of Management and Budget; OMB Control Number: 1625–0040

**AGENCY:** Coast Guard, DHS.

**ACTION:** Sixty-day notice requesting comments.

**SUMMARY:** In compliance with the Paperwork Reduction Act of 1995, the U.S. Coast Guard intends to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting approval for reinstatement, without change, of the following collection of information: 1625–0040, Application for Merchant Mariner Credential (MMC), Application for Merchant Mariner Medical Certificate, Applications for Merchant Mariner Medical Certificate for Entry Level Ratings, Small Vessel Sea Service Form, DOT/USCG Periodic Drug Testing Form, Disclosure Statement for Narcotics, DWI/DUI, and/or Other Convictions, Merchant Mariner Medical Certificates, Recognition of Foreign Certificate. This is a resubmission of this ICR. Our ICR describes the information we seek to collect from the public. Before submitting this ICR to OIRA, the Coast Guard is inviting comments as described below.

**DATES:** Comments must reach the Coast Guard on or before December 26, 2017.

**ADDRESSES:** You may submit comments identified by Coast Guard docket number USCG–2015–0694 to the Coast Guard using the Federal eRulemaking Portal at *http://www.regulations.gov.* See the ''Public participation and request for comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

A copy of the ICR is available through the docket on the Internet at *http://www.regulations.gov.* Additionally, copies are available from: Commandant (CG–612), Attn: Paperwork Reduction Act Manager, U.S. Coast Guard, 2703 Martin Luther King, Jr. Ave. SE., Stop 7710, Washington, DC 20593–7710.

**FOR FURTHER INFORMATION CONTACT:** Contact Mr. Anthony Smith, Office of Information Management, telephone 202–475–3532, or fax 202–372–8405, for questions on these documents.

**SUPPLEMENTARY INFORMATION:**

**Public Participation and Request for Comments**

A sixty-day Notice was originally published in the **Federal Register** on October 15, 2017, and a thirty-day Notice published on February 17, 2017, for this ICR. This ICR is being resubmitted due to the length of time since publication of the thirty-day notice and to provide the public with an opportunity to further comment on this collection. We did receive one comment on this ICR during the prior submission and it is discussed below under the section, ''Submitting comments.''

This Notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology. In response to your comments, we may revise this ICR or decide not to seek reinstatement of the Collection. We will consider all comments and material received during the comment period.

We encourage you to respond to this request by submitting comments and related materials. Comments must contain the OMB Control Number of the ICR and the docket number of this request, [USCG–2015–0694], and must be received by December 26, 2017.

**Submitting Comments**

We encourage you to submit comments through the Federal

eRulemaking Portal at *http://www.regulations.gov.* If your material cannot be submitted using *http://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at *http://www.regulations.gov* and can be viewed by following that Web site's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

We accept anonymous comments. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided. For more about privacy and the docket, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

We did receive one comment on the earlier submission of this ICR. The commenter requested that we provide more detail on the progress of an application while it is being processed. Although this is not a comment directed at the collection, we do provide the following response.

The Coast Guard provides process guides for the application of mariner credentials that are available upon the National Maritime Center (NMC) Web site at [*http://www.dco.uscg.mil/Our-Organization/Assistant-Commandant-for-Prevention-Policy-CG-P/National-Maritime-Center/*] which detail the processes that are followed for the evaluation of merchant mariners. Furthermore, during the mariner evaluation process, the applicants are provided email updates (if email address is provided) detailing the status of their application(s).

**Information Collection Request**

*Title:* Application for Merchant Mariner Credential (MMC), Application for Merchant Mariner Medical Certificate, Application for Merchant Mariner Medical Certificate for Entry Level Ratings, Small Vessel Sea Service Form, DOT/USCG Periodic Drug Testing Form, Disclosure Statement for Narcotics, DWI/DUI, and/or Other Convictions, Merchant Mariner Medical Certificate, Recognition of Foreign Certificate.

*OMB Control Number:* 1625–0040.

*Summary:* The Application for Merchant Mariner Credential (MMC), Application for Merchant Mariner Medical Certificate, Application for Merchant Mariner Medical Certificate for Entry Level Ratings, Small Vessel Sea Service Form, DOT/USCG Periodic Drug Testing Form, Disclosure Statement for Narcotics, DWI/DUI, and/or Other Convictions, contains the following information: Signature of applicant and supplementary material required to show that the mariner meets the mandatory requirements for the credential or medical certificate sought; proof of applicant passing all applicable vision, hearing, medical, and/or physical exams; negative chemical test for dangerous drugs; discharges or other documentary evidence of sea service indicating the name, tonnage, propulsion mode and power of the vessels, dates of service, capacity in which the applicant served, and on what waters; and disclosure documentation for narcotics, DWI/DUI, and/or other convictions.

*Need:* Title 46 United States Code (U.S.C.) Subtitle II, Part E, Title 46 Code of Federal Regulation (CFR) Part 10, Subpart B, and International Convention on Standards of Training, Certification and Watchkeeping for Seafarers, 1978, as amended (STCW Convention) and the STCW Code, including the STCW Final Rule (Docket No. USCG–2004–17914) published on December 24, 2013, requires MMC and Medical Certificate applicants to apply at one of the Coast Guard's seventeen Regional Examination Centers located nationwide. MMCs are established for individuals who are required to hold a credential under Subtitle II. The Coast Guard has the responsibility of issuing MMCs and Medical Certificates to applicants found qualified as to age, character, habits of life, experience, professional qualifications, and physical fitness. The instruments contained within OMB Control No. 1625–0040 serve as a means for the applicant to apply for a MMC and Medical Certificate.

*Forms:* CG–719B, Application for Merchant Mariner Credential (MMC); CG–719C, Disclosure Statement for Narcotics, DWI/DUI, and/or Other Convictions; CG–719K, Application for Merchant Mariner Medical Certificate; CG–719K/E, Application for Merchant Mariner Medical Certificate for Entry Level Ratings; CG–719S, Small Vessel Sea Service Form; CG–719P, DOT/USCG Periodic Drug Testing Form.

*Respondents:* Applicants for MMC, whether original, renewal, duplicate, raise of grade, or a new endorsement on a previously issued MMC. Applicants for Medical Certificates to include National and STCW credentialed mariners, and first-class pilots.

*Frequency:* On occasion.

*Hour Burden Estimate:* The estimated burden remains 47,444 hours a year (CG–719B = 8,475 hours, CG–719K = 16,440 hours, CG–719K/E = 2,283 hours, CG–719S = 14,125 hours, CG–719P = 4,708 hours, and CG–719C = 1,413).

**Authority:** The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended.

Dated: October 17, 2017.

**James D. Roppel,**

*U.S. Coast Guard, Acting Chief, Office of Information Management.*

[FR Doc. 2017–23218 Filed 10–25–17; 8:45 am]

**BILLING CODE 9110–04–P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

**[Docket No. USCG–2017–0901]**

### Information Collection Request to Office of Management and Budget; OMB

Control Number: 1625–0036

**AGENCY:** Coast Guard, DHS.

**ACTION:** Sixty-day notice requesting comments.

**SUMMARY:** In compliance with the Paperwork Reduction Act of 1995, the U.S. Coast Guard intends to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting an extension of its approval for the following collection of information: 1625–0036, Plan Approval and Records for U.S. and Foreign Tank Vessels Carrying Oil in Bulk; without change. Our ICR describes the information we seek to collect from the public. Before submitting this ICR to OIRA, the Coast Guard is inviting comments as described below.

**DATES:** Comments must reach the Coast Guard on or before December 26, 2017.

**ADDRESSES:** You may submit comments identified by Coast Guard docket number [USCG–2017–0901] to the Coast Guard using the Federal eRulemaking Portal at *http://www.regulations.gov.* See the ''Public participation and request for comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

A copy of the ICR is available through the docket on the Internet at *http://www.regulations.gov.* Additionally, copies are available from: Commandant (CG–612), Attn: Paperwork Reduction Act Manager, U.S. Coast Guard, 2703 Martin Luther King Jr. Ave. SE., Stop 7710, Washington, DC 20593–7710.

**FOR FURTHER INFORMATION CONTACT:** Mr. Anthony Smith, Office of Information Management, telephone 202–475–3532, or fax 202–372–8405, for questions on these documents.

**SUPPLEMENTARY INFORMATION:**

**Public Participation and Request for Comments**

This Notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) the practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology. In response to your comments, we may revise this ICR or decide not to seek an extension of approval for the Collection. We will consider all comments and material received during the comment period.

We encourage you to respond to this request by submitting comments and related materials. Comments must contain the OMB Control Number of the ICR and the docket number of this request, [USCG–2017–0901], and must be received by December 26, 2017.

**Submitting Comments**

We encourage you to submit comments through the Federal eRulemaking Portal at *http://www.regulations.gov.* If your material cannot be submitted using *http://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at *http://www.regulations.gov* and can be viewed by following that Web site's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

We accept anonymous comments. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided. For more about privacy and the docket, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

**Information Collection Request**

*Title:* Plan Approval and Records for U.S. and Foreign Tank Vessels Carrying Oil in Bulk.

*OMB Control Number:* 1625–0036.

*Summary:* This information collection aids the Coast Guard in determining if a vessel complies with certain safety and environmental protection standards. Plans, to include records, for construction or modification of U.S. or foreign vessels submitted and maintained on board are required for compliance with these standards.

*Need:* Title 46 U.S.C. 3703 provides the Coast Guard with the authority to regulate design, construction, alteration, repair, maintenance, operation, equipping, personnel qualification, and manning of vessels carrying oil in bulk. See *e.g.,* 33 CFR part 157, Rules for the Protection of the Marine Environment Relating to Tank Vessels Carrying Oil in Bulk, and 46 CFR chapter I, subchapter D, Tank Vessels.

*Forms:* Not applicable.

*Respondents:* Owners and operators of vessels.

*Hour Burden Estimate:* The estimated burden has increased from 2,033 hours to 2,106 hours a year due to an increase in the estimated number of respondents.

**Authority:** The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended.

Dated: October 16, 2017.

**James D. Roppel,**

*U.S. Coast Guard, Acting Chief, Office of Information Management.*

[FR Doc. 2017–23303 Filed 10–25–17; 8:45 am]

**BILLING CODE 9110–04–P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

**[Docket No. USCG–2017–0951]**

### Information Collection Request to Office of Management and Budget; OMB Control Number: 1625–0109

**AGENCY:** Coast Guard, DHS.

**ACTION:** Sixty-day notice requesting comments.

**SUMMARY:** In compliance with the Paperwork Reduction Act of 1995, the U.S. Coast Guard intends to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting an extension of its approval for the following collection of information: 1625–0109, Drawbridge Operation Regulations; without change.

Our ICR describes the information we seek to collect from the public. Before submitting this ICR to OIRA, the Coast Guard is inviting comments as described below.

**DATES:** Comments must reach the Coast Guard on or before December 26, 2017.

**ADDRESSES:** You may submit comments identified by Coast Guard docket number [USCG–2017–0951] to the Coast Guard using the Federal eRulemaking Portal at *http://www.regulations.gov.* See the ''Public participation and request for comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

A copy of the ICR is available through the docket on the Internet at *http://www.regulations.gov.* Additionally, copies are available from: Commandant (CG–612), Attn: Paperwork Reduction Act Manager, U.S. Coast Guard, 2703 Martin Luther King, Jr. Ave. SE., Stop 7710, Washington, DC 20593–7710.

**FOR FURTHER INFORMATION CONTACT:** Mr. Anthony Smith, Office of Information Management, telephone 202–475–3532, or fax 202–372–8405, for questions on these documents.

**SUPPLEMENTARY INFORMATION:**

**Public Participation and Request for Comments**

This Notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate

comments addressing: (1) The practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology. In response to your comments, we may revise this ICR or decide not to seek an extension of approval for the Collection. We will consider all comments and material received during the comment period.

We encourage you to respond to this request by submitting comments and related materials. Comments must contain the OMB Control Number of the ICR and the docket number of this request, [USCG–2017–0951], and must be received by December 26, 2017.

**Submitting Comments**

We encourage you to submit comments through the Federal eRulemaking Portal at *http://www.regulations.gov.* If your material cannot be submitted using *http://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at *http://www.regulations.gov* and can be viewed by following that Web site's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

We accept anonymous comments. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided. For more about privacy and the docket, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

**Information Collection Request**

*Title:* Drawbridge Operation Regulations.

*OMB Control Number:* 1625–0109.

*Summary:* The Bridge Program receives approximately 150 requests from bridge owners or the general public per year to change the operating schedule of various drawbridges across the navigable water of the United States. The information needed for the change to the operating schedule can only be obtained from the bridge owner and is generally provided to the Coast Guard in a written format.

*Need:* 33 U.S.C. 499 authorizes the Coast Guard to change the operating schedules drawbridges that cross over navigable waters of the United States.

*Forms:* None.

*Respondents:* The public and private owners of bridges over navigable waters of the United States.

*Frequency:* On occasion.

*Hour Burden Estimate:* The estimated annual burden remains 150 hours.

**Authority:** The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended.

Dated: October 16, 2017.

**James D. Roppel,**

*U.S. Coast Guard, Acting Chief, Office of Information Management.*

[FR Doc. 2017–23301 Filed 10–25–17; 8:45 am]

**BILLING CODE 9110–04–P**

## DEPARTMENT OF HOMELAND SECURITY

### U.S. Customs and Border Protection

**[Docket No. USCBP–2017–0044]**

### Commercial Customs Operations Advisory Committee (COAC)

**AGENCY:** U.S. Customs and Border Protection (CBP), Department of Homeland Security (DHS).

**ACTION:** Committee management; Notice of Federal Advisory Committee Meeting.

**SUMMARY:** The Commercial Customs Operations Advisory Committee (COAC) will hold its quarterly meeting on Tuesday, November 14, 2017 in Washington, DC The meeting will be open to the public.

**DATES:** The COAC will meet on Tuesday, November 14, 2017, from 1:00 p.m. to 5:00 p.m. EST. Please note that the meeting may close early if the committee has completed its business.

**ADDRESSES:** The meeting will be held at U.S. Customs & Border Protection, 1717 H Street NW., Room 700, Washington, DC 20006. For information on facilities or services for individuals with disabilities or to request special assistance at the meeting, contact Ms. Florence Constant-Gibson, Office of Trade Relations, U.S. Customs & Border Protection, at (202) 344–1440 as soon as possible.

*Pre-Registration:* Meeting participants may attend either in person or via webinar after pre-registering using one of the methods indicated below:

For members of the public who plan to attend the meeting in person, please register by 5:00 p.m. EST by November 13, 2017, either online at *https://apps.cbp.gov/te_reg/index.asp?w=119;* by email to *tradeevents@dhs.gov;* or by fax to (202) 325–4290. You must register prior to the meeting in order to attend the meeting in person.

For members of the public who plan to participate via webinar, please register online at *https://apps.cbp.gov/te_reg/index.asp?w=118* by 5:00 p.m. EST, November 13, 2017.

Please feel free to share this information with other interested members of your organization or association.

Members of the public who are pre-registered to attend and later need to cancel, please do so by November 13, 2017, utilizing the following links: *https://apps.cbp.gov/te_reg/cancel.asp?w=119* to cancel an in person registration or *https://apps.cbp.gov/te_reg/cancel.asp?w=118* to cancel a webinar registration.

To facilitate public participation, we are inviting public comment on the issues the committee will consider prior to the formulation of recommendations as listed in the Agenda section below.

Comments must be submitted in writing no later than November 8, 2017, and must be identified by Docket No. USCBP–2017–0044, and may be submitted by *one (1)* of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: tradeevents@dhs.gov.* Include the docket number in the subject line of the message.
- *Fax:* (202) 325–4290, Attention Florence Constant-Gibson.
- *Mail:* Ms. Florence Constant-Gibson, Office of Trade Relations, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW., Room 3.5A, Washington, DC 20229.

*Instructions:* All submissions received must include the words ''Department of Homeland Security'' and the docket number (USCBP–2017–0044) for this action. Comments received will be posted without alteration at *http://www.regulations.gov.* Please do not submit personal information to this docket.

*Docket:* For access to the docket or to read background documents or comments, go to *http://www.regulations.gov* and search for Docket Number USCBP–2017–0044. To submit a comment, click the ''Comment Now!'' button located on the top-right hand side of the docket page.

There will be multiple public comment periods held during the meeting on November 14, 2017. Speakers are requested to limit their comments to two (2) minutes or less to facilitate greater participation. Contact the individual listed below to register as

a speaker. Please note that the public comment period for speakers may end before the time indicated on the schedule that is posted on the CBP Web page, *http://www.cbp.gov/trade/stakeholder-engagement/coac.*

**FOR FURTHER INFORMATION CONTACT:** Ms. Florence Constant-Gibson, Office of Trade Relations, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW., Room 3.5A, Washington, DC 20229; telephone (202) 344–1440; facsimile (202) 325–4290; or Mr. Bradley Hayes, Executive Director and Designated Federal Officer, can be reached at (202) 344–1440.

**SUPPLEMENTARY INFORMATION:** Notice of this meeting is given under the *Federal Advisory Committee Act,* 5 U.S.C. Appendix. The Commercial Customs Operations Advisory Committee (COAC) provides advice to the Secretary of Homeland Security, the Secretary of the Treasury, and the Commissioner of U.S. Customs and Border Protection (CBP) on matters pertaining to the commercial operations of CBP and related functions within the Department of Homeland Security and the Department of the Treasury.

**Agenda**

The COAC will hear from the following subcommittees on the topics listed below and then will review, deliberate, provide observations, and formulate recommendations on how to proceed:

1. The Trade Enforcement & Revenue Collection (TERC) Subcommittee will discuss new TERC recommendations and provide any necessary updates from the Anti-Dumping and Countervailing Duty, Bond, Forced Labor, and Intellectual Property Rights Working Groups.

2. The Global Supply Chain Subcommittee will present the status of a pilot that will test the utilization of existing Automated Commercial Environment (ACE) automation in the pipeline mode of transportation. The committee will also discuss the progress of the Global Supply Chain Subcommittee's new Emerging Technologies Working Group.

3. The One U.S. Government Subcommittee will continue discussions on the progress of the Fish & Wildlife Service Working Group and will present the final white paper on the Harmonized Tariff Schedule (HTS) project. The subcommittee will also discuss the progress of the newly created Technical and Operational Outages Working Group.

4. The Exports Subcommittee will discuss the Post Departure Filing (PDF) Working Group's progress on the implementation plan of the PDF Proposal and will include steps to initiate a proof of concept. The subcommittee will also discuss the progress of the Manifest Working Group and progress on issues with the ongoing manifest pilots. The working group may present recommendations in the area of manifest timelines during the November meeting.

5. The Trusted Trader Subcommittee will continue the discussion for an enhanced Trusted Trader program that includes engagement with CBP to include relevant partner government agencies with a potential for international interoperability. A review of the pilot program status and benefits will also be undertaken in parallel to determine the optimum benefits that would be assigned to Trusted Trader participants.

6. The Trade Modernization Subcommittee will discuss its plans for the topics that will be addressed during the next quarter.

Meeting materials will be available by November 10, 2017, at: *http://www.cbp.gov/trade/stakeholder-engagement/coac/coac-public-meetings.*

Dated: October 23, 2017.

**Bradley F. Hayes,**

*Executive Director, Office of Trade Relations.*

[FR Doc. 2017–23282 Filed 10–25–17; 8:45 am]

**BILLING CODE 9111–14–P**

## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

**[Docket ID FEMA–2017–0002; Internal Agency Docket No. FEMA–B–1754]**

### Proposed Flood Hazard Determinations

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Notice.

**SUMMARY:** Comments are requested on proposed flood hazard determinations, which may include additions or modifications of any Base Flood Elevation (BFE), base flood depth, Special Flood Hazard Area (SFHA) boundary or zone designation, or regulatory floodway on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports for the communities listed in the table below. The purpose of this notice is to seek general information and comment regarding the preliminary FIRM, and where applicable, the FIS report that the Federal Emergency Management Agency (FEMA) has provided to the affected communities. The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP). In addition, the FIRM and FIS report, once effective, will be used by insurance agents and others to calculate appropriate flood insurance premium rates for new buildings and the contents of those buildings.

**DATES:** Comments are to be submitted on or before January 24, 2018.

**ADDRESSES:** The Preliminary FIRM, and where applicable, the FIS report for each community are available for inspection at both the online location and the respective Community Map Repository address listed in the tables below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *www.msc.fema.gov* for comparison.

You may submit comments, identified by Docket No. FEMA–B–1754, to Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW., Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov.*

**FOR FURTHER INFORMATION CONTACT:** Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW., Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Map Information eXchange (FMIX) online at *www.floodmaps.fema.gov/fhm/fmx_main.html.*

**SUPPLEMENTARY INFORMATION:** FEMA proposes to make flood hazard determinations for each community listed below, in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR 67.4(a).

These proposed flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other

Federal, State, or regional entities. These flood hazard determinations are used to meet the floodplain management requirements of the NFIP and also are used to calculate the appropriate flood insurance premium rates for new buildings built after the FIRM and FIS report become effective.

The communities affected by the flood hazard determinations are provided in the tables below. Any request for reconsideration of the revised flood hazard information shown on the Preliminary FIRM and FIS report that satisfies the data requirements outlined in 44 CFR 67.6(b) is considered an appeal. Comments unrelated to the flood hazard determinations also will be considered before the FIRM and FIS report become effective.

Use of a Scientific Resolution Panel (SRP) is available to communities in support of the appeal resolution process. SRPs are independent panels of experts in hydrology, hydraulics, and other pertinent sciences established to review conflicting scientific and technical data and provide recommendations for resolution. Use of the SRP only may be exercised after FEMA and local communities have been engaged in a collaborative consultation process for at least 60 days without a mutually acceptable resolution of an appeal. Additional information regarding the SRP process can be found online at *http://floodsrp.org/pdfs/srp_fact_sheet.pdf.*

The watersheds and/or communities affected are listed in the tables below. The Preliminary FIRM, and where applicable, FIS report for each community are available for inspection at both the online location and the respective Community Map Repository address listed in the tables. For communities with multiple ongoing Preliminary studies, the studies can be identified by the unique project number and Preliminary FIRM date listed in the tables. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *www.msc.fema.gov* for comparison.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Dated: October 13, 2017.

**Roy E. Wright,**

*Deputy Associate Administrator for Insurance and Mitigation, Department of Homeland Security, Federal Emergency Management Agency.*

I. Non-watershed-based studies:

| Community | Community map repository address |
|---|---|
| **Will County, Illinois and Incorporated Areas** | |
| **Maps Available for Inspection Online at: *http://www.fema.gov/preliminaryfloodhazarddata*** | |
| **Project: 13–05–4873S Preliminary Date: February 1, 2017** | |
| City of Aurora | Engineering Department, City Hall, 44 East Downer Place, Aurora, IL 60507. |
| City of Braidwood | City Hall, 141 West Main Street, Braidwood, IL 60408. |
| City of Crest Hill | City Hall, 1610 Plainfield Road, Crest Hill, 60403. |
| City of Joliet | City Hall, 150 West Jefferson Street, Joliet, IL 60432. |
| City of Lockport | Public Works and Engineering, 17112 South Prime Boulevard, Lockport, IL 60441. |
| City of Naperville | City Hall, 400 South Eagle Street, Naperville, IL 60540. |
| City of Wilmington | City Hall, 1165 South Water Street, Wilmington, IL 60481. |
| Unincorporated Areas of Will County | Land Use Department, 58 East Clinton Street, Suite 100, Joliet, IL 60432. |
| Village of Beecher | Village Hall, 625 Dixie Highway, Beecher, IL 60401. |
| Village of Bolingbrook | Village Hall, 375 West Briarcliff Road, Bolingbrook, IL 60440. |
| Village of Channahon | Village Hall, 24555 South Navajo Drive, Channahon, IL 60410. |
| Village of Coal City | Village Hall, 515 South Broadway Street, Coal City, IL 60416. |
| Village of Crete | Village Hall, 524 West Exchange Street, Crete, IL 60417. |
| Village of Diamond | Village Hall, 1750 East Division Street, Diamond, IL 60416. |
| Village of Elwood | Village Hall, 401 East Mississippi Avenue, Elwood, IL 60421. |
| Village of Frankfort | Village Hall, 432 West Nebraska Street, Frankfort, IL 60423. |
| Village of Homer Glen | Village Hall, 14240 West 151st Street, Homer Glen, IL 60491. |
| Village of Lemont | Village Hall, 418 Main Street, Lemont, IL 60439. |
| Village of Manhattan | Village Hall, 260 Market Place, Manhattan, IL 60442. |
| Village of Minooka | Village Hall, 121 East McEvilly Road, Minooka, IL 60447. |
| Village of Mokena | Village Hall, 11004 Carpenter Street, Mokena, IL 60448. |
| Village of Monee | Village Hall, 5130 West Court Street, Monee, IL 60449. |
| Village of New Lenox | Village Hall, 1 Veterans Parkway, New Lenox, IL 60451. |
| Village of Orland Park | Village Hall, 14700 South Ravinia Avenue, Orland Park, IL 60462. |
| Village of Park Forest | Village Hall, 350 Victory Drive, Park Forest, IL 60466. |
| Village of Peotone | Village Hall, 208 East Main Street, Peotone, IL 60468. |
| Village of Plainfield | Village Hall, 24401 West Lockport Street, Plainfield, IL 60544. |
| Village of Rockdale | Village Hall, 79 Moen Avenue, Rockdale, IL 60436. |
| Village of Romeoville | Village Hall, 1050 West Romeo Road, Romeoville, IL 60446. |
| Village of Shorewood | Village Hall, One Towne Center Boulevard, Shorewood, IL 60404. |
| Village of Steger | Village Hall, 3320 Lewis Avenue, Steger, IL 60475. |
| Village of Tinley Park | Village Hall, 16250 South Oak Park Avenue, Tinley Park, IL 60477. |
| Village of University Park | Village Hall, 698 Burnham Drive, University Park, IL 60484. |
| Village of Woodridge | Village Hall, 5 Plaza Drive, Woodridge, IL 60517. |

[FR Doc. 2017–23253 Filed 10–25–17; 8:45 am]

**BILLING CODE 9110–12–P**

## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

**[Internal Agency Docket No. FEMA–3384–EM; Docket ID FEMA–2017–0001]**

### Puerto Rico; Amendment No. 2 to Notice of an Emergency Declaration

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Notice.

**SUMMARY:** This notice amends the notice of an emergency declaration for the Commonwealth of Puerto Rico (FEMA–3384–EM), dated September 5, 2017, and related determinations.

**DATES:** The change occurred on October 10, 2017.

**FOR FURTHER INFORMATION CONTACT:** Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

**SUPPLEMENTARY INFORMATION:** The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Michael F. Byrne, of FEMA is appointed to act as the Federal Coordinating Officer for this emergency.

This action terminates the appointment of Alejandro DeLaCampa as Federal Coordinating Officer for this emergency.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

**Brock Long,**

*Administrator, Federal Emergency Management Agency.*

[FR Doc. 2017–23246 Filed 10–25–17; 8:45 am]

**BILLING CODE 9111–23–P**

## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

**[Internal Agency Docket No. FEMA–3392–EM; Docket ID FEMA–2017–0001]**

### Louisiana; Emergency and Related Determinations

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Notice.

**SUMMARY:** This is a notice of the Presidential declaration of an emergency for the State of Louisiana (FEMA–3392–EM), dated October 6, 2017, and related determinations.

**DATES:** The declaration was issued October 6, 2017.

**FOR FURTHER INFORMATION CONTACT:** Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

**SUPPLEMENTARY INFORMATION:** Notice is hereby given that, in a letter dated October 6, 2017, the President issued an emergency declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5207 (the Stafford Act), as follows:

I have determined that the emergency conditions in certain areas of the State of Louisiana resulting from Tropical Storm Nate beginning on October 5, 2017, and continuing, are of sufficient severity and magnitude to warrant an emergency declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (''the Stafford Act''). Therefore, I declare that such an emergency exists in the State of Louisiana.

You are authorized to provide appropriate assistance for required emergency measures, authorized under Title V of the Stafford Act, to save lives and to protect property and public health and safety, and to lessen or avert the threat of a catastrophe in the designated areas. Specifically, you are authorized to provide assistance for emergency protective measures (Category B), including direct Federal assistance, under the Public Assistance program.

Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Public Assistance will be limited to 75 percent of the total eligible costs. In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal emergency assistance and administrative expenses.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, Department of Homeland Security, under Executive Order 12148, as amended, William J. Doran III, of FEMA is appointed to act as the Federal Coordinating Officer for this declared emergency.

The following areas of the State of Louisiana have been designated as adversely affected by this declared emergency:

The parishes of Assumption, Iberia, Jefferson, Lafourche, Livingston, Orleans, Plaquemines, St. Bernard, St. Charles, St. James, St. John the Baptist, St. Martin, St. Mary, St. Tammany, Tangipahoa, Terrebonne, and Vermillion for emergency protective measures (Category B), including direct federal assistance, under the Public Assistance program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households in Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

**Brock Long,**

*Administrator, Federal Emergency Management Agency.*

[FR Doc. 2017–23240 Filed 10–25–17; 8:45 am]

**BILLING CODE 9111–23–P**

## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

**[Internal Agency Docket No. FEMA–4339–DR; Docket ID FEMA–2017–0001]**

### Puerto Rico; Amendment No. 3 to Notice of a Major Disaster Declaration

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Notice.

**SUMMARY:** This notice amends the notice of a major disaster declaration for the Commonwealth of Puerto Rico (FEMA–4339–DR), dated September 20, 2017, and related determinations.

**DATES:** The change occurred on October 10, 2017.

**FOR FURTHER INFORMATION CONTACT:** Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

**SUPPLEMENTARY INFORMATION:** The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Michael F. Byrne, of FEMA is appointed to act as the Federal Coordinating Officer for this disaster.

This action terminates the appointment of Alejandro DeLaCampa as Federal Coordinating Officer for this disaster.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

**Brock Long,**

*Administrator, Federal Emergency Management Agency.*

[FR Doc. 2017–23241 Filed 10–25–17; 8:45 am]

**BILLING CODE 9111–23–P**

## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

**[Internal Agency Docket No. FEMA–4336–DR; Docket ID FEMA–2017–0001]**

### Puerto Rico; Amendment No. 5 to Notice of a Major Disaster Declaration

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Notice.

**SUMMARY:** This notice amends the notice of a major disaster declaration for the Commonwealth of Puerto Rico (FEMA–4336–DR), dated September 10, 2017, and related determinations.

**DATES:** The change occurred on October 10, 2017.

**FOR FURTHER INFORMATION CONTACT:** Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

**SUPPLEMENTARY INFORMATION:** The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Michael F. Byrne, of FEMA is appointed to act as the Federal Coordinating Officer for this disaster.

This action terminates the appointment of Alejandro DeLaCampa as Federal Coordinating Officer for this disaster.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

**Brock Long,**

*Administrator, Federal Emergency Management Agency.*

[FR Doc. 2017–23243 Filed 10–25–17; 8:45 am]

**BILLING CODE 9111–23–P**

## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

**[Docket ID FEMA–2017–0002]**

### Final Flood Hazard Determinations

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Final Notice.

**SUMMARY:** Flood hazard determinations, which may include additions or modifications of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or regulatory floodways on the Flood Insurance Rate Maps (FIRMs) and where applicable, in the supporting Flood Insurance Study (FIS) reports have been made final for the communities listed in the table below.

The FIRM and FIS report are the basis of the floodplain management measures that a community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the Federal Emergency Management Agency's (FEMA's) National Flood Insurance Program (NFIP). In addition, the FIRM and FIS report are used by insurance agents and others to calculate appropriate flood insurance premium rates for buildings and the contents of those buildings.

**DATES:** The date of January 5, 2018 has been established for the FIRM and, where applicable, the supporting FIS report showing the new or modified flood hazard information for each community.

**ADDRESSES:** The FIRM, and if applicable, the FIS report containing the final flood hazard information for each community is available for inspection at the respective Community Map Repository address listed in the tables below and will be available online through the FEMA Map Service Center at *www.msc.fema.gov* by the date indicated above.

**FOR FURTHER INFORMATION CONTACT:** Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW., Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Map Information eXchange (FMIX) online at *www.floodmaps.fema.gov/fhm/fmx_main.html.*

**SUPPLEMENTARY INFORMATION:** The Federal Emergency Management Agency (FEMA) makes the final determinations listed below for the new or modified flood hazard information for each community listed. Notification of these changes has been published in newspapers of local circulation and 90 days have elapsed since that publication. The Deputy Associate Administrator for Insurance and Mitigation has resolved any appeals resulting from this notification.

This final notice is issued in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR part 67. FEMA has developed criteria for floodplain management in floodprone areas in accordance with 44 CFR part 60.

Interested lessees and owners of real property are encouraged to review the new or revised FIRM and FIS report available at the address cited below for each community or online through the FEMA Map Service Center at *www.msc.fema.gov.*

The flood hazard determinations are made final in the watersheds and/or communities listed in the table below.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Dated: October 13, 2017.

**Roy E. Wright,**

*Deputy Associate Administrator for Insurance and Mitigation, Department of Homeland Security, Federal Emergency Management Agency.*

I. Watershed-based studies:

| Community | Community map repository address |
|---|---|
| **Upper Chattahoochee Watershed** | |
| **Habersham County, Georgia and Incorporated Areas Docket No.: FEMA–B–1647** | |
| City of Baldwin | City Hall, 130 Airport Road, Baldwin, GA 30511. |
| City of Clarkesville | City Hall, 123 North Laurel Drive, Clarkesville, GA 30523. |
| City of Cornelia | City Hall, 181 Larkin Street, Cornelia, GA 30531. |
| City of Demorest | City Hall, 546 Georgia Street, Demorest, GA 30535. |
| Town of Alto | Town Hall, 162 South Grant Street, Alto, GA 30510. |
| Unincorporated Areas of Habersham County | Habersham County Planning and Development Department, 555 Monroe Street, Suite 70, Clarkesville, GA 30523. |
| **White County, Georgia and Incorporated Areas Docket No.: FEMA–B–1647** | |
| City of Cleveland | City Clerk's Office, 85 South Main Street, Cleveland, GA 30528. |
| City of Helen | City Hall, 25 Alpenrosen Strasse, Helen, GA 30545. |
| Unincorporated Areas of White County | White County Planning Office, 1241 Helen Highway, Cleveland, GA 30528. |
| **Lower Sabine Watershed** | |
| **Beauregard Parish, Louisiana and Incorporated Areas Docket No.: FEMA–B–1644** | |
| Town of Merryville | Town Hall, 1009 State Highway 110 West, Merryville, LA 70653. |
| Unincorporated Areas of Beauregard Parish | Beauregard Parish Department of Public Works, 201 West 2nd Street, DeRidder, LA 70634. |

II. Non-watershed-based studies:

| Community | Community map repository address |
|---|---|
| **Glynn County, Georgia and Incorporated Areas Docket No.: FEMA–B–1642** | |
| City of Brunswick | City Hall, 601 Gloucester Street, Brunswick, GA 31520. |
| Jekyll Island State Park Authority | Fire and EMS Department, 200 Stable Road, Jekyll Island, GA 31527. |
| Unincorporated Areas of Glynn County | Glynn County Offices, Harold Pate Building, 1725 Reynolds Street, 2nd Floor, Brunswick, GA 31520. |

[FR Doc. 2017–23227 Filed 10–25–17; 8:45 am]

**BILLING CODE 9110–12–P**

## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

**[Docket ID FEMA–2017–0002; Internal Agency Docket No. FEMA–B–1756]**

### Changes in Flood Hazard Determinations

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Notice.

**SUMMARY:** This notice lists communities where the addition or modification of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or the regulatory floodway (hereinafter referred to as flood hazard determinations), as shown on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports, prepared by the Federal Emergency Management Agency (FEMA) for each community, is appropriate because of new scientific or technical data. The FIRM, and where applicable, portions of the FIS report, have been revised to reflect these flood hazard determinations through issuance of a Letter of Map Revision (LOMR). The LOMR will be used by insurance agents and others to calculate appropriate flood insurance premium rates for new buildings and the contents of those buildings. For rating purposes, the currently effective community number is shown in the table below and must be used for all new policies and renewals.

**DATES:** These flood hazard determinations will be finalized on the dates listed in the table below and revise the FIRM panels and FIS report in effect prior to this determination for the listed communities.

From the date of the second publication of notification of these

changes in a newspaper of local circulation, any person has 90 days in which to request through the community that the Deputy Associate Administrator for Insurance and Mitigation reconsider the changes. The flood hazard determination information may be changed during the 90-day period.

**ADDRESSES:** The affected communities are listed in the table below. Revised flood hazard information for each community is available for inspection at both the online location and the respective community map repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *www.msc.fema.gov* for comparison.

Submit comments and/or appeals to the Chief Executive Officer of the community as listed in the table below.

**FOR FURTHER INFORMATION CONTACT:** Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW., Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Map Information eXchange (FMIX) online at *www.floodmaps.fema.gov/fhm/fmx_main.html.*

**SUPPLEMENTARY INFORMATION:** The specific flood hazard determinations are not described for each community in this notice. However, the online location and local community map repository address where the flood hazard determination information is available for inspection is provided.

Any request for reconsideration of flood hazard determinations must be submitted to the Chief Executive Officer of the community as listed in the table below.

The modifications are made pursuant to section 201 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.,* and with 44 CFR part 65.

The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

These flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. The flood hazard determinations are in accordance with 44 CFR 65.4.

The affected communities are listed in the following table. Flood hazard determination information for each community is available for inspection at both the online location and the respective community map repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *www.msc.fema.gov* for comparison.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Dated: October 13, 2017.

**Roy E. Wright,**

*Deputy Associate Administrator for Insurance and Mitigation, Department of Homeland Security, Federal Emergency Management Agency.*

| State and county | Location and case No. | Chief executive officer of community | Community map repository | Online location of letter of map revision | Date of modification | Community No. |
|---|---|---|---|---|---|---|
| Alaska: Anchorage | Municipality of Anchorage (17–10–0709P). | The Honorable Ethan Berkowitz, Mayor, Municipality of Anchorage, 632 West 6th Avenue, Suite 840, Anchorage, AK 99501. | City Hall, 632 West 6th Avenue, Anchorage, AK 99501. | *http://www.msc.fema.gov/lomc* | Jan. 12, 2018 ..... | 020005 |
| California: | | | | | | |
| Riverside ..... | City of Corona (17–09–0805P). | The Honorable Dick Haley, Mayor, City of Corona, 400 South Vicentia Avenue, Corona, CA 92882. | City Hall, 400 South Vicentia Avenue, Corona, CA 92882. | *http://www.msc.fema.gov/lomc* | Jan. 19, 2018 ..... | 060250 |
| Riverside ..... | Unincorporated Areas of Riverside County (17–09–0805P). | The Honorable John F. Tavaglione, Chairman, Board of Supervisors, Riverside County, 4080 Lemon Street, 5th Floor, Riverside, CA 92501. | Riverside County Flood and Water Conservation District, 1995 Market Street, Riverside, CA 92502. | *http://www.msc.fema.gov/lomc* | Jan. 19, 2018 ..... | 060245 |
| Sacramento .... | Unincorporated Areas of Sacramento County (16–09–2857P). | The Honorable Don Nottoli, Chairman, Board of Supervisors, Sacramento County, 700 H Street, Suite 2450, Sacramento, CA 95814. | Sacramento County, Department of Water Resources, 827 7th Street, Suite 301, Sacramento, CA 95814. | *http://www.msc.fema.gov/lomc* | Jan. 10, 2018 ..... | 060262 |
| San Benito ..... | City of Hollister (17–09–1234P). | The Honorable Ignacio Velazquez, Mayor, City of Hollister, 375 5th Street, Hollister, CA 95023. | Planning Department, 420 Hill Street, Building A, Hollister, CA 95023. | *http://www.msc.fema.gov/lomc* | Jan. 8, 2018 ..... | 060268 |
| San Benito ..... | Unincorporated Areas of San Benito County (17–09–1234P). | The Honorable Jaime De La Cruz, Chairman, Board of Supervisors, San Benito County, 481 4th Street, 1st Floor, Hollister, CA 95023. | San Benito County Department of Public Works, 3220 Southside Road, Hollister, CA 95023. | *http://www.msc.fema.gov/lomc* | Jan. 8, 2018 ..... | 060267 |

| State and county | Location and case No. | Chief executive officer of community | Community map repository | Online location of letter of map revision | Date of modification | Community No. |
|---|---|---|---|---|---|---|
| San Luis Obispo. | Unincorporated Areas of San Luis Obispo County (16–09–3181P). | The Honorable John Peschong, Chairman, Board of Supervisors, San Luis Obispo County, 1055 Monterey Street, Suite D430, San Luis Obispo, CA 93408. | San Luis Obispo County Public Works Department, 976 Osos Street, Room 207, San Luis Obispo, CA 93401. | *http://www.msc.fema.gov/lomc* | Jan. 11, 2018 ..... | 060304 |
| Santa Clara .... | City of San Jose (16–09–3074P). | The Honorable Sam Liccardo, Mayor, City of San Jose, 200 East Santa Clara Street, 18th Floor, San Jose, CA 95113. | Department of Public Works, 200 East Santa Clara Street, 5th Floor, San Jose, CA 95113. | *http://www.msc.fema.gov/lomc* | Jan. 5, 2018 ..... | 060349 |
| Florida: St. Johns .. | Unincorporated Areas of St. Johns County (17–04–4604P). | The Honorable James K. Johns, Chairman, St. Johns County Board of Commissioners, 500 San Sebastian View, St. Augustine, FL 32084. | St. Johns County Administration Building, 4020 Lewis Speedway, St. Augustine, FL 32084. | *http://www.msc.fema.gov/lomc* | Jan. 12, 2018 ..... | 125147 |
| Idaho: | | | | | | |
| Ada ..... | City of Eagle (17–10–1535P). | The Honorable Stan Ridgeway, Mayor, City of Eagle, City Hall, 660 East Civic Lane, Eagle, ID 83616. | City Hall, 660 East Civic Street, Eagle, ID 83616. | *http://www.msc.fema.gov/lomc* | Jan. 16, 2018 ..... | 160003 |
| Ada ..... | Unincorporated Areas of Ada County (17–10–1535P). | The Honorable David L. Case, Chairman, Ada County Board of Commissioners, 200 West Front Street, 3rd Floor, Boise, ID 83702. | Ada County Courthouse, 200 Front West Street, Boise, ID 83702. | *http://www.msc.fema.gov/lomc* | Jan. 16, 2018 ..... | 160001 |
| Kansas: Johnson .. | City of Overland Park (17–07–1247P). | The Honorable Carl Gerlach, Mayor, City of Overland Park, City Hall, 8500 Santa Fe Drive, Overland Park, KS 66212. | City Hall, 8500 Santa Fe Drive, Overland Park, KS 66212. | *http://www.msc.fema.gov/lomc* | Jan. 5, 2018 ..... | 200174 |

[FR Doc. 2017–23230 Filed 10–25–17; 8:45 am]

**BILLING CODE 9110–12–P**

## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

**[Docket ID FEMA–2017–0002; Internal Agency Docket No. FEMA–B–1751]**

### Proposed Flood Hazard Determinations

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Notice.

**SUMMARY:** Comments are requested on proposed flood hazard determinations, which may include additions or modifications of any Base Flood Elevation (BFE), base flood depth, Special Flood Hazard Area (SFHA) boundary or zone designation, or regulatory floodway on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports for the communities listed in the table below. The purpose of this notice is to seek general information and comment regarding the preliminary FIRM, and where applicable, the FIS report that the Federal Emergency Management Agency (FEMA) has provided to the affected communities. The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP). In addition, the FIRM and FIS report, once effective, will be used by insurance agents and others to calculate appropriate flood insurance premium rates for new buildings and the contents of those buildings.

**DATES:** Comments are to be submitted on or before January 24, 2018.

**ADDRESSES:** The Preliminary FIRM, and where applicable, the FIS report for each community are available for inspection at both the online location and the respective Community Map Repository address listed in the tables below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *www.msc.fema.gov* or *http://www.fema.gov/preliminaryfloodhazarddata* for comparison.

You may submit comments, identified by Docket No. FEMA–B–1751, to Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW., Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov.*

**FOR FURTHER INFORMATION CONTACT:** Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW., Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Map Information eXchange (FMIX) online at *www.floodmaps.fema.gov/fhm/fmx_main.html.*

**SUPPLEMENTARY INFORMATION:** FEMA proposes to make flood hazard determinations for each community listed below, in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR 67.4(a).

These proposed flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be

construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. These flood hazard determinations are used to meet the floodplain management requirements of the NFIP and also are used to calculate the appropriate flood insurance premium rates for new buildings built after the FIRM and FIS report become effective.

The communities affected by the flood hazard determinations are provided in the tables below. Any request for reconsideration of the revised flood hazard information shown on the Preliminary FIRM and FIS report that satisfies the data requirements outlined in 44 CFR 67.6(b) is considered an appeal. Comments unrelated to the flood hazard determinations also will be considered before the FIRM and FIS report become effective.

Use of a Scientific Resolution Panel (SRP) is available to communities in support of the appeal resolution process. SRPs are independent panels of experts in hydrology, hydraulics, and other pertinent sciences established to review conflicting scientific and technical data and provide recommendations for resolution. Use of the SRP only may be exercised after FEMA and local communities have been engaged in a collaborative consultation process for at least 60 days without a mutually acceptable resolution of an appeal. Additional information regarding the SRP process can be found online at *http://floodsrp.org/pdfs/srp_fact_sheet.pdf.*

The watersheds and/or communities affected are listed in the tables below. The Preliminary FIRM, and where applicable, FIS report for each community are available for inspection at both the online location and the respective Community Map Repository address listed in the tables. For communities with multiple ongoing Preliminary studies, the studies can be identified by the unique project number and Preliminary FIRM date listed in the tables. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *www.msc.fema.gov* for comparison.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Dated: October 13, 2017.

**Roy E. Wright,**

*Deputy Associate Administrator for Insurance and Mitigation, Department of Homeland Security, Federal Emergency Management Agency.*

| Community | Community map repository address |
|---|---|
| **Charleston County, South Carolina and Incorporated Areas** | |
| **Project: 07–04–4771S Preliminary Date: September 9, 2016** | |
| City of Charleston | Engineering Department, 2 George Street, Suite 2100, Charleston, SC 29401. |
| City of Folly Beach | City Hall, 21 Center Street, Folly Beach, SC 29439. |
| City of Isle of Palms | City Hall, 1207 Palm Boulevard, Isle of Palms, SC 29451. |
| City of North Charleston | City Hall, 2500 City Hall Lane, North Charleston, SC 29406. |
| Town of Awendaw | Town Hall, 6971 Doar Road, Awendaw, SC 29429. |
| Town of Hollywood | Town Hall, 6278 Highway 162, Hollywood, SC 29449. |
| Town of James Island | Town Hall, 1238–B Camp Road, James Island, SC 29412. |
| Town of Kiawah Island | Town Hall, 4475 Betsy Kerrison Parkway, Kiawah Island, SC 29455. |
| Town of McClellanville | Town Hall, 405 Pinckney Street, McClellanville, SC 29458. |
| Town of Meggett | Town Hall, 4776 Highway 165, Meggett, SC 29449. |
| Town of Mount Pleasant | Municipal Complex, 100 Ann Edwards Lane, Mount Pleasant, SC 29464. |
| Town of Ravenel | Town Hall, 5962 Highway 165, Suite 100, Ravenel, SC 29470. |
| Town of Rockville | Rockville Presbyterian Church, 2479 Sea Island Yacht Club Road, Wadmalaw Island, SC 29487. |
| Town of Seabrook Island | Town Hall, 2001 Seabrook Island Road, Seabrook Island, SC 29455. |
| Town of Sullivan's Island | Town Hall, 2056 Middle Street, Sullivan's Island, SC 29482. |
| Unincorporated Areas of Charleston County | Charleston County Lonnie Hamilton, III Public Services Building, 4045 Bridge View Drive, North Charleston, SC 29405. |
| **Travis County, Texas and Incorporated Areas** | |
| **Project: 13–06–0041S Preliminary Date: April 7, 2017** | |
| City of Austin | Watershed Engineering Division, 505 Barton Springs Road, 12th Floor, Austin, TX 78704. |
| City of Bee Cave | City Hall, 4000 Galleria Parkway, Bee Cave, TX 78738. |
| City of Jonestown | City Hall, 18649 FM 1431, Suite 4A, Jonestown, TX 78645. |
| City of Lago Vista | City Hall, 5803 Thunderbird Street, Lago Vista, TX 78645. |
| City of Lakeway | City Hall, 1102 Lohmans Crossing Road, Lakeway, TX 78734. |
| City of Leander | City Hall, 200 West Willis Street, Leander, TX 78641. |
| City of West Lake Hills | City Hall, 911 Westlake Drive, West Lake Hills, TX 78746. |
| Unincorporated Areas of Travis County | Travis County Transportation and Natural Resources, 700 Lavaca Street, 5th Floor, Austin, TX 78701. |
| Village of The Hills | Administrative Offices, 102 Trophy Drive, The Hills, TX 78738. |

[FR Doc. 2017–23228 Filed 10–25–17; 8:45 am]

BILLING CODE 9110–12–P

## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

**[Internal Agency Docket No. FEMA–3392–EM; Docket ID FEMA–2017–0001]**

### Louisiana; Amendment No. 2 to Notice of an Emergency Declaration

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Notice.

**SUMMARY:** This notice amends the notice of an emergency declaration for the State of Louisiana (FEMA–3392–EM), dated October 6, 2017, and related determinations.

**DATES:** This amendment was issued October 13, 2017.

**FOR FURTHER INFORMATION CONTACT:** Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

**SUPPLEMENTARY INFORMATION:** Notice is hereby given that the incident period for this emergency is closed effective October 8, 2017.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

**Brock Long,**

*Administrator, Federal Emergency Management Agency.*

[FR Doc. 2017–23238 Filed 10–25–17; 8:45 am]

BILLING CODE 9111–23–P

## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

**[Internal Agency Docket No. FEMA–4343–DR; Docket ID FEMA–2017–0001]**

### Wisconsin; Amendment No. 1 to Notice of a Major Disaster Declaration

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Notice.

**SUMMARY:** This notice amends the notice of a major disaster declaration for the State of Wisconsin (FEMA–4343–DR), dated October 7, 2017, and related determinations.

**DATES:** The change occurred on October 8, 2017.

**FOR FURTHER INFORMATION CONTACT:** Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

**SUPPLEMENTARY INFORMATION:** The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Janet M. Odeshoo, of FEMA is appointed to act as the Federal Coordinating Officer for this emergency.

This action terminates the appointment of Benigno Bern Ruiz as Federal Coordinating Officer for this disaster.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

**Brock Long,**

*Administrator, Federal Emergency Management Agency.*

[FR Doc. 2017–23249 Filed 10–25–17; 8:45 am]

BILLING CODE 9111–23–P

## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

**[Internal Agency Docket No. FEMA–4343–DR; Docket ID FEMA–2017–0001]**

### Wisconsin; Major Disaster and Related Determinations

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Notice.

**SUMMARY:** This is a notice of the Presidential declaration of a major disaster for the State of Wisconsin (FEMA–4343–DR), dated October 7, 2017, and related determinations.

**DATES:** The declaration was issued October 7, 2017.

**FOR FURTHER INFORMATION CONTACT:** Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

**SUPPLEMENTARY INFORMATION:** Notice is hereby given that, in a letter dated October 7, 2017, the President issued a major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''), as follows:

I have determined that the damage in certain areas of the State of Wisconsin resulting from severe storms, straight-line winds, flooding, landslides, and mudslides during the period of July 19–23, 2017, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''). Therefore, I declare that such a major disaster exists in the State of Wisconsin.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Public Assistance in the designated areas and Hazard Mitigation throughout the State. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Hazard Mitigation will be limited to 75 percent of the total eligible costs. Federal funds provided under the Stafford Act for Public Assistance also will be limited to 75 percent of the total eligible costs, with the exception of projects that meet the eligibility criteria for a higher Federal cost-sharing percentage under the Public Assistance Alternative Procedures Pilot Program for Debris Removal implemented pursuant to section 428 of the Stafford Act.

Further, you are authorized to make changes to this declaration for the approved

assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Benigno Bern Ruiz, of FEMA is appointed to act as the Federal Coordinating Officer for this major disaster.

The following areas of the State of Wisconsin have been designated as adversely affected by this major disaster:

Buffalo, Crawford, Grant, Iowa, Jackson, La Crosse, Lafayette, Monroe, Richland, Trempealeau, and Vernon Counties for Public Assistance.

All areas within the State of Wisconsin are eligible for assistance under the Hazard Mitigation Grant Program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

**Brock Long,**

*Administrator, Federal Emergency Management Agency.*

[FR Doc. 2017–23251 Filed 10–25–17; 8:45 am]

**BILLING CODE 9111–23–P**

## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

**[Internal Agency Docket No. FEMA–3391–EM; Docket ID FEMA–2017–0001]**

### Puerto Rico; Amendment No. 1 to Notice of an Emergency Declaration

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Notice.

**SUMMARY:** This notice amends the notice of an emergency declaration for the Commonwealth of Puerto Rico (FEMA–3391–EM), dated September 18, 2017, and related determinations.

**DATES:** The change occurred on October 10, 2017.

**FOR FURTHER INFORMATION CONTACT:** Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

**SUPPLEMENTARY INFORMATION:** The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Michael F. Byrne, of FEMA is appointed to act as the Federal Coordinating Officer for this emergency.

This action terminates the appointment of Alejandro DeLaCampa as Federal Coordinating Officer for this emergency.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

**Brock Long,**

*Administrator, Federal Emergency Management Agency.*

[FR Doc. 2017–23245 Filed 10–25–17; 8:45 am]

**BILLING CODE 9111–23–P**

## DEPARTMENT OF HOMELAND SECURITY

### National Protection and Programs Directorate; Notification of Issuance of Binding Operational Directive 18–01

**AGENCY:** National Protection and Programs Directorate, DHS.

**ACTION:** Issuance of a binding operational directive; notice of availability.

**SUMMARY:** To safeguard Federal information and information systems, DHS has issued a binding operational directive (BOD) to all Federal, executive branch departments and agencies relating to enhanced email and web security. The BOD requires agencies to take specific actions on their information systems to improve email and web security. DHS is publishing this notice of availability to provide awareness of the BOD.

**DATES:** Binding Operational Directive 18–01 was issued on October 16, 2017.

**ADDRESSES:** The text of Binding Operational Directive 18–01 is available at *https://cyber.dhs.gov.* Submit any inquiries about this notice of availability to *BOD.Feedback@hq.dhs.gov.*

**SUPPLEMENTARY INFORMATION:** The Department of Homeland Security (''DHS'' or ''the Department'') has the statutory responsibility, in consultation with the Office of Management and Budget, to administer the implementation of agency information security policies and practices for information systems, which includes assisting agencies and providing certain government-wide protections. 44 U.S.C. 3553(b). As part of that responsibility, the Department is authorized to ''develop[] and oversee[] the implementation of binding operational directives to agencies to implement the policies, principles, standards, and guidance developed by the Director [of the Office of Management and Budget] and [certain] requirements of [the Federal Information Security Modernization Act of 2014.]'' 44 U.S.C. 3553(b)(2). A BOD is ''a compulsory direction to an agency that (A) is for purposes of safeguarding Federal information and information systems from a known or reasonably suspected information security threat, vulnerability, or risk; [and] (B) [is] in accordance with policies, principles, standards, and guidelines issued by the Director[.]'' 44 U.S.C. 3552(b)(1). Agencies are required to comply with these directives. 44 U.S.C. 3554(a)(1)(B)(ii).

#### Overview of BOD 18–01

In carrying out this statutory responsibility, the Department issued BOD 18–01, titled ''Enhance Email and Web Security.'' For email security, the BOD requires agencies to take specific technical actions to ensure that agency email can be encrypted in transit and is more difficult to spoof. For web security, the BOD requires agencies to take specific technical actions to ensure publicly accessible Federal Web sites and services are provided through secure connections. Across both topics, the BOD requires that agencies disable and discontinue use of certain, vulnerable ciphers and Secure Socket Layer configurations.

**Jeanette Manfra,**

*Assistant Secretary, Office of Cybersecurity and Communications, Department of Homeland Security.*

[FR Doc. 2017–23317 Filed 10–25–17; 8:45 am]

**BILLING CODE 9110–9P–P**

## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

**[Docket No. FR–5815–N–03]**

## Statutorily Mandated Designation of Difficult Development Areas and Qualified Census Tracts: Revision of Effective Date for 2015 Designations

**AGENCY:** Office of the Assistant Secretary for Policy Development and Research, HUD.

**ACTION:** Notice.

**SUMMARY:** This document revises the effective date for designations of ''Difficult Development Areas'' (DDAs) and ''Qualified Census Tracts'' (QCTs) for purposes of the Low-Income Housing Tax Credit (LIHTC) under Internal Revenue Code (IRC) Section 42 published on October 3, 2014 at 79 FR 59855 and amended December 17, 2015 at 80 FR 78749 in areas approved for Federal disaster-related individual assistance under the Stafford Act. This Notice extends from 730 days to 850 days the period for which the 2015 lists of QCTs and DDAs are effective for projects located in an area that was approved for individual assistance under the Stafford Act in 2017, not on subsequent lists of DDAs or QCTs; and submitted applications while the area was a 2015 QCT or DDA.

**FOR FURTHER INFORMATION CONTACT:** For questions on how areas are designated and on geographic definitions, contact Michael K. Hollar, Senior Economist, Economic Development and Public Finance Division, Office of Policy Development and Research, Department of Housing and Urban Development, 451 Seventh Street SW., Room 8234, Washington, DC 20410–6000; telephone number (202) 402–5878, or send an email to *Michael.K.Hollar@hud.gov.* For specific legal questions, contact Branch 5, Office of the Associate Chief Counsel, Passthroughs and Special Industries, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC 20224; telephone number (202) 317–4137, fax number (855) 591–7867. (These are not toll-free telephone numbers.) Additional copies of this notice are available through HUD User at (800) 245–2691 for a small fee to cover duplication and mailing costs.

**COPIES AVAILABLE ELECTRONICALLY:** This notice and additional information about DDAs and QCTs are available electronically on the Internet at *http://www.huduser.org/datasets/qct.html.*

**SUPPLEMENTARY INFORMATION:**

### This Notice

This notice extends from 730 days to 850 days the period for which the 2015 lists of QCTs and DDAs are effective for projects located in areas approved for federal individual assistance under the Robert T. Stafford Disaster Relief and Emergency Assistance Act (Stafford Act) (42 U.S.C. 5170, et al.) due to a Presidentially-declared natural disaster in 2017 (hereafter, ''declared counties'') and were not in areas on subsequent lists of DDAs or QCTs but submitted applications while the area was a 2015 QCT or DDA. DDAs and QCTs for 2016 were published on November 24, 2015 at 80 FR 73201. DDAs and QCTs for 2017 were published on October 17, 2016 at 81 FR 71523. DDAs and QCTs for 2018 were published on September 11, 2017 at 82 FR 42694. This applies to declared counties in each of the 50 states, the District of Columbia, Puerto Rico, American Samoa, Guam, the Northern Mariana Islands, and the U.S. Virgin Islands. The actual designations of 2015 QCTs and DDAs are not affected by this notice. HUD is revising the effective date of the 2015 QCTs and DDAs in declared counties at this time to aid the ability of areas affected by natural disasters to place in service affordable housing.

For LIHTC and bond-financed projects located in declared counties, the sections entitled ''Effective Date'' and ''Interpretive Examples of Effective Date'' of the 2015 DDA and QCT designations as published October 3, 2014 at 79 FR 59855 and December 17, 2015 at 80 FR78749 are hereby revised to read as follows:

### Effective Date

The 2015 lists of QCTs and DDAs are effective:

(1) For allocations of credit after December 31, 2014; or

(2) For purposes of IRC section 42(h)(4), if the bonds are issued and the building is placed in service after December 31, 2014.

If an area is not on a subsequent list of DDAs, the 2015 lists are effective for the area if:

(1) The allocation of credit to an applicant is made no later than the end of the 850-day period after the applicant submits a complete application to the LIHTC-allocating agency, and the submission is made before the effective date of the subsequent lists; or

(2) For purposes of IRC section 42(h)(4), if:

(a) The bonds are issued or the building is placed in service no later than the end of the 850-day period after the applicant submits a complete application to the bond-issuing agency, and

(b) The submission is made before the effective date of the subsequent lists, provided that both the issuance of the bonds and the placement in service of the building occur after the application is submitted.

An application is deemed to be submitted on the date it is filed if the application is determined to be complete by the credit-allocating or bond-issuing agency. A ''complete application'' means that no more than de minimis clarification of the application is required for the agency to make a decision about the allocation of tax credits or issuance of bonds requested in the application.

In the case of a ''multiphase project,'' the DDA or QCT status of the site of the project that applies for all phases of the project is that which applied when the project received its first allocation of LIHTC. For purposes of IRC section 42(h)(4), the DDA or QCT status of the site of the project that applies for all phases of the project is that which applied when the first of the following occurred: (a) The building(s) in the first phase were placed in service, or (b) the bonds were issued.

For purposes of this notice, a ''multiphase project'' is defined as a set of buildings to be constructed or rehabilitated under the rules of the LIHTC and meeting the following criteria:

(1) The multiphase composition of the project (*i.e.,* total number of buildings and phases in project, with a description of how many buildings are to be built in each phase and when each phase is to be completed, and any other information required by the agency) is made known by the applicant in the first application of credit for any building in the project, and that applicant identifies the buildings in the project for which credit is (or will be) sought;

(2) The aggregate amount of LIHTC applied for on behalf of, or that would eventually be allocated to, the buildings on the site exceeds the one-year limitation on credits per applicant, as defined in the Qualified Allocation Plan (QAP) of the LIHTC-allocating agency, or the annual per-capita credit authority of the LIHTC allocating agency, and is the reason the applicant must request multiple allocations over two or more years; and

(3) All applications for LIHTC for buildings on the site are made in immediately consecutive years.

Members of the public are hereby reminded that the Secretary of Housing and Urban Development, or the

Secretary's designee, has legal authority to designate DDAs and QCTs, in accordance with 26 U.S.C. 42(d)(5), by publishing lists of geographic entities as defined by, in the case of DDAs, the Census Bureau, the several states and the governments of the insular areas of the United States and, in the case of QCTs, by the Census Bureau; and to establish the effective dates of such lists. The Secretary of the Treasury, through the IRS thereof, has sole legal authority to interpret, and to determine and enforce compliance with the IRC and associated regulations, including **Federal Register** notices published by HUD for purposes of designating DDAs and QCTs. Representations made by any other entity as to the content of HUD notices designating DDAs and QCTs that do not precisely match the language published by HUD should not be relied upon by taxpayers in determining what actions are necessary to comply with HUD notices.

**Interpretive Examples of Effective Date**

For the convenience of readers of this notice, interpretive examples are provided below to illustrate the consequences of the effective date in areas that gain or lose DDA status. The examples covering DDAs are equally applicable to QCT designations.

(Case A) Project A is located in a 2015 DDA that is NOT a designated DDA in 2016, 2017, or 2018 and is in a declared county. A complete application for tax credits for Project A is filed with the allocating agency on November 15, 2015. Credits are allocated to Project A on January 30, 2018. Project A is eligible for the increase in basis accorded a project in a 2015 DDA because the application was filed BEFORE January 1, 2016 (the effective date for the 2016 DDA lists), and because tax credits were allocated no later than the end of the 850-day period after the filing of the complete application for an allocation of tax credits.

(Case B) Project B is located in a 2015 DDA that is NOT a designated DDA in 2016, 2017, or 2018 and is in a declared county. A complete application for tax credits for Project B is filed with the allocating agency on December 1, 2015. Credits are allocated to Project B on June 30, 2018. Project B is NOT eligible for the increase in basis accorded a project in a 2015 DDA because, although the application for an allocation of tax credits was filed BEFORE January 1, 2016 (the effective date of the 2016 DDA lists), the tax credits were allocated later than the end of the 850-day period after the filing of the complete application.

(Case C) Project C is located in a 2015 DDA that was not a DDA in 2014. Project C was placed in service on November 15, 2014. A complete application for tax-exempt bond financing for Project C is filed with the bond-issuing agency on January 15, 2015. The bonds that will support the permanent financing of Project C are issued on September 30, 2015. Project C is NOT eligible for the increase in basis otherwise accorded a project in a 2015 DDA, because the project was placed in service BEFORE January 1, 2015.

(Case D) Project D is located in an area that is a DDA in 2015, but is NOT a DDA in 2016, 2017, or 2018 and is in a declared county. A complete application for tax-exempt bond financing for Project D is filed with the bond-issuing agency on October 30, 2015. Bonds are issued for Project D on January 30, 2018, but Project D is not placed in service until July 30, 2018. Project D is eligible for the increase in basis available to projects located in 2015 DDAs because: (1) One of the two events necessary for triggering the effective date for buildings described in Section 42(h)(4)(B) of the IRC (the two events being bonds issued and buildings placed in service) took place on January 30, 2018, within the 850-day period after a complete application for tax-exempt bond financing was filed, (2) the application was filed during a time when the location of Project D was in a DDA, and (3) both the issuance of the bonds and placement in service of Project D occurred after the application was submitted.

**Findings and Certifications**

*A. Environmental Impact*

This notice involves the establishment of fiscal requirements or procedures that are related to rate and cost determinations and do not constitute a development decision affecting the physical condition of specific project areas or building sites. Accordingly, under 40 CFR 1508.4 of the regulations of the Council on Environmental Quality and 24 CFR 50.19(c)(6) of HUD's regulations, this notice is categorically excluded from environmental review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321).

*B. Federalism Impact*

Executive Order 13132 (entitled ''Federalism'') prohibits an agency from publishing any policy document that has federalism implications if the document either imposes substantial direct compliance costs on state and local governments and is not required by statute, or the document preempts state law, unless the agency meets the consultation and funding requirements of section 6 of the executive order. This notice merely designates DDAs as required under IRC Section 42, as amended, for the use by political subdivisions of the states in allocating the LIHTC. As a result, this notice is not subject to review under the order.

Dated: October 19, 2017.

**Kurt G. Usowski,**

*Deputy Assistant Secretary for Economic Affairs.*

[FR Doc. 2017–23306 Filed 10–25–17; 8:45 am]

**BILLING CODE 4210–67–P**

## DEPARTMENT OF THE INTERIOR

### Bureau of Indian Affairs

**[189A2100DD/AAKC001030/A0A501010.999900 253G]**

### Indian Gaming; Tribal-State Class III Gaming Compact Taking Effect in the State of New Mexico

**AGENCY:** Bureau of Indian Affairs, Interior.

**ACTION:** Notice.

**SUMMARY:** The notice announces that the Tribal-State Class III Gaming Compact between the Pueblo of Pojoaque and State of New Mexico is taking effect.

**DATES:** This notice is applicable as of October 26, 2017.

**FOR FURTHER INFORMATION CONTACT:** Ms. Paula L. Hart, Director, Office of Indian Gaming, Office of the Deputy Assistant Secretary—Policy and Economic Development, Washington, DC 20240, (202) 219–4066.

**SUPPLEMENTARY INFORMATION:** Under section 11 of the Indian Gaming Regulatory Act (IGRA) Public Law 100–497, 25 U.S.C. 2701 *et seq.,* the Secretary of the Interior shall publish in the **Federal Register** notice of approved Tribal-State compacts for the purpose of engaging in Class III gaming activities on Indian lands. As required by IGRA and 25 CFR 293.4, all compacts are subject to review and approval by the Secretary. The Secretary took no action on the compact between the Pueblo of Pojoaque and the State of New Mexico within 45 days of its submission. Therefore, the Compact is considered to have been approved, but only to the extent the Compact is consistent with IGRA. *See* 25 U.S.C. 2710(d)(8)(C).

Dated: October 23, 2017.

**Gavin Clarkson,**

*Deputy Assistant Secretary, Policy and Economic Development—Indian Affairs.*

[FR Doc. 2017–23343 Filed 10–25–17; 8:45 am]

**BILLING CODE 4337–15–P**

## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

**[17X.LLAK930000.L13100000.EI0000.241A]**

### Notice of National Petroleum Reserve in Alaska Oil and Gas Lease Sale 2017; Notice of Availability of the Detailed Statement of Sale for the NPR–A 2017 Oil and Gas Lease Sale

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice.

**SUMMARY:** The Bureau of Land Management's (BLM) Alaska State Office will hold an oil and gas lease sale bid opening for all available tracts in the National Petroleum Reserve in Alaska (NPR–A).

**DATES:** The oil and gas lease sale bid opening will be at 1 p.m. (AKST) on Wednesday, December 6, 2017. The BLM must receive all sealed bids by 4 p.m. (AKST), Monday, December 4, 2017. The Detailed Statement of Sale for the NPR–A Oil and Gas Lease Sale 2017 will be available to the public on October 26, 2017.

**ADDRESSES:** Sealed bids must be received at the BLM-Alaska State Office, ATTN: Carol Taylor (AK932); 222 West 7th Avenue, #13; Anchorage, AK 99513–7504. You may get the Detailed Statement of Sale from the BLM Alaska Web site at *https://on.doi.gov/2fgHGRq,* or request a copy from the Public Information Center, BLM Alaska State Office, 222 West 7th Avenue, #13; Anchorage, AK 99513–7504; 907–271–5960.

**FOR FURTHER INFORMATION CONTACT:** Robert Brumbaugh, 907–271–4429. People who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

**SUPPLEMENTARY INFORMATION:** The December 2017 NPR–A Oil and Gas Lease Sale will include all 900 tracts (approximately 10.3 million acres) that are available for leasing under the NPR–A Integrated Activity Plan/Environmental Impact Statement Record of Decision (ROD) that was finalized in February 2013. This is the first time that all available tracts, as designated available for development in the 2013 Record of Decision, will be offered for sale.

The opening and reading of the bids for the 2017 lease sale will be available for online public viewing via video livestreaming at *http://www.blm.gov/live.*

The Detailed Statement of Sale will include a description of the areas the BLM is offering for lease, as well as the lease terms, conditions, special stipulations, required operating procedures, and directions for how to submit bids. If you plan to submit a bid(s), please note that all bids must be sealed in accordance with the provisions identified in the Detailed Statement of Sale. The United States reserves the right to withdraw any tract from this sale prior to issuance of a written acceptance of a bid.

**Authority:** 43 CFR 3131.4–1 and 42 U.S.C. 6506a.

**Karen Mouritsen,**

*Acting State Director, Alaska.*

[FR Doc. 2017–23281 Filed 10–25–17; 8:45 am]

**BILLING CODE 4310–JA–P**

## DEPARTMENT OF THE INTERIOR

### National Park Service

**[NPS–WASO–CR–4426; PPWOCRADP3, PCU00RP14.R50000; OMB Control Number 1024–0038]**

### Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Procedures for State, Tribal, and Local Government Historic Preservation Programs

**AGENCY:** National Park Service, Interior.

**ACTION:** Notice of information collection; request for comments.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995, the National Park Service is proposing to renew an information collection.

**DATES:** Interested persons are invited to submit comments on or before November 27, 2017.

**ADDRESSES:** Send written comments on this information collection request (ICR) to the Office of Management and Budget's Desk Officer for the Department of the Interior by email at *OIRA_Submission@omb.eop.gov;* or via facsimile to (202) 395–5806. Please provide a copy of your comments to Tim Goddard, Information Collection Clearance Officer, National Park Service, 12201 Sunrise Valley Drive, MS–242, Reston, VA 20192 (mail); or *tim_goddard@nps.gov* (email). Please reference OMB Control Number 1024–0038 in the subject line of your comments.

**FOR FURTHER INFORMATION CONTACT:** To request additional information about this ICR, contact Kristine Brunsman by email at *Kristine_Brunsman@nps.gov,* or by telephone at (202) 354–2153. You may also view the ICR at *http://www.reginfo.gov/public/do/PRAMain.*

**SUPPLEMENTARY INFORMATION:** We, the National Park Service (NPS), in accordance with the Paperwork Reduction Act of 1995, provide the general public and other Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

A **Federal Register** notice with a 60-day public comment period soliciting comments on this collection of information was published on July 26, 2017 (82 FR 34688). No comments were received.

We are again soliciting comments on the proposed ICR that is described below. We are especially interested in public comment addressing the following issues: (1) Is the collection necessary to the proper functions of the NPS; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the NPS enhance the quality, utility, and clarity of the information to be collected; and (5) how might the NPS minimize the burden of this collection on the respondents, including through the use of information technology.

Comments that you submit in response to this notice are a matter of public record. 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.

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.

*Title of Collection:* Procedures for State, Tribal, and Local Government Historic Preservation Programs.

*OMB Control Number:* 1024–0038.

*Form Number:* None.

*Type of Review:* Extension of a currently approved collection.

*Respondents/Affected Public:* State, tribal, and local governments.

*Total Estimated Number of Annual Responses:* 43,108.

*Total Estimated Number of Annual Burden Hours:* 40,761.

*Total Estimated Number of Annual Respondents:* 2,229.

*Estimated Completion Time per Response:* Varies from 15 minutes to 166 hours, depending on activity.

*Respondent's Obligation:* Required to Obtain or Retain a Benefit.

*Frequency of Collection:* Annually or on occasion.

*Total Estimated Annual Nonhour Burden Cost:* $0.00.

*Abstract:* This set of information collections has an impact on State, Tribal, and local governments that wish to participate formally with the NPS in the National Historic Preservation Partnership (NHPP) Program, and State and Tribal governments that wish to apply for Historic Preservation Fund (HPF) grants. The NPS uses the information collections to ensure compliance with the National Historic Preservation Act, as amended (54 U.S.C. 300101, *et seq.*), as well as government-wide grant requirements OMB has issued and the Department of the Interior implements through 43 CFR part 12. The information collections also produce performance data NPS uses to assess its progress in meeting its statutory mission goals pursuant to the 1993 Government Performance and Results Act, as amended. This request for OMB approval includes local government burden for information collections associated with various aspects of the Certified Local Government (CLG) program; State government burden for information collections related to the CLG program; the program-specific aspects of HPF grants to States, maintenance of a State inventory of historic and prehistoric properties, tracking State Historic Preservation Office historic preservation consultation with Federal agencies, developing the Statewide Historic Preservation Plan, reporting on other State historic preservation accomplishments, the State role in the State program review process, and evaluating NPS-provided program, grants management, and CLG training for State officials; and Tribal government burden for information collections related to the program-specific aspects of HPF grants to Tribal Historic Preservation Officers/Offices (THPOs).

This request includes information collections related to HPF grants to States and to THPOs. Section 101(b) of the National Historic Preservation Act, as amended, (54 U.S.C. 302301), specifies the role of States in the NHPP Program. Section 101(c), section 103(c), and section 301 of the Act (54 U.S.C. 302502, 54 U.S.C. 302902, and 54 U.S.C. 300301), specify the role of local governments in the NHPP program. Section 101(d) of the Act (54 U.S.C. 302701) specifies the role of tribes in the NHPP Program. Section 108 of the Act (54 U.S.C. 303101) created the HPF to support activities that carry out the purposes of the Act. Section 101(e)(1) of the Act (54 U.S.C. 302902) directs the Secretary of the Interior through the NPS to ''administer a program of matching grants to the States for the purposes of carrying out'' the Act. Similarly, sections 101(d) and 101(e) of the Act direct the NPS to administer a program of grants to THPOs for carrying out their responsibilities under the Act. Section 101j of the Act (54 U.S.C. 303903) directs the NPS to provide historic preservation-related education and training.

Each year Congress directs the NPS to use part of the annual appropriation from the HPF for the State grant program and the Tribal grant programs. The purpose of both the HPF State grant program and the HPF THPO grant program is to assist States and Tribes in carrying out their statutory role in the national historic preservation program. HPF grants to States and THPOs are program grants; *i.e.,* each State/THPO selects its own HPF-eligible activities and projects. Each HPF grant to a State/THPO has two years of fund availability. At the end of the first year, the NPS employs a ''Use or Lose'' policy to ensure efficient and effective use of the grant funds. All 59 states, territories, and the District of Columbia participate in the NHPP Program. Almost 2,000 local governments have become Certified Local Governments (CLGs) in order to participate in the NHPP program. Approximately 30 local governments become CLGs each year. Almost 170 federally-recognized tribes have formally joined the NHPP Program and have established THPOs and tribal historic preservation offices. Typically, each year six to nine tribes join the partnership.

The NPS developed the information collections associated with 36 CFR part 61 in consultation with State, Tribal, and local government partners. The obligation to respond is required to provide information to evaluate whether or not State, Tribal, and local governments meet minimum standards and requirements for participation in the National Historic Preservation Program; and to meet program specific requirements as well as government-wide requirements for Federal grant programs.

The authorities for this action are the National Historic Preservation Act (NHPA) (54 U.S.C. 300101 *et seq.*) and the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

**Tim Goddard,**

*Information Collection Clearance Officer, National Park Service.*

[FR Doc. 2017–23268 Filed 10–25–17; 8:45 am]

**BILLING CODE 4312–52–P**

## DEPARTMENT OF THE INTERIOR

### National Park Service

**[NPS–WASO–NRNHL–24228; PPWOCRADI0, 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 September 23, 2017, for listing or related actions in the National Register of Historic Places.

**DATES:** Comments should be submitted by November 13, 2017.

**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 September 23, 2017. 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:

**NEW JERSEY**

**Ocean County**

Hubbard, L. Ron, House, 666 East Ave., Bay Head Borough, SG100001777

**Sussex County**

Erickson Lakeside Cabin, 103 Lakeside Dr., Lake Wallkill, SG100001778

**RHODE ISLAND**

**Providence County**

Angell, Otis, Gristmill, 1 Governor Notte Pkwy., North Providence, SG100001779

Woonsocket Senior High and Junior High Schools, 357 Park Place, Woonsocket, SG100001780

**SOUTH DAKOTA**

**Lawrence County**

Spearfish Historic Commercial District (Boundary Decrease), Various, Spearfish, BC100001782

**WISCONSIN**

**Dane County**

Maple Bluff Boy Scout Cabin, 296 Woodland Cir., Maple Bluff, SG100001783

**Jefferson County**

Palmyra Boy Scout Cabin, 105 N. 1st St., Palmyra, SG100001784

**Sheboygan County**

Atlanta (steam screw) Shipwreck, 1.02 mi. NNE. of Amsterdam Park boat launch in L. Michigan, Cedar Grove vicinity, SG100001785

A request for removal has been made for the following resource(s):

**SOUTH DAKOTA**

**Edmunds County**

Eisenbeis, John, House, (German-Russian Folk Architecture TR), Address Restricted, Bowdle vicinity, OT84003283

Nominations submitted by Federal Preservation Officers:

The State Historic Preservation Officer reviewed the following nomination and responded to the Federal Preservation Officer within 45 days of receipt of the nomination and supports listing the property in the National Register of Historic Places.

**ALASKA**

**Kenai Peninsula Borough**

Tuxedni Bay Pictograph Site, Address Restricted, Port Alsworth vicinity, SG100001776

**Authority:** 60.13 of 36 CFR part 60.

Dated: September 28, 2017.

**J. Paul Loether,**

*Chief, National Register of Historic Places/National Historic Landmarks Program and Keeper, National Register of Historic Places.*

[FR Doc. 2017–23330 Filed 10–25–17; 8:45 am]

**BILLING CODE 4312–52–P**

## DEPARTMENT OF THE INTERIOR

### National Park Service

**[NPS–WASO–NRNHL–24417; PPWOCRADI0, 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 September 30, 2017, for listing or related actions in the National Register of Historic Places.

**DATES:** Comments should be submitted by November 13, 2017.

**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 September 30, 2017. 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**

Beadle House No. 11, 4323 E. McDonald Dr., Phoenix, SG100001786

**COLORADO**

**Mesa County**

TBM Avenger Aircraft N53503, 780 Heritage Way, Grand Junction Regional Airport, Grand Junction vicinity, SG100001791

**Montezuma County**

Haynie Site, (Great Pueblo Period of the McElmo Drainage Unit MPS), 29619 Cty. Rd. L, Mancos vicinity, MP100001792

**IOWA**

**Polk County**

I.O.O.F. (International Order of Odd Fellows) Valley Junction Lodge Hall No. 604, 216–218 5th St., West Des Moines, SG100001793

**MARYLAND**

**Montgomery County**

Mesrobian, Mihran, House, 7410 Connecticut Ave., Chevy Chase, SG100001794

**MICHIGAN**

**Isabella County**

Mount Pleasant Indian Industrial Boarding School, Bounded by Crawford, Pickard, Bamber, River Rds., Mount Pleasant, SG100001795

**NEBRASKA**

**Antelope County**

Downtown Neligh Historic District, Main St. from 5th to 2nd Sts., Neligh, SG100001796

**Buffalo County**

Kearney Downtown Historic District, Multiple, Kearney, SG100001797

**Douglas County**

Chiodo Apartments, (Apartments, Flats and Tenements in Omaha, Nebraska from 1880–1962 MPS), 2556 Marcy St., Omaha, MP100001798

Tong, On Leong, House, 1518 Cass St., Omaha, SG100001799

**Hall County**

Grand Island Historic District, Multiple, Grand Island, SG100001800

**NEW YORK**

**Kings County**

Lefferts Manor Historic District (Boundary Increase), Fenimore, Maple & Midwood Sts., Lincoln & Rutland Rds., Bedford Ave., Brooklyn, BC100001801

**New York County**

Caffe Cino, 31 Cornelia St., New York, SG100001802

Holy Cross African Orthodox Pro-Cathedral, 122 W. 129th St., New York, SG100001803

**Oneida County**

Forest Hill Cemetery, 2201 Oneida St., Utica, SG100001804

**Ontario County**

Warren—Benham House, 5680 Seneca Point Rd., Bristol Springs, SG100001805

**Oswego County**

Oswego and Syracuse Railroad Freight House, 20–24 W. Utica St., Oswego, SG100001806

**Queens County**

Spear and Company Factory, 94–15 100th St., Ozone Park, SG100001807

**Suffolk County**

Bethel Christian Avenue Historic District, Roughly Christian Ave., Hill & Locust Sts., Setauket, SG100001808

Farnum, William A., Boathouse, 52 Actor's Colony Rd., Sag Harbor, SG100001809
Old Bethel Cemetery, Christian & Woodfield Aves., Stony Brook, SG100001810
Squires, Ellis Jr., House, 186 & 190 Squiretown Rd., Hampton Bays, SG100001811

**Ulster County**

Saugerties and New York Steamboat Company Warehouse, 2 Ferry St., Saugerties, SG100001812

**WISCONSIN**

**Kenosha County**

Kenosha Elks Club, 5706 8th Ave., Kenosha, SG100001815

An owner objection received for the following resource:

**NORTH DAKOTA**

**Wells County**

Manfred Historic District, All of the original town of Manfred & the LeGrand's Addition, Manfred, SG100001813

A request for removal has been made for the following resources:

**COLORADO**

**Eagle County**

Dotsero Bridge, (Highway Bridges in Colorado MPS), I–70 Service Rd. at milepost 133.51, Dotsero, OT02001155
Eagle River Bridge, (Highway Bridges in Colorado MPS), US 6 at milepost 150.24, Eagle vicinity, OT02001156

Additional documentation has been received for the following resources:

**ARIZONA**

**Pima County**

Barrio El Hoyo Historic District, 460 S. Otero Ave., Tucson, AD08000763

**COLORADO**

**Denver County**

Montview Boulevard Presbyterian Church, 1980 Dahlia St., Denver, AD04000262

**Authority:** 60.13 of 36 CFR part 60.

Dated: October 6, 2017.

**J. Paul Loether,**

*Chief, National Register of Historic Places/ National Historic Landmarks Program and Keeper, National Register of Historic Places.*

[FR Doc. 2017–23331 Filed 10–25–17; 8:45 am]

**BILLING CODE 4312–52–P**

## DEPARTMENT OF THE INTERIOR

## National Park Service

**[NPS–WASO–NRNHL–24452; PPWOCRADI0, 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 October 7, 2017, for listing or related actions in the National Register of Historic Places.

**DATES:** Comments should be submitted by November 13, 2017.

**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 October 7, 2017. 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:

**HAWAII**

**Honolulu County**

Smith, Francis J., Apartment Building, 2240 Waikolu Way, Honolulu, SG100001818

**IOWA**

**Woodbury County**

Belfrage, W.L. and Winnie (Woodfield), Farmstead Historic District, 2410 Port Neal Rd., Sergeant Bluff, SG100001819

**TENNESSEE**

**Carroll County**

Leach Fire Lookout Tower, (Tennessee Division of Forestry Fire Lookout Towers MPS), RT 1 Leach Rd., Cedar Grove, MP100001821

**Coffee County**

Wilson—Crouch House, (Tullahoma MPS), 216 S. Jackson St., Tullahoma, MP100001820

**Davidson County**

Tennessee War Memorial, 301 6th Ave. N., Nashville, SG100001822

**Gibson County**

Mt. Zion Negro School, 30 Mt. Zion Rd., Bradford vicinity, SG100001823

**Greene County**

Blue Springs Lutheran Church and Cemetery, 920 Main St., Mosheim, SG100001824

**Lawrence County**

Farmers and Merchants Bank, 213 Depot St., Ethridge, SG100001825

**Maury County**

Hardison Mill Farm, 4554 US 431, Columbia, SG100001826
Pottsville General Store, 4205 US 431, Columbia vicinity, SG100001827

**Scott County**

Black Creek Fire Lookout Tower, (Tennessee Division of Forestry Fire Lookout Towers MPS), Black Creek Rd., Robbins, MP100001828

A request for removal has been made for the following resources:

**COLORADO**

**Fremont County**

Rio Grande Railroad Viaduct, (Highway Bridges in Colorado MPS), CO 120 at milepost 0.17, Florence vicinity, OT02001148
Portland Bridge, (Vehicular Bridges in Colorado TR), SR 120, Portland, OT85000210

**TENNESSEE**

**Williamson County**

Wilson, Joseph, House, (Williamson County MRA), Clovercroft Rd. 2/10 mi. W of Wilson Pike, Franklin vicinity, OT88000372

*Nomination submitted by Federal Preservation Officer:* The State Historic Preservation Officer reviewed the following nomination and responded to the Federal Preservation Officer within 45 days of receipt of the nomination and supports listing the property in the National Register of Historic Places.

**UTAH**

**San Juan County**

Moon House Complex, Address Restricted, Blanding vicinity, SG100001830

**Authority:** 60.13 of 36 CFR part 60.

Dated: October 12, 2017.

**J. Paul Loether,**

*Chief, National Register of Historic Places/ National Historic Landmarks Program and Keeper, National Register of Historic Places.*

[FR Doc. 2017–23332 Filed 10–25–17; 8:45 am]

**BILLING CODE 4312–52–P**

## DEPARTMENT OF THE INTERIOR

### Bureau of Ocean Energy Management

### Notice of Availability of the Proposed Notice of Sale for Gulf of Mexico Outer Continental Shelf Oil and Gas Region-Wide Lease Sale 250; MMAA 104000

**AGENCY:** Bureau of Ocean Energy Management, Interior.

**ACTION:** Notice of Availability of the Proposed Notice of Sale for Gulf of Mexico Outer Continental Shelf Oil and Gas Region-wide Lease Sale 250.

**SUMMARY:** The Bureau of Ocean Energy Management (BOEM) announces the availability of the Proposed Notice of Sale (NOS) for the proposed Gulf of Mexico (GOM) Outer Continental Shelf (OCS) Oil and Gas Lease Sale 250 (GOM Region-wide Sale 250). This Notice is published pursuant to 30 CFR 556.304(c). With regard to oil and gas leasing on the OCS, the Secretary of the Interior, pursuant to section 19 of the Outer Continental Shelf Lands Act, provides affected states the opportunity to review the Proposed NOS. The Proposed NOS sets forth the proposed terms and conditions of the sale, including minimum bids, royalty rates, and rental rates.

**DATES:** Affected states may comment on the size, timing, and location of proposed GOM Region-wide Sale 250 within 60 days following their receipt of the Proposed NOS. The Final NOS will be published in the **Federal Register** at least 30 days prior to the date of bid opening. Bid opening is currently scheduled for March 21, 2018.

**SUPPLEMENTARY INFORMATION:** The Proposed NOS for GOM Region-wide Sale 250 and Proposed NOS Package containing information essential to potential bidders may be obtained from the Public Information Unit, Gulf of Mexico Region, Bureau of Ocean Energy Management, 1201 Elmwood Park Boulevard, New Orleans, Louisiana 70123–2394; telephone: (504) 736–2519. The Proposed NOS and Proposed NOS Package also are available on BOEM's Web site at *http://www.boem.gov/Sale-250/.*

**AGENCY CONTACT:** Dr. Andrew Krueger, Chief, Sales Coordination Branch, 703–787–1554, *andrew.krueger@boem.gov.*

Dated: October 23, 2017.

**Walter D. Cruickshank,**

*Acting Director, Bureau of Ocean Energy Management.*

[FR Doc. 2017–23310 Filed 10–25–17; 8:45 am]

**BILLING CODE 4310–MR–P**

## INTERNATIONAL TRADE COMMISSION

**[Investigation Nos. 701–TA–442 and 731–TA–1095–1096 (Second Review)]**

### Lined Paper School Supplies From China and India; Scheduling of an Expedited Five-Year Review

**AGENCY:** United States International Trade Commission.

**ACTION:** Notice.

**SUMMARY:** The Commission hereby gives notice of the scheduling of an expedited review pursuant to the Tariff Act of 1930 (''the Act'') to determine whether revocation of the antidumping duty and countervailing duty orders on lined paper school supplies from China and India would be likely to lead to continuation or recurrence of material injury within a reasonably foreseeable time.

**DATES:** October 6, 2017.

**FOR FURTHER INFORMATION CONTACT:** Calvin Chang (202–205–3062), Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. Hearing-impaired persons can obtain information on this matter 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 (*https://www.usitc.gov*). The public record for this review may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

**SUPPLEMENTARY INFORMATION:**

*Background.*—On October 6, 2017, the Commission determined that the domestic interested party group response to its notice of institution (82 FR 30902, July 3, 2017) of the subject five-year review was adequate and that the respondent interested party group response was inadequate. The Commission did not find any other circumstances that would warrant conducting a full review.[1] Accordingly, the Commission determined that it would conduct an expedited review pursuant to section 751(c)(3) of the Tariff Act of 1930 (19 U.S.C. 1675(c)(3)).

For further information concerning the conduct of this review and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207).

*Staff report.*—A staff report containing information concerning the subject matter of the review will be placed in the nonpublic record on October 31, 2017, and made available to persons on the Administrative Protective Order service list for this review. A public version will be issued thereafter, pursuant to section 207.62(d)(4) of the Commission's rules.

*Written submissions.*—As provided in section 207.62(d) of the Commission's rules, interested parties that are parties to the review and that have provided individually adequate responses to the notice of institution,[2] and any party other than an interested party to the review may file written comments with the Secretary on what determination the Commission should reach in the review. Comments are due on or before November 3, 2017 and may not contain new factual information. Any person that is neither a party to the five-year review nor an interested party may submit a brief written statement (which shall not contain any new factual information) pertinent to the review by November 3, 2017. However, should the Department of Commerce extend the time limit for its completion of the final results of its review, the deadline for comments (which may not contain new factual information) on Commerce's final results is three business days after the issuance of Commerce's results. If comments contain business proprietary information (BPI), they must conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's rules with respect to filing were revised effective July 25, 2014. *See* 79 Fed. Reg. 35920 (June 25, 2014), and the revised Commission Handbook on E-filing, available from the Commission's Web site at *https://edis.usitc.gov.*

In accordance with sections 201.16(c) and 207.3 of the rules, each document filed by a party to the review must be served on all other parties to the review (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

*Authority:* This review is being conducted under authority of title VII of

[1] A record of the Commissioners' votes, the Commission's statement on adequacy, and any individual Commissioner's statements will be available from the Office of the Secretary and at the Commission's Web site.

[2] The Commission has found the response submitted by the Association of American School Paper Suppliers (''AASPS'') to be individually adequate. Comments from other interested parties will not be accepted (*see* 19 CFR 207.62(d)(2)).

the Tariff Act of 1930; this notice is published pursuant to section 207.62 of the Commission's rules.

By order of the Commission.

Issued: October 23, 2017.

**Lisa R. Barton,**

*Secretary to the Commission.*

WORK SCHEDULE

Investigation Nos. 701–TA–442 and 731–TA–1095–1096 (Second Review)

LINED PAPER SCHOOL SUPPLIES FROM CHINA AND INDIA

*Staff Assigned*

| | |
|---|---|
| Investigator | Calvin Chang ((202) 205–3062). |
| Commodity-Industry Analyst. | Vincent Honnold ((202) 205–3314). |
| Attorney | Heng Loke ((202) 708–1528). |
| Supervisory Investigator | Fred Ruggles ((202) 205–3187). |

| | Date |
|---|---|
| Institution | Monday, July 03, 2017. |
| Report to the Commission and to Parties. | October 31. |
| Comments of Parties due [1]. | November 3. |
| Legal issues memorandum to the Commission. | November 13. |
| Briefing and vote (suggested date). | November 20. |
| Determination and views to Commerce. | Thursday, November 30, 2017. |

[1] If comments contain business proprietary information, a nonbusiness proprietary version is due the following business day.

[FR Doc. 2017–23315 Filed 10–25–17; 8:45 am]

**BILLING CODE 7020–02–P**

## INTERNATIONAL TRADE COMMISSION

**[Investigation No. 731–TA–891 (Third Review)]**

## Foundry Coke From China; Scheduling of a Full Five-Year Review

**AGENCY:** United States International Trade Commission.

**ACTION:** Notice.

**SUMMARY:** The Commission hereby gives notice of the scheduling of a full review pursuant to the Tariff Act of 1930 (''the Act'') to determine whether revocation of the antidumping duty order countervailing duty order on foundry coke from China would be likely to lead to continuation or recurrence of material injury within a reasonably foreseeable time.

**DATES:** October 20, 2017.

**FOR FURTHER INFORMATION CONTACT:** Ayanna Butler (202–708–2208), Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. Hearing-impaired persons can obtain information on this matter 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 (*https://www.usitc.gov*). The public record for this review may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

**SUPPLEMENTARY INFORMATION:**

*Background.*—On August 4, 2017, the Commission determined that responses to its notice of institution of the subject five-year review were such that a full review should proceed (82 FR 41053, August 29, 2017); accordingly, a full review is being scheduled pursuant to section 751(c)(5) of the Tariff Act of 1930 (19 U.S.C. 1675(c)(5)). A record of the Commissioners' votes, the Commission's statement on adequacy, and any individual Commissioner's statements are available from the Office of the Secretary and at the Commission's Web site.

*Participation in the review and public service list.*—Persons, including industrial users of the subject merchandise and, if the merchandise is sold at the retail level, representative consumer organizations, wishing to participate in this review as parties must file an entry of appearance with the Secretary to the Commission, as provided in section 201.11 of the Commission's rules, by 45 days after publication of this notice. A party that filed a notice of appearance following publication of the Commission's notice of institution of the review need not file an additional notice of appearance. The Secretary will maintain a public service list containing the names and addresses of all persons, or their representatives, who are parties to the review.

For further information concerning the conduct of this review and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207).

*Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and BPI service list.*—Pursuant to section 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in this review available to authorized applicants under the APO issued in the review, provided that the application is made by 45 days after publication of this notice. Authorized applicants must represent interested parties, as defined by 19 U.S.C. 1677(9), who are parties to the review. A party granted access to BPI following publication of the Commission's notice of institution of the review need not reapply for such access. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

*Staff report.*—The prehearing staff report in the review will be placed in the nonpublic record on February 7, 2018, and a public version will be issued thereafter, pursuant to section 207.64 of the Commission's rules.

*Hearing.*—The Commission will hold a hearing in connection with the review beginning at 9:30 a.m. on Thursday, February 22, 2018, at the U.S. International Trade Commission Building. Requests to appear at the hearing should be filed in writing with the Secretary to the Commission on or before February 16, 2018. A nonparty who has testimony that may aid the Commission's deliberations may request permission to present a short statement at the hearing. All parties and nonparties desiring to appear at the hearing and make oral presentations should participate in a prehearing conference to be held on February 21, 2018, at the U.S. International Trade Commission Building, if deemed necessary. Oral testimony and written materials to be submitted at the public hearing are governed by sections 201.6(b)(2), 201.13(f), 207.24, and 207.66 of the Commission's rules. Parties must submit any request to present a portion of their hearing testimony *in camera* no later than 7 business days prior to the date of the hearing.

*Written submissions.*—Each party to the review may submit a prehearing brief to the Commission. Prehearing briefs must conform with the provisions of section 207.65 of the Commission's rules; the deadline for filing is February 14, 2018. Parties may also file written testimony in connection with their presentation at the hearing, as provided in section 207.24 of the Commission's rules, and posthearing briefs, which must conform with the provisions of section 207.67 of the Commission's rules. The deadline for filing posthearing briefs is March 1, 2018. In addition, any person who has not entered an appearance as a party to the review may submit a written statement of information pertinent to the subject of the review on or before March 1, 2018. On March 23, 2018, the Commission

will make available to parties all information on which they have not had an opportunity to comment. Parties may submit final comments on this information on or before March 27, 2018, but such final comments must not contain new factual information and must otherwise comply with section 207.68 of the Commission's rules. All written submissions must conform with the provisions of section 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's Handbook on E-Filing, available on the Commission's Web site at *https://edis.usitc.gov,* elaborates upon the Commission's rules with respect to electronic filing.

Additional written submissions to the Commission, including requests pursuant to section 201.12 of the Commission's rules, shall not be accepted unless good cause is shown for accepting such submissions, or unless the submission is pursuant to a specific request by a Commissioner or Commission staff.

In accordance with sections 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the review must be served on all other parties to the review (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

*Authority:* This review is being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.62 of the Commission's rules.

By order of the Commission.

Issued: October 23, 2017.

**Lisa R. Barton,**

*Secretary to the Commission.*

[FR Doc. 2017–23313 Filed 10–25–17; 8:45 am]

**BILLING CODE 7020–02–P**

## INTERNATIONAL TRADE COMMISSION

**[Investigation No. 731–TA–860 (Third Review)]**

## Tin- and Chromium-Coated Steel Sheet From Japan; Scheduling of a Full Five-Year Review

**AGENCY:** United States International Trade Commission.

**ACTION:** Notice.

**SUMMARY:** The Commission hereby gives notice of the scheduling of a full review pursuant to the Tariff Act of 1930 (''the Act'') to determine whether revocation of the antidumping duty order on tin- and chromium-coated steel sheet from Japan would be likely to lead to continuation or recurrence of material injury within a reasonably foreseeable time.

**DATES:** October 20, 2017.

**FOR FURTHER INFORMATION CONTACT:** Robert Casanova (202–708–2719), Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. Hearing-impaired persons can obtain information on this matter 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 (*https://www.usitc.gov*). The public record for this review may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

**SUPPLEMENTARY INFORMATION:**

*Background.*—On August 4, 2017, the Commission determined that responses to its notice of institution of the subject five-year review were such that a full review should proceed (82 FR 40168, August 24, 2017); accordingly, a full review is being scheduled pursuant to section 751(c)(5) of the Tariff Act of 1930 (19 U.S.C. 1675(c)(5)). A record of the Commissioners' votes, the Commission's statement on adequacy, and any individual Commissioner's statements are available from the Office of the Secretary and at the Commission's Web site.

*Participation in the review and public service list.*—Persons, including industrial users of the subject merchandise and, if the merchandise is sold at the retail level, representative consumer organizations, wishing to participate in this review as parties must file an entry of appearance with the Secretary to the Commission, as provided in section 201.11 of the Commission's rules, by 45 days after publication of this notice. A party that filed a notice of appearance following publication of the Commission's notice of institution of the review need not file an additional notice of appearance. The Secretary will maintain a public service list containing the names and addresses of all persons, or their representatives, who are parties to the review.

For further information concerning the conduct of this review and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207).

*Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and BPI service list.*—Pursuant to section 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in this review available to authorized applicants under the APO issued in the review, provided that the application is made by 45 days after publication of this notice. Authorized applicants must represent interested parties, as defined by 19 U.S.C. 1677(9), who are parties to the review. A party granted access to BPI following publication of the Commission's notice of institution of the review need not reapply for such access. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

*Staff report.*—The prehearing staff report in the review will be placed in the nonpublic record on February 9, 2018, and a public version will be issued thereafter, pursuant to section 207.64 of the Commission's rules.

*Hearing.*—The Commission will hold a hearing in connection with the review beginning at 9:30 a.m. on March 1, 2018, at the U.S. International Trade Commission Building. Requests to appear at the hearing should be filed in writing with the Secretary to the Commission on or before February 21, 2018. A nonparty who has testimony that may aid the Commission's deliberations may request permission to present a short statement at the hearing. All parties and nonparties desiring to appear at the hearing and make oral presentations should participate in a prehearing conference to be held on February 28, 2018, at the U.S. International Trade Commission Building, if deemed necessary. Oral testimony and written materials to be submitted at the public hearing are governed by sections 201.6(b)(2), 201.13(f), 207.24, and 207.66 of the Commission's rules. Parties must submit any request to present a portion of their hearing testimony *in camera* no later than 7 business days prior to the date of the hearing.

*Written submissions.*—Each party to the review may submit a prehearing brief to the Commission. Prehearing briefs must conform with the provisions of section 207.65 of the Commission's rules; the deadline for filing is February 20, 2018. Parties may also file written testimony in connection with their presentation at the hearing, as provided in section 207.24 of the Commission's

rules, and posthearing briefs, which must conform with the provisions of section 207.67 of the Commission's rules. The deadline for filing posthearing briefs is March 9, 2018. In addition, any person who has not entered an appearance as a party to the review may submit a written statement of information pertinent to the subject of the review on or before March 9, 2018. On April 3, 2018, the Commission will make available to parties all information on which they have not had an opportunity to comment. Parties may submit final comments on this information on or before April 5, 2018, but such final comments must not contain new factual information and must otherwise comply with section 207.68 of the Commission's rules. All written submissions must conform with the provisions of section 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's Handbook on E-Filing, available on the Commission's Web site at *https://edis.usitc.gov,* elaborates upon the Commission's rules with respect to electronic filing.

Additional written submissions to the Commission, including requests pursuant to section 201.12 of the Commission's rules, shall not be accepted unless good cause is shown for accepting such submissions, or unless the submission is pursuant to a specific request by a Commissioner or Commission staff.

In accordance with sections 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the review must be served on all other parties to the review (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

*Authority:* This review is being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.62 of the Commission's rules.

By order of the Commission.

Issued: October 23, 2017.

**Lisa R. Barton,**

*Secretary to the Commission.*

[FR Doc. 2017–23314 Filed 10–25–17; 8:45 am]

**BILLING CODE 7020–02–P**

## INTERNATIONAL TRADE COMMISSION

### Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest

**AGENCY:** U.S. International Trade Commission.

**ACTION:** Notice.

**SUMMARY:** Notice is hereby given that the U.S. International Trade Commission has received a complaint entitled *Certain Glucosylated Steviol Glycosides, and Products Containing Same, DN 3266;* the Commission is soliciting comments on any public interest issues raised by the complaint or complainant's filing pursuant to the Commission's Rules of Practice and Procedure.

**FOR FURTHER INFORMATION CONTACT:** Lisa R. Barton, Secretary to the Commission, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–2000. The public version of the complaint can be accessed on the Commission's Electronic Document Information System (EDIS) at *https://edis.usitc.gov,* and will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–2000.

General information concerning the Commission may also be obtained by accessing its Internet server at United States International Trade Commission (USITC) at *https://www.usitc.gov*. The public record for this investigation may be viewed on the Commission's Electronic Document Information System (EDIS) at *https://edis.usitc.gov*. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

**SUPPLEMENTARY INFORMATION:** The Commission has received a complaint and a submission pursuant to § 210.8(b) of the Commission's Rules of Practice and Procedure filed on behalf of PureCircle USA Inc. and PureCircle Sdn Bhd on October 20, 2017. The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain glucosylated steviol glycosides, and products containing same. The complaint names as respondents Sweet Green Fields USA LLC of Bellingham, WA; Sweet Green Fields Co., Ltd of Bellingham, WA; and Ningbo Green-Health Pharma-ceutical Co., Ltd. a/k/a NB Green-Health Pharma-ceutical Co., Ltd. of China. The complainant requests that the Commission issue a limited exclusion order, cease and desist orders, and impose a bond upon respondents' alleged infringing articles during the 60-day Presidential review period pursuant to 19 U.S.C. 1337(j).

Proposed respondents, other interested parties, and members of the public are invited to file comments, not to exceed five (5) pages in length, inclusive of attachments, on any public interest issues raised by the complaint or § 210.8(b) filing. Comments should address whether issuance of the relief specifically requested by the complainant in this investigation would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) Explain how the articles potentially subject to the requested remedial orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the requested remedial orders;

(iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the requested exclusion order and/or a cease and desist order within a commercially reasonable time; and

(v) explain how the requested remedial orders would impact United States consumers.

Written submissions must be filed no later than by close of business, eight calendar days after the date of publication of this notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above and submit 8 true paper copies to the Office of the Secretary by

noon the next day pursuant to § 210.4(f) of the Commission's Rules of Practice and Procedure (19 CFR 210.4(f)). Submissions should refer to the docket number (''Docket No. 3266'') in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, Electronic Filing Procedures [1]). Persons with questions regarding filing should contact the Secretary (202–205–2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this Investigation may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel,[2] solely for cybersecurity purposes. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.[3]

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of §§ 201.10 and 210.8(c) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.8(c)).

By order of the Commission.

Issued: October 20, 2017.

**Lisa R. Barton,**

*Secretary to the Commission.*

[FR Doc. 2017–23233 Filed 10–25–17; 8:45 am]

**BILLING CODE 7020–02–P**

[1] Handbook for Electronic Filing Procedures: *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf.*

[2] All contract personnel will sign appropriate nondisclosure agreements.

[3] Electronic Document Information System (EDIS): *https://edis.usitc.gov.*

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

**[Docket No. DEA–392]**

### Importer of Controlled Substances Application: Galephar Pharmaceutical Research, Inc.

**ACTION:** Notice of application.

**DATES:** Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before November 27, 2017. Such persons may also file a written request for a hearing on the application on or before November 27, 2017.

**ADDRESSES:** Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DRW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for hearing must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for hearing should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/LJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DRW, 8701 Morrissette Drive, Springfield, Virginia 22152.

**SUPPLEMENTARY INFORMATION:** The Attorney General has delegated his authority under the Controlled Substances Act to the Administrator of the Drug Enforcement Administration (DEA), 28 CFR 0.100(b). Authority to exercise all necessary functions with respect to the promulgation and implementation of 21 CFR part 1301, incident to the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been redelegated to the Assistant Administrator of the DEA Diversion Control Division (''Assistant Administrator'') pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.34(a), this is notice that on August 2, 2017, Galephar Pharmaceutical Research, Inc., #100 Carr 198, Industrial Park, Juncos, Puerto Rico 00777–3873 applied to be registered as an importer of hydromorphone (9150), a basic class of controlled substance in schedule II.

The company plans to import the listed controlled substance in finished dosage form for clinical trials, research and analytical purposes.

The import of this class of controlled substance will be granted only for analytical testing, research, and clinical trials. This authorization does not extend to the import of a finished FDA approved or non-approved dosage form for commercial sale.

Dated: October 18, 2017.

**Demetra Ashley,**

*Acting Assistant Administrator.*

[FR Doc. 2017–23328 Filed 10–25–17; 8:45 am]

**BILLING CODE 4410–09–P**

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

**[Docket No. 17–28]**

### Yoon H. Choi, M.D.; Decision and Order

On April 4, 2017, the Assistant Administrator, Division of Diversion Control, issued an Order to Show Cause to Yoon H. Choi, M.D. (Respondent), of Brockton, Massachusetts. The Show Cause Order proposed the revocation of Respondent's DEA Certificate of Registration as a practitioner, on the ground that he does not have authority to dispense controlled substances in Massachusetts, the State in which he is registered with the Agency. Show Cause Order, at 1.

As to the Agency's jurisdiction, the Show Cause Order alleged that Respondent holds DEA Certificate of Registration No. BC6966381, which authorizes him to dispense controlled substances in schedules II through V as a practitioner, at the registered address of Steward Medical Group, One Pearl Street, Suite 2200, Brockton, Massachusetts. *Id.* The Show Cause Order alleged that this registration does not expire until August 31, 2018. *Id.*

As to the substantive ground for the proceeding, the Show Cause Order alleged that ''[o]n January 5, 2017, the Commonwealth of Massachusetts Board of Registration in Medicine indefinitely suspended [his] medical license'' and that ''[t]his order remains in effect.'' *Id.* The Order thus alleged that Respondent is ''without authority to handle controlled substances in . . . Massachusetts, the [S]tate in which [he is] registered,'' that he is ''required to

possess authority from a [S]tate in order to obtain or retain a DEA registration,'' and that the Agency ''must revoke [his registration] based upon [his] lack of authority to handle controlled substances in . . . Massachusetts in violation of 21 U.S.C. 823(f) and 824(a)(3).'' [1] *Id.* at 1–2.

The Show Cause Order also notified Respondent of his right to request a hearing on the allegations or to submit a written statement while waiving his right to a hearing, the procedure for electing either option, and the consequence for failing to elect either option. *Id.* at 2. The Show Cause Order also notified Respondent of his right to submit a Corrective Action Plan under 21 U.S.C. 824(c)(2)(C). *Id.* at 2–3.

On May 8, 2017, Respondent, through his counsel, timely requested a hearing.[2] Resp.'s Hearing Request, at 1. The matter was placed on the docket of the Office of Administrative Law Judges and assigned to ALJ Charles Wm. Dorman, who issued a scheduling order the following day. Order Granting Summary Disposition, at 2. Under the ALJ's order, the Government was required to file any motion for summary disposition by May 16, 2017 and Respondent was required to file its opposition to the motion by ''2:00 p.m. EDT on May 26, 2017.'' *Id.*

On May 16, 2017, the Government filed its motion for summary disposition. Therein, the Government maintained that it is undisputed that Respondent lacks authority to dispense controlled substances in Massachusetts, the State in which he is registered, and that therefore, he ''no longer meets the statutory definition of a practitioner.'' Mot. for Summ. Disp., at 3–4. As support for the motion, the Government attached a copy of the Final Decision and Order of the Commonwealth of Massachusetts Board of Registration in Medicine, which indefinitely suspended Respondent's medical license, effective January 5, 2017. The Government also attached a printout from the Board's Web site which it obtained on May 12, 2017 and which shows that Respondent's medical license was still suspended, as well as a copy of Respondent's Corrective Action Plan and his Certificate of Registration.

Respondent did not file any pleading in response to the Government's motion. Order Granting Summary Disposition, at 2. Accordingly, on June 5, 2017, the ALJ granted the Government's motion, finding it undisputed that Respondent's state ''medical license is currently suspended'' and that he ''lacks state authorization to handle controlled substances in Massachusetts,'' the State in which he is registered. *Id.* at 5. Because ''DEA precedent requires that the Respondent cannot maintain a DEA registration for any location in that [S]tate,'' the ALJ recommended that I revoke his registration. *Id.* at 5–6.

Neither party filed exceptions to the ALJ's Order. Thereafter, on July 11, 2017, the ALJ forwarded the record to my Office for Final Agency Action.

Upon review of the record, the former Acting Administrator noted that while Respondent had filed a Corrective Action Plan the record contained no evidence as to the Assistant Administrator's decision as to the adequacy of Respondent's Corrective Action Plan. Accordingly, on September 22, 2017, the former Acting Administrator issued an Order directing the Government to notify my Office of the status of Respondent's Corrective Action Plan, and in the event the Assistant Administrator had issued a decision on review of the Plan, to provide a copy of that decision. The former Acting Administrator provided Respondent with the right to reply to the Government's submission no later than five business days from the date of receipt of the Government's submission.

On September 25, 2017, the Government submitted a copy of the former Assistant Administrator's letter of June 12, 2017 rejecting Respondent's Corrective Action Plan.[3] The former Assistant Administrator also explained that ''there [was] no potential modification of [Respondent's Plan] that could or would alter my decision.'' Letter from Assistant Administrator, Diversion Control Division, to Respondent's Counsel (June 12, 2017). Respondent did not file a response to the Government's submission.

Having considered the record in its entirety, I adopt the ALJ's factual finding that Respondent's Massachusetts medical license has been suspended, as well as his legal conclusion that he currently lacks authority to dispense controlled substances in Massachusetts and thus, he ''cannot maintain'' his DEA registration. I also adopt the ALJ's recommended Order that I revoke his registration. I make the following factual findings.

## Findings

Respondent is the holder of DEA Certificate of Registration No. BC6966381, pursuant to which he is authorized to dispense controlled substances in schedules II through V as a practitioner, at the registered address of Steward Medical Group Brockton, One Pearl Street Suite 2200, Brockton, MA 02301. GX 1. This registration does not expire until August 31, 2018.

Respondent is also the holder of Medical License No. 206555 issued by the Commonwealth of Massachusetts Board of Registration in Medicine. GX 2, at Attachment B. However, on January 5, 2017, the Board issued a Final Decision and Order which ''indefinitely suspended'' his medical license. GX 2, at Attachment A. According to the Board's Physician Profile Web page of which I take Official Notice, *see* 5 U.S.C. 556(e),[4] the suspension remains in effect as of the date of this Decision and Order.[5]

## Discussion

Pursuant to 21 U.S.C. 824(a)(3), the Attorney General is authorized to suspend or revoke a registration issued under section 823, ''upon a finding that the Registrant . . . has had his State license . . . suspended [or] revoked . . . by competent State authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances.'' Moreover, DEA has held repeatedly that the possession of authority to dispense controlled substances under the laws of the State in which a practitioner engages in professional practice is a fundamental condition for obtaining and maintaining a practitioner's registration. *See, e.g., James L. Hooper,* 76 FR 71371 (2011), *pet. for rev. denied,* 481 Fed Appx. 826 (4th Cir. 2012).

This rule derives from the text of two provisions of the CSA. First, Congress defined ''the term 'practitioner' [to] mean[] a . . . physician . . . or other

[1] The Government's allegation erroneously suggests that Respondent's mere holding of a registration when his state authority had been suspended constitutes a violation of these provisions. These provisions are, however, grants of authority to the Attorney General to grant an application or revoke an existing registration. While these provisions (along with 21 U.S.C. 802(21)) manifest that a practitioner must hold state authority to obtain or maintain a registration, a practitioner does not violate the CSA simply by continuing to hold a registration after a State suspends or revokes his medical license. If, however, a practitioner prescribed controlled substances without holding state authority, he would violate a DEA regulation. *See* 21 CFR 1306.03(a)(1).

[2] In his hearing request, Respondent also noted that he had filed a Corrective Action Plan with the Assistant Administrator, Diversion Control Division. Hearing Request, at 1 n.1.

[3] A copy of this letter does not appear to have been previously provided to the ALJ.

[4] Respondent may refute this finding by filing a properly supported motion for reconsideration with the Office of the Administrator within 10 business days of the date of this Decision and Order.

[5] While the Board's Order provides that ''Respondent may petition to stay [the] suspension upon successful completion of a clinical skills assessment by a board-approved entity and entry into a Probation Agreement,'' the suspension remains in effect as of the date of this Order.

person licensed, registered or otherwise permitted, by . . . the jurisdiction in which he practices . . . to distribute, dispense, [or] administer . . . a controlled substance in the course of professional practice.'' 21 U.S.C. 802(21). Second, in setting the requirements for obtaining a practitioner's registration, Congress directed that ''[t]he Attorney General shall register practitioners . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.'' 21 U.S.C. 823(f). Because Congress has clearly mandated that a physician possess state authority in order to be deemed a practitioner under the Act, DEA has held that revocation of a practitioner's registration is the appropriate sanction whenever he is no longer authorized to dispense controlled substances under the laws of the State in which he practices medicine. *See, e.g., Calvin Ramsey,* 76 FR 20034, 20036 (2011); *Sheran Arden Yeates, M.D.,* 71 FR 39130, 39131 (2006); *Dominick A. Ricci,* 58 FR 51104, 51105 (1993); *Bobby Watts,* 53 FR 11919, 11920 (1988); *see also Hooper* v. *Holder,* 481 Fed. Appx. at 828.

As a consequence of the Board's Final Decision and Order, Respondent is not currently authorized to dispense controlled substances in Massachusetts, the State in which he is registered. Because the CSA makes clear that the possession of authority to dispense controlled substances under the laws of the State in which a practitioner engages in professional practice is a fundamental condition for both obtaining and maintaining a practitioner's registration, it is of no consequence that the Board's Order provided that he may petition to stay the suspension upon meeting certain conditions. *Cf. Hooper* v. *Holder,* 481 F. App'x at 828 (upholding revocation of a physician's registration as based on a reasonable interpretation of the CSA, notwithstanding that the physician's medical license was subject to a suspension of known duration); *see also James L. Hooper,* 76 FR 71371, 71371–72 (2011).[6] As of this date, Respondent is not currently authorized to dispense controlled substances in Massachusetts, and therefore, he is not entitled to maintain his registration in that State. Accordingly, I will order that his registration be revoked and that any pending application to renew his registration, or for any other registration in the Commonwealth of Massachusetts be denied.

[6] By contrast, Respondent's suspension is of unknown duration.

**Order**

Pursuant to the authority vested in me by 21 U.S.C. 824(a), as well as 28 CFR 0.100(b), I order that DEA Certificate of Registration No. BC6966381 issued to Yoon Choi, M.D., be, and it hereby is, revoked. Pursuant to the authority vested in me by 21 U.S.C. 823(f), I further order that any application of Yoon Choi, M.D., to renew or modify this registration, or for any other registration in the Commonwealth of Massachusetts, be, and it hereby is, denied. This Order is effective November 27, 2017.

Dated: October 17, 2017.

**Robert W. Patterson,**

*Acting Administrator.*

[FR Doc. 2017–23329 Filed 10–25–17; 8:45 am]

**BILLING CODE 4410–09–P**

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

### Harinder Takyar, M.D.; Decision and Order

On January 24, 2017, the Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause to Harinder Takyar, M.D. (hereinafter, Respondent) of Mesa, Arizona. GX 4. The Show Cause Order proposed the revocation of Respondent's Certificate of Registration on the grounds that Respondent does ''not have authority to handle controlled substances in the State of Arizona,'' the State in which he is registered, and that Respondent's ''registration would be inconsistent with the public interest.'' GX 4, at 1 (citing 21 U.S.C. 823(f), 824(a)(3) and (4)).

As to the Agency's jurisdiction, the Show Cause Order alleged that Respondent holds DEA Certificate of Registration No. BT9321150 which authorizes him to dispense controlled substances in schedules II through V as a practitioner at the registered address of 9341 East McKellips Road, Mesa, Arizona 85207. GX 4, at 1. *See also* GX 1 (Controlled Substance Registration Certificate) (including ''Reform Physicians'') and GX 2, at 1 (Certification of Registration History) (9341 E McKellips Road, Mesa, AZ 85207–8520). The Show Cause Order alleged that this registration expires on November 30, 2019. GX 4, at 1. *See also* GX 2, at 1.

As the first substantive ground for the proceeding, the Show Cause Order alleged that Respondent is ''currently without authority to handle controlled substances in Arizona.'' GX 4, at 1. It alleged that, on December 21, 2016, Respondent ''entered into an Interim Consent Agreement for Practice Restriction with the Arizona Medical Board'' which ''prohibited [Respondent] from engaging in the practice of medicine in the State of Arizona . . . until he applies to the Executive Director and receives permission to do so.'' GX 4, at 1 and GX 3, at 5 (Interim Consent Agreement For Practice Restriction), respectively. The Show Cause Order alleged that Respondent was ''still currently prohibited from practicing medicine in the state in which . . . [he is] registered with the DEA . . . [and] therefore, the DEA must revoke . . . [his] DEA . . . [registration] based upon . . . [his] lack of authority to handle controlled substances in the State of Arizona.'' GX 4, at 2 (citing 21 U.S.C. 802(21), 823(f), and 824(a)(3)).

As the second substantive ground for the proceeding, the Show Cause Order alleged that the Arizona Attorney General's Office and the Pinal County (Arizona) Task Force ''initiated an investigation of . . . [Respondent's] medical practice after receiving information from a cooperating source that . . . [he] routinely prescribed large quantities of oxycodone, a Schedule II controlled substance, without performing an examination.'' GX 4, at 2. After summarizing two law enforcement officers' undercover visits to Respondent's medical practice, the Show Cause Order alleged that, concerning the first undercover officer, Respondent prescribed schedule II and IV controlled substances ''after conducting only a cursory medical examination[, or no physical examination but falsely documenting a full physical exam] . . . without inquiring about whether the agent experienced sleeplessness, anxiety, or panic[, and without] . . . properly execut[ing] . . . a prescription . . . as required by 21 CFR 1306.05(a) by not listing the full address of the patient on the face of the prescription . . . [or] maintain[ing] an adequate patient chart.'' GX 4, at 2–3.

Concerning the second undercover officer, the Show Cause Order alleged that Respondent prescribed a schedule II controlled substance the first time ''despite the agent informing . . . [Respondent] that he felt no pain during . . . [Respondent's] brief examination of him . . . [, and a second time without] conduct[ing] a physical exam . . . and falsely documenting a full physical

exam.'' GX 4, at 4. The Show Cause Order concluded that Respondent ''unlawfully prescribed controlled substances to undercover law enforcement officers for other than a legitimate medical purpose and outside the usual course of professional practice'' in violation of Federal and State law, and violated Arizona medical practice standards when he ''failed to maintain appropriate patient records that supported the prescribing of controlled substances and . . . failed to conduct an appropriate physical examination, or establish a . . . doctor-patient relationship before prescribing a controlled substance.'' GX 4, at 2 (citing 21 CFR 1306.04(a), Ariz. Rev. Stat. § 32–1401.27(e), (j), (q), and (SS), and Ariz. Rev. Stat. § 32–901(15)).

The Show Cause Order notified Respondent of his right to request a hearing on the allegations or to submit a written statement while waiving his right to a hearing, the procedures for electing each option, and the consequences for failing to elect either option. GX 4, at 5 (citing 21 CFR 1301.43). The Show Cause Order also notified Respondent of the opportunity to submit a Corrective Action Plan. GX 4, at 5 (citing 21 U.S.C. 824(c)(2)(C)).

By letter dated February 22, 2017, Respondent, by his counsel, asked the Administrative Law Judge for ''an extension of 30 days within which to file a written request for hearing concerning the Order to Show Cause.'' GX 5. The letter alleged that ''good cause'' supported the request because Respondent's counsel ''has only recently been retained,'' the ''discovery concerning the listed allegations is voluminous,'' and counsel ''needed [time] to gather necessary information concerning the allegations . . . and more effectively complete the request for hearing letter.'' *Id.* By Order dated March 1, 2017, the Chief Administrative Law Judge, John J. Mulrooney, II, granted an ''enlargement of the time allotted to request a hearing . . . to the extent (but only to the extent) that, if the Respondent elects to request a hearing, he must do so no later than March 17, 2017.'' GX 6, at 2 (Order Granting in Part the Respondent's Request for an Extension of the Time to File a Request for Hearing).

By Motion dated March 27, 2017, the Government requested that further proceedings be terminated because ''[a]s of the date of this filing, Respondent has not notified this tribunal or Government counsel of any request for hearing.'' GX 7, at 2 (Government's Motion for Termination of Proceedings). By Order dated April 3, 2017, the Presiding Judge issued an Order Terminating Proceedings, finding that ''no request for a hearing was filed.'' GX 8 (Order Terminating Proceedings).

I find that the Government's service of the Show Cause Order on Respondent was legally sufficient, that the Respondent did not timely request a hearing, and that Respondent has waived his right to a hearing and his right to submit a written statement. 21 CFR 1301.43(d). I therefore issue this Decision and Order based on the record submitted by the Government. 21 CFR 1301.43(e).

## Findings of Fact

### *Respondent's DEA Registration*

Respondent currently holds DEA practitioner registration BT9321150 authorizing him to dispense controlled substances in schedules II through V at the address of Reform Physicians, 9341 E McKellips Road, Mesa, AZ 85207–8520. GX 1. This registration expires on November 30, 2019. *Id.*

### *The Investigations of Respondent and the Status of Respondent's State Licenses*

On December 21, 2016, Respondent and the Executive Director of the Arizona Medical Board (hereinafter, ''Board'') signed an ''Interim Consent Agreement for Practice Restriction.'' GX 3. Pursuant to the Interim Consent Agreement for Practice Restriction, Respondent elected to relinquish all rights to a hearing and to appeal, and agreed not to dispute, but did not concede, its allegations. GX 3, at 6, 4, respectively. It contained the allegations that Respondent ''deviated from the standard of care'' for one patient by ''failing to substantiate and justify a reason for prescribing opioids to . . . her[,] to acknowledge and deal with aberrant behavior manifested by frequent Emergency Room . . . visits usually for overdoses and documentation [sic] cocaine use[,] . . . to utilize urine drug screens[,] . . . to access [the patient's] Controlled Substance Prescription Monitoring Program (''CSPMP'') profile to monitor [the patient's] prescription medication use[, and] . . . by performing trigger point injections without identifying physical trigger points on examination, usually with a concomitant IM injection of Toradol.'' GX 3, at 2. The Interim Consent Agreement for Practice Restriction contained the allegation that this patient ''experienced actual harm as Respondent caused or contributed to her abuse and apparent addiction of controlled substances.'' *Id.*

The Interim Consent Agreement for Practice Restriction also contained allegations that Respondent deviated from the standard of care for another patient ''by failing to substantiate and justify a reason for prescribing opioids to . . . [her], failing to monitor his opioid prescribing, failing to access the CSPMP, and failing to utilize urine drug screens.'' GX 3, at 3. Those allegations included that Respondent ''failed to identify aberrant behavior including frequent ER visits, and claims of lost or stolen medications and requests for early refills.'' *Id.* According to the allegations, Respondent's patient ''experienced actual harm in that Respondent either created an addictive state or contributed to a pre-existing addictive state.'' *Id.*

The Interim Consent Agreement for Practice Restriction contained allegations concerning a third patient of Respondent's. Those allegations included that ''Respondent deviated from the standard of care for . . . [the patient] by failing to identify a source of pain for . . . [him], and failing to demonstrate that the prescribing of opioids met the goals of reduction of pain and improvement of function.'' *Id.* Additional allegations concerning the third patient were that ''Respondent failed to monitor his opioid prescribing, failed to access the CSPMP and failed to utilize urine drug screens until April of 2016.'' *Id.* According to the allegations, Respondent's patient ''experienced actual harm in that Respondent ignored abnormal urine drug screens and aberrant behavior,'' and faced the ''potential for harm'' due to ''inappropriate medication prescribing, including side effects such as sedation, gastrointestinal dysfunction, cognitive impairment, respiratory depression, insomnia and addiction.'' GX 3, at 3–4.

The Interim Consent Agreement for Practice Restriction explicitly stated that Respondent agreed not to dispute its allegations ''[f]or the purposes of entering this Interim Consent Agreement and for these purposes only.'' GX 3, at 4. It also stated that Respondent did ''not concede these allegations and this Interim Consent Agreement is not intended for use in any subsequent proceeding, either civil or criminal, as evidence of any kind.'' *Id.*

The Interim Consent Agreement for Practice Restriction's Interim Order prohibited Respondent from engaging in the practice of medicine in the State of Arizona ''until he applies to the Executive Director and receives permission to do so.'' GX 3, at 5 (citing A.R.S. § 32–1401(22)). The Interim Order stated that Respondent may request release and/or modification of the Interim Consent Agreement for

Practice Restriction in writing accompanied by ''information demonstrating that he is safe to practice medicine, including having successfully completed a competency evaluation at a facility approved by the Board or its staff.'' GX 3, at 5. Among other things, the Interim Order also stated that it is not a ''final decision by the Board,'' is ''subject to further consideration,'' and ''[o]nce the investigation is complete, it will be promptly provided to the Board for its review and appropriate action.'' *Id.* The Interim Consent Agreement for Practice Restriction was ''effective on the date signed by the Board's Executive Director,'' December 21, 2016. GX 3, at 5, 8–9. Respondent entered into the Interim Consent Agreement for Practice Restriction voluntarily. GX 3, at 6. He understood that ''any violation of this Interim Consent Agreement constitutes unprofessional conduct under A.R.S. § 32–1401(27)(r).'' GX 3, at 8.

On May 9, 2017, the DEA Diversion Investigator assigned to the investigation of Respondent's medical practice (hereinafter, DI) signed a Declaration. GX 9. According to that Declaration, the DI ''confirmed'' with the Senior Investigator for the Board that ''the current prohibition on . . . [Respondent's] practice of medicine also includes a prohibition on his authorization to handle controlled substances.'' GX 9, at 2. Further, as of April 24, 2017, the Declaration stated that the Board's Senior Investigator informed the DI that Respondent ''remains prohibited from practicing medicine in Arizona, pending revocation proceedings currently before the Board.'' *Id.*

As found above, Respondent waived his right to a hearing and to submit a written statement while waiving his right to a hearing concerning the Show Cause Order. Accordingly, there is no evidence to refute the allegations of the Show Cause Order. I, therefore, find that Respondent currently is prohibited from engaging in the practice of medicine, and currently is without authority to dispense controlled substances, in Arizona, the State in which he is registered.

**Discussion**

Pursuant to 21 U.S.C. 824(a)(3), the Attorney General is authorized to suspend or revoke a registration issued under section 823 of the Controlled Substances Act (hereinafter, CSA), ''upon a finding that the registrant . . . has had his State License or registration suspended [or] revoked by competent State authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances.'' With respect to a practitioner, the DEA has also long held that the possession of authority to dispense controlled substances under the laws of the State in which a practitioner engages in professional practice is a fundamental condition for obtaining and maintaining a practitioner's registration. *See, e.g., James L. Hooper, M.D.,* 76 FR 71,371 (2011), *pet. for rev. denied,* 481 Fed. Appx. 826 (4th Cir. 2012); *Bourne Pharmacy, Inc.,* 72 FR 18,273, 18,274 (2007) (''Under the Controlled Substances Act . . . , it is irrelevant that Respondent's state registration is being held in escrow pending state proceedings. Under the Act, a practitioner must be currently authorized to handle controlled substances in 'the jurisdiction in which [it] practices' in order to maintain its DEA registration.''); *Anne Lazar Thorn, M.D.,* 62 FR 12,847, 12, 848 (1997) (The ''controlling question'' is ''whether the Respondent is currently authorized to handle controlled substances in the state.''); *Frederick Marsh Blanton, M.D.,* 43 FR 27,616 (1978).

This rule derives from the text of two provisions of the CSA. First, Congress defined the term ''practitioner'' [to] mean[ ] a . . . physician . . . or other person licensed, registered, or otherwise permitted, by . . . the jurisdiction in which he practices . . . , to distribute, dispense, [or] administer . . . a controlled substance in the course of professional practice . . . .'' 21 U.S.C. 801(21). Second, in setting the requirements for obtaining a practitioner's registration, Congress directed that ''[t]he Attorney General shall register practitioners . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.'' 21 U.S.C. 823(f). Because Congress has clearly mandated that a practitioner possess State authority in order to be deemed a practitioner under the CSA, the DEA has held repeatedly that revocation of a practitioner's registration is the appropriate sanction whenever he is no longer authorized to dispense controlled substances under the laws of the State in which he practices. *See, e.g., Hooper, supra,* 76 FR at 71,371–72; *Sheran Arden Yeates, M.D.,* 71 FR 39,130, 39,131 (2006); *Dominick A. Ricci, M.D.,* 58 FR 51,104, 51,105 (1993); *Bobby Watts,* 53 FR 11,919, 11,920 (1988); *Thorn, supra,* 62 FR at 12,848; *Blanton, supra,* 43 FR at 27,616.

Under Arizona law, a ''doctor of medicine'' is a ''natural person holding a license, registration or permit to practice medicine pursuant to this chapter.'' A.R.S. § 32–1401(10) (2017). *See also* A.R.S. § 32–1401(21) (2017) (A ''physician'' is a ''doctor of medicine who is licensed pursuant to this chapter.'') The ''practice of medicine'' means ''the diagnosis, the treatment or the correction of or the attempt or the claim to be able to diagnose, treat or correct any and all human diseases . . . by any means, method, devices or instrumentalities . . . .'' A.R.S. § 32–1401(22) (2017). ''Medicine'' means ''allopathic medicine as practiced by the recipient of a degree of doctor of medicine.'' A.R.S. § 32–1401(19) (2017). ''Restrict'' means ''taking a disciplinary action that alters the physician's practice or professional activities if the board determines that there is evidence that the physician is or may be medically incompetent or guilty of unprofessional conduct.'' A.R.S. § 32–1401(23) (2017). Further, a physician who ''wishes to dispense a controlled substance . . . shall be currently licensed to practice medicine in Arizona.'' Arizona Medical Board Licensure, R4–16–301 (2017). ''Dispense,'' under Arizona law, means ''the delivery by a doctor of medicine of a prescription drug or device to a patient . . . and includes the prescribing, administering, packaging, labeling and security necessary to prepare and safeguard the drug or device for delivery.'' A.R.S. § 32–1401(9) (2017).

In this case, the Arizona Medical Board and Respondent entered into an ''Interim Consent Agreement for Practice Restriction'' which prohibits Respondent from engaging in the practice of medicine in the State of Arizona ''until he applies to the Executive Director and receives permission to do so.'' GX 3, at 5 (citing A.R.S. § 32–1401(22)). Further, the unrefuted DI Declaration stated that ''the current prohibition on . . . [Respondent's] practice of medicine also includes a prohibition on his authorization to handle controlled substances.'' GX 9, at 2. Consequently, Respondent is not currently authorized to handle controlled substances in the State of Arizona, the State in which he is registered and, therefore, he is not entitled to maintain his DEA registration. *Thorn, supra; Blanton, supra.* Accordingly, I will order that his registration be revoked and that any pending application for the renewal or modification of his registration be denied. 21 U.S.C. 824(a)(3).

**Order**

Pursuant to the authority vested in me by 21 U.S.C. 824(a), as well as 28 CFR 0.100(b), I order that DEA Certificate of Registration BT9321150 issued to

Harinder Takyar, M.D., be, and it hereby is, revoked. I further order that any pending application of Harinder Takyar, M.D., to renew or modify this registration, as well as any other pending application by him for registration in the State of Arizona, be, and it hereby is, denied. This order is effective November 27, 2017.

Dated: October 18, 2017.

**Robert W. Patterson,**

*Acting Administrator.*

[FR Doc. 2017–23338 Filed 10–25–17; 8:45 am]

**BILLING CODE 4410–09–P**

## DEPARTMENT OF JUSTICE

**[OLP Docket No. 165]**

## Federal Law Protections for Religious Liberty

**AGENCY:** Department of Justice.

**ACTION:** Notice.

**SUMMARY:** This notice provides the text of the Attorney General's Memorandum of October 6, 2017, for all executive departments and agencies entitled ''Federal Law Protections for Religious Liberty'' and the appendix to this Memorandum.

**DATES:** This notice is applicable on October 6, 2017.

**FOR FURTHER INFORMATION CONTACT:** Jennifer Dickey, Counsel, Office of Legal Policy, U.S. Department of Justice, 950 Pennsylvania Avenue NW., Washington, D.C. 20530, phone (202) 514–4601.

**SUPPLEMENTARY INFORMATION:** The President instructed the Attorney General to issue guidance interpreting religious liberty protections in federal law, as appropriate. Exec. Order 13798, § 4 (May 4, 2017). Pursuant to that instruction and consistent with the authority to provide advice and opinions on questions of existing law to the Executive Branch, the Attorney General issued the following memorandum to the heads of all executive departments and agencies on October 6, 2017.

Dated: October 20, 2017.

**Beth Ann Williams,**

*Assistant Attorney General, Office of Legal Policy.*

MEMORANDUM FOR ALL EXECUTIVE DEPARTMENTS AND AGENCIES

FROM: THE ATTORNEY GENERAL

SUBJECT: *Federal Law Protections for Religious Liberty*

The President has instructed me to issue guidance interpreting religious liberty protections in federal law, as appropriate. Exec. Order No. 13798 § 4, 82 Fed. Reg. 21675 (May 4, 2017). Consistent with that instruction, I am issuing this memorandum and appendix to guide all administrative agencies and executive departments in the execution of federal law.

### Principles of Religious Liberty

Religious liberty is a foundational principle of enduring importance in America, enshrined in our Constitution and other sources of federal law. As James Madison explained in his Memorial and Remonstrance Against Religious Assessments, the free exercise of religion ''is in its nature an unalienable right'' because the duty owed to one's Creator ''is precedent, both in order of time and in degree of obligation, to the claims of Civil Society.'' [1] Religious liberty is not merely a right to personal religious beliefs or even to worship in a sacred place. It also encompasses religious observance and practice. Except in the narrowest circumstances, no one should be forced to choose between living out his or her faith and complying with the law. Therefore, to the greatest extent practicable and permitted by law, religious observance and practice should be reasonably accommodated in all government activity, including employment, contracting, and programming. The following twenty principles should guide administrative agencies and executive departments in carrying out this task. These principles should be understood and interpreted in light of the legal analysis set forth in the appendix to this memorandum.

**1. The freedom of religion is a fundamental right of paramount importance, expressly protected by federal law.**

Religious liberty is enshrined in the text of our Constitution and in numerous federal statutes. It encompasses the right of all Americans to exercise their religion freely, without being coerced to join an established church or to satisfy a religious test as a qualification for public office. It also encompasses the right of all Americans to express their religious beliefs, subject to the same narrow limits that apply to all forms of speech. In the United States, the free exercise of religion is not a mere policy preference to be traded against other policy preferences. It is a fundamental right.

[1] James Madison, Memorial and Remonstrance Against Religious Assessments (June 20, 1785), *in* 5 The Founders' Constitution 82 (Philip B. Kurland & Ralph Lerner eds., 1987).

**2. The free exercise of religion includes the right to *act* or *abstain from action* in accordance with one's religious beliefs.**

The Free Exercise Clause protects not just the right to believe or the right to worship; it protects the right to perform or abstain from performing certain physical acts in accordance with one's beliefs. Federal statutes, including the Religious Freedom Restoration Act of 1993 (''RFRA''), support that protection, broadly defining the exercise of religion to encompass all aspects of observance and practice, whether or not central to, or required by, a particular religious faith.

**3. The freedom of religion extends to persons *and* organizations.**

The Free Exercise Clause protects not just persons, but persons collectively exercising their religion through churches or other religious denominations, religious organizations, schools, private associations, and even businesses.

**4. Americans do not give up their freedom of religion by participating in the marketplace, partaking of the public square, or interacting with government.**

Constitutional protections for religious liberty are not conditioned upon the willingness of a religious person or organization to remain separate from civil society. Although the application of the relevant protections may differ in different contexts, individuals and organizations do not give up their religious-liberty protections by providing or receiving social services, education, or healthcare; by seeking to earn or earning a living; by employing others to do the same; by receiving government grants or contracts; or by otherwise interacting with federal, state, or local governments.

**5. Government may not restrict acts or abstentions because of the beliefs they display.**

To avoid the very sort of religious persecution and intolerance that led to the founding of the United States, the Free Exercise Clause of the Constitution protects against government actions that target religious conduct. Except in rare circumstances, government may not treat the same conduct as lawful when undertaken for secular reasons but unlawful when undertaken for religious reasons. For example, government may not attempt to target religious persons or conduct by allowing the distribution of political leaflets in a park but forbidding the distribution of religious leaflets in the same park.

**6. Government may not target religious individuals or entities for special disabilities based on their religion.**

Much as government may not restrict actions only because of religious belief, government may not target persons or individuals because of their religion. Government may not exclude religious organizations as such from secular aid programs, at least when the aid is not being used for explicitly religious activities such as worship or proselytization. For example, the Supreme Court has held that if government provides reimbursement for scrap tires to replace child playground surfaces, it may not deny participation in that program to religious schools. Nor may government deny religious schools—including schools whose curricula and activities include religious elements—the right to participate in a voucher program, so long as the aid reaches the schools through independent decisions of parents.

**7. Government may not target religious individuals or entities through discriminatory enforcement of neutral, generally applicable laws.**

Although government generally may subject religious persons and organizations to neutral, generally applicable laws—e.g., across-the-board criminal prohibitions or certain time, place, and manner restrictions on speech—government may not apply such laws in a discriminatory way. For instance, the Internal Revenue Service may not enforce the Johnson Amendment—which prohibits 501(c)(3) non-profit organizations from intervening in a political campaign on behalf of a candidate—against a religious non-profit organization under circumstances in which it would not enforce the amendment against a secular non-profit organization. Likewise, the National Park Service may not require religious groups to obtain permits to hand out fliers in a park if it does not require similarly situated secular groups to do so, and no federal agency tasked with issuing permits for land use may deny a permit to an Islamic Center seeking to build a mosque when the agency has granted, or would grant, a permit to similarly situated secular organizations or religious groups.

**8. Government may not officially favor or disfavor particular religious groups.**

Together, the Free Exercise Clause and the Establishment Clause prohibit government from officially preferring one religious group to another. This principle of denominational neutrality means, for example, that government cannot selectively impose regulatory burdens on some denominations but not others. It likewise cannot favor some religious groups for participation in the Combined Federal Campaign over others based on the groups' religious beliefs.

**9. Government may not interfere with the autonomy of a religious organization.**

Together, the Free Exercise Clause and the Establishment Clause also restrict governmental interference in intra-denominational disputes about doctrine, discipline, or qualifications for ministry or membership. For example, government may not impose its nondiscrimination rules to require Catholic seminaries or Orthodox Jewish yeshivas to accept female priests or rabbis.

**10. The Religious Freedom Restoration Act of 1993 prohibits the federal government from substantially burdening any aspect of religious observance or practice, unless imposition of that burden on a particular religious adherent satisfies strict scrutiny.**

RFRA prohibits the federal government from substantially burdening a person's exercise of religion, unless the federal government demonstrates that application of such burden to the religious adherent is the least restrictive means of achieving a compelling governmental interest. RFRA applies to all actions by federal administrative agencies, including rulemaking, adjudication or other enforcement actions, and grant or contract distribution and administration.

**11. RFRA's protection extends not just to individuals, but also to organizations, associations, and at least some for-profit corporations.**

RFRA protects the exercise of religion by individuals and by corporations, companies, associations, firms, partnerships, societies, and joint stock companies. For example, the Supreme Court has held that Hobby Lobby, a closely held, for-profit corporation with more than 500 stores and 13,000 employees, is protected by RFRA.

**12. RFRA does not permit the federal government to second-guess the reasonableness of a religious belief.**

RFRA applies to all sincerely held religious beliefs, whether or not central to, or mandated by, a particular religious organization or tradition. Religious adherents will often be required to draw lines in the application of their religious beliefs, and government is not competent to assess the reasonableness of such lines drawn, nor would it be appropriate for government to do so. Thus, for example, a government agency may not second-guess the determination of a factory worker that, consistent with his religious precepts, he can work on a line producing steel that might someday make its way into armaments but cannot work on a line producing the armaments themselves. Nor may the Department of Health and Human Services second-guess the determination of a religious employer that providing contraceptive coverage to its employees would make the employer complicit in wrongdoing in violation of the organization's religious precepts.

**13. A governmental action substantially burdens an exercise of religion under RFRA if it bans an aspect of an adherent's religious observance or practice, compels an act inconsistent with that observance or practice, or substantially pressures the adherent to modify such observance or practice.**

Because the government cannot second-guess the reasonableness of a religious belief or the adherent's assessment of the religious connection between the government mandate and the underlying religious belief, the substantial burden test focuses on the extent of governmental compulsion involved. In general, a government action that bans an aspect of an adherent's religious observance or practice, compels an act inconsistent with that observance or practice, or substantially pressures the adherent to modify such observance or practice, will qualify as a substantial burden on the exercise of religion. For example, a Bureau of Prisons regulation that bans a devout Muslim from growing even a half-inch beard in accordance with his religious beliefs substantially burdens his religious practice. Likewise, a Department of Health and Human Services regulation requiring employers to provide insurance coverage for contraceptive drugs in violation of their religious beliefs or face significant fines substantially burdens their religious practice, and a law that conditions receipt of significant government benefits on willingness to work on Saturday substantially burdens the religious practice of those who, as a matter of religious observance or practice, do not work on that day. But a law that infringes, even severely, an aspect of an adherent's religious observance or practice that the adherent himself regards as unimportant or inconsequential imposes no substantial

burden on that adherent. And a law that regulates only the government's internal affairs and does not involve any governmental compulsion on the religious adherent likewise imposes no substantial burden.

**14. The strict scrutiny standard applicable to RFRA is exceptionally demanding.**

Once a religious adherent has identified a substantial burden on his or her religious belief, the federal government can impose that burden on the adherent only if it is the least restrictive means of achieving a compelling governmental interest. Only those interests of the highest order can outweigh legitimate claims to the free exercise of religion, and such interests must be evaluated not in broad generalities but as applied to the particular adherent. Even if the federal government could show the necessary interest, it would also have to show that its chosen restriction on free exercise is the least restrictive means of achieving that interest. That analysis requires the government to show that it cannot accommodate the religious adherent while achieving its interest through a viable alternative, which may include, in certain circumstances, expenditure of additional funds, modification of existing exemptions, or creation of a new program.

**15. RFRA applies even where a religious adherent seeks an exemption from a legal obligation requiring the adherent to confer benefits on third parties.**

Although burdens imposed on third parties are relevant to RFRA analysis, the fact that an exemption would deprive a third party of a benefit does not categorically render an exemption unavailable. Once an adherent identifies a substantial burden on his or her religious exercise, RFRA requires the federal government to establish that denial of an accommodation or exemption to that adherent is the least restrictive means of achieving a compelling governmental interest.

**16. Title VII of the Civil Rights Act of 1964, as amended, prohibits covered employers from discriminating against individuals on the basis of their religion.**

Employers covered by Title VII may not fail or refuse to hire, discharge, or discriminate against any individual with respect to compensation, terms, conditions, or privileges of employment because of that individual's religion. Such employers also may not classify their employees or applicants in a way that would deprive or tend to deprive any individual of employment opportunities because of the individual's religion. This protection applies regardless of whether the individual is a member of a religious majority or minority. But the protection does not apply in the same way to religious employers, who have certain constitutional and statutory protections for religious hiring decisions.

**17. Title VII's protection extends to discrimination on the basis of religious observance or practice as well as belief, unless the employer cannot reasonably accommodate such observance or practice without undue hardship on the business.**

Title VII defines ''religion'' broadly to include all aspects of religious observance or practice, except when an employer can establish that a particular aspect of such observance or practice cannot reasonably be accommodated without undue hardship to the business. For example, covered employers are required to adjust employee work schedules for Sabbath observance, religious holidays, and other religious observances, unless doing so would create an undue hardship, such as materially compromising operations or violating a collective bargaining agreement. Title VII might also require an employer to modify a no-head-coverings policy to allow a Jewish employee to wear a yarmulke or a Muslim employee to wear a headscarf. An employer who contends that it cannot reasonably accommodate a religious observance or practice must establish undue hardship on its business with specificity; it cannot rely on assumptions about hardships that might result from an accommodation.

**18. The Clinton Guidelines on Religious Exercise and Religious Expression in the Federal Workplace provide useful examples for private employers of reasonable accommodations for religious observance and practice in the workplace.**

President Clinton issued Guidelines on Religious Exercise and Religious Expression in the Federal Workplace (''Clinton Guidelines'') explaining that federal employees may keep religious materials on their private desks and read them during breaks; discuss their religious views with other employees, subject to the same limitations as other forms of employee expression; display religious messages on clothing or wear religious medallions; and invite others to attend worship services at their churches, except to the extent that such speech becomes excessive or harassing. The Clinton Guidelines have the force of an Executive Order, and they also provide useful guidance to private employers about ways in which religious observance and practice can reasonably be accommodated in the workplace.

**19. Religious employers are entitled to employ only persons whose beliefs and conduct are consistent with the employers' religious precepts.**

Constitutional and statutory protections apply to certain religious hiring decisions. Religious corporations, associations, educational institutions, and societies—that is, entities that are organized for religious purposes and engage in activity consistent with, and in furtherance of, such purposes—have an express statutory exemption from Title VII's prohibition on religious discrimination in employment. Under that exemption, religious organizations may choose to employ only persons whose beliefs and conduct are consistent with the organizations' religious precepts. For example, a Lutheran secondary school may choose to employ only practicing Lutherans, only practicing Christians, or only those willing to adhere to a code of conduct consistent with the precepts of the Lutheran community sponsoring the school. Indeed, even in the absence of the Title VII exemption, religious employers might be able to claim a similar right under RFRA or the Religion Clauses of the Constitution.

**20. As a general matter, the federal government may not condition receipt of a federal grant or contract on the effective relinquishment of a religious organization's hiring exemptions or attributes of its religious character.**

Religious organizations are entitled to compete on equal footing for federal financial assistance used to support government programs. Such organizations generally may not be required to alter their religious character to participate in a government program, nor to cease engaging in explicitly religious activities outside the program, nor effectively to relinquish their federal statutory protections for religious hiring decisions.

**Guidance for Implementing Religious Liberty Principles**

Agencies must pay keen attention, in everything they do, to the foregoing principles of religious liberty.

**Agencies as Employers**

Administrative agencies should review their current policies and practices to ensure that they comply

with all applicable federal laws and policies regarding accommodation for religious observance and practice in the federal workplace, and all agencies must observe such laws going forward. In particular, all agencies should review the Guidelines on Religious Exercise and Religious Expression in the Federal Workplace, which President Clinton issued on August 14, 1997, to ensure that they are following those Guidelines. All agencies should also consider practical steps to improve safeguards for religious liberty in the federal workplace, including through subject-matter experts who can answer questions about religious nondiscrimination rules, information websites that employees may access to learn more about their religious accommodation rights, and training for all employees about federal protections for religious observance and practice in the workplace.

**Agencies Engaged in Rulemaking**

In formulating rules, regulations, and policies, administrative agencies should also proactively consider potential burdens on the exercise of religion and possible accommodations of those burdens. Agencies should consider designating an officer to review proposed rules with religious accommodation in mind or developing some other process to do so. In developing that process, agencies should consider drawing upon the expertise of the White House Office of Faith-Based and Neighborhood Partnerships to identify concerns about the effect of potential agency action on religious exercise. Regardless of the process chosen, agencies should ensure that they review all proposed rules, regulations, and policies that have the potential to have an effect on religious liberty for compliance with the principles of religious liberty outlined in this memorandum and appendix before finalizing those rules, regulations, or policies. The Office of Legal Policy will also review any proposed agency or executive action upon which the Department's comments, opinion, or concurrence are sought, *see, e.g.,* Exec. Order 12250 § 1–2, 45 Fed. Reg. 72995 (Nov. 2, 1980), to ensure that such action complies with the principles of religious liberty outlined in this memorandum and appendix. The Department will not concur in any proposed action that does not comply with federal law protections for religious liberty as interpreted in this memorandum and appendix, and it will transmit any concerns it has about the proposed action to the agency or the Office of Management and Budget as appropriate. If, despite these internal reviews, a member of the public identifies a significant concern about a prospective rule's compliance with federal protections governing religious liberty during a period for public comment on the rule, the agency should carefully consider and respond to that request in its decision. *See Perez* v. *Mortgage Bankers Ass'n,* 135 S. Ct. 1199, 1203 (2015). In appropriate circumstances, an agency might explain that it will consider requests for accommodations on a case-by-case basis rather than in the rule itself, but the agency should provide a reasoned basis for that approach.

**Agencies Engaged in Enforcement Actions**

Much like administrative agencies engaged in rulemaking, agencies considering potential enforcement actions should consider whether such actions are consistent with federal protections for religious liberty. In particular, agencies should remember that RFRA applies to agency enforcement just as it applies to every other governmental action. An agency should consider RFRA when setting agency-wide enforcement rules and priorities, as well as when making decisions to pursue or continue any particular enforcement action, and when formulating any generally applicable rules announced in an agency adjudication.

Agencies should remember that discriminatory enforcement of an otherwise nondiscriminatory law can also violate the Constitution. Thus, agencies may not target or single out religious organizations or religious conduct for disadvantageous treatment in enforcement priorities or actions. The President identified one area where this could be a problem in Executive Order 13798, when he directed the Secretary of the Treasury, to the extent permitted by law, not to take any ''adverse action against any individual, house of worship, or other religious organization on the basis that such individual or organization speaks or has spoken about moral or political issues from a religious perspective, where speech of *similar character*'' from a non-religious perspective has not been treated as participation or intervention in a political campaign. Exec. Order No. 13798, § 2, 82 Fed. Reg. at 21675. But the requirement of nondiscrimination toward religious organizations and conduct applies across the enforcement activities of the Executive Branch, including within the enforcement components of the Department of Justice.

**Agencies Engaged in Contracting and Distribution of Grants**

Agencies also must not discriminate against religious organizations in their contracting or grant-making activities. Religious organizations should be given the opportunity to compete for government grants or contracts and participate in government programs on an equal basis with nonreligious organizations. Absent unusual circumstances, agencies should not condition receipt of a government contract or grant on the effective relinquishment of a religious organization's Section 702 exemption for religious hiring practices, or any other constitutional or statutory protection for religious organizations. In particular, agencies should not attempt through conditions on grants or contracts to meddle in the internal governance affairs of religious organizations or to limit those organizations' otherwise protected activities.

* * * * *

Any questions about this memorandum or the appendix should be addressed to the Office of Legal Policy, U.S. Department of Justice, 950 Pennsylvania Avenue NW., Washington, DC 20530, phone (202) 514–4601.

**APPENDIX**

Although not an exhaustive treatment of all federal protections for religious liberty, this appendix summarizes the key constitutional and federal statutory protections for religious liberty and sets forth the legal basis for the religious liberty principles described in the foregoing memorandum.

*Constitutional Protections*

The people, acting through their Constitution, have singled out religious liberty as deserving of unique protection. In the original version of the Constitution, the people agreed that ''no religious Test shall ever be required as a Qualification to any Office or public Trust under the United States.'' U.S. Const., art. VI, cl. 3. The people then amended the Constitution during the First Congress to clarify that ''Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof.'' U.S. Const. amend. I, cl. 1. Those protections have been incorporated against the States. *Everson* v. *Bd. of Educ. of Ewing,* 330 U.S. 1, 15 (1947) (Establishment Clause); *Cantwell* v. *Connecticut,* 310 U.S. 296, 303 (1940) (Free Exercise Clause).

A. Free Exercise Clause

The Free Exercise Clause recognizes and guarantees Americans the ''right to believe and profess whatever religious doctrine [they] desire [ ].'' *Empl't Div.* v. *Smith,* 494 U.S. 872, 877 (1990). Government may not attempt to *regulate* religious beliefs, *compel* religious beliefs, or *punish* religious beliefs. *See id.; see also Sherbert* v. *Verner,* 374 U.S. 398, 402 (1963); *Torcaso* v. *Watkins,* 367 U.S. 488, 492–93, 495 (1961); *United States* v. *Ballard,* 322 U.S. 78, 86 (1944). It may not lend its power to one side in intra-denominational disputes about dogma, authority, discipline, or qualifications for ministry or membership. *Hosanna-Tabor Evangelical Lutheran Church & Sch.* v. *EEOC,* 565 U.S. 171, 185 (2012); *Smith,* 494 U.S. at 877; *Serbian Eastern Orthodox Diocese* v. *Milivojevich,* 426 U.S. 696, 724–25 (1976); *Presbyterian Church* v. *Mary Elizabeth Blue Hull Mem'l Presbyterian Church,* 393 U.S. 440, 451 (1969); *Kedroff* v. *St. Nicholas Cathedral of the Russian Orthodox Church,* 344 U.S. 94, 116, 120–21 (1952). It may not discriminate against or impose special burdens upon individuals because of their religious beliefs or status. *Smith,* 494 U.S. at 877; *McDaniel* v. *Paty,* 435 U.S. 618, 627 (1978). And with the exception of certain historical limits on the freedom of speech, government may not punish or otherwise harass churches, church officials, or religious adherents for speaking on religious topics or sharing their religious beliefs. *See Widmar* v. *Vincent,* 454 U.S. 263, 269 (1981); *see also* U.S. Const., amend. I, cl. 3. The Constitution's protection against government regulation of religious belief is absolute; it is not subject to limitation or balancing against the interests of the government. *Smith,* 494 U.S. at 877; *Sherbert,* 374 U.S. at 402; *see also West Virginia State Bd. of Educ.* v. *Barnette,* 319 U.S. 624, 642 (1943) (''If there is any fixed star in our constitutional constellation, it is that no official, high or petty, can prescribe what shall be orthodox in politics, nationalism, religion, or other matters of opinion or force citizens to confess by word or act their faith therein.'').

The Free Exercise Clause protects beliefs rooted in religion, even if such beliefs are not mandated by a particular religious organization or shared among adherents of a particular religious tradition. *Frazee* v. *Illinois Dept. of Emp't Sec.,* 489 U.S. 829, 833–34 (1989). As the Supreme Court has repeatedly counseled, ''religious beliefs need not be acceptable, logical, consistent, or comprehensible to others in order to merit First Amendment protection.'' *Church of the Lukumi Babalu Aye* v. *Hialeah,* 508 U.S. 520, 531 (1993) (internal quotation marks omitted). They must merely be ''sincerely held.'' *Frazee,* 489 U.S. at 834.

Importantly, the protection of the Free Exercise Clause also extends to acts undertaken in accordance with such sincerely-held beliefs. That conclusion flows from the plain text of the First Amendment, which guarantees the freedom to ''*exercise*'' religion, not just the freedom to ''believe'' in religion. *See Smith,* 494 U.S. at 877; *see also Thomas,* 450 U.S. at 716; *Paty,* 435 U.S. at 627; *Sherbert,* 374 U.S. at 403–04; *Wisconsin* v. *Yoder,* 406 U.S. 205, 219–20 (1972). Moreover, no other interpretation would actually guarantee the freedom of belief that Americans have so long regarded as central to individual liberty. Many, if not most, religious beliefs require external observance and practice through physical acts or abstention from acts. The tie between physical acts and religious beliefs may be readily apparent (e.g., attendance at a worship service) or not (e.g., service to one's community at a soup kitchen or a decision to close one's business on a particular day of the week). The ''exercise of religion'' encompasses all aspects of religious observance and practice. And because individuals may act collectively through associations and organizations, it encompasses the exercise of religion by such entities as well. *See, e.g., Hosanna-Tabor,* 565 U.S. at 199; *Church of the Lukumi Babalu Aye,* 508 U.S. at 525–26, 547; *see also Burwell* v. *Hobby Lobby Stores, Inc.,* 134 S. Ct. 2751, 2770, 2772–73 (2014) (even a closely held for-profit corporation may exercise religion if operated in accordance with asserted religious principles).

As with most constitutional protections, however, the protection afforded to Americans by the Free Exercise Clause for physical acts is not absolute, *Smith,* 491 U.S. at 878–79, and the Supreme Court has identified certain principles to guide the analysis of the scope of that protection. First, government may not restrict ''acts or abstentions only when they are engaged in for religious reasons, or only because of the religious belief that they display,'' *id.* at 877, nor ''target the religious for special disabilities based on their religious status,'' *Trinity Lutheran Church of Columbia, Inc.* v. *Comer,* 582 U.S. ___, ___ (2017) (slip op. at 6) (internal quotation marks omitted), for it was precisely such ''historical instances of religious persecution and intolerance that gave concern to those who drafted the Free Exercise Clause.'' *Church of the Lukumi Babalu Aye,* 508 U.S. at 532 (internal quotation marks omitted). The Free Exercise Clause protects against ''indirect coercion or penalties on the free exercise of religion'' just as surely as it protects against ''outright prohibitions'' on religious exercise. *Trinity Lutheran,* 582 U.S. at ___( (slip op. at 11) (internal quotation marks omitted). ''It is too late in the day to doubt that the liberties of religion and expression may be infringed by the denial of or placing of conditions upon a benefit or privilege.'' *Id.* (quoting *Sherbert,* 374 U.S. at 404).

Because a law cannot have as its official ''object or purpose . . . the suppression of religion or religious conduct,'' courts must ''survey meticulously'' the text and operation of a law to ensure that it is actually neutral and of general applicability. *Church of the Lukumi Babalu Aye,* 508 U.S. at 533–34 (internal quotation marks omitted). A law is not neutral if it singles out particular religious conduct for adverse treatment; treats the same conduct as lawful when undertaken for secular reasons but unlawful when undertaken for religious reasons; visits ''gratuitous restrictions on religious conduct''; or ''accomplishes . . . a 'religious gerrymander,' an impermissible attempt to target [certain individuals] and their religious practices.'' *Id.* at 533–35, 538 (internal quotation marks omitted). A law is not generally applicable if ''in a selective manner [it] impose[s] burdens only on conduct motivated by religious belief,'' *id.* at 543, including by ''fail[ing] to prohibit nonreligious conduct that endangers [its] interests in a similar or greater degree than . . . does'' the prohibited conduct, *id.,* or enables, expressly or de facto, ''a system of individualized exemptions,'' as discussed in *Smith,* 494 U.S. at 884; *see also Church of the Lukumi Babalu Aye,* 508 U.S. at 537.

''Neutrality and general applicability are interrelated, . . . [and] failure to satisfy one requirement is a likely indication that the other has not been satisfied.'' *Id.* at 531. For example, a law that disqualifies a religious person or organization from a right to compete for a public benefit—including a grant or contract—because of the person's religious character is neither neutral nor generally applicable. *See Trinity Lutheran,* 582 U.S. at ___–___ (slip op. at 9–11). Likewise, a law that selectively prohibits the killing of animals for religious reasons and fails to prohibit the killing of animals for many nonreligious reasons, or that selectively prohibits a business from refusing to stock a product for religious reasons but fails to prohibit such refusal for myriad

commercial reasons, is neither neutral, nor generally applicable. *See Church of the Lukumi Babalu Aye,* 508 U.S. at 533–36, 542–45. Nonetheless, the requirements of neutral and general applicability are separate, and any law burdening religious practice that fails one or both must be subjected to strict scrutiny, *id.* at 546.

Second, even a neutral, generally applicable law is subject to strict scrutiny under this Clause if it restricts the free exercise of religion and another constitutionally protected liberty, such as the freedom of speech or association, or the right to control the upbringing of one's children. *See Smith,* 494 U.S. at 881–82; *Axson-Flynn* v. *Johnson,* 356 F.3d 1277, 1295–97 (10th Cir. 2004). Many Free Exercise cases fall in this category. For example, a law that seeks to compel a private person's speech or expression contrary to his or her religious beliefs implicates both the freedoms of speech and free exercise. *See, e.g., Wooley* v. *Maynard,* 430 U.S. 705, 707–08 (1977) (challenge by Jehovah's Witnesses to requirement that state license plates display the motto ''Live Free or Die''); *Axson-Flynn,* 356 F.3d at 1280 (challenge by Mormon student to University requirement that student actors use profanity and take God's name in vain during classroom acting exercises). A law taxing or prohibiting door-to-door solicitation, at least as applied to individuals distributing religious literature and seeking contributions, likewise implicates the freedoms of speech and free exercise. *Murdock* v. *Pennsylvania,* 319 U.S. 105, 108–09 (1943) (challenge by Jehovah's Witnesses to tax on canvassing or soliciting); *Cantwell,* 310 U.S. at 307 (same). A law requiring children to receive certain education, contrary to the religious beliefs of their parents, implicates both the parents' right to the care, custody, and control of their children and to free exercise. *Yoder,* 406 U.S. at 227–29 (challenge by Amish parents to law requiring high school attendance).

Strict scrutiny is the ''most rigorous'' form of scrutiny identified by the Supreme Court. *Church of the Lukumi Babalu Aye,* 508 U.S. at 546; *see also City of Boerne* v. *Flores,* 521 U.S. 507, 534 (1997) (''Requiring a State to demonstrate a compelling interest and show that it has adopted the least restrictive means of achieving that interest is the most demanding test known to constitutional law.''). It is the same standard applied to governmental classifications based on race, *Parents Involved in Cmty. Sch.* v. *Seattle Sch. Dist. No. 1,* 551 U.S. 701, 720 (2007), and restrictions on the freedom of speech, *Reed* v. *Town of Gilbert, Ariz.,* 135 S. Ct. 2218, 2228 (2015). *See Church of the Lukumi Babalu Aye,* 508 U.S. at 546–47. Under this level of scrutiny, government must establish that a challenged law ''advance[s] interests of the highest order'' and is ''narrowly tailored in pursuit of those interests.'' *Id.* at 546 (internal quotation marks omitted). ''[O]nly in rare cases'' will a law survive this level of scrutiny. *Id.*

Of course, even when a law is neutral and generally applicable, government may run afoul of the Free Exercise Clause if it interprets or applies the law in a manner that discriminates against religious observance and practice. *See, e.g., Church of the Lukumi Babalu Aye,* 508 U.S. at 537 (government discriminatorily interpreted an ordinance prohibiting the unnecessary killing of animals as prohibiting only killing of animals for religious reasons); *Fowler* v. *Rhode Island,* 345 U.S. 67, 69–70 (1953) (government discriminatorily enforced ordinance prohibiting meetings in public parks against only certain religious groups). The Free Exercise Clause, much like the Free Speech Clause, requires equal treatment of religious adherents. *See Trinity Lutheran,* 582 U.S. at __ (slip op. at 6); *cf. Good News Club* v. *Milford Central Sch.,* 533 U.S. 98, 114 (2001) (recognizing that Establishment Clause does not justify discrimination against religious clubs seeking use of public meeting spaces); *Rosenberger* v. *Rector & Visitors of Univ. of Va.,* 515 U.S. 819, 837, 841 (1995) (recognizing that Establishment Clause does not justify discrimination against religious student newspaper's participation in neutral reimbursement program). That is true regardless of whether the discriminatory application is initiated by the government itself or by private requests or complaints. *See, e.g., Fowler,* 345 U.S. at 69; *Niemotko* v. *Maryland,* 340 U.S. 268, 272 (1951).

B. Establishment Clause

The Establishment Clause, too, protects religious liberty. It prohibits government from establishing a religion and coercing Americans to follow it. *See Town of Greece, N.Y.* v. *Galloway,* 134 S. Ct. 1811, 1819–20 (2014); *Good News Club,* 533 U.S. at 115. It restricts government from interfering in the internal governance or ecclesiastical decisions of a religious organization. *Hosanna-Tabor,* 565 U.S. at 188–89. And it prohibits government from officially favoring or disfavoring particular religious groups as such or officially advocating particular religious points of view. *See Galloway,* 134 S. Ct. at 1824; *Larson* v. *Valente,* 456 U.S. 228, 244–46 (1982). Indeed, ''a significant factor in upholding governmental programs in the face of Establishment Clause attack is their *neutrality* towards religion.'' *Rosenberger,* 515 U.S. at 839 (emphasis added). That ''guarantee of neutrality is respected, not offended, when the government, following neutral criteria and evenhanded policies, extends benefits to recipients whose ideologies and viewpoints, including religious ones, are broad and diverse.'' *Id.* Thus, religious adherents and organizations may, like nonreligious adherents and organizations, receive indirect financial aid through independent choice, or, in certain circumstances, direct financial aid through a secular-aid program. *See, e.g., Trinity Lutheran,* 582 U.S. at ___ (slip. op. at 6) (scrap tire program); *Zelman* v. *Simmons-Harris,* 536 U.S. 639, 652 (2002) (voucher program).

C. Religious Test Clause

Finally, the Religious Test Clause, though rarely invoked, provides a critical guarantee to religious adherents that they may serve in American public life. The Clause reflects the judgment of the Framers that a diversity of religious viewpoints in government would enhance the liberty of all Americans. And after the Religion Clauses were incorporated against the States, the Supreme Court shared this view, rejecting a Tennessee law that ''establishe[d] as a condition of office the willingness to eschew certain protected religious practices.'' *Paty,* 435 U.S. at 632 (Brennan, J., and Marshall, J., concurring in judgment); *see also id.* at 629 (plurality op.) (''[T]he American experience provides no persuasive support for the fear that clergymen in public office will be less careful of anti-establishment interests or less faithful to their oaths of civil office than their unordained counterparts.'').

*Statutory Protections*

Recognizing the centrality of religious liberty to our nation, Congress has buttressed these constitutional rights with statutory protections for religious observance and practice. These protections can be found in, among other statutes, the Religious Freedom Restoration Act of 1993, 42 U.S.C. 2000bb *et seq.;* the Religious Land Use and Institutionalized Persons Act, 42 U.S.C. 2000cc *et seq.;* Title VII of the Civil Rights Act of 1964, 42 U.S.C. 2000e *et seq.;* and the American Indian Religious Freedom Act, 42 U.S.C. 1996. Such protections ensure not only that government tolerates religious observance and practice, but that it embraces religious adherents as full

members of society, able to contribute through employment, use of public accommodations, and participation in government programs. The considered judgment of the United States is that we are stronger through accommodation of religion than segregation or isolation of it.

A. Religious Freedom Restoration Act of 1993 (RFRA)

The Religious Freedom Restoration Act of 1993 (RFRA), 42 U.S.C. 2000bb *et seq.,* prohibits the federal government from ''substantially burden[ing] a person's exercise of religion'' unless ''it demonstrates that application of the burden to the person (1) is in furtherance of a compelling governmental interest; and (2) is the least restrictive means of furthering that compelling governmental interest.'' *Id.* § 2000bb–1(a), (b). The Act applies even where the burden arises out of a ''rule of general applicability'' passed without animus or discriminatory intent. *See id.* § 2000bb-1(a). It applies to ''any exercise of religion, whether or not compelled by, or central to, a system of religious belief,'' *see* §§ 2000bb–2(4), 2000cc–5(7), and covers ''individuals'' as well as ''corporations, companies, associations, firms, partnerships, societies, and joint stock companies,'' 1 U.S.C. 1, including for-profit, closely-held corporations like those involved in *Hobby Lobby,* 134 S. Ct. at 2768.

Subject to the exceptions identified below, a law ''substantially burden[s] a person's exercise of religion,'' 42 U.S.C. 2000bb–1, if it bans an aspect of the adherent's religious observance or practice, compels an act inconsistent with that observance or practice, or substantially pressures the adherent to modify such observance or practice, *see Sherbert,* 374 U.S. at 405–06. The ''threat of criminal sanction'' will satisfy these principles, even when, as in *Yoder,* the prospective punishment is a mere $5 fine. 406 U.S. at 208, 218. And the denial of, or condition on the receipt of, government benefits may substantially burden the exercise of religion under these principles. *Sherbert,* 374 U.S. at 405–06; *see also Hobbie* v. *Unemployment Appeals Comm'n of Fla.,* 480 U.S. 136, 141 (1987); *Thomas,* 450 U.S. at 717–18. But a law that infringes, even severely, an aspect of an adherent's religious observance or practice that the adherent himself regards as unimportant or inconsequential imposes no substantial burden on that adherent. And a law that regulates only the government's internal affairs and does not involve any governmental compulsion on the religious adherent likewise imposes no substantial burden. *See, e.g., Lyng* v. *Nw. Indian Cemetery Protective Ass'n,* 485 U.S. 439, 448–49 (1988); *Bowen* v. *Roy,* 476 U.S. 693, 699–700 (1986).

As with claims under the Free Exercise Clause, RFRA does not permit a court to inquire into the reasonableness of a religious belief, including into the adherent's assessment of the religious connection between a belief asserted and what the government forbids, requires, or prevents. *Hobby Lobby,* 134 S. Ct. at 2778. If the proffered belief is sincere, it is not the place of the government or a court to second-guess it. *Id.* A good illustration of the point is *Thomas* v. *Review Board of Indiana Employment Security Division*—one of the *Sherbert* line of cases, whose analytical test Congress sought, through RFRA, to restore, 42 U.S.C. 2000bb. There, the Supreme Court concluded that the denial of unemployment benefits was a substantial burden on the sincerely held religious beliefs of a Jehovah's Witness who had quit his job after he was transferred from a department producing sheet steel that could be used for military armaments to a department producing turrets for military tanks. *Thomas,* 450 U.S. at 716–18. In doing so, the Court rejected the lower court's inquiry into ''what [the claimant's] belief was and what the religious basis of his belief was,'' noting that no one had challenged the sincerity of the claimant's religious beliefs and that ''[c]ourts should not undertake to dissect religious beliefs because the believer admits that he is struggling with his position or because his beliefs are not articulated with the clarity and precision that a more sophisticated person might employ.'' *Id.* at 714–15 (internal quotation marks omitted). The Court likewise rejected the lower court's comparison of the claimant's views to those of other Jehovah's Witnesses, noting that ''[i]ntrafaith differences of that kind are not uncommon among followers of a particular creed, and the judicial process is singularly ill equipped to resolve such differences.'' *Id.* at 715. The Supreme Court reinforced this reasoning in *Hobby Lobby,* rejecting the argument that ''the connection between what the objecting parties [were required to] do (provide health-insurance coverage for four methods of contraception that may operate after the fertilization of an egg) and the end that they [found] to be morally wrong (destruction of an embryo) [wa]s simply too attenuated.'' 134 S. Ct. at 2777. The Court explained that the plaintiff corporations had a sincerely-held religious belief that provision of the coverage was morally wrong, and it was ''not for us to say that their religious beliefs are mistaken or insubstantial.'' *Id.* at 2779.

Government bears a heavy burden to justify a substantial burden on the exercise of religion. ''[O]nly those interests of the highest order . . . can overbalance legitimate claims to the free exercise of religion.'' *Thomas,* 450 U.S. at 718 (quoting *Yoder,* 406 U.S. at 215). Such interests include, for example, the ''fundamental, overriding interest in eradicating racial discrimination in education—discrimination that prevailed, with official approval, for the first 165 years of this Nation's history,'' *Bob Jones Univ.* v. *United States,* 461 U.S. 574, 604 (1983), and the interest in ensuring the ''mandatory and continuous participation'' that is ''indispensable to the fiscal vitality of the social security system,'' *United States* v. *Lee,* 455 U.S. 252, 258–59 (1982). But ''broadly formulated interests justifying the general applicability of government mandates'' are insufficient. *Gonzales* v. *O Centro Espirita Beneficente Uniao do Vegetal,* 546 U.S. 418, 431 (2006). The government must establish a compelling interest to deny an accommodation to the particular claimant. *Id.* at 430, 435–38. For example, the military may have a compelling interest in its uniform and grooming policy to ensure military readiness and protect our national security, but it does not necessarily follow that those interests would justify denying a particular soldier's request for an accommodation from the uniform and grooming policy. *See, e.g.,* Secretary of the Army, Army Directive 2017–03, Policy for Brigade-Level Approval of Certain Requests for Religious Accommodation (2017) (recognizing the ''successful examples of Soldiers currently serving with'' an accommodation for ''the wear of a hijab; the wear of a beard; and the wear of a turban or under-turban/patka, with uncut beard and uncut hair'' and providing for a reasonable accommodation of these practices in the Army). The military would have to show that it has a compelling interest in denying that particular accommodation. An asserted compelling interest in denying an accommodation to a particular claimant is undermined by evidence that exemptions or accommodations have been granted for other interests. *See O Centro,* 546 U.S. at 433, 436–37; *see also Hobby Lobby,* 134 S. Ct. at 2780.

The compelling-interest requirement applies even where the accommodation sought is ''an exemption from a legal obligation requiring [the claimant] to

confer benefits on third parties.'' *Hobby Lobby,* 134 S. Ct. at 2781 n.37. Although ''in applying RFRA 'courts must take adequate account of the burdens a requested accommodation may impose on nonbeneficiaries,' '' the Supreme Court has explained that almost any governmental regulation could be reframed as a legal obligation requiring a claimant to confer benefits on third parties. *Id.* (quoting *Cutter* v. *Wilkinson,* 544 U.S. 709, 720 (2005)). As nothing in the text of RFRA admits of an exception for laws requiring a claimant to confer benefits on third parties, 42 U.S.C. 2000bb–1, and such an exception would have the potential to swallow the rule, the Supreme Court has rejected the proposition that RFRA accommodations are categorically unavailable for laws requiring claimants to confer benefits on third parties. *Hobby Lobby,* 134 S. Ct. at 2781 n.37.

Even if the government can identify a compelling interest, the government must also show that denial of an accommodation is the least restrictive means of serving that compelling governmental interest. This standard is ''exceptionally demanding.'' *Hobby Lobby,* 134 S. Ct. at 2780. It requires the government to show that it cannot accommodate the religious adherent while achieving its interest through a viable alternative, which may include, in certain circumstances, expenditure of additional funds, modification of existing exemptions, or creation of a new program. *Id.* at 2781. Indeed, the existence of exemptions for other individuals or entities that could be expanded to accommodate the claimant, while still serving the government's stated interests, will generally defeat a RFRA defense, as the government bears the burden to establish that no accommodation is viable. *See id.* at 2781–82.

B. Religious Land Use and Institutionalized Persons Act of 2000 (RLUIPA)

Although Congress's leadership in adopting RFRA led many States to pass analogous statutes, Congress recognized the unique threat to religious liberty posed by certain categories of state action and passed the Religious Land Use and Institutionalized Persons Act of 2000 (RLUIPA) to address them. RLUIPA extends a standard analogous to RFRA to state and local government actions regulating land use and institutionalized persons where ''the substantial burden is imposed in a program or activity that receives Federal financial assistance'' or ''the substantial burden affects, or removal of that substantial burden would affect, commerce with foreign nations, among the several States, or with Indian tribes.'' 42 U.S.C. 2000cc(a)(2), 2000cc–1(b).

RLUIPA's protections must ''be construed in favor of a broad protection of religious exercise, to the maximum extent permitted by [RLUIPA] and the Constitution.'' *Id.* § 2000cc–3(g). RLUIPA applies to ''any exercise of religion, whether or not compelled by, or central to, a system of religious belief,'' *id.* § 2000cc–5(7)(A), and treats ''[t]he use, building, or conversion of real property for the purpose of religious exercise'' as the ''religious exercise of the person or entity that uses or intends to use the property for that purpose,'' *id.* § 2000cc–5(7)(B). Like RFRA, RLUIPA prohibits government from substantially burdening an exercise of religion unless imposition of the burden on the religious adherent is the least restrictive means of furthering a compelling governmental interest. *See id.* § 2000cc–1(a). That standard ''may require a government to incur expenses in its own operations to avoid imposing a substantial burden on religious exercise.'' *Id.* § 2000cc–3(c); *cf. Holt* v. *Hobbs,* 135 S. Ct. 853, 860, 864–65 (2015).

With respect to land use in particular, RLUIPA also requires that government not ''treat[] a religious assembly or institution on less than equal terms with a nonreligious assembly or institution,'' 42 U.S.C. 2000cc(b)(1), ''impose or implement a land use regulation that discriminates against any assembly or institution on the basis of religion or religious denomination,'' *id.* § 2000cc(b)(2), or ''impose or implement a land use regulation that (A) totally excludes religious assemblies from a jurisdiction; or (B) unreasonably limits religious assemblies, institutions, or structures within a jurisdiction,'' *id.* § 2000cc(b)(3). A claimant need not show a substantial burden on the exercise of religion to enforce these antidiscrimination and equal terms provisions listed in § 2000cc(b). *See id.* § 2000cc(b); *see also Lighthouse Inst. for Evangelism, Inc.* v. *City of Long Branch,* 510 F.3d 253, 262–64 (3d Cir. 2007), *cert. denied,* 553 U.S. 1065 (2008). Although most RLUIPA cases involve places of worship like churches, mosques, synagogues, and temples, the law applies more broadly to religious schools, religious camps, religious retreat centers, and religious social service facilities. Letter from U.S. Dep't of Justice Civil Rights Division to State, County, and Municipal Officials re: The Religious Land Use and Institutionalized Persons Act (Dec. 15, 2016).

C. Other Civil Rights Laws

To incorporate religious adherents fully into society, Congress has recognized that it is not enough to limit governmental action that substantially burdens the exercise of religion. It must also root out public and private discrimination based on religion. Religious discrimination stood alongside discrimination based on race, color, and national origin, as an evil to be addressed in the Civil Rights Act of 1964, and Congress has continued to legislate against such discrimination over time. Today, the United States Code includes specific prohibitions on religious discrimination in places of public accommodation, 42 U.S.C. 2000a; in public facilities, *id.* § 2000b; in public education, *id.* § 2000c–6; in employment, *id.* §§ 2000e, 2000e–2, 2000e–16; in the sale or rental of housing, *id.* § 3604; in the provision of certain real-estate transaction or brokerage services, *id.* §§ 3605, 3606; in federal jury service, 28 U.S.C. 1862; in access to limited open forums for speech, 20 U.S.C. 4071; and in participation in or receipt of benefits from various federally-funded programs, 15 U.S.C. 3151; 20 U.S.C. 1066c(d), 1071(a)(2), 1087–4, 7231d(b)(2), 7914; 31 U.S.C. 6711(b)(3); 42 U.S.C. 290cc–33(a)(2), 300w–7(a)(2), 300x–57(a)(2), 300x–65(f), 604a(g), 708(a)(2), 5057(c), 5151(a), 5309(a), 6727(a), 9858l(a)(2), 10406(2)(B), 10504(a), 10604(e), 12635(c)(1), 12832, 13791(g)(3), 13925(b)(13)(A).

Invidious religious discrimination may be directed at religion in general, at a particular religious belief, or at particular aspects of religious observance and practice. *See, e.g., Church of the Lukumi Babalu Aye,* 508 U.S. at 532–33. A law drawn to prohibit a specific religious practice may discriminate just as severely against a religious group as a law drawn to prohibit the religion itself. *See id.* No one would doubt that a law prohibiting the sale and consumption of Kosher meat would discriminate against Jewish people. True equality may also require, depending on the applicable statutes, an awareness of, and willingness reasonably to accommodate, religious observance and practice. Indeed, the denial of reasonable accommodations may be little more than cover for discrimination against a particular religious belief or religion in general and is counter to the general determination of Congress that the United States is best served by the participation of religious adherents in society, not their withdrawal from it.

1. Employment

i. Protections for Religious Employees

Protections for religious individuals in employment are the most obvious example of Congress's instruction that religious observance and practice be reasonably accommodated, not marginalized. In Title VII of the Civil Rights Act, Congress declared it an unlawful employment practice for a covered employer to (1) ''fail or refuse to hire or to discharge any individual, or otherwise . . . discriminate against any individual with respect to his compensation, terms, conditions, or privileges of employment, because of such individual's . . . religion,'' as well as (2) to ''limit, segregate, or classify his employees or applicants for employment in any way which would deprive or tend to deprive any individual of employment opportunities or otherwise adversely affect his status as an employee, because of such individual's . . . religion.'' 42 U.S.C. 2000e–2(a); *see also* 42 U.S.C. 2000e–16(a) (applying Title VII to certain federal-sector employers); 3 U.S.C. 411(a) (applying Title VII employment in the Executive Office of the President). The protection applies ''regardless of whether the discrimination is directed against [members of religious] majorities or minorities.'' *Trans World Airlines, Inc.* v. *Hardison,* 432 U.S. 63, 71–72 (1977).

After several courts had held that employers did not violate Title VII when they discharged employees for refusing to work on their Sabbath, Congress amended Title VII to define ''[r]eligion'' broadly to include ''all aspects of religious observance and practice, as well as belief, unless an employer demonstrates that he is unable to reasonably accommodate to an employee's or prospective employee's religious observance or practice without undue hardship on the conduct of the employer's business.'' 42 U.S.C. 2000e(j); *Hardison,* 432 U.S. at 74 n.9. Congress thus made clear that discrimination on the basis of religion includes discrimination on the basis of any aspect of an employee's religious observance or practice, at least where such observance or practice can be reasonably accommodated without undue hardship.

Title VII's reasonable accommodation requirement is meaningful. As an initial matter, it requires an employer to consider what adjustment or modification to its policies would effectively address the employee's concern, for ''[a]n *ineffective* modification or adjustment will not *accommodate*'' a person's religious observance or practice, within the ordinary meaning of that word. *See U.S. Airways, Inc.* v. *Barnett,* 535 U.S. 391, 400 (2002) (considering the ordinary meaning in the context of an ADA claim). Although there is no obligation to provide an employee with his or her preferred reasonable accommodation, *see Ansonia Bd. of Educ.* v. *Philbrook,* 479 U.S. 60, 68 (1986), an employer may justify a refusal to accommodate only by showing that ''an undue hardship [on its business] would *in fact* result from *each available* alternative method of accommodation.'' 29 CFR § 1605.2(c)(1) (emphasis added). ''A mere assumption that many more people, with the same religious practices as the person being accommodated, may also need accommodation is not evidence of undue hardship.'' *Id.* Likewise, the fact that an accommodation may grant the religious employee a preference is not evidence of undue hardship as, ''[b]y definition, any special 'accommodation' requires the employer to treat an employee . . . differently, *i.e.,* preferentially.'' *U.S. Airways,* 535 U.S. at 397; *see also E.E.O.C.* v. *Abercrombie & Fitch Stores, Inc.,* 135 S. Ct. 2028, 2034 (2015) (''Title VII does not demand mere neutrality with regard to religious practices—that they may be treated no worse than other practices. Rather, it gives them favored treatment.'').

Title VII does not, however, require accommodation at all costs. As noted above, an employer is not required to accommodate a religious observance or practice if it would pose an undue hardship on its business. An accommodation might pose an ''undue hardship,'' for example, if it would require the employer to breach an otherwise valid collective bargaining agreement, *see, e.g., Hardison,* 432 U.S. at 79, or carve out a special exception to a seniority system, *id.* at 83; *see also U.S. Airways,* 535 U.S. at 403. Likewise, an accommodation might pose an ''undue hardship'' if it would impose ''more than a de minimis cost'' on the business, such as in the case of a company where weekend work is ''essential to [the] business'' and many employees have religious observances that would prohibit them from working on the weekends, so that accommodations for all such employees would result in significant overtime costs for the employer. *Hardison,* 432 U.S. at 80, 84 & n.15. In general, though, Title VII expects positive results for society from a cooperative process between an employer and its employee ''in the search for an acceptable reconciliation of the needs of the employee's religion and the exigencies of the employer's business.'' *Philbrook,* 479 U.S. at 69 (internal quotations omitted).

The area of religious speech and expression is a useful example of reasonable accommodation. Where speech or expression is part of a person's religious observance and practice, it falls within the scope of Title VII. *See* 42 U.S.C. 2000e, 2000e–2. Speech or expression outside of the scope of an individual's employment can almost always be accommodated without undue hardship to a business. Speech or expression within the scope of an individual's employment, during work hours, or in the workplace may, depending upon the facts and circumstances, be reasonably accommodated. *Cf. Abercrombie,* 135 S. Ct. at 2032.

The federal government's approach to free exercise in the federal workplace provides useful guidance on such reasonable accommodations. For example, under the Guidelines issued by President Clinton, the federal government permits a federal employee to ''keep a Bible or Koran on her private desk and read it during breaks''; to discuss his religious views with other employees, subject ''to the same rules of order as apply to other employee expression''; to display religious messages on clothing or wear religious medallions visible to others; and to hand out religious tracts to other employees or invite them to attend worship services at the employee's church, except to the extent that such speech becomes excessive or harassing. Guidelines on Religious Exercise and Religious Expression in the Federal Workplace, § 1(A), Aug. 14, 1997 (hereinafter ''Clinton Guidelines''). The Clinton Guidelines have the force of an Executive Order. *See Legal Effectiveness of a Presidential Directive, as Compared to an Executive Order,* 24 Op. O.L.C. 29, 29 (2000) (''[T]here is no substantive difference in the legal effectiveness of an executive order and a presidential directive that is styled other than as an executive order.''); *see also* Memorandum from President William J. Clinton to the Heads of Executive Departments and Agencies (Aug. 14, 1997) (''All civilian executive branch agencies, officials, and employees must follow these Guidelines carefully.''). The successful experience of the federal government in applying the Clinton Guidelines over the last twenty years is evidence that religious speech and expression can be reasonably accommodated in the workplace without exposing an employer to liability under workplace harassment laws.

Time off for religious holidays is also often an area of concern. The observance of religious holidays is an ''aspect[ ] of religious observance and practice'' and is therefore protected by Title VII. 42 U.S.C. 2000e, 2000e–2. Examples of reasonable accommodations for that practice could include a change of job assignments or lateral transfer to a position whose schedule does not conflict with the employee's religious holidays, 29 CFR 1605.2(d)(1)(iii); a voluntary work schedule swap with another employee, *id.* § 1065.2(d)(1)(i); or a flexible scheduling scheme that allows employees to arrive or leave early, use floating or optional holidays for religious holidays, or make up time lost on another day, *id.* § 1065.2(d)(1)(ii). Again, the federal government has demonstrated reasonable accommodation through its own practice: Congress has created a flexible scheduling scheme for federal employees, which allows employees to take compensatory time off for religious observances, 5 U.S.C. 5550a, and the Clinton Guidelines make clear that ''[a]n agency must adjust work schedules to accommodate an employee's religious observance—for example, Sabbath or religious holiday observance—if an adequate substitute is available, or if the employee's absence would not otherwise impose an undue burden on the agency,'' Clinton Guidelines § 1(C). If an employer regularly permits accommodation in work scheduling for secular conflicts and denies such accommodation for religious conflicts, ''such an arrangement would display a discrimination against religious practices that is the antithesis of reasonableness.'' *Philbrook,* 479 U.S. at 71.

Except for certain exceptions discussed in the next section, Title VII's protection against disparate treatment, 42 U.S.C. 2000e–2(a)(1), is implicated *any time* religious observance or practice is a motivating factor in an employer's covered decision. *Abercrombie,* 135 S. Ct. at 2033. That is true even when an employer acts without actual knowledge of the need for an accommodation from a neutral policy but with ''an unsubstantiated suspicion'' of the same. *Id.* at 2034.

ii. Protections for Religious Employers

Congress has acknowledged, however, that religion sometimes *is* an appropriate factor in employment decisions, and it has limited Title VII's scope accordingly. Thus, for example, where religion ''is a bona fide occupational qualification reasonably necessary to the normal operation of [a] particular business or enterprise,'' employers may hire and employ individuals based on their religion. 42 U.S.C. 2000e–2(e)(1). Likewise, where educational institutions are ''owned, supported, controlled or managed, [in whole or in substantial part] by a particular religion or by a particular religious corporation, association, or society'' or direct their curriculum ''toward the propagation of a particular religion,'' such institutions may hire and employ individuals of a particular religion. *Id.* And ''a religious corporation, association, educational institution, or society'' may employ ''individuals of a particular religion to perform work connected with the carrying on by such corporation, association, educational institution, or society of its activities.'' *Id.* § 2000e–1(a); *Corp. of Presiding Bishop of Church of Jesus Christ of Latter-Day Saints* v. *Amos,* 483 U.S. 327, 335–36 (1987).

Because Title VII defines ''religion'' broadly to include ''all aspects of religious observance and practice, as well as belief,'' 42 U.S.C. 2000e(j), these exemptions include decisions ''to employ only persons whose beliefs and conduct are consistent with the employer's religious precepts.'' *Little* v. *Wuerl,* 929 F.2d 944, 951 (3d Cir. 1991); *see also Killinger* v. *Samford Univ.,* 113 F.3d 196, 198–200 (11th Cir. 1997). For example, in *Little,* the Third Circuit held that the exemption applied to a Catholic school's decision to fire a divorced Protestant teacher who, though having agreed to abide by a code of conduct shaped by the doctrines of the Catholic Church, married a baptized Catholic without first pursuing the official annulment process of the Church. 929 F.2d at 946, 951.

Section 702 broadly exempts from its reach religious corporations, associations, educational institutions, and societies. The statute's terms do not limit this exemption to non-profit organizations, to organizations that carry on only religious activities, or to organizations established by a church or formally affiliated therewith. *See* Civil Rights Act of 1964, § 702(a), *codified at* 42 U.S.C. 2000e–1(a); *see also Hobby Lobby,* 134 S. Ct. at 2773–74; *Corp. of Presiding Bishop,* 483 U.S. at 335–36. The exemption applies whenever the organization is ''religious,'' which means that it is organized for religious purposes and engages in activity consistent with, and in furtherance of, such purposes. Br. of Amicus Curiae the U.S. Supp. Appellee, *Spencer* v. *World Vision, Inc.,* No. 08–35532 (9th Cir. 2008). Thus, the exemption applies not just to religious denominations and houses of worship, but to religious colleges, charitable organizations like the Salvation Army and World Vision International, and many more. In that way, it is consistent with other broad protections for religious entities in federal law, including, for example, the exemption of religious entities from many of the requirements under the Americans with Disabilities Act. *See* 28 CFR app. C; 56 Fed. Reg. 35544, 35554 (July 26, 1991) (explaining that ''[t]he ADA's exemption of religious organizations and religious entities controlled by religious organizations is very broad, encompassing a wide variety of situations'').

In addition to these explicit exemptions, religious organizations may be entitled to additional exemptions from discrimination laws. *See, e.g., Hosanna-Tabor,* 565 U.S. at 180, 188–90. For example, a religious organization might conclude that it cannot employ an individual who fails faithfully to adhere to the organization's religious tenets, either because doing so might itself inhibit the organization's exercise of religion or because it might dilute an expressive message. *Cf. Boy Scouts of Am.* v. *Dale,* 530 U.S. 640, 649–55 (2000). Both constitutional and statutory issues arise when governments seek to regulate such decisions.

As a constitutional matter, religious organizations' decisions are protected from governmental interference to the extent they relate to ecclesiastical or internal governance matters. *Hosanna-Tabor,* 565 U.S. at 180, 188–90. It is beyond dispute that ''it would violate the First Amendment for courts to apply [employment discrimination] laws to compel the ordination of women by the Catholic Church or by an Orthodox Jewish seminary.'' *Id.* at 188. The same is true for other employees who ''minister to the faithful,'' including those who are not themselves the head of the religious congregation and who are not engaged solely in religious functions. *Id.* at 188, 190, 194–95; *see also* Br. of Amicus Curiae the U.S. Supp. Appellee, *Spencer* v. *World Vision, Inc.,* No. 08–35532 (9th Cir. 2008) (noting that the First Amendment protects ''the right to employ staff who share the religious organization's religious beliefs'').

Even if a particular associational decision could be construed to fall outside this protection, the government would likely still have to show that any interference with the religious organization's associational rights is justified under strict scrutiny. *See Roberts* v. *U.S. Jaycees,* 468 U.S. 609, 623 (1984) (infringements on expressive association are subject to strict

scrutiny); *Smith,* 494 U.S. at 882 (''[I]t is easy to envision a case in which a challenge on freedom of association grounds would likewise be reinforced by Free Exercise Clause concerns.''). The government may be able to meet that standard with respect to race discrimination, *see Bob Jones Univ.,* 461 U.S. at 604, but may not be able to with respect to other forms of discrimination. For example, at least one court has held that forced inclusion of women into a mosque's religious men's meeting would violate the freedom of expressive association. *Donaldson* v. *Farrakhan,* 762 N.E.2d 835, 840–41 (Mass. 2002). The Supreme Court has also held that the government's interest in addressing sexual-orientation discrimination is not sufficiently compelling to justify an infringement on the expressive association rights of a private organization. *Boy Scouts,* 530 U.S. at 659.

As a statutory matter, RFRA too might require an exemption or accommodation for religious organizations from antidiscrimination laws. For example, ''prohibiting religious organizations from hiring only coreligionists can 'impose a significant burden on their exercise of religion, even as applied to employees in programs that must, by law, refrain from specifically religious activities.''' *Application of the Religious Freedom Restoration Act to the Award of a Grant Pursuant to the Juvenile Justice and Delinquency Prevention Act,* 31 Op. O.L.C. 162, 172 (2007) (quoting *Direct Aid to Faith-Based Organizations Under the Charitable Choice Provisions of the Community Solutions Act of 2001,* 25 Op. O.L.C. 129, 132 (2001)); *see also Corp. of Presiding Bishop,* 483 U.S. at 336 (noting that it would be ''a significant burden on a religious organization to require it, on pain of substantial liability, to predict which of its activities a secular court w[ould] consider religious'' in applying a nondiscrimination provision that applied only to secular, but not religious, activities). If an organization establishes the existence of such a burden, the government must establish that imposing such burden on the organization is the least restrictive means of achieving a compelling governmental interest. That is a demanding standard and thus, even where Congress has not expressly exempted religious organizations from its antidiscrimination laws—as it has in other contexts, *see, e.g.,* 42 U.S.C. 3607 (Fair Housing Act), 12187 (Americans with Disabilities Act)—RFRA might require such an exemption.

2. Government Programs

Protections for religious organizations likewise exist in government contracts, grants, and other programs. Recognizing that religious organizations can make important contributions to government programs, *see, e.g.,* 22 U.S.C. 7601(19), Congress has expressly permitted religious organizations to participate in numerous such programs on an equal basis with secular organizations, *see, e.g.,* 42 U.S.C. 290kk–1, 300x–65 604a, 629i. Where Congress has not expressly so provided, the President has made clear that ''[t]he Nation's social service capacity will benefit if all eligible organizations, including faith-based and other neighborhood organizations, are able to compete on an equal footing for Federal financial assistance used to support social service programs.'' Exec. Order No. 13559, § 1, 75 Fed. Reg. 71319, 71319 (Nov. 17, 2010) (amending Exec. Order No. 13279, 67 Fed. Reg. 77141 (2002)). To that end, no organization may be ''discriminated against on the basis of religion or religious belief in the administration or distribution of Federal financial assistance under social service programs.'' *Id.* ''Organizations that engage in explicitly religious activities (including activities that involve overt religious content such as worship, religious instruction, or proselytization)'' are eligible to participate in such programs, so long as they conduct such activities outside of the programs directly funded by the federal government and at a separate time and location. *Id.*

The President has assured religious organizations that they are ''eligible to compete for Federal financial assistance used to support social service programs and to participate fully in the social services programs supported with Federal financial assistance without impairing their independence, autonomy, expression outside the programs in question, or religious character.'' *See id.; see also* 42 U.S.C. 290kk–1(e) (similar statutory assurance). Religious organizations that apply for or participate in such programs may continue to carry out their mission, ''including the definition, development, practice, and expression of . . . religious beliefs,'' so long as they do not use any ''direct Federal financial assistance'' received ''to support or engage in any explicitly religious activities'' such as worship, religious instruction, or proselytization. Exec. Order No. 13559, § 1. They may also ''use their facilities to provide social services supported with Federal financial assistance, without removing or altering religious art, icons, scriptures, or other symbols from these facilities,'' and they may continue to ''retain religious terms'' in their names, select ''board members on a religious basis, and include religious references in . . . mission statements and other chartering or governing documents.'' *Id.*

With respect to government contracts in particular, Executive Order 13279, 67 Fed. Reg. 77141 (Dec. 12, 2002), confirms that the independence and autonomy promised to religious organizations include independence and autonomy in religious hiring. Specifically, it provides that the employment nondiscrimination requirements in Section 202 of Executive Order 11246, which normally apply to government contracts, do ''not apply to a Government contractor or subcontractor that is a religious corporation, association, educational institution, or society, with respect to the employment of individuals of a particular religion to perform work connected with the carrying on by such corporation, association, educational institution, or society of its activities.'' Exec. Order No. 13279, § 4, *amending* Exec. Order No. 11246, § 204(c), 30 Fed. Reg. 12319, 12935 (Sept. 24, 1965).

Because the religious hiring protection in Executive Order 13279 parallels the Section 702 exemption in Title VII, it should be interpreted to protect the decision ''to employ only persons whose beliefs and conduct are consistent with the employer's religious precepts.'' *Little,* 929 F.2d at 951. That parallel interpretation is consistent with the Supreme Court's repeated counsel that the decision to borrow statutory text in a new statute is ''strong indication that the two statutes should be interpreted pari passu.'' *Northcross* v. *Bd. of Educ. of Memphis City Sch.,* 412 U.S. 427 (1973) (per curiam); *see also Jerman* v. *Carlisle, McNellie, Rini, Kramer & Ulrich L.P.A.,* 559 U.S. 573, 590 (2010). It is also consistent with the Executive Order's own usage of discrimination on the basis of ''religion'' as something distinct and more expansive than discrimination on the basis of ''religious belief.'' *See, e.g.,* Exec. Order No. 13279, § 2(c) (''No organization should be discriminated against on the basis of religion *or* religious belief . . . '' (emphasis added)); *id.* § 2(d) (''All organizations that receive Federal financial assistance under social services programs should be prohibited from discriminating against beneficiaries or potential beneficiaries of the social services programs on the basis of religion or religious belief. Accordingly, organizations, in providing services

supported in whole or in part with Federal financial assistance, and in their outreach activities related to such services, should not be allowed to discriminate against current or prospective program beneficiaries on the basis of religion, a religious belief, a refusal to hold a religious belief, or a refusal to actively participate in a religious practice.''). Indeed, because the Executive Order uses ''on the basis of religion or religious belief'' in both the provision prohibiting discrimination against religious organizations and the provision prohibiting discrimination ''against beneficiaries or potential beneficiaries,'' a narrow interpretation of the protection for religious organizations' hiring decisions would lead to a narrow protection for beneficiaries of programs served by such organizations. *See id.* §§ 2(c), (d). It would also lead to inconsistencies in the treatment of religious hiring across government programs, as some program-specific statutes and regulations expressly confirm that ''[a] religious organization's exemption provided under section 2000e–1 of this title regarding employment practices shall not be affected by its participation, or receipt of funds from, a designated program.'' 42 U.S.C. 290kk–1(e); *see also* 6 CFR § 19.9 (same).

Even absent the Executive Order, however, RFRA would limit the extent to which the government could condition participation in a federal grant or contract program on a religious organization's effective relinquishment of its Section 702 exemption. RFRA applies to all government conduct, not just to legislation or regulation, *see* 42 U.S.C. 2000bb–1, and the Office of Legal Counsel has determined that application of a religious nondiscrimination law to the hiring decisions of a religious organization can impose a substantial burden on the exercise of religion. *Application of the Religious Freedom Restoration Act to the Award of a Grant,* 31 Op. O.L.C. at 172; *Direct Aid to Faith-Based Organizations,* 25 Op. O.L.C. at 132. Given Congress's ''recognition that religious discrimination in employment is permissible in some circumstances,'' the government will not ordinarily be able to assert a compelling interest in prohibiting that conduct as a general condition of a religious organization's receipt of any particular government grant or contract. *Application of the Religious Freedom Restoration Act to the Award of a Grant,* 31 Op. of O.L.C. at 186. The government will also bear a heavy burden to establish that requiring a particular contractor or grantee effectively to relinquish its Section 702 exemption is the least restrictive means of achieving a compelling governmental interest. *See* 42 U.S.C. 2000bb–1.

The First Amendment also ''supplies a limit on Congress' ability to place conditions on the receipt of funds.'' *Agency for Int'l Dev.* v. *All. for Open Soc'y Int'l, Inc.,* 133 S. Ct. 2321, 2328 (2013) (internal quotation marks omitted)). Although Congress may specify the activities that it wants to subsidize, it may not ''seek to leverage funding'' to regulate constitutionally protected conduct ''outside the contours of the program itself.'' *See id.* Thus, if a condition on participation in a government program—including eligibility for receipt of federally backed student loans—would interfere with a religious organization's constitutionally protected rights, *see, e.g., Hosanna-Tabor,* 565 U.S. at 188–89, that condition could raise concerns under the ''unconstitutional conditions'' doctrine, *see All. for Open Soc'y Int'l, Inc.,* 133 S. Ct. at 2328.

Finally, Congress has provided an additional statutory protection for educational institutions controlled by religious organizations who provide education programs or activities receiving federal financial assistance. Such institutions are exempt from Title IX's prohibition on sex discrimination in those programs and activities where that prohibition ''would not be consistent with the religious tenets of such organization[s].'' 20 U.S.C. 1681(a)(3). Although eligible institutions may ''claim the exemption'' in advance by ''submitting in writing to the Assistant Secretary a statement by the highest ranking official of the institution, identifying the provisions . . . [that] conflict with a specific tenet of the religious organization,'' 34 CFR § 106.12(b), they are not required to do so to have the benefit of it, *see* 20 U.S.C. 1681.

3. Government Mandates

Congress has undertaken many similar efforts to accommodate religious adherents in diverse areas of federal law. For example, it has exempted individuals who, ''by reason of religious training and belief,'' are conscientiously opposed to war from training and service in the armed forces of the United States. 50 U.S.C. 3806(j). It has exempted ''ritual slaughter and the handling or other preparation of livestock for ritual slaughter'' from federal regulations governing methods of animal slaughter. 7 U.S.C. 1906. It has exempted ''private secondary school[s] that maintain [ ] a religious objection to service in the Armed Forces'' from being required to provide military recruiters with access to student recruiting information. 20 U.S.C. 7908. It has exempted federal employees and contractors with religious objections to the death penalty from being required to ''be in attendance at or to participate in any prosecution or execution.'' 18 U.S.C. 3597(b). It has allowed individuals with religious objections to certain forms of medical treatment to opt out of such treatment. *See, e.g.,* 33 U.S.C. 907(k); 42 U.S.C. 290bb–36(f). It has created tax accommodations for members of religious faiths conscientiously opposed to acceptance of the benefits of any private or public insurance, *see, e.g.,* 26 U.S.C. 1402(g), 3127, and for members of religious orders required to take a vow of poverty, *see, e.g.,* 26 U.S.C. 3121(r).

Congress has taken special care with respect to programs touching on abortion, sterilization, and other procedures that may raise religious conscience objections. For example, it has prohibited entities receiving certain federal funds for health service programs or research activities from requiring individuals to participate in such program or activity contrary to their religious beliefs. 42 U.S.C. 300a–7(d), (e). It has prohibited discrimination against health care professionals and entities that refuse to undergo, require, or provide training in the performance of induced abortions; to provide such abortions; or to refer for such abortions, and it will deem accredited any health care professional or entity denied accreditation based on such actions. *Id.* § 238n(a), (b). It has also made clear that receipt of certain federal funds does not require an individual ''to perform or assist in the performance of any sterilization procedure or abortion if [doing so] would be contrary to his religious beliefs or moral convictions'' nor an entity to ''make its facilities available for the performance of'' those procedures if such performance ''is prohibited by the entity on the basis of religious beliefs or moral convictions,'' nor an entity to ''provide any personnel for the performance or assistance in the performance of'' such procedures if such performance or assistance ''would be contrary to the religious beliefs or moral convictions of such personnel.'' *Id.* § 300a–7(b). Finally, no ''qualified health plan[s] offered through an Exchange'' may discriminate against any health care professional or entity that refuses to ''provide, pay for, provide coverage of, or refer for abortions,'' § 18023(b)(4); *see also* Consolidated Appropriations Act, 2016, Public Law

114–113, div. H, § 507(d), 129 Stat. 2242, 2649 (Dec. 18, 2015).

Congress has also been particularly solicitous of the religious freedom of American Indians. In 1978, Congress declared it the ''policy of the United States to protect and preserve for American Indians their inherent right of freedom to believe, express, and exercise the traditional religions of the American Indian, Eskimo, Aleut, and Native Hawaiians, including but not limited to access to sites, use and possession of sacred objects, and the freedom to worship through ceremonials and traditional rites.'' 42 U.S.C. 1996. Consistent with that policy, it has passed numerous statutes to protect American Indians' right of access for religious purposes to national park lands, Scenic Area lands, and lands held in trust by the United States. *See, e.g.,* 16 U.S.C. 228i(b), 410aaa–75(a), 460uu–47, 543f, 698v–11(b)(11). It has specifically sought to preserve lands of religious significance and has required notification to American Indians of any possible harm to or destruction of such lands. *Id.* § 470cc. Finally, it has provided statutory exemptions for American Indians' use of otherwise regulated articles such as bald eagle feathers and peyote as part of traditional religious practice. *Id.* §§ 668a, 4305(d); 42 U.S.C. 1996a.

The depth and breadth of constitutional and statutory protections for religious observance and practice in America confirm the enduring importance of religious freedom to the United States. They also provide clear guidance for all those charged with enforcing federal law: The free exercise of religion is not limited to a right to hold personal religious beliefs or even to worship in a sacred place. It encompasses all aspects of religious observance and practice. To the greatest extent practicable and permitted by law, such religious observance and practice should be reasonably accommodated in all government activity, including employment, contracting, and programming. *See Zorach* v. *Clauson,* 343 U.S. 306, 314 (1952) (''[Government] follows the best of our traditions . . . [when it] respects the religious nature of our people and accommodates the public service to their spiritual needs.'').

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## DEPARTMENT OF JUSTICE

### Notice of Lodging of Proposed Consent Decree Under the Oil Pollution Act

On October 19, 2017, the Department of Justice lodged a proposed Consent Decree (''Consent Decree'') with the United States District Court for the District of Massachusetts in the lawsuit entitled *United States, et al.* v. *Bouchard Transportation Company, Inc., et al.,* Civil Action No. 1:17–cv–12046–NMG.

The proposed Consent Decree will settle claims of the United States (on behalf of the Department of Commerce/National Oceanic and Atmospheric Administration and the Department of the Interior/Fish and Wildlife Service), the Commonwealth of Massachusetts, and the State of Rhode Island for injuries to birds (other than piping plover) under the Oil Pollution Act, 33 U.S.C. 2701, *et seq.,* (''Trustees'') against Bouchard Transportation Company, Inc., and related companies (''Defendants''), caused by an oil spill from the tank barge *Bouchard No. 120* which occurred in April 2003 in Buzzards Bay. Under the proposed Consent Decree, the Defendants will pay $13,300,000 to the Trustees as damages for injuries to wildlife resources, as defined in the Consent Decree. The payment will be used to plan for and implement the restoration, rehabilitation, replacement, or acquisition of the equivalent of the damaged resources. In addition, the Defendants acknowledge payment of almost $3,500,000 to the Trustees for reimbursement of their assessment costs. The proposed Consent Decree is the second settlement between the Trustees and the Defendants for injuries to natural resources caused by the oil spill. Under the first settlement, entered by the District Court in 2011, the Defendants paid the Trustees $6,076,393 for injuries to other natural resources caused by the oil spill.

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, et al.* v. *Bouchard Transportation Company, Inc., et al.,* D.J. Ref. No. 90–5–1–1–08159/1. 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:* | *Send them to:* |
|---|---|
| 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 Web site: *https://www.justice.gov/enrd/consent-decrees.* 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 $22.75 (25 cents per page reproduction cost), payable to the United States Treasury.

**Robert E. Maher, Jr.,**

*Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.*

[FR Doc. 2017–23259 Filed 10–25–17; 8:45 am]

**BILLING CODE 4410–15–P**

## DEPARTMENT OF JUSTICE

### Office of Justice Programs

**[OMB Number 1121–0197]**

### Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension of Currently Approved Collection

**AGENCY:** Office of Justice Programs, Department of Justice.

**ACTION:** 60 day notice.

**SUMMARY:** The Department of Justice, Bureau of Justice Assistance, is 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:** The Department of Justice encourages public comment and will accept input until December 26, 2017.

**FOR FURTHER INFORMATION CONTACT:** If you have additional comments especially 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 Michelle Martin, Senior Management Analyst, Bureau of Justice Assistance,

810 Seventh Street NW., Washington, DC 20531 (phone: 202 514–9354).

**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 Bureau of Justice Assistance, 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:* Extension of currently approved collection.

2. *The Title of the Form/Collection: State Criminal Alien Assistance Program.*

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* Bureau of Justice Assistance, Office of Justice Programs, United States Department of Justice.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

*Primary:* States and local units of general government including the 50 state governments, the District of Columbia, Guam, Puerto Rico, the U.S. Virgin Islands, and the more than 3,000 counties and cities with correctional facilities.

*Other:* None.

*Abstract:* In response to the Violent Crime Control and Law Enforcement Act of 1994 Section 130002(b) as amended in 1996, BJA administers the State Criminal Alien Assistance Program (SCAAP) with the Bureau of Immigration and Customs Enforcement (ICE), and the Department of Homeland Security (DHS). SCAAP provides federal payments to States and localities that incurred correctional officer salary costs for incarcerating undocumented criminal aliens with at least one felony or two misdemeanor convictions for violations of state or local law, and who are incarcerated for at least 4 consecutive days during the designated reporting period and for the following correctional purposes:

Salaries for corrections officers

Overtime costs

Performance based bonuses

Corrections work force recruitment and retention

Construction of corrections facilities

Training/education for offenders

Training for corrections officers related to offender population management

Consultants involved with offender population

Medical and mental health services

Vehicle rental/purchase for transport of offenders

Prison Industries

Pre-release/reentry programs

Technology involving offender management/inter agency information sharing

Disaster preparedness continuity of operations for corrections facilities

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* It is estimated that no more than 800 respondents will apply. Each application takes approximately 120 minutes to complete and is submitted once per year (annually).

6. *An estimate of the total public burden (in hours) associated with the collection:* The total hour burden to complete the applications is 1,600 hours. 800 × 120 minutes = 96,000/60 minutes per hour = 1,600 burden hours

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE., 3E.405A, Washington, DC 20530.

Dated: October 23, 2017.

**Melody Braswell,**

*Department Clearance Officer for PRA, U.S. Department of Justice.*

[FR Doc. 2017–23279 Filed 10–25–17; 8:45 am]

**BILLING CODE 4410–18–P**

## DEPARTMENT OF LABOR

### Employment and Training Administration

### Notice of the Task Force on Apprenticeship Expansion Charter Establishment and Public Meeting

**AGENCY:** Employment and Training Administration (ETA), Labor.

**ACTION:** Notice.

**SUMMARY:** The Department of Labor is publishing this notice to announce the establishment of a Charter for the Task Force on Apprenticeship Expansion (hereinafter ''the Task Force'' or ''the panel''), a non-discretionary federal advisory committee authorized pursuant to section 8 of Executive Order 13801, entitled ''Expanding Apprenticeships in America'' (hereinafter ''the Executive Order''), which was issued on June 15, 2017 (82 FR 28229) and which directed the Secretary of Labor to establish and chair such a panel in the Department of Labor and to provide notice, pursuant to section 10 of the Federal Advisory Committee Act (FACA), of the initial public meeting of the Task Force to be held on November 13, 2017.

**DATES:** The initial public meeting of the Task Force will begin at approximately 3:00 p.m. Eastern Standard Time on November 13, 2017.

**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 Web site: *https://www.dol.gov/apprenticeship/task-force.htm.*

**FOR FURTHER INFORMATION CONTACT:** Mr. John V. Ladd, Administrator, Office of Apprenticeship, Employment and Training Administration, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210, Telephone: (202) 693–2796 (this is not a toll-free number).

**SUPPLEMENTARY INFORMATION:**

**I. Task Force Charter**

The Task Force has been established in accordance with the provisions of FACA, as amended, 5 U.S.C. App. 2, and its implementing regulations (41 CFR 101–6 and 102–3). Interested parties can obtain the Task Force's charter on the Task Force Web site: *https://www.dol.gov/apprenticeship/task-force.htm.* The Task Force is charged with the mission of identifying strategies and proposals to promote apprenticeships, especially in sectors where apprenticeship programs are

insufficient. Upon completion of this assignment, the Task Force shall submit to the President of the United States a final report detailing these strategies and proposals. Pursuant to the Executive Order and the charter, the report must specifically address the following four topics:

- Federal initiatives to promote apprenticeships;
- Administrative and legislative reforms that would facilitate the formation and success of apprenticeship programs;
- The most effective strategies for creating industry-recognized apprenticeships; and
- The most effective strategies for amplifying and encouraging private-sector initiatives to promote apprenticeships.

The Task Force is solely advisory in nature, and will consider testimony, reports, comments, research, evidence, and existing practices as appropriate to develop recommendations for inclusion in its final report to the President. While the Executive Order did not set forth a definite time by which the panel must complete its development of apprenticeship-related strategies and proposals and submit its final report to the President, it is important to note that the Task Force will not be continuing in nature. Additionally, given the nature and mission of the Task Force, some of the meeting proceedings could be included in a regulatory docket for an apprenticeship rulemaking, or other collection of documents made available by the agency for public viewing. Pursuant to both the Executive Order and the Charter, the Task Force shall terminate 30 days after it submits its final report to the President.

Under both the Executive Order and the Charter, the Secretary of Labor shall serve as the Chair of the Task Force. The Secretaries of Education and Commerce shall serve as Vice-Chairs of the Task Force. The Secretary of Labor has appointed the representative members of the Task Force, which consists of twenty (20) individuals who work for or represent the perspectives of trade and industry groups, companies, workforce advocacy organizations, unions, joint labor-management organizations, educational institutions, state or local governments, and such other persons as the Secretary of Labor may from time to time designate. These members include distinguished citizens from outside of the Federal Government with relevant experience concerning the development of a skilled workforce through quality apprenticeship programs. Pursuant to the Executive Order and the charter, a member of the Task Force may designate a senior member of his or her organization to attend any Task Force meeting. Members of the Task Force shall serve without compensation for their work on the Task Force, but shall be allowed travel expenses, including per diem in lieu of subsistence, to the extent permitted by law for persons serving intermittently in the Government service (5 U.S.C. 5701—5707), consistent with the availability of funds. Each member of the Task Force shall serve at the pleasure of the Secretary of Labor for a term that will cease 30 days after the delivery of the panel's final report to the President, at which time the Task Force will be disbanded officially.

## II. Initial Public Meeting of the Task Force

In order to promote openness, and increase public participation, a viewing room will be made available for members of the public to observe the meeting proceedings. Registration is required. Instructions on how to register are listed below and will be posted prominently on the Task Force Web site: *https://www.dol.gov/apprenticeship/task-force.htm.* Members of the public that will view the meeting in-person, from the viewing room, are encouraged to arrive 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, Metro rail is the easiest way to travel to the Frances Perkins Building. For individuals wishing to take metro rail, the closest metro stop to the building is Judiciary Square on the Red Line.

### *Notice of Intent To Attend the Meeting:*

All members of the public are being asked to register for the Task Force meeting by Tuesday, November 7, 2017, via the public registration Web site using the following link: *https://secure.thegateam.com/dol-aetf-reg/.* Additionally, if individuals have special needs and/or disabilities that will require special accommodations, please send an email to *Apprenticeshiptaskforce@dol.gov,* subject line ''Special Accommodations for the November 2017 Task Force Meeting'' no later than Tuesday, November 7, 2017.

The tentative agenda for this meeting includes the following:

- Strategies and proposals to promote apprenticeships
- Federal initiatives to promote apprenticeships
- Administrative and legal reforms
- Effective strategies for creating industry-recognized apprenticeships
- Effective strategies for amplifying and encouraging private-sector initiatives
- Adjourn

Any member of the public who wishes to provide a written statement should send an email to *Apprenticeshiptaskforce@dol.gov,* subject line ''Public Comment November 2017 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 updates will be posted to the Task Force Web site: *https://www.dol.gov/apprenticeship/task-force.htm.*

**Nancy M. Rooney,**

*Deputy Assistant Secretary for the Employment and Training Administration.*

[FR Doc. 2017–23305 Filed 10–25–17; 8:45 am]

**BILLING CODE 4510–FR–P**

## DEPARTMENT OF LABOR

### Occupational Safety and Health Administration

**[Docket No. OSHA–2016–0005]**

### Preparations for the 34th Session of the UN Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals (UNSCEGHS)

**AGENCY:** Occupational Safety and Health Administration, Department of Labor.

**ACTION:** Notice of public meeting.

**SUMMARY:** This notice is to advise interested persons that on Tuesday, November 14, 2017, from 1 p.m. to 4 p.m., OSHA will conduct a public meeting to discuss proposals in preparation for the 34th session of the United Nations Sub-Committee of

Experts on the Globally Harmonized System of Classification and Labelling of Chemicals (UNSCEGHS) to be held December 6 through December 8, 2017, in Geneva, Switzerland. OSHA, along with the U.S. Interagency GHS (Globally Harmonized System of Classification and Labelling of Chemicals) Coordinating Group, plans to consider the comments and information gathered at this public meeting when developing the U.S. Government positions for the UNSCEGHS meeting. OSHA also will give an update on the Regulatory Cooperation Council (RCC).

On Tuesday, November 14, 2017, from 9:00 a.m. to 12:00 p.m., the Department of Transportation (DOT), Pipeline and Hazardous Materials Safety Administration (PHMSA) will conduct a public meeting (See Docket No. PHMSA–2017–0037 Notice No. 2017–06) to discuss proposals in preparation for the 52nd session of the United Nations Sub-Committee of Experts on the Transport of Dangerous Goods (UNSCE TDG) to be held November 27 to December 6, 2017, in Geneva, Switzerland. During this meeting, PHMSA is also requesting comments relative to potential new work items that may be considered for inclusion in its international agenda. PHMSA will also provide an update on recent actions to enhance transparency and stakeholder interaction through improvements to the international standards portion of its Web site.

**DATES:** Tuesday, November 14, 2017.

**ADDRESSES:** Both meetings will be held at the DOT Headquarters Conference Center, West Building, Oklahoma City Conference Room, 1200 New Jersey Avenue SE., Washington, DC 20590.

*Times and Locations:* PHMSA public meeting: 9:00 a.m. to 12:00 p.m. EDT, Oklahoma City Conference Room, OSHA public meeting: 1:00 p.m. to 4:00 p.m. EDT, Oklahoma City Conference Room

*Advanced Meeting Registration:* The DOT requests that attendees pre-register for these meetings by completing the form at: *https://www.surveymonkey.com/r/GHSZ2Q9* . Attendees may use the same form to pre-register for both meetings. Failure to pre-register may delay your access into the DOT Headquarters building. Additionally, if you are attending in-person, arrive early to allow time for security checks necessary to access the building.

Conference call-in and ''Skype meeting'' capability will be provided for both meetings. Specific information on such access will be posted when available at: *http://www.phmsa.dot.gov/hazmat/regs/international,* under Upcoming Events. This information will also be posted on OSHA's Hazard Communication Web site on the international tab at: *https://www.osha.gov/dsg/hazcom/hazcom_international.html#meeting-notice*.

**FOR FURTHER INFORMATION CONTACT:**

*At the Department of Transportation, please contact:* Mr. Steven Webb or Mr. Aaron Wiener, Office of Hazardous Materials Safety, Department of Transportation, Washington, DC 20590, telephone: (202) 366–8553.

*At the Department of Labor, please contact:* Ms. Maureen Ruskin, OSHA Directorate of Standards and Guidance, Department of Labor, Washington, DC 20210, telephone: (202) 693–1950, email: *ruskin.maureen@dol.gov*.

**SUPPLEMENTARY INFORMATION:**

*The OSHA Meeting:* OSHA is hosting an open informal public meeting of the U.S. Interagency GHS Coordinating Group to provide interested groups and individuals with an update on GHS-related issues and an opportunity to express their views orally and in writing for consideration in developing U.S. Government positions for the upcoming UNSCEGHS meeting.

General topics on the agenda include:

- Review of Working/Informal papers
- Correspondence Group updates
- Regulatory Cooperation Council (RCC) Update

Information on the work of the UNSCEGHS, including meeting agendas, reports, and documents from previous sessions, can be found on the United Nations Economic Commission for Europe (UNECE) Transport Division Web site located at the following Web address: *http://www.unece.org/trans/danger/publi/ghs/ghs_welcome_e.html*.

The UNSCEGHS bases its decisions on Working Papers. The Working Papers for the 34th session of the UNSCEGHS are located at: *https://www.unece.org/trans/main/dgdb/dgsubc4/c42017.html*.

Informal Papers submitted to the UNSCEGHS provide information for the Sub-committee and are used either as a mechanism to provide information to the Sub-committee or as the basis for future Working Papers.

In addition to participating at the Public meeting, interested parties may submit comments on the Working and Informal Papers for the 34th session of the UNSCEGHS to the docket established for International/Globally Harmonized System (GHS) efforts at *http://www.regulations.gov,* Docket No. OSHA–2016–0005.

*The PHMSA Meeting:* The **Federal Register** notice and additional detailed information relating to PHMSA's public meeting will be available upon publication at: *http://www.regulations.gov* (Docket No. PHMSA–2017–0037, Notice No. 2017–06), and on the PHMSA Web site at: *http://www.phmsa.dot.gov/hazmat/regs/international*.

PHMSA will host the meeting to gain input from the public concerning proposals submitted to the UNSCE TDG for the 21st Revised Edition of the United Nations Recommendations on the Transport of Dangerous Goods Model Regulations, which may be implemented into relevant domestic, regional, and international regulations beginning January 1, 2021. During this meeting, PHMSA is also soliciting input relative to preparing for the 52nd session of the UNSCE TDG as well as potential new work items that may be considered for inclusion in its international agenda.

Copies of working documents, informal documents, and the meeting agenda may be obtained from the United Nations Transport Division's Web site at: *http://www.unece.org/trans/danger/danger.html*.

**Authority and Signature**

This document was prepared under the direction of Loren Sweatt, Acting Deputy Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, pursuant to sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657), and Secretary's Order 1–2012 (77 FR 3912), (Jan. 25, 2012).

Signed at Washington, DC, on October 16, 2017.

**Loren Sweatt,**

*Deputy Assistant Secretary of Labor for Occupational Safety and Health.*

[FR Doc. 2017–23261 Filed 10–25–17; 8:45 am]

**BILLING CODE 4510–26–P**

## DEPARTMENT OF LABOR

### Mine Safety and Health Administration

### Petitions for Modification of Application of Existing Mandatory Safety Standards

**AGENCY:** Mine Safety and Health Administration, Labor.

**ACTION:** Notice.

**SUMMARY:** This notice is a summary of petitions for modification submitted to the Mine Safety and Health Administration (MSHA) by the parties listed below.

**DATES:** All comments on the petitions must be received by MSHA's Office of

Standards, Regulations, and Variances on or before November 27, 2017.

**ADDRESSES:** You may submit your comments, identified by ''docket number'' on the subject line, by any of the following methods:

1. *Electronic Mail: zzMSHA-comments@dol.gov.* Include the docket number of the petition in the subject line of the message.

2. *Facsimile:* 202–693–9441.

3. *Regular Mail or Hand Delivery:* MSHA, Office of Standards, Regulations, and Variances, 201 12th Street South, Suite 4E401, Arlington, Virginia 22202–5452, Attention: Sheila McConnell, Director, Office of Standards, Regulations, and Variances. Persons delivering documents are required to check in at the receptionist's desk in Suite 4E401. Individuals may inspect copies of the petition and comments during normal business hours at the address listed above.

MSHA will consider only comments postmarked by the U.S. Postal Service or proof of delivery from another delivery service such as UPS or Federal Express on or before the deadline for comments.

**FOR FURTHER INFORMATION CONTACT:** Barbara Barron, Office of Standards, Regulations, and Variances at 202–693–9447 (Voice), *barron.barbara@dol.gov* (Email), or 202–693–9441 (Facsimile). [These are not toll-free numbers.]

**SUPPLEMENTARY INFORMATION:** Section 101(c) of the Federal Mine Safety and Health Act of 1977 and Title 30 of the Code of Federal Regulations Part 44 govern the application, processing, and disposition of petitions for modification.

## I. Background

Section 101(c) of the Federal Mine Safety and Health Act of 1977 (Mine Act) allows the mine operator or representative of miners to file a petition to modify the application of any mandatory safety standard to a coal or other mine if the Secretary of Labor determines that:

1. An alternative method of achieving the result of such standard exists which will at all times guarantee no less than the same measure of protection afforded the miners of such mine by such standard; or

2. That the application of such standard to such mine will result in a diminution of safety to the miners in such mine.

In addition, the regulations at 30 CFR 44.10 and 44.11 establish the requirements and procedures for filing petitions for modification.

## II. Petitions for Modification

*Docket Number:* M–2017–018–C.

*Petitioner:* Revelation Energy, LLC, P.O. Box 249, Stanville, Kentucky 41659.

*Mine:* D–1A Garmeada Mine, MSHA I.D. No. 15–19791, located in Bell County, Kentucky.

*Regulation Affected:* 30 CFR 75.364(b)(2) (Weekly examination).

*Modification Request:* The petitioner requests a modification of the existing standard in reference to weekly examinations in its entirety for the hazardous condition of return air course. The petitioner states that:

(1) As a result of a dip with a steep incline on the end, a large pool of water has developed at the outby end of the Northwest Mains and extending inby approximately 1200 feet in the right-side return, in the No. 5 entry. This mine utilizes split air and there are two returns. There is a return entry in the No. 1 entry also. Currently, a 10-horse-power pump with a 2-inch discharge line is installed in the pool of water. This is a low spot in the mine with elevations rising going in each direction. The mine height in this area is approximately 12 feet. The water level is currently 4½ feet deep. The water has been pumped down to current levels, reducing the affected area to approximately 70 feet in length. It is proposed to utilize a metal catwalk bridge, with handrails to provide safe travel through this area for the weekly examinations. The bridge would provide safer travel through the area, as the bridge is level. If the water is completely pumped out, it would result in a steep, slippery slope that would be treacherous to travel and could contribute to slip, trip, and fall hazards. It would be difficult to establish and maintain safe travel in this portion of the right return, No. 5 entry.

(2) The remaining life of the reserve is approximately 10 years. Access to this reserve is only possible through the existing mine drifts, as all other approaches are blocked by abandoned mines. The procedures listed in this petition will provide a level of safety no less than equivalent to that afforded by 30 CFR 75.364(b)(2) for the remaining life of the mine.

(3) Therefore, the petitioner proposes an alternate plan to provide safe access over pooled water in the right return, No. 5 entry for approximately 70 feet at the outby end of the Northwest Mains. The petitioner states that use of the bridge as described below will keep employees from being exposed to hazardous travel in order to meet the requirements of the applicable standard:

(a) A metal catwalk bridge approximately 75 feet long with handrails will be utilized to provide safe access for travel across a pool of water.

(b) Each end of the bridge across the entry will be blocked with danger signs, flagging, and/or fencing to warn miners of the potential hazard and that travel through this area is only permitted across the bridge.

(c) A pump will be maintained in the pool to maintain the water level.

(d) Life vests will be provided and worn while traveling across the bridge.

(e) All miners at the D–1A Garmeada mine will be given notice of this request for modification during safety meetings.

Within 60 days after approval of this petition and the order becoming final, the petitioner will submit proposed revisions to the Part 48 training plan to the District Manager. These revisions will apply to initial and refresher training.

The petitioner asserts that the proposed alternative method will at all times guarantee no less than the same measure of protection afforded by the existing standard.

*Docket Number:* M–2017–019–C.

*Petitioner:* Marfork Coal Company, Inc., 500 Lee Street, East, Suite 701 (25301), Post Office Box 2548, Charleston, WV 25329.

*Mine:* Slip Ridge Cedar Grove Mine, MSHA I.D. No. 46–09048, located in Raleigh County, West Virginia.

*Regulation Affected:* 30 CFR 75.360 (Preshift examination at fixed intervals).

*Modification Request:* The petitioner requests a modification of the existing standard as it pertains to preshift examinations that are only required on a side of the mine that is active (*i.e.* both sides of the mine only have to be fully examined when both sides are active). The petitioner states that:

(1) The Slip Ridge mine is a large underground coal mine that has been permanently divided into three separate areas via the installation of MSHA-approved 120 PSI mine seals.

(2) On the East end of the mine is the Ellis Creek Side and this is the active mining side with two continuous miner sections producing 5 to 6 days a week.

(3) The West end of the mine is called the Slip Ridge Transfer and this end of the mine serves only as a belt through (*i.e.* transfer) for coal from two other Marfork mines (Horse Creek and Allen Powellton) on its way to the Marfork Plant.

(4) The East and West ends of the mine are separated by approximately 3.66 miles of old mine works that were sealed on each end with MSHA-approved 120 PSI seals.

(5) The East and West ends of the mine are ventilated by separate mine fans.

(6) The East and West ends of the mine are monitored by separate CO systems.

(7) The East and West ends of the mine have their own dispatcher.

(8) Other than being on the opposite ends of a common sealed area, the East and West ends of the mine are effectively separate and independent underground coal mines.

(9) Currently, if the East side of the mine is scheduled to produce coal, the regulations require preshift examinations in accordance with 30 CFR 75.360 be completed on both sides of the mine, regardless of their autonomy.

(10) Application of the existing standard may result in a diminution of safety to the miners as it currently requires that preshift examination on both the East and West ends of the mine be performed on any day that either end of the mine will be active (*i.e.* the West end has to be fully examined preshift every day that the East end wants to produce coal even if the West end is idle). Preshift examination of the idle side of the Slip Ridge Mine does not advance safety for the miners working on the active side of the mine and can expose examiners on the idle side to additional time and hazards underground.

The petitioner proposes the following alternative method of compliance to the existing standard:

(a) Since the East and West side are separated by two sets of 120 PSI seals, ventilated with their own mine fans and monitored by independent CO systems, each end of the mine should be treated separately for purposes of 30 CFR 75.360.

(b) On any active side of the Slip Ridge Mine, a preshift examination as set forth in 30 CFR 75.360 will be performed.

(b) No preshift examination under 30 CFR 75.360 will be required on an idle side of the mine.

(c) Preshift examinations of the idle side of the mine will be performed prior to work being performed underground on the previously idle side of the mine.

(d) Marfork will update the CO monitoring systems to allow either side of the dispatcher to monitor the CO systems for both sides of the mine. This dual monitoring will allow the atmospheric conditions in the idle side of the mine to be monitored by the dispatcher on the active side of the mine.

(e) If a CO event occurs that would otherwise require evacuation, both sides will withdraw personnel.

(f) Marfork will set up dual monitoring of both mine fans so that the status of each fan can be monitored from both sides of the mine.

(g) In the event of a fan stoppage on one side of the mine, both sides will withdraw personnel.

(h) In the event of a fan stoppage on an idle side of the mine, the active side would be alerted via an alarm and personnel will be withdrawn from the active side.

The petitioner asserts that the proposed alternative method will at all times guarantee no less than the same measure of protection afforded by the existing standard by ensuring that the examinations are performed on the active side of the mine while continually monitoring the fan and CO systems on the idle side of the mine.

*Docket Number:* M–2017–020–C.

*Petitioner:* Spartan Mining Company, 500 Lee Street, East, Suite 701 (25301), Post Office Box 2548, Charleston, WV 25329.

*Mine:* Road Fork #52 Mine, MSHA I.D. No. 46–09522, located in Wyoming County, West Virginia.

*Regulation Affected:* 30 CFR 75.1700 (Oil and gas wells).

*Modification Request:* The petitioner requests a modification of the existing standard in the following three situations: (1) When mining within 50 feet (+1-degree accuracy factor) of a horizontal wellbore; (2) when initially mining through a horizontal wellbore; and (3) when subsequently mining through horizontal wellbores as addressed in this petition. The petitioner states that:

(1) Potential in-seam methane in the majority of the Road Fork #52 Mine reserve area has been reduced and/or extracted by the drilling operation of horizontal coalbed methane wells by CDX Gas, LLC (''CDX''). The first well in the area was put into production in January 2006 and the last in October 2006. The location of these wells in relation to the future mining for the Road Fork #52 Mine is shown on the map attached to this petition as Exhibit A. (Road Fork #52 Mine will mine coal to the left of the mining shown on the map).

(2) CDX will use the following methodology to drill these wells:

(a) A vertical wellbore (access hole) is drilled and cased to a point 150 feet or more above the coal seal;

(b) From the bottom of the casing in the access hole, a curved hole is drilled to intersect the coal seal at a tangent point;

(c) From the tangent point, a short common horizontal bore is drilled horizontally through the coal seam for a distance up to 500 feet;

(d) From the end of the common horizontal bore, several interconnected horizontal bores, ranging from 5 to 6.5 inches in diameter are drilled horizontally through the coalbed for distances up to 3500 feet;

(e) A second vertical wellbore (production hole) is drilled to intersect the common horizontal bore. The production hole is commonly cased with 7-inch O.D. casing to a point 100 feet more or less above the coal seam. The production hole is drilled 50 to 100 feet below the coal seam to provide a ''rat-hole'' for pumping liquid from the well; and

(f) Coal bed methane gas entering the horizontal wellbores travels through the common horizontal bore to the production hole and then to the surface.

(3) The Road Fork #52 Mine will employ the continuous mining room and pillar method of mining. It is anticipated that each lateral wellbore will be mined through at least once.

(4) Prior to mining within 50 feet (+1-degree accuracy factor) of a horizontal wellbore, the petitioner proposes to verify that the following procedures have been performed on the well:

(a) The well will be vented to outside atmosphere pressure for at least 8 hours;

(b) A volume of fresh water sufficient to fill the horizontal (lateral) wellbores will be injected into the well with sufficient pressure to attain a bottomhole pressure of approximately 500 pounds per square inch (PSI);

(c) The liquid will be bailed from the production hole, using normal bailing equipment, to a point just above the level of the coal seam;

(d) A volume of gel, made up of 2 to 4 percent bentonite and fresh water, sufficient to fill the horizontal wellbores plus 25 percent excess, will be injected into the well with sufficient pressure to attain a bottomhole pressure of approximately 500 PSI; and

(e) The wellbore will be filled to the surface with fresh water and allowed to stand for at least 72 hours, with the water level being supplemented as required. In the alternative, water will be injected into the wellbore for 72 hours at an average rate of 2 gallons per minute or more.

(5) Prior to mining through the first lateral wellbore of a horizontal coalbed methane well, the petitioner proposes to verify that the following procedures have been performed on the well:

(a) The water will be bailed from the vertical section of the wellbore, as close to the coal seam elevation as practical using normal bailing equipment;

(b) The surface wellhead will be maintained open to bring the vertical

section of the wellbore to outside atmospheric pressure;

(c) The petitioner further states that the MSHA District Manager and the appropriate West Virginia Office of Miners' Health Safety and Training representative will be notified at least 48 hours prior to the anticipated mine-through time;

(d) Drivage sights will be installed within 80 feet of the mine-through point;

(e) Firefighting equipment will be provided near the working face, including two 10-pound fire extinguishers, 240 pounds of rock dust, and fire hose of sufficient length to reach the working face and capable of delivering at least 50 gallons per minute of water at minimum pressure of 50 PSI;

(f) At least 9,000 CFM of intake air at the face will be supplied, but no less than the amount in the approved ventilation plan;

(g) The continuous miner methane monitor will be calibrated prior to use when the mine-through is anticipated or is occurring;

(h) A test for methane will be conducted with a hand-held methane detector at least every 10 minutes during the time mining commences at the minimum barrier distance line or within 30 feet of the wellbore, whichever is greater;

(i) All equipment will be deenergized and the area thoroughly examined when the wellbore is intersected;

(j) Once the area has been determined to be safe and mining has resumed, hand-held methane detector tests will continue at least every 10 minutes during production shifts, until mining has progressed 20 feet past the initial mine-through point;

(k) No persons will be permitted in the area of the mine-through operation except those persons actually engaged in the operation, including mine management, personnel from MSHA, and personnel from the appropriate State agency; and

(l) A certified official will directly supervise the mine-through operation and only the certified official in charge will issue instructions concerning the mine-through operation.

(6) Prior to mining through a lateral wellbore of a coalbed methane well which has already at least one lateral wellbore mined through, the petitioner proposes to verify the following procedures have been performed on the well:

(a) The water will be bailed from the vertical section of the wellbore, as close to the coal seam elevation as practical using normal bailing equipment;

(b) The surface well head will be maintained open to bring the vertical section of the wellbore to outside atmospheric pressure;

(c) Drivage sights will be installed within 80 feet of the mine-through point;

(d) Firefighting equipment will be provided near the working face, including two 10-pound fire extinguishers, 240 pounds of rock dust, and fire hose of sufficient length to reach the working face and capable of delivering at least 50 gallons per minute of water at minimum pressure of 50 PSI;

(e) At least 9,000 CFM of intake air at the face will be supplied, but no less than the amount in the approved ventilation plan;

(f) The continuous miner methane monitor will be calibrated on one of the five production shifts prior to the shift during which the mine-through is anticipated;

(g) A test for methane will be provided with a hand-held methane detector at least every 10 minutes during the time mining is conducted within 30 feet of the wellbore;

(h) All equipment will be deenergized and the area thoroughly examined when the wellbore is intersected;

(i) Once the area has been determined to be safe and mining has resumed, hand-held methane detector tests will continue at lease every 10 minutes during production shifts, until mining has progressed 20 feet past the initial mine-through point;

(j) No persons will be permitted in the area of the mine-through operation except those persons actually engaged in the operation, including mine management, personnel from MSHA, and personnel from the appropriate State agency;

(k) A certified official will directly supervise the mine-through operation and only the certified official in charge will issue instructions concerning the mine-through operation; and

(l) The production hole will remain open and accessible until all mining susceptible of intersecting horizontal wellbores has been completed.

The petitioner asserts that the proposed alternative method will at all times guarantee no less than the same measure of protection afforded by the existing standard.

**Sheila McConnell,**

*Director, Office of Standards, Regulations, and Variances.*

[FR Doc. 2017–23263 Filed 10–25–17; 8:45 am]

**BILLING CODE 4520–43–P**

## LEGAL SERVICES CORPORATION

### Notice of Intent To Award—Grant Awards for the Provision of Civil Legal Services to Eligible Low-Income Clients Beginning January 1, 2018

**AGENCY:** Legal Services Corporation.

**ACTION:** Announcement of intention to make FY 2018 Grant Awards.

**SUMMARY:** The Legal Services Corporation (LSC) hereby announces its intention to award grants to provide economical and effective delivery of high quality civil legal services to eligible low-income clients, beginning January 1, 2018.

**DATES:** All comments and recommendations must be received on or before the close of business on November 27, 2017.

**ADDRESSES:** Legal Services Corporation—Grant Awards, Legal Services Corporation; 3333 K Street NW., Third Floor, Washington, DC 20007.

**FOR FURTHER INFORMATION CONTACT:** Reginald Haley, Office of Program Performance, at (202) 295–1545, or *haleyr@lsc.gov.*

**SUPPLEMENTARY INFORMATION:** Pursuant to LSC's announcement of funding availability on March 22, 2017, 82 FR 14753, and Grant Renewal applications due beginning June 5, 2017, LSC intends to award funds to provide civil legal services in the indicated service areas. Applicants for each service area are listed below. The amounts below are estimates based on the 2017 grant awards to each service area. The estimates incorporate the adjustments for the agricultural worker population as described at *http://www.lsc.gov/ag-worker-data.* The funding estimates may change based on the final FY 2018 appropriation.

LSC will post all updates and/or changes to this notice at *http://www.grants.lsc.gov/grants-grantee-resources.* Interested parties are asked to visit *http://www.grants.lsc.gov/grants-grantee-resources* regularly for updates on the LSC grants process.

| Name of applicant organization | State | Service area | Estimated annualized 2018 funding |
|---|---|---|---|
| Alaska Legal Services Corporation | AK | AK–1 | $741,073 |
| Alaska Legal Services Corporation | AK | NAK–1 | 556,121 |
| Legal Services Alabama | AL | AL–4 | 6,072,761 |
| Legal Aid of Arkansas | AR | AR–6 | 1,458,221 |
| Center for Arkansas Legal Services | AR | AR–7 | 2,121,222 |
| American Samoa Legal Aid | AS | AS–1 | 216,951 |
| DNA-Peoples Legal Services | AZ | AZ–2 | 423,371 |
| Community Legal Services | AZ | AZ–3 | 5,403,988 |
| Southern Arizona Legal Aid | AZ | AZ–5 | 2,145,113 |
| Community Legal Services | AZ | MAZ | 205,629 |
| DNA-Peoples Legal Services | AZ | NAZ–5 | 2,683,310 |
| Southern Arizona Legal Aid | AZ | NAZ–6 | 655,456 |
| California Indian Legal Services | CA | CA–1 | 20,695 |
| Inland Counties Legal Services | CA | CA–12 | 5,227,831 |
| Legal Aid Society of San Diego | CA | CA–14 | 2,997,072 |
| Legal Aid Society of Orange County | CA | CA–19 | 3,861,757 |
| Greater Bakersfield Legal Assistance | CA | CA–2 | 1,135,641 |
| Central California Legal Services | CA | CA–26 | 3,226,959 |
| Legal Services of Northern California | CA | CA–27 | 3,878,184 |
| Bay Area Legal Aid | CA | CA–28 | 4,156,552 |
| Legal Aid Foundation of Los Angeles | CA | CA–29 | 6,247,806 |
| Neighborhood Legal Services of Los Angeles County | CA | CA–30 | 4,391,958 |
| California Rural Legal Assistance | CA | CA–31 | 5,019,889 |
| California Rural Legal Assistance | CA | MCA | 2,525,354 |
| California Indian Legal Services | CA | NCA–1 | 908,493 |
| Colorado Legal Services | CO | CO–6 | 4,093,066 |
| Colorado Legal Services | CO | MCO | 209,157 |
| Colorado Legal Services | CO | NCO–1 | 98,754 |
| Statewide Legal Services of Connecticut | CT | CT–1 | 2,499,625 |
| Pine Tree Legal Assistance | CT | NCT–1 | 16,099 |
| Neighborhood Legal Services Program of DC | DC | DC–1 | 754,782 |
| Legal Services Corporation of Delaware | DE | DE–1 | 761,226 |
| Legal Aid Bureau | DE | MDE | 12,961 |
| Legal Services of North Florida | FL | FL–13 | 1,463,367 |
| Three Rivers Legal Services | FL | FL–14 | 2,163,335 |
| Community Legal Services of Mid-Florida | FL | FL–15 | 4,660,189 |
| Bay Area Legal Services | FL | FL–16 | 3,430,322 |
| Florida Rural Legal Services | FL | FL–17 | 3,918,976 |
| Coast to Coast Legal Aid of South Florida | FL | FL–18 | 2,104,893 |
| Legal Services of Greater Miami | FL | FL–5 | 3,623,941 |
| Florida Rural Legal Services | FL | MFL | 539,561 |
| Atlanta Legal Aid Society | GA | GA–1 | 3,802,513 |
| Georgia Legal Services Program | GA | GA–2 | 8,192,300 |
| Georgia Legal Services Program | GA | MGA | 268,109 |
| Guam Legal Services Corporation | GU | GU–1 | 244,499 |
| Legal Aid Society of Hawaii | HI | HI–1 | 1,284,668 |
| Legal Aid Society of Hawaii | HI | NHI–1 | 235,552 |
| Iowa Legal Aid | IA | IA–3 | 2,184,470 |
| Iowa Legal Aid | IA | MIA | 324,185 |
| Idaho Legal Aid Services | ID | ID–1 | 1,374,816 |
| Idaho Legal Aid Services | ID | MID | 248,309 |
| Idaho Legal Aid Services | ID | NID–1 | 66,807 |
| Land of Lincoln Legal Assistance Foundation | IL | IL–3 | 2,551,787 |
| Legal Assistance Foundation | IL | IL–6 | 5,874,008 |
| Prairie State Legal Services | IL | IL–7 | 3,632,099 |
| Legal Assistance Foundation | IL | MIL | 249,804 |
| Indiana Legal Services | IN | IN–5 | 6,461,021 |
| Indiana Legal Services | IN | MIN | 183,575 |
| Kansas Legal Services | KS | KS–1 | 2,610,245 |
| Legal Aid of the Bluegrass | KY | KY–10 | 1,439,798 |
| Legal Aid Society | KY | KY–2 | 1,254,797 |
| Appalachian Research and Defense Fund of Kentucky | KY | KY–5 | 1,593,861 |
| Kentucky Legal Aid | KY | KY–9 | 1,104,495 |
| Acadiana Legal Service Corporation | LA | LA–10 | 1,459,894 |
| Acadiana Legal Service Corporation | LA | LA–11 | 1,535,486 |
| Southeast Louisiana Legal Services Corporation | LA | LA–13 | 2,970,261 |
| Community Legal Aid | MA | MA–10 | 1,463,593 |
| Volunteer Lawyers Project of the Boston Bar Assoc. | MA | MA–11 | 2,005,092 |
| South Coastal Counties Legal Services | MA | MA–12 | 838,353 |
| Northeast Legal Aid | MA | MA–4 | 800,614 |
| Legal Aid Bureau | MD | MD–1 | 3,973,616 |
| Legal Aid Bureau | MD | MMD | 49,208 |

| Name of applicant organization | State | Service area | Estimated annualized 2018 funding |
|---|---|---|---|
| Pine Tree Legal Assistance | ME | ME–1 | 1,168,230 |
| Pine Tree Legal Assistance | ME | MMX–1 | 253,514 |
| Pine Tree Legal Assistance | ME | NME–1 | 66,279 |
| Michigan Advocacy Program | MI | MI–12 | 1,532,726 |
| Lakeshore Legal Aid | MI | MI–13 | 4,265,840 |
| Legal Services of Eastern Michigan | MI | MI–14 | 1,579,715 |
| Legal Aid of Western Michigan | MI | MI–15 | 2,205,241 |
| Legal Services of Northern Michigan | MI | MI–9 | 799,487 |
| Michigan Advocacy Program | MI | MMI | 317,148 |
| Michigan Indian Legal Services | MI | NMI–1 | 169,276 |
| Southern Minnesota Regional Legal Services | MN | MMN | 280,032 |
| Legal Aid Service of Northeastern Minnesota | MN | MN–1 | 439,608 |
| Legal Services of Northwest Minnesota Corporation | MN | MN–4 | 319,678 |
| Southern Minnesota Regional Legal Services | MN | MN–5 | 1,525,475 |
| Central Minnesota Legal Services | MN | MN–6 | 1,604,909 |
| Anishinabe Legal Services | MN | NMN–1 | 245,745 |
| Legal Aid of Western Missouri | MO | MMO | 193,905 |
| Legal Aid of Western Missouri | MO | MO–3 | 1,913,195 |
| Legal Services of Eastern Missouri | MO | MO–4 | 1,894,630 |
| Mid-Missouri Legal Services Corporation | MO | MO–5 | 443,463 |
| Legal Services of Southern Missouri | MO | MO–7 | 1,752,017 |
| Micronesian Legal Services | MP | MP–1 | 1,226,169 |
| Mississippi Center for Legal Services | MS | MS–10 | 2,525,075 |
| North Mississippi Rural Legal Services | MS | MS–9 | 1,591,595 |
| Mississippi Center for Legal Services | MS | NMS–1 | 85,478 |
| Montana Legal Services Association | MT | MMT | 105,592 |
| Montana Legal Services Association | MT | MT–1 | 944,446 |
| Montana Legal Services Association | MT | NMT–1 | 163,734 |
| Legal Aid of North Carolina | NC | MNC | 377,999 |
| Legal Aid of North Carolina | NC | NC–5 | 11,003,144 |
| Legal Aid of North Carolina | NC | NNC–1 | 224,422 |
| Southern Minnesota Regional Legal Services | ND | MND | 118,792 |
| Legal Services of North Dakota | ND | ND–3 | 442,291 |
| Legal Services of North Dakota | ND | NND–3 | 276,997 |
| Legal Aid of Nebraska | NE | MNE | 222,006 |
| Legal Aid of Nebraska | NE | NE–4 | 1,328,345 |
| Legal Aid of Nebraska | NE | NNE–1 | 33,990 |
| Legal Advice & Referral Center | NH | NH–1 | 780,387 |
| South Jersey Legal Services | NJ | MNJ | 69,612 |
| Legal Services of Northwest Jersey | NJ | NJ–15 | 404,393 |
| Central Jersey Legal Services | NJ | NJ–17 | 1,140,290 |
| Northeast New Jersey Legal Services Corporation | NJ | NJ–18 | 1,896,940 |
| South Jersey Legal Services | NJ | NJ–20 | 2,241,706 |
| Essex-Newark Legal Services Project | NJ | NJ–8 | 882,685 |
| New Mexico Legal Aid | NM | MNM | 95,692 |
| DNA-Peoples Legal Services | NM | NM–1 | 177,469 |
| New Mexico Legal Aid | NM | NM–5 | 2,701,602 |
| DNA-Peoples Legal Services | NM | NNM–2 | 23,363 |
| New Mexico Legal Aid | NM | NNM–4 | 477,790 |
| Nevada Legal Services | NV | NNV–1 | 136,737 |
| Nevada Legal Services | NV | NV–1 | 2,910,481 |
| Legal Aid Society of Mid-New York | NY | MNY | 243,284 |
| Legal Services of the Hudson Valley | NY | NY–20 | 1,749,323 |
| Legal Aid Society of Northeastern New York | NY | NY–21 | 1,274,588 |
| Legal Aid Society of Mid-New York | NY | NY–22 | 1,641,366 |
| Legal Assistance of Western New York | NY | NY–23 | 1,666,745 |
| Neighborhood Legal Services | NY | NY–24 | 1,223,693 |
| Nassau/Suffolk Law Services Committee | NY | NY–7 | 1,319,382 |
| Legal Services NYC | NY | NY–9 | 11,772,176 |
| Legal Aid of Western Ohio | OH | MOH | 224,663 |
| Legal Aid Society of Greater Cincinnati | OH | OH–18 | 1,620,098 |
| Community Legal Aid Services | OH | OH–20 | 1,780,903 |
| The Legal Aid Society of Cleveland | OH | OH–21 | 2,216,388 |
| Legal Aid of Western Ohio | OH | OH–23 | 2,978,972 |
| Ohio State Legal Services | OH | OH–24 | 3,358,791 |
| Legal Aid Services of Oklahoma | OK | MOK | 138,399 |
| Oklahoma Indian Legal Services | OK | NOK–1 | 841,963 |
| Legal Aid Services of Oklahoma | OK | OK–3 | 4,116,455 |
| Legal Aid Services of Oregon | OR | MOR | 443,163 |
| Legal Aid Services of Oregon | OR | NOR–1 | 189,825 |
| Legal Aid Services of Oregon | OR | OR–6 | 3,952,261 |
| Philadelphia Legal Assistance Center | PA | MPA | 177,851 |

| Name of applicant organization | State | Service area | Estimated annualized 2018 funding |
|---|---|---|---|
| Philadelphia Legal Assistance Center | PA | PA–1 | 2,650,729 |
| Southwestern Pennsylvania Legal Services | PA | PA–11 | 416,614 |
| Legal Aid of Southeastern Pennsylvania | PA | PA–23 | 1,302,652 |
| North Penn Legal Services | PA | PA–24 | 1,877,867 |
| MidPenn Legal Services | PA | PA–25 | 2,429,480 |
| Northwestern Legal Services | PA | PA–26 | 652,434 |
| Laurel Legal Services | PA | PA–5 | 593,479 |
| Neighborhood Legal Services Association | PA | PA–8 | 1,372,284 |
| Puerto Rico Legal Services | PR | MPR | 53,561 |
| Puerto Rico Legal Services | PR | PR–1 | 10,783,976 |
| Community Law Office | PR | PR–2 | 241,905 |
| Rhode Island Legal Services | RI | RI–1 | 986,794 |
| South Carolina Legal Services | SC | MSC | 128,776 |
| South Carolina Legal Services | SC | SC–8 | 5,626,709 |
| Dakota Plains Legal Services | SD | NSD–1 | 960,128 |
| East River Legal Services | SD | SD–2 | 396,301 |
| Dakota Plains Legal Services | SD | SD–4 | 400,598 |
| Legal Aid Society of Middle TN and the Cumberlands | TN | TN–10 | 3,107,225 |
| Memphis Area Legal Services | TN | TN–4 | 1,553,797 |
| West Tennessee Legal Services | TN | TN–7 | 698,100 |
| Legal Aid of East Tennessee | TN | TN–9 | 2,497,599 |
| Texas RioGrande Legal Aid | TX | MSX–2 | 1,608,920 |
| Texas RioGrande Legal Aid | TX | NTX–1 | 32,183 |
| Lone Star Legal Aid | TX | TX–13 | 10,395,557 |
| Legal Aid of NorthWest Texas | TX | TX–14 | 9,004,475 |
| Texas RioGrande Legal Aid | TX | TX–15 | 10,707,097 |
| Utah Legal Services | UT | MUT | 76,980 |
| Utah Legal Services | UT | NUT–1 | 84,598 |
| Utah Legal Services | UT | UT–1 | 2,241,282 |
| Central Virginia Legal Aid Society | VA | MVA | 155,344 |
| Southwest Virginia Legal Aid Society | VA | VA–15 | 716,279 |
| Legal Aid Society of Eastern Virginia | VA | VA–16 | 1,296,346 |
| Virginia Legal Aid Society | VA | VA–17 | 897,396 |
| Central Virginia Legal Aid Society | VA | VA–18 | 1,185,499 |
| Blue Ridge Legal Services | VA | VA–19 | 790,876 |
| Legal Services of Northern Virginia | VA | VA–20 | 1,460,820 |
| Legal Services of the Virgin Islands | VI | VI–1 | 161,119 |
| Legal Services Law Line of Vermont | VT | VT–1 | 467,902 |
| Northwest Justice Project | WA | MWA | 585,992 |
| Northwest Justice Project | WA | NWA–1 | 292,929 |
| Northwest Justice Project | WA | WA–1 | 5,645,286 |
| Legal Action of Wisconsin | WI | MWI | 331,424 |
| Wisconsin Judicare | WI | NWI–1 | 159,512 |
| Wisconsin Judicare | WI | WI–2 | 897,777 |
| Legal Action of Wisconsin | WI | WI–5 | 3,806,115 |
| Legal Aid of West Virginia | WV | WV–5 | 2,235,497 |
| Legal Aid of Wyoming | WY | NWY–1 | 177,694 |
| Legal Aid of Wyoming | WY | WY–4 | 434,973 |

These grants will be awarded under the authority conferred on LSC by section 1006(a)(1) of the Legal Services Corporation Act, 42 U.S.C. 2996e(a)(l). Awards will be made so that each service area is served, although no listed organization is guaranteed an award. Grants will become effective and grant funds will be distributed on or about January 1, 2018.

This notice is issued pursuant to 42 U.S.C. 2996f(f). Comments and recommendations concerning potential grantees are invited, and should be delivered to LSC within 30 days from the date of publication of this notice.

Dated: October 23, 2017.

**Stefanie K. Davis,**

*Assistant General Counsel.*

[FR Doc. 2017–23299 Filed 10–25–17; 8:45 am]

**BILLING CODE 7050–01–P**

## NATIONAL SCIENCE FOUNDATION

### Notice of Permit Applications Received Under the Antarctic Conservation Act of 1978

**AGENCY:** National Science Foundation.

**ACTION:** Notice of Permit Applications Received.

**SUMMARY:** The National Science Foundation (NSF) is required to publish a notice of permit applications received to conduct activities regulated under the Antarctic Conservation Act of 1978. NSF has published regulations under the Antarctic Conservation Act in the Code of Federal Regulations. This is the required notice of permit applications received.

**DATES:** Interested parties are invited to submit written data, comments, or views with respect to this permit application by November 27, 2017. This application may be inspected by interested parties at the Permit Office, address below.

**ADDRESSES:** Comments should be addressed to Permit Office, Office of Polar Programs, National Science

Foundation, 2415 Eisenhower Avenue, Alexandria, Virginia 22314.

**FOR FURTHER INFORMATION CONTACT:** Nature McGinn, ACA Permit Officer, at the above address, 703–292–8030, or *ACApermits@nsf.gov.*

**SUPPLEMENTARY INFORMATION:** The National Science Foundation, as directed by the Antarctic Conservation Act of 1978 (Pub. L. 95–541, 45 CFR 670), as amended by the Antarctic Science, Tourism and Conservation Act of 1996, has developed regulations for the establishment of a permit system for various activities in Antarctica and designation of certain animals and certain geographic areas a requiring special protection. The regulations establish such a permit system to designate Antarctic Specially Protected Areas.

**Application Details**

*Applicant*

Permit Application: 2018–022 Jennifer Burns, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, Virginia 22314.

*Activity for Which Permit is Requested*

Harmful Interference. The applicant will be conducting programmatic oversight activities that may involve approaching seabird colonies near Palmer Station in the Antarctic Peninsula. The applicant is seeking a permit for harmful interference for incidental disturbance of penguins or petrels during the conduct of the oversight activities.

*Location*

Torgersen Island; Humble Island; Palmer Basin (ASMA 7).

*Dates*

December 12–20, 2017.

**Nadene G. Kennedy,**

*Polar Coordination Specialist, Office of Polar Programs.*

[FR Doc. 2017–23272 Filed 10–25–17; 8:45 am]

**BILLING CODE 7555–01–P**

## NATIONAL SCIENCE FOUNDATION

### Notice of Permit Modification Received Under the Antarctic Conservation Act of 1978

**AGENCY:** National Science Foundation.

**ACTION:** Notice of permit modification request.

**SUMMARY:** The National Science Foundation (NSF) is required to publish a notice of requests to modify permits issued to conduct activities regulated under the Antarctic Conservation Act of 1978. This is the required notice of a requested permit modification.

**DATES:** Interested parties are invited to submit written data, comments, or views with respect to this permit application by November 27, 2017. Permit applications may be inspected by interested parties at the Permit Office, address below.

**ADDRESSES:** Comments should be addressed to Permit Office, Office of Polar Programs, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, Virginia 22314.

**FOR FURTHER INFORMATION CONTACT:** Nature McGinn, ACA Permit Officer, at the above address, 703–292–8030, or *ACApermits@nsf.gov.*

**SUPPLEMENTARY INFORMATION:** The National Science Foundation, as directed by the Antarctic Conservation Act of 1978 (Pub. L. 95–541), as amended by the Antarctic Science, Tourism and Conservation Act of 1996, has developed regulations for the establishment of a permit system for various activities in Antarctica and designation of certain animals and certain geographic areas a requiring special protection. The regulations establish such a permit system to designate Antarctic Specially Protected Areas.

*Description of Permit Modification Requested:* The Foundation issued a permit (ACA 2017–034) to David W. Johnston on January 6, 2017. The issued permit allows the permit holder and his agents to use unmanned aircraft systems (UAS) for photogrammetry and capture of behavior by video of whales and seabirds, including penguins. The UAS is also used to conduct transect-type surveys of penguin and other seabird colonies, including colonies at Avian Island, ASPA no. 117.

Now the applicant proposes a modification to his permit to use unmanned aircraft systems (UAS) for photogrammetry and population assessments by video of Antarctic seals. The permit holder plans overflights that may result in the disturbance of Antarctic fur seals (n=6000/year), crabeater seals (n=6000/year), leopard seals (n=2000/year), southern elephant seals (n=2000/year), and Weddell seals (n=2000/year). Authorization for the overflight of seals by UAS from the National Marine Fisheries Service under the authority of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*) is pending.

*Location:* Antarctic Peninsula region; Torgersen Island; ASPA No. 117, Avian Island, Marguerite Bay.

*Dates of Permitted Activities:* November 1, 2017–March 31, 2019.

**Nadene G. Kennedy,**

*Polar Coordination Specialist, Office of Polar Programs.*

[FR Doc. 2017–23316 Filed 10–25–17; 8:45 am]

**BILLING CODE 7555–01–P**

## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–81914; File No. SR–NYSE–2017–32]**

### Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Designation of a Longer Period for Commission Action on Proposed Rule Change To Amend Section 202.06 of the NYSE Listed Company Manual To Prohibit Listed Companies From Issuing Material News After the Official Closing Time for the Exchange's Trading Session Until the Earlier of Publication of Such Company's Official Closing Price on the Exchange or Five Minutes After the Official Closing Time

October 20, 2017.

On August 17, 2017, New York Stock Exchange LLC (''NYSE'' or the ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend the NYSE Listed Company Manual (the ''Manual'') to prohibit listed companies from issuing material news after the official closing time for the Exchange's trading session until the earlier of publication of such company's official closing price on the Exchange or five minutes after the official closing time. The proposed rule change was published for comment in the **Federal Register** on September 5, 2017.[3] The Commission received one comment letter on the proposed rule change.[4]

Section 19(b)(2) of the Act [5] provides that, within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or as to which the self-regulatory organization consents, the Commission shall either approve the

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 81494 (August 29, 2017), 82 FR 42008.

[4] *See* letter to Eduardo A. Aleman, Assistant Secretary, Commission from John Dibacco Virtu Financial LLC, dated September 20, 2017.

[5] 15 U.S.C. 78s(b)(2).

proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day for this filing is October 20, 2017.

The Commission is extending the 45-day time period for Commission action on the proposed rule change. The Commission finds that it is appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the Exchange's proposal, as described above. Accordingly, pursuant to Section 19(b)(2) of the Act,[6] the Commission designates December 4, 2017, as the date by which the Commission shall either approve or disapprove or institute proceedings to determine whether to disapprove the proposed rule change (File No. SR–NYSE–2017–32).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[7]

**Eduardo A. Aleman,**

*Assistant Secretary.*

[FR Doc. 2017–23264 Filed 10–25–17; 8:45 am]

**BILLING CODE 8011–01–P**

## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–81915; File No. SR–NYSEArca–2017–90]**

### Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change, as Modified by Amendment No. 1 Thereto, To List and Trade Shares of the Hartford Municipal Opportunities ETF Under NYSE Arca Rule 8.600–E

October 20, 2017.

On August 17, 2017, NYSE Arca, Inc. (''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to list and trade shares of the Hartford Municipal Opportunities ETF under NYSE Arca Rule 8.600–E. The proposed rule change was published for comment in the **Federal Register** on September 6, 2017.[3] On October 17, 2017, the Exchange filed Amendment No. 1 to the proposed rule change.[4] The Commission has not received any comments on the proposed rule change.

Section 19(b)(2) of the Act[5] provides that within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding, or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be approved or disapproved. The 45th day after publication of the notice for this proposed rule change is October 21, 2017. The Commission is extending this 45-day time period.

The Commission finds it appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider this proposed rule change, as modified by the recently filed amendment. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[6] designates December 5, 2017, as the date by which the Commission shall either approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change (File No. SR–NYSEArca–2017–90), as modified by Amendment No. 1.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[7]

**Eduardo A. Aleman,**

*Assistant Secretary.*

[FR Doc. 2017–23265 Filed 10–25–17; 8:45 am]

**BILLING CODE 8011–01–P**

[6] 15 U.S.C. 78s(b)(2).

[7] 17 CFR 200.30–3(a)(31).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 81505 (August 30, 2017), 82 FR 42147.

[4] In Amendment No. 1, which amended and replaced the proposed rule change in its entirety, the Exchange, among other things, clarified that: (i) The list of municipal securities included in the section of the Notice entitled Hartford Municipal Opportunities ETF are the Municipal Securities in which the Fund may invest at least 80% of its net assets; (ii) redemption orders are not subject to acceptance by the distributor of the Fund; and (iii) the cut-off time for receipt of orders is 1 o'clock p.m. Amendment No. 1 also made non-substantive, technical amendments. Because Amendment No. 1 makes only clarifying and technical changes, and does not present unique or novel regulatory issues, it is not subject to notice and comment. Amendment No. 1 is available at: *https://www.sec.gov/comments/sr-nysearca-2017-90/nysearca201790.htm.*

[5] 15 U.S.C. 78s(b)(2).

[6] *Id.*

[7] 17 CFR 200.30–3(a)(31).

## SOCIAL SECURITY ADMINISTRATION

**[Docket No. SSA 2017–0044]**

### Privacy Act of 1974; Matching Program

**AGENCY:** Social Security Administration (SSA).

**ACTION:** Notice of a New Matching Program.

**SUMMARY:** In accordance with the provisions of the Privacy Act, as amended, this notice announces a new computer matching program that we are currently conducting with the Internal Revenue Service (IRS).

This computer matching agreement sets forth the terms, conditions, and safeguards under which IRS will disclose to SSA certain return information for the purpose of verifying eligibility for the Prescription Drug Subsidy Program (Subsidy) and or determining the correct subsidy percentage of benefits provided under section 1860D–14 of the Social Security Act (Act).

**DATES:** The deadline to submit comments on the proposed matching program is 30 days from October 26, 2017. The matching program will be effective on November 11, 2017, or once a minimum of 30 days after publication of this notice has elapsed, whichever is later. The matching program will expire on May 10, 2019.

**ADDRESSES:** Interested parties may comment on this notice by either telefaxing to (410) 966–0869, writing to Mary Ann Zimmerman, Acting Executive Director, Office of Privacy and Disclosure, Office of the General Counsel, Social Security Administration, 617 Altmeyer Building, 6401 Security Boulevard, Baltimore, MD 21235–6401, or email at *Mary.Ann.Zimmerman@ssa.gov.* All comments received will be available for public inspection at this address.

**FOR FURTHER INFORMATION CONTACT:** Interested parties may submit general questions about the matching program to Mary Ann Zimmerman, Acting Executive Director, Office of Privacy and Disclosure, Office of the General Counsel, by any of the means shown above.

**SUPPLEMENTARY INFORMATION:** The Computer Matching and Privacy Protection Act of 1988 (Pub. L. 100–503), amended the Privacy Act (5 U.S.C. 552a) by describing the conditions under which computer matching involving the Federal government could be performed and adding certain protections for persons applying for, and receiving, Federal benefits. Section 7201 of the Omnibus Budget

Reconciliation Act of 1990 (Pub. L. 101–508) further amended the Privacy Act regarding protections for such persons.

The Privacy Act, as amended, regulates the use of computer matching by Federal agencies when records in a system of records are matched with other Federal, State, or local government records. It requires Federal agencies involved in computer matching programs to:

(1) Negotiate written agreements with the other agency or agencies participating in the matching programs;

(2) Obtain approval of the matching agreement by the Data Integrity Boards of the participating Federal agencies;

(3) Publish notice of the computer matching program in the **Federal Register**;

(4) Furnish detailed reports about matching programs to Congress and OMB;

(5) Notify applicants and beneficiaries that their records are subject to matching; and

(6) Verify match findings before reducing, suspending, terminating, or denying a person's benefits or payments.

We have taken action to ensure that all of our computer matching programs comply with the requirements of the Privacy Act, as amended.

**Mary Ann Zimmerman,**

*Acting Executive Director, Office of Privacy and Disclosure, Office of the General Counsel.*

*Participating Agencies:* SSA and IRS.

*Authority for Conducting the Matching Program:* The legal authority for Internal Revenue Code (IRC) section 6103(1)(7) authorizes IRS to disclose return information with respect to unearned income to Federal, state, and local agencies administering certain benefit programs under the Act. Section 1860D–14 of the Act requires the Commissioner of Social Security to determine the eligibility of applicants for the prescription drug subsidy who self-certify their income, resources, and family size. Pursuant to section 1860D–14(a)(3) of the Act (42 U.S.C. 1395w–114(a)(3)), SSA must determine whether a Social Security Part D eligible individual is a subsidy-eligible individual, and whether the individual is an individual as described in section 1860D–14(a) of the Act.

*Purpose(s):* The purpose of this matching program is to sets forth the terms, conditions, and safeguards under which IRS will disclose to us certain return information for the purpose of verifying eligibility for the Prescription Drug Subsidy Program (Subsidy) and or determining the correct subsidy percentage of benefits provided under section 1860D–14 of the Act. (42 U.S.C. 1395w–114). This matching agreement between IRS and us is executed under the Privacy Act of 1974, (5 U.S.C. 552a), as amended by the Computer Matching and Privacy Protection Act of 1988, and the regulations and guidance promulgated thereunder.

*Categories of Individuals:* The individuals whose information is involved in this matching program are beneficiaries who apply for Medicare prescription drug subsidy under section 1860D–14 of the Act. They will self–certificate on the application form the applicant's income, resources, and family size. We will verify each applicant's self-certification information before making a subsidy determination. When Medicare beneficiaries apply for the subsidy, and we cannot otherwise verify the income information provided on an application, SSA discloses to IRS the applicant's name and Social Security number.

*Categories of Records:* When beneficiaries apply for the Medicare prescription drug subsidy under section 1860D–14 of the Act, they must self-certify on the application form the applicant's income, resources, and family size. Once each year, we electronically transmit the identifying information of each current subsidy recipient to IRS.

When there is a match of individual identifier, IRS discloses to us:

a. Payee Account Number,

b. Payee Name and Mailing Address,

c. Payee Taxpayer Identification Number (TIN),

d. Payer Name and Address,

e. Payer TIN, and

f. Income Type and Amount.

*System(s) of Records:* We will provide IRS with identifying information with respect to applicants for, and recipients of, the prescription drug subsidy from the existing Medicare Database (MDB File) system of records, 60–0321 published at 71 FR 42159 (July 25, 2006). Unearned income information provided by IRS is maintained in the MDB File. IRS extracts return information with respect to unearned income from the IRMF, Treasury/IRS 22.061, as published at 77 FR 47946 (August 10, 2012).

[FR Doc. 2017–23280 Filed 10–25–17; 8:45 am]

**BILLING CODE 4191–02–P**

## SOCIAL SECURITY ADMINISTRATION

**[Docket No. SSA 2017–0022]**

### Privacy Act of 1974; Matching Program

**AGENCY:** Social Security Administration (SSA).

**ACTION:** Notice of a new matching program.

**SUMMARY:** In accordance with the provisions of the Privacy Act, as amended, this notice announces a new computer matching program that we are currently conducting with the Office of Child Support Enforcement (OCSE).

**DATES:** The deadline to submit comments on the proposed matching program is 30 days from the date of publication of this notice. The matching program will be effective on November 1, 2017, or once a minimum of 30 days after publication of this notice has elapsed, whichever is later. The matching program will expire on October 31, 2018.

**ADDRESSES:** Interested parties may comment on this notice by either telefaxing to (410) 966–0869, writing to Mary Ann Zimmerman, Acting Executive Director, Office of Privacy and Disclosure, Office of the General Counsel, Social Security Administration, 617 Altmeyer Building, 6401 Security Boulevard, Baltimore, MD 21235–6401, or email at *Mary.Ann.Zimmerman@ssa.gov.* All comments received will be available for public inspection at this address.

**FOR FURTHER INFORMATION CONTACT:** Interested parties may submit general questions about the matching program to Mary Ann Zimmerman, Acting Executive Director, Office of Privacy and Disclosure, Office of the General Counsel, by any of the means shown above.

**SUPPLEMENTARY INFORMATION:** The Computer Matching and Privacy Protection Act of 1988 (Public Law (Pub. L.) 100–503), amended the Privacy Act (5 U.S.C. 552a) by describing the conditions under which computer matching involving the Federal government could be performed and adding certain protections for persons applying for, and receiving, Federal benefits. Section 7201 of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101–508) further amended the Privacy Act regarding protections for such persons.

The Privacy Act, as amended, regulates the use of computer matching by Federal agencies when records in a system of records are matched with other Federal, State, or local government records. It requires Federal agencies involved in computer matching programs to:

(1) Negotiate written agreements with the other agency or agencies participating in the matching programs;

(2) Obtain approval of the matching agreement by the Data Integrity Boards of the participating Federal agencies;

(3) Publish notice of the computer matching program in the **Federal Register**;

(4) Furnish detailed reports about matching programs to Congress and OMB;

(5) Notify applicants and beneficiaries that their records are subject to matching; and

(6) Verify match findings before reducing, suspending, terminating, or denying a person's benefits or payments.

We have taken action to ensure that all of our computer matching programs comply with the requirements of the Privacy Act, as amended.

**Mary Ann Zimmerman,**

*Acting Executive Director, Office of Privacy and Disclosure, Office of the General Counsel.*

*Participating Agencies:* SSA and OCSE.

*Authority for Conducting the Matching Program:* The legal authorities for disclosures under this agreement are the Social Security Act (Act) and the Privacy Act of 1974, as amended. Subsection 453(j)(4) of the Act provides that OCSE shall provide the Commissioner of SSA with all information in the NDNH. 42 U.S.C. 653(j)(4). SSA has authority to use data to determine entitlement to and eligibility for programs it administers pursuant to sections 453(j)(4), 1631(e)(1)(B) and(f), and 1860D–14(a)(3) of the Act. 42 U.S.C. 653(j)(4), 1383(e)(1)(B) and (f), and 1395w–114(a)(3). Disclosures under this agreement shall be made in accordance with 5 U.S.C. 552a(b)(3), and in compliance with the matching procedures in 5 U.S.C. 552a(o), (p), and (r).

The Act provides that the determination of whether a Part D eligible individual residing in a state is a subsidy-eligible individual shall be determined under the state plan for medical assistance under section 1860D–14(a)(3)(B)(1) of the Act. 42 U.S.C. 1395w–114(a)(3)(B)(1).

SSA has independent authority to collect this information regarding Medicare Parts A–D via sections 202–205, 223, 226, 228, 1611, 1631, 1818, 1836, 1839, 1840, and 1860D–1 to 1860D–15 of the Act (42 U.S.C. 402–405, 423, 426, 428, 1382, 1383, 1395i–2, 1395o, 1395r, 1395s, and 1395w–101 to 1395w–115).

*Purpose(s):* This computer matching agreement, hereinafter ''agreement,'' governs a matching program between the Office of Child Support Enforcement (OCSE) and the Social Security Administration (SSA). The agreement covers information exchange operations between OCSE and SSA that will provide SSA with quarterly wage and unemployment insurance information located in the National Directory of New Hires (NDNH) to allow SSA to determine eligibility of applicants for Extra Help (low-income subsidy assistance) under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173) (Extra Help). This agreement also governs the use, treatment, and safeguarding of the information exchanged. OCSE is the ''source agency'' and SSA is the ''recipient agency,'' as defined by the Privacy Act. 5 U.S.C. 552a(a)(9) and (11).

This agreement assists SSA in (1) determining eligibility of applicants for Extra Help; (2) redetermining eligibility of existing Extra Help beneficiaries during periodic screening; and (3) administering the Extra Help program.

The Privacy Act provides that no record contained in a system of record (SOR) may be disclosed for use in a computer matching program except pursuant to a written agreement containing specified provisions. 5 U.S.C. 552a(o). SSA and OCSE are executing this agreement to comply with the Privacy Act of 1974, as amended, and the regulations and guidance promulgated thereunder. OCSE and SSA have been parties to matching agreements and recertifications for this purpose since April 1, 2005. Appendix A provides background information about these prior agreements.

The SSA component responsible for this agreement and its contents is the Office of Privacy and Disclosure. The responsible component for OCSE is the Division of Federal Systems.

This agreement is applicable to personnel, facilities, and information systems of SSA and OCSE involved in the processing and storage of NDNH information. Personnel are defined as employees, contractors, or agents of OCSE and SSA.

This agreement includes a security addendum and four appendices.

*Categories of Individuals:* The individuals whose information is involved in this matching program are new hires, quarterly wage earners, and recipients of unemployment insurance.

*Categories of Records:*

SSA will provide OCSE the following data elements electronically in the Finder File:

- COSSN (SSN)
- Name

OCSE will provide electronically to SSA the following data elements from the NDNH quarterly wage file:

- Quarterly wage record identifier
- For employees:
  (1) Name (first, middle, last)
  (2) SSN
  (3) Verification request code
  (4) Processed date
  (5) Non-verifiable indicator
  (6) Wage amount
  (7) Reporting period
- For employers of individuals in the quarterly wage file of the NDNH:
  (1) Name
  (2) Employer identification number
  (3) Address(es)
- Transmitter Agency Code
- Transmitter State Code
- State or Agency Name

OCSE will provide electronically to SSA the following data elements from the NDNH unemployment insurance file:

- Unemployment insurance record identifier
- Processed date
- SSN
- Verification request code
- Name (first, middle, last)
- Address
- Unemployment insurance benefit amount
- Reporting period
- Transmitter Agency Code
- Transmitter State Code
- State or Agency Name

Data Elements SSA updates in the OCSEFITM table, if there is a match:

- QW record identifier
- For employees:
  (1) Employee's SSN
  (2) Employee's wage amount
  (3) Reporting period
- For employers of individuals:
  (1) Employer identification number
  (2) Employer's name
- UI identifier:
  (1) Claimant SSN
  (2) Unemployment insurance benefit amount
  (3) Reporting period
  (4) Transmitter State Name

*System(s) of Records:* SSA collects and maintains this information in the Medicare Database (MDB) system of records, No. 60–0321, published at 69 FR 77816 (December 28, 2004) and 71 FR 42159–42164 (July 25, 2006). The MDB contains information related to Medicare Part A, Part B, Medicare Advantage Part C, and Medicare Part D.

OCSE will match SSA information in the MDB against the quarterly wage and unemployment insurance information furnished by state and federal agencies maintained in its system of records

''OCSE National Directory of New Hires'' (NDNH), No. 09–80–0381, established by publication in the **Federal Register** on January 5, 2011 at 76 FR 560. The disclosure of NDNH information by OCSE to SSA constitutes a ''routine use,'' as defined by the Privacy Act. 5 U.S.C. 552a(b)(3). Routine use (#9) of the SOR authorizes disclosure of NDNH information to SSA, 76 FR 560, 562 (January 5, 2011).

[FR Doc. 2017–23326 Filed 10–25–17; 8:45 am]

**BILLING CODE 4191–02–P**

## SOCIAL SECURITY ADMINISTRATION

**[Docket No: SSA–2017–0056]**

### Agency Information Collection Activities: Proposed Request

The Social Security Administration (SSA) publishes a list of information collection packages requiring clearance by the Office of Management and Budget (OMB) in compliance with Public Law 104–13, the Paperwork Reduction Act of 1995, effective October 1, 1995. This notice includes revisions of OMB-approved information collections.

SSA is soliciting comments on the accuracy of the agency's burden estimate; the need for the information; its practical utility; ways to enhance its quality, utility, and clarity; and ways to minimize burden on respondents, including the use of automated collection techniques or other forms of information technology. Mail, email, or fax your comments and recommendations on the information collection(s) to the OMB Desk Officer and SSA Reports Clearance Officer at the following addresses or fax numbers.

(OMB), Office of Management and Budget, Attn: Desk Officer for SSA, Fax: 202–395–6974, Email address: *OIRA_Submission@omb.eop.gov*

(SSA), Social Security Administration, OLCA, Attn: Reports Clearance Director, 3100 West High Rise, 6401 Security Blvd., Baltimore, MD 21235, Fax: 410–966–2830, Email address: *OR.Reports.Clearance@ssa.gov*

Or you may submit your comments online through *www.regulations.gov,* referencing Docket ID Number [SSA–2017–0056].

The information collections below are pending at SSA. SSA will submit them to OMB within 60 days from the date of this notice. To be sure we consider your comments, we must receive them no later than December 26, 2017. Individuals can obtain copies of the collection instruments by writing to the above email address.

*1. Request for Review of Hearing Decision/Order—20 CFR 404.967–404.981, 416.1467–416.1481—0960–0277.* Claimants have a statutory right under the Social Security Act and current regulations to request review of an administrative law judge's (ALJ) hearing decision or dismissal of a hearing request on Title II and Title XVI claims. Claimants may request Appeals Council review by filing a written request using paper Form HA–520, or the Internet application, i520. SSA uses the information we collect to establish the claimant filed the request for review within the prescribed time, and to ensure the claimant completed the requisite steps permitting the Appeals Council review. The Appeals Council then uses the information to: (1) Document the claimant's reason(s) for disagreeing with the ALJ's decision or dismissal; (2) determine whether the claimant has additional evidence to submit; and (3) determine whether the claimant has a representative or wants to appoint one. The respondents are claimants requesting review of an ALJ's decision or dismissal of hearing.

*Type of Request:* Revision of an OMB-approved information collection.

| Modality of completion | Number of respondents | Frequency of response | Average burden per response (minutes) | Estimated total annual burden (hours) |
|---|---|---|---|---|
| HA–520—Paper | 105,000 | 1 | 10 | 17,500 |
| i520—Internet | 70,000 | 1 | 15 | 17,500 |
| Totals | 175,000 | | | 35,000 |

*2. You Can Make Your Payment by Credit Card—0960–0462.* SSA uses the information we collect on Form SSA–4588, and its electronic application, Form SSA–4589, to update individuals' Social Security records to reflect payments made on their overpayments. In addition, SSA uses this information to process payments through the appropriate credit card company. SSA provides a copy of the SSA–4588 when we inform an individual that we detected an overpayment. Individuals may choose to make a one-time payment or recurring monthly payments when they complete and submit the SSA–4588. When individuals choose to telephone the Program Service Centers to make a one-time payment in lieu of completing Form SSA–4588, an SSA debtor contact representative completes the SSA–4589 electronic Intranet application. Respondents are Old Age Survivors and Disability Insurance (OASDI) beneficiaries and Supplemental Security Income (SSI) recipients who have outstanding overpayments.

*Type of Request:* Revision of an OMB-approved information collection.

| Modality of completion | Number of respondents | Frequency of response | Average burden per response (minutes) | Estimated total annual burden (hours) |
|---|---|---|---|---|
| SSA–4588 (Paper) | 16,500 | 1 | 10 | 2,750 |
| SSA–4589 (Electronic intranet application) | 258,500 | 1 | 5 | 21,542 |
| Totals | 275,000 | | | 24,292 |

*3. Request to Show Cause for Failure to Appear—20 CFR 404.938, 404.957(a)(ii), 416.1438—0960–0794.* When claimants who requested a hearing before an ALJ fail to appear at their scheduled hearing, the ALJ may reschedule the hearing if the claimants establish good cause for missing the hearings. To establish good cause,

claimants must show one of the following: (1) SSA did not properly notify the claimant of the hearing, or (2) an unexpected event occurred without sufficient time for the claimant to request a postponement. The claimants can use paper Form HA–L90 or HA–L90–OP1 to provide their reason for not appearing at their scheduled hearings; or the claimants' representatives can use Electronic Records Express (ERE), OMB Control No. 0960–0753, Internet screens to submit the HA–L90 online. SSA uses the HA–L90 for new cases, and the HA–L90–OP1 for redeterminations cases. We need two versions of the paper form, as the ALJ follows different procedures when determining the good cause on redetermination cases (cases that have a prior decision and evidence on file), than they do for new cases (where we have no evidence on file). The ERE modality automatically adjusts for redetermination cases, so we only need one version of the Internet screens. If the ALJ determines the claimants established good cause for failure to appear at the hearing, the ALJ will schedule a supplemental hearing; if not, the ALJ will make a claims eligibility determination based on the claimants' evidence of record. Respondents are claimants, or their representatives, seeking to establish good cause for failure to appear at a scheduled hearing before an ALJ.

*Type of Request:* Revision of an OMB-approved information collection.

| Modality of completion | Number of responses | Frequency of response | Average burden per response (minutes) | Estimated total annual burden (hours) |
|---|---|---|---|---|
| HA–L90 | 39,500 | 1 | 10 | 6,583 |
| HA–L90–OP1 | 500 | 1 | 10 | 83 |
| Totals | 40,000 | ..... | ..... | 6,666 |

*We do not account for the ERE Internet screens here as we account for them under OMB Control No. 0960–0753.

Dated: October 23, 2017.

**Naomi R. Sipple,**

*Reports Clearance Officer, Social Security Administration.*

[FR Doc. 2017–23342 Filed 10–25–17; 8:45 am]

**BILLING CODE 4191–02–P**

## SURFACE TRANSPORTATION BOARD

**[Docket No. FD 36142 (Sub-No. 1)]**

### Savage Companies—Continuance in Control Exemption—Savage Davenport Railroad Company

**AGENCY:** Surface Transportation Board.

**ACTION:** Correction to notice of exemption.

On September 1, 2017, notice of the above exemption was served and published in the **Federal Register** (82 FR 41,674). The exemption became effective on September 15, 2017. On October 4, 2017, a correction was filed with the Board advising that the parent company, which was inadvertently referred to in the continuance in control filing as ''Savage Services Corporation'' should have been referred to as ''Savage Companies,'' a privately held Utah corporation. This notice corrects the name of the parent company. All other information in the notice is correct.

Board decisions and notices are available on our Web site at ''*WWW.STB.GOV*.''

Decided: October 23, 2017.

By the Board, Scott M. Zimmerman, Acting Director, Office of Proceedings.

**Kenyatta Clay,**

*Clearance Clerk.*

[FR Doc. 2017–23325 Filed 10–25–17; 8:45 am]

**BILLING CODE 4915–01–P**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

### Third RTCA SC–236 Joint Plenary With EUROCAE WG–96

**AGENCY:** Federal Aviation Administration (FAA), U.S. Department of Transportation (DOT).

**ACTION:** Third RTCA SC–236, Wireless Airborne Intra Communications (WAIC), joint Plenary with EUROCAE WG–96.

**SUMMARY:** The FAA is issuing this notice to advise the public of a meeting of Third RTCA SC–236, Wireless Airborne Intra Communications (WAIC), joint Plenary with EUROCAE WG–96.

**DATES:** The meeting will be held November 28–December 1, 2017 9:00 a.m.–5:00 p.m.

**ADDRESSES:** The meeting will be held at: EASA Headquarters, Konrad-Adenauer-Ufer 3, D–50668 Cologne, Germany.

**FOR FURTHER INFORMATION CONTACT:** Rebecca Morrison at *rmorrison@rtca.org* or 202–330–0654, or The RTCA Secretariat, 1150 18th Street NW., Suite 910, Washington, DC 20036, or by telephone at (202) 833–9339, fax at (202) 833–9434, or Web site at *http://www.rtca.org.*

**SUPPLEMENTARY INFORMATION:** Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C., App.), notice is hereby given for a meeting of the Third RTCA SC–236 joint Plenary with EUROCAE WG–96. The agenda will include the following:

**Tuesday, November 28, 2017—9:00AM–5:00PM**

1. Welcome/Administrative Duties
2. IPR/Membership Call-Out and Introductions
3. Acceptance of Meeting Minutes for the Second Joint Plenary of SC–236/WG–96
4. Review Plenary Agenda and Sub-Working Group Schedule
5. Break Into Sub-Working Group Meetings When Plenary Business Complete
6. Reports of the Sub-Working Groups
7. Review of Special Committee Schedule
8. New Business Discussions
9. Review of Action Items
10. Plan for Next Meeting
11. Adjourn

**Wednesday, November 29, 2017—9:00AM–5:00PM**

12. Continue With Plenary or Sub-Working Group Meetings

**Thursday, November 30, 2017—9:00AM–5:00PM**

13. Continue With Plenary or Sub-Working Group Meetings

**Friday, December 1, 2017—9:00AM–12:00PM**

14. Continue With Plenary or Sub-Working Group Meetings

Registration is required for attendance. Attendance is open to the

interested public but limited to space availability. With the approval of the chairman, members of the public may present oral statements at the meeting. Persons wishing to attend or to present statements or obtain information should contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. Members of the public may present a written statement to the committee at any time. Issued in Washington, DC on

Dated: October 23, 2017.

**Mohannad Dawoud,**

*Management & Program Analyst, Partnership Contracts Branch, ANG–A17, NextGen, Procurement Services Division, Federal Aviation Administration.*

[FR Doc. 2017–23278 Filed 10–25–17; 8:45 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF TRANSPORTATION

### Federal Railroad Administration

**[Docket Number FRA–2017–0105]**

### Petition for Waiver of Compliance

Under part 211 of Title 49 Code of Federal Regulations (CFR), this provides the public notice that on October 4, 2017, the Association of American Railroads (AAR) petitioned the Federal Railroad Administration (FRA) for a waiver of compliance from certain provisions of the Federal Railroad safety regulations contained at 49 CFR 229.23. FRA assigned the petition Docket Number FRA–2017–0105.

Section 229.23(a) requires each locomotive to be inspected on an interval not to exceed 92 days; section 229.23(b) allows a locomotive equipped with advanced microprocessor-based on-board electronic condition monitoring controls to be inspected on an interval not to exceed 184 days. AAR states in its petition that it believes the approximately 422 locomotives equipped with 26–L brake systems and microprocessor-based on-board pneumatic condition monitoring controls should fall within section 229.23(b), and petitions for a two-year test waiver to demonstrate the appropriateness of that categorization.

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:

- *Web site: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* Docket Operations Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE., W12–140, Washington, DC 20590.
- *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 December 11, 2017 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. 2017–23237 Filed 10–25–17; 8:45 am]

**BILLING CODE 4910–06–P**

## DEPARTMENT OF TRANSPORTATION

### Federal Railroad Administration

**[Docket Number FRA–2013–0019]**

### Petition for Waiver of Compliance

Under part 211 of Title 49 of the Code of Federal Regulations (CFR), this document provides the public notice that on August 15, 2017, Old Augusta Railroad (OAR) petitioned the Federal Railroad Administration (FRA) for a waiver of compliance from certain provisions of the hours of service laws contained at Title 49 United States Code (U.S.C.) section 21103(a), in accordance with the authority of section 21102(b). FRA assigned the petition docket number FRA–2013–0019.

OAR requested an extension of its existing waiver of relief from the provisions of 49 U.S.C. 21103(a), which prohibits a train employee from remaining or going on duty for a period in excess of 12 consecutive hours. 49 U.S.C. 21102(b) allows railroads with 15 or fewer employees to be exempted from the restriction outlined at 49 U.S.C. 21103(a)(4)(B). The existing waiver allows OAR employees to initiate an on-duty period each day for seven (7) consecutive days followed by 72 hours off duty. An employee may initiate an on-duty period for an eighth consecutive day followed by 72 hours off duty, if all eight assignments do not infringe upon the 10:00 p.m. to 5:00 a.m. time period. Employees' schedules may be extended no more than one time within any 30-day period. An employee must agree to have his or her series of consecutive days extended. If an employee's series of consecutive days is extended and he or she subsequently feels fatigues, he or she may request up to 24 hours of time off duty, which OAR shall allow the employee to receive. For any employee whose series of consecutive days is extended subject to this waiver, the hours of service records for the relevant series of consecutive days must indicate that the limitation has been extended by waiver.

OAR states that its operation has not had a single incident attributable to fatigue during the effective period of the waiver. In addition, the relief has enabled the railroad to serve their customers safely and efficiently, utilizing their own experienced employees, and without having to rely on less experienced personnel obtained from other areas or entities. OAR states that its employees have unanimously consented to the waiver, and it has full support from both management and train service employees.

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 Department of Transportation's Docket Operations Facility, 1200 New Jersey Ave. 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, 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:

- *Web site: http://www.regulations.gov*. Follow the online instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* Docket Operations Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE., W12–140, Washington, DC 20590.
- *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 December 11, 2017 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. 2017–23236 Filed 10–25–17; 8:45 am]

**BILLING CODE 4910–06–P**

## DEPARTMENT OF TRANSPORTATION

### Federal Railroad Administration

**[Docket Number FRA–2009–0074]**

### 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 July 28, 2017, the Canadian National Railway Company (CN), the Transportation Division of the International Association of Sheet Metal, Air, Rail, and Transportation Workers (TD–SMART) and the Brotherhood of Locomotive Engineers and Trainmen (BLET) collectively petitioned the Federal Railroad Administration (FRA) for an extension of CN's existing waiver of compliance from certain provisions of the hours of service laws contained at Title 49 United States Code (U.S.C.) section 21103(a)(4). FRA assigned the petition Docket Number FRA–2009–0074.

CN requested an extension of its existing waiver from the provisions of 49 U.S.C. 21103(a), which prohibits a train employee from remaining or going on duty after that employee has initiated an on-duty period each day for six consecutive days, unless that employee has had at least 48 consecutive hours off duty at the employee's home terminal. Specifically, CN, on behalf of its railroad operating subsidiaries based in the United States, and its unions, seeks a waiver to allow train employees to initiate an on-duty period each day for 6 consecutive days followed by 24 hours off duty. In support of the request, CN, BLET, and SMART explained that CN has operated these schedules of 6 consecutive on-duty periods followed by 24 hours off duty successfully since 2002. CN, BLET, and SMART indicate that these schedules have not had an adverse impact on safety.

CN also provided an analysis of the most current 12-month period of train-employee on-duty human factor-related accidents and injuries. CN indicates that its analyses revealed that of the 13 human factor-related accidents involving CN employees in the preceding 12 months, none involved employees covered under the waiver working 6 consecutive days followed by 24 hours off duty.

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 Department of Transportation's Docket Operations Facility, 1200 New Jersey Ave. 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, 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:

- *Web site: http://www.regulations.gov*. Follow the online instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* Docket Operations Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE., W12–140, Washington, DC 20590.
- *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 December 11, 2017 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. 2017–23235 Filed 10–25–17; 8:45 am]

**BILLING CODE 4910–06–P**

## DEPARTMENT OF TRANSPORTATION

### Federal Railroad Administration

**[Docket Number FRA–2003–15196]**

### 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 September 27, 2017, New Jersey Transit (NJT) petitioned the Federal Railroad Administration (FRA) for an extension of a waiver of compliance from certain provisions of the Federal railroad safety regulations contained at 49 CFR part 213, Track Safety Standards. The docket number associated with this petition is FRA–2003–15196.

NJT seeks an extension of its existing waiver from 49 CFR 213.233(c), relating to the frequency of the required visual track inspections for FRA Class 3 and 4 track carrying passenger traffic. FRA issued the initial waiver that granted NJT relief on August 25, 1999 (FRA Docket No. RST–97–5), and FRA extended the waiver on April 28, 2003, May 1, 2008, and December 17, 2012 for three 5-year periods.

NJT requests an extension of its waiver for reduced frequency of required visual track inspections specifically for those tracks constructed with continuous welded rail. NJT proposes to conduct one visual track inspection per week, instead of the two inspections per week that are required in 49 CFR part 213, and to supplement its visual inspections with the operation of an automated track geometry measuring vehicle over the affected main tracks and sidings four times per year.

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 Department of Transportation's Docket Operations Facility, 1200 New Jersey Ave. 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, 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:

- *Web site: http://www.regulations.gov*. Follow the online instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* Docket Operations Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE., W12–140, Washington, DC 20590.
- *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 December 11, 2017 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. 2017–23234 Filed 10–25–17; 8:45 am]

**BILLING CODE 4910–06–P**

## DEPARTMENT OF THE TREASURY

### Office of Foreign Assets Control

### Sanctions Action Pursuant to Executive Order 13067 and Executive Order 13412

**AGENCY:** Office of Foreign Assets Control, Treasury.

**ACTION:** Notice.

**SUMMARY:** The Department of the Treasury's Office of Foreign Assets Control (OFAC) has removed from the Specially Designated Nationals and Blocked Persons List (SDN List) the names of persons whose property and interests in property had been blocked pursuant to Sudan sanctions authorities.

**DATES:** OFAC's action described in this notice was taken on October 12, 2017.

**FOR FURTHER INFORMATION CONTACT:** OFAC: Associate Director for Global Targeting, tel.: 202–622–2420; Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490; Assistant Director for Licensing, tel.: 202–622–2480; or the Department of the Treasury's Office of the General Counsel: Office of the Chief Counsel (Foreign Assets Control), tel.: 202–622–2410.

**SUPPLEMENTARY INFORMATION:**

#### Electronic Availability

The Specially Designated Nationals and Blocked Persons List and additional information concerning OFAC sanctions programs are available on OFAC's Web site (*www.treasury.gov/ofac*).

#### Notice of OFAC Action(s)

Effective October 12, 2017, sections 1 and 2 of Executive Order (E.O.) 13067 of November 3, 1997, ''Blocking Sudanese Government Property and Prohibiting Transactions With Sudan'' and all of E.O. 13412 of October 13, 2006, ''Blocking Property of and Prohibiting Transactions With the Government of Sudan'' were revoked, pursuant to E.O. 13761 of January 13, 2017, ''Recognizing Positive Actions by the Government of Sudan and Providing for the Revocation of Certain Sudan-Related Sanctions,'' as amended by E.O. 13804 of July 11, 2017, ''Allowing Additional Time for Recognizing Positive Actions by the Government of Sudan and Amending Executive Order 13761.''

Sections 1 and 2 of E.O. 13067 and E.O. 13412 blocked the property of the Government of Sudan and generally prohibited U.S. persons from engaging in transactions with Sudan and the Government of Sudan. As a result of the revocation of these sanctions provisions, effective October 12, 2017, the individuals and entities listed below are no longer subject to the blocking provisions in E.O. 13067 and E.O. 13412, and therefore were removed from the SDN List.

#### Entities

1. ACCOUNTS & ELECTRONICS EQUIPMENTS (a.k.a. ACCOUNTS AND

ELECTRONICS EQUIPMENTS), P.O. Box 97, Khartoum, Sudan; c/o ENGINEERING EQUIPMENT CORPORATION, undetermined [SUDAN].

2. ADVANCED ENGINEERING WORKS, Street No. 53, P.O. Box 44690, Khartoum, Sudan [SUDAN].

3. ADVANCED MINING WORKS COMPANY LIMITED, Elmek Nimir Street, Khartoum Bahri/Industrial Area, P.O. Box 1034, Khartoum 11, Sudan; Email Address *admico@sudanmail.net* [SUDAN].

4. ADVANCED PETROLEUM COMPANY (a.k.a. APCO), House No. 10, Block 9, Street 33, Amarat, P.O. Box 12811, Khartoum, Sudan [SUDAN].

5. ADVANCED TRADING AND CHEMICAL WORKS COMPANY LIMITED (a.k.a. ADVANCED CHEMICAL WORKS; a.k.a. ADVANCED COMMERCIAL AND CHEMICAL WORKS COMPANY LIMITED), 19 Al Amarat Street, P.O. Box 44690, Khartoum, Sudan; Email Address *advance@sudanmail.net;* Email Address *accw@htg-sdn.com* [SUDAN].

6. AFRICAN DRILLING COMPANY, Khartoum, Sudan [SUDAN].

7. AFRICAN OIL CORPORATION, P.O. Box 1, Khartoum North, Sudan [SUDAN].

8. AGRICULTURAL BANK OF SUDAN, P.O. Box 1363, Khartoum, Sudan [SUDAN].

9. AL SUNUT DEVELOPMENT COMPANY (a.k.a. ALSUNUT DEVELOPMENT COMPANY), No. 1 Block 5 East, Khartoum 2, P.O. Box 1840, Khartoum, Sudan; Web site *www.alsunut.com;* Email Address *info.AlsunutKhartoum@alsunut.com;* Email Address *info.AlsunutDubai@alsunut.com* [SUDAN].

10. ALAKTAN COTTON TRADING COMPANY (a.k.a. ALAKTAN TRADING COMPANY), P.O. Box 2067, Khartoum, Sudan [SUDAN].

11. ALFARACHEM COMPANY LIMITED (a.k.a. AL PHARAKIM; a.k.a. ALFARACHEM PHARMACEUTICALS INDUSTRIES LIMITED; a.k.a. ALFARAKIM), 27 Al Amarat Street, Khartoum, Sudan [SUDAN].

12. AMIN EL GEZAI COMPANY (a.k.a. EL AMIN EL GEZAI COMPANY), Khartoum, Sudan [SUDAN].

13. ARAB CEMENT COMPANY, Durdeib, Sudan; P.O. Box 6180, Khartoum, Sudan [SUDAN].

14. ARAB SUDANESE BLUE NILE AGRICULTURAL COMPANY, Khartoum, Sudan [SUDAN].

15. ARAB SUDANESE SEED COMPANY, Khartoum, Sudan [SUDAN].

16. ARAB SUDANESE VEGETABLE OIL COMPANY, Khartoum, Sudan [SUDAN].

17. ASSALAYA SUGAR COMPANY LIMITED, Eastern Bank of White Nile River, near Rabak town (about 300 km from Khartoum, P.O. Box 511, Khartoum, Sudan [SUDAN].

18. AUTOMOBILE CORPORATION, Khartoum, Sudan [SUDAN].

19. BABANOUSA MILK PRODUCTS FACTORY, P.O. Box 16, Babanousa, Sudan [SUDAN].

20. BANK OF SUDAN, Sharia El Gamaa, P.O. Box 313, Khartoum, Sudan; Atbara, Sudan; P.O. Box 27, El Obeid, Sudan; P.O. Box 136, Juba, Sudan; P.O. Box 73, Kosti, Sudan; Nyala, Sudan; P.O. Box 34, Port Sudan, Sudan; Wad Medani, Sudan; Wau, Sudan [SUDAN].

21. BASHAIER, Khartoum, Sudan [SUDAN].

22. BLUE NILE BREWERY, P.O. Box 1408, Khartoum, Sudan [SUDAN].

23. BLUE NILE PACKING CORPORATION, P.O. Box 385, Khartoum, Sudan [SUDAN].

24. BUILDING MATERIALS AND REFRACTORIES CORPORATION, P.O. Box 2241, Khartoum, Sudan [SUDAN].

25. COPTRADE COMPANY LIMITED—PHARMACEUTICAL AND CHEMICAL DIVISION, P.O. Box 246, Khartoum, Sudan; Port Sudan, Sudan [SUDAN].

26. COPTRADE ENG AND AUTOMOBILE SERVICES CO LTD. (f.k.a. KORDOFAN AUTOMOBILE COMPANY), P.O. Box 97, Khartoum, Sudan [SUDAN].

27. DUTY FREE SHOPS CORPORATION, P.O. Box 1789, Khartoum, Sudan [SUDAN].

28. EL GEZIRA AUTOMOBILE COMPANY (a.k.a. GEZIRA AUTOMOBILE COMPANY), P.O. Box 232, Khartoum, Sudan [SUDAN].

29. EL NILEIN BANK (n.k.a. EL NILEIN INDUSTRIAL DEVELOPMENT BANK (SUDAN); n.k.a. EL NILEIN INDUSTRIAL DEVELOPMENT BANK GROUP; n.k.a. NILEIN INDUSTRIAL DEVELOPMENT BANK (SUDAN)), Parliament Street, P.O. Box 466, Khartoum, Sudan; P.O. Box 6013, Abu Dhabi City, United Arab Emirates; P.O. Box 466/1722, United Nations Square, Khartoum, Sudan [SUDAN].

30. EL TAKA AUTOMOBILE COMPANY (a.k.a. TAKA AUTOMOBILE COMPANY), P.O. Box 221, Khartoum, Sudan [SUDAN].

31. EMIRATES AND SUDAN INVESTMENT COMPANY LIMITED, P.O. Box 7036, Khartoum, Sudan; Port Sudan, Sudan [SUDAN].

32. ENGINEERING EQUIPMENT COMPANY, P.O. Box 97, Khartoum, Sudan; c/o ENGINEERING EQUIPMENT CORPORATION, undetermined [SUDAN].

33. ENGINEERING EQUIPMENT CORPORATION, P.O. Box 97, Khartoum, Sudan [SUDAN].

34. EXPLORATION AND PRODUCTION AUTHORITY (SUDAN), Kuwait Building, Nile Avenue, Khartoum, Sudan; P.O. Box 2986, Khartoum, Sudan [SUDAN].

35. FOOD INDUSTRIES CORPORATION, P.O. Box 2341, Khartoum, Sudan [SUDAN].

36. FRIENDSHIP SPINNING FACTORY, Hassaheisa, Sudan [SUDAN].

37. GEZIRA TANNERY, Gezira, Sudan [SUDAN].

38. GEZIRA TRADE & SERVICES COMPANY LIMITED (a.k.a. GEZIRA TRADE AND SERVICES COMPANY LIMITED), P.O. Box 215, Khartoum, Sudan; P.O. Box 17, Port Sudan, Sudan; El Obeid, Sudan; Gedarit, Sudan; Juba, Sudan; Kosti, Sudan; Sennar, Sudan; Wad Medani, Sudan [SUDAN].

39. GIAD AUTOMOTIVE INDUSTRY COMPANY LIMITED (a.k.a. GIAD AUTOMOTIVE AND TRUCK; a.k.a. GIAD AUTOMOTIVE COMPANY; a.k.a. GIAD CARS & HEAVY TRUCKS COMPANY; a.k.a. GIAD CARS AND HEAVY TRUCKS COMPANY), Gazera State (40 km distance from Khartoum), P.O. Box 444/13600, Khartoum 1111, Sudan; Web site *www.giadmotors.com/giad_auto.html* [SUDAN].

40. GIAD MOTOR INDUSTRY COMPANY LIMITED (a.k.a. GIAD MOTOR COMPANY), Basheer Mohammad Saeed Building, Baladia Street, P.O. Box 13610, Khartoum, Sudan; Web site *www.giadmotors.com* [SUDAN].

41. GINEID SUGAR FACTORY, P.O. Box 1, Gineid, Sudan [SUDAN].

42. GREATER NILE PETROLEUM OPERATING COMPANY LIMITED (a.k.a. GNPOC), Hotel Palace, Room 420, El Nil Avenue, Khartoum, Sudan; El Harr Oilfield, Muglad Basin, Sudan; El Nar Oilfield, Muglad Basin, Sudan; El Toor Oilfield, Muglad Basin, Sudan; Heglig Oilfield, Muglad Basin, Sudan; Heglig Processing Facility, Muglad Basin, Sudan; Kaikang Oilfield, Muglad Basin, Sudan; Toma South Oilfield, Muglad Basin, Sudan; Unity Oilfield, Muglad Basin, Sudan; Pipeline, Heglig via El-Obeid to Port Sudan, Sudan; Red Sea Export Terminal, Marsa al-Basha'ir, Sudan [SUDAN].

43. GROUPED INDUSTRIES CORPORATION, P.O. Box 2241, Khartoum, Sudan [SUDAN].

44. GUNEID SUGAR COMPANY LIMITED (a.k.a. GUNEID SUGAR FACTORY), P.O. Box 511, Khartoum, Sudan [SUDAN].

45. HAGGAR ASSALAYA SUGAR FACTORY, Haggar Assalaya, Sudan [SUDAN].

46. HI TECH GROUP (a.k.a. HIGH TECH GROUP; a.k.a. HIGHTECH GROUP; a.k.a. HITECH GROUP), Amarat Street No. 31, P.O. Box 44690, Khartoum, Sudan; Web site *www.htg-sdn.com* [SUDAN].

47. HICOM (a.k.a. HI–COM), Khartoum, Sudan [SUDAN].

48. HICONSULT (a.k.a. HI–CONSULT), Khartoum, Sudan [SUDAN].

49. HI–TECH CHEMICALS, Khartoum, Sudan [SUDAN].

50. HI–TECH PETROLEUM GROUP, Khartoum, Sudan [SUDAN].

51. ICDB (a.k.a. ISLAMIC CO–OPERATIVE DEVELOPMENT BANK), P.O. Box 62, Khartoum, Sudan [SUDAN].

52. INDUSTRIAL BANK COMPANY FOR TRADE & DEVELOPMENT LIMITED (a.k.a. INDUSTRIAL BANK COMPANY FOR TRADE & DEVELOPMENT LIMITED), Khartoum, Sudan [SUDAN].

53. INDUSTRIAL BANK OF SUDAN (n.k.a. EL NILEIN INDUSTRIAL DEVELOPMENT BANK GROUP), United Nations Square, P.O. Box 1722, Khartoum, Sudan [SUDAN].

54. INDUSTRIAL PRODUCTION CORPORATION, P.O. Box 1034, El Gamaa Street, Khartoum, Sudan [SUDAN].

55. INDUSTRIAL RESEARCH AND CONSULTANCY INSTITUTE, P.O. Box 268, Khartoum, Sudan [SUDAN].

56. INGASSANA MINES HILLS CORPORATION (a.k.a. INGESSANA HILLS MINES CORPORATION), P.O. Box 2241, Khartoum, Sudan; P.O. Box 1108, Khartoum, Sudan [SUDAN].

57. JUBA DUTY FREE SHOP, Juba, Sudan [SUDAN].

58. KARIMA DATE FACTORY, Karima, Sudan [SUDAN].

59. KARIMA FRUIT AND VEGETABLE CANNING FACTORY, P.O. Box 54, Karima, Sudan [SUDAN].

60. KASSALA FRUIT PROCESSING COMPANY, Khartoum, Sudan [SUDAN].

61. KASSALA ONION DEHYDRATION FACTORY, P.O. Box 22, Kassala, Sudan [SUDAN].
62. KENAF SOCKS FACTORY, Abu Naama, Sudan [SUDAN].
63. KHARTOUM CENTRAL FOUNDRY, Khartoum, Sudan [SUDAN].
64. KHARTOUM COMMERCIAL AND SHIPPING COMPANY LIMITED, Kasr Avenue, P.O. Box 221, Khartoum, Sudan [SUDAN].
65. KHARTOUM TANNERY, P.O. Box 134, Khartoum South, Sudan [SUDAN].
66. KHOR OMER ENGINEERING COMPANY, P.O. Box 305, Khartoum, Sudan [SUDAN].
67. KORDOFAN COMPANY, Khartoum, Sudan [SUDAN].
68. KRIKAH INDUSTRIES GROUP, P.O. Box 755, Khartoum North, Sudan [SUDAN].
69. LEATHER INDUSTRIES CORPORATION (a.k.a. LEATHER INDUSTRIES TANNERIES), P.O. Box 1639, Khartoum, Sudan [SUDAN].
70. MALUT SUGAR FACTORY, Malut, Sudan [SUDAN].
71. MANGALA SUGAR FACTORY, Mangala, Sudan [SUDAN].
72. MASPIO CEMENT CORPORATION, P.O. Box 96, Atbara, Sudan [SUDAN].
73. MAY ENGINEERING COMPANY, P.O. Box 97, Khartoum, Sudan; c/o ENGINEERING EQUIPMENT CORPORATION, undetermined [SUDAN].
74. MILITARY COMMERCIAL CORPORATION, P.O. Box 221, Khartoum, Sudan [SUDAN].
75. MODERN ELECTRONIC COMPANY, Khartoum, Sudan [SUDAN].
76. MODERN LAUNDRY BLUE FACTORY (a.k.a. THE MODERN LAUNDRY BLUE FACTORY), P.O. Box 2241, Khartoum, Sudan [SUDAN].
77. MODERN PLASTIC & CERAMICS INDUSTRIES COMPANY (a.k.a. MODERN PLASTIC AND CERAMICS INDUSTRIES COMPANY), Khartoum, Sudan [SUDAN].
78. NATIONAL CIGARETTES CO. LTD., P.O. Box 2083, Khartoum, Sudan; and all other branches in Sudan [SUDAN].
79. NATIONAL COTTON AND TRADE COMPANY, P.O. Box 1552, Khartoum, Sudan [SUDAN].
80. NATIONAL ELECTRICITY CORPORATION, P.O. Box 1380, Khartoum, Sudan [SUDAN].
81. NATIONAL REINSURANCE COMPANY (SUDAN) LIMITED, P.O. Box 443, Khartoum, Sudan [SUDAN].
82. NEW HAIFA SUGAR FACTORY, Kashm el Girba, Sudan [SUDAN].
83. NEW HALFA SUGAR FACTORY COMPANY LIMITED (a.k.a. NEW HALFA SUGAR COMPANY), El Gamaa Street (Aljama Street), New Halfa, P.O. Box 511/3047, Khartoum, Sudan; Email Address *sukar@sudanmail.net* [SUDAN].
84. NEW KHARTOUM TANNERY, P.O. Box 17, Khartoum, Sudan [SUDAN].
85. NORTHWEST SENNAR SUGAR FACTORY, Northwest Sennar, Sudan [SUDAN].
86. OIL CORPORATION, P.O. Box 64, Khartoum, Sudan [SUDAN].
87. OMDURMAN SHOE FACTORY, Omdurman, Sudan [SUDAN].
88. PETROHELP PETROLEUM COMPANY LIMITED, Building No. 20, Street No. 42, Al Riyadh Area, P.O. Box 44690, Khartoum, Sudan [SUDAN].
89. PETROLEUM GENERAL ADMINISTRATION, P.O. Box 2649, Khartoum, Sudan [SUDAN].
90. PORT SUDAN COTTON AND TRADE COMPANY (a.k.a. PORT SUDAN COTTON COMPANY), P.O. Box 590, Khartoum, Sudan; P.O. Box 261, Port Sudan, Sudan [SUDAN].
91. PORT SUDAN DUTY FREE SHOP, Port Sudan, Sudan [SUDAN].
92. PORT SUDAN EDIBLE OILS STORAGE CORPORATION, P.O. Box 429, Port Sudan, Sudan [SUDAN].
93. PORT SUDAN REFINERY LIMITED, P.O. Box 354, Port Sudan, Sudan [SUDAN].
94. PORT SUDAN SPINNING FACTORY, Port Sudan, Sudan [SUDAN].
95. POSTS AND TELEGRAPHS PUBLIC CORPORATION, Khartoum, Sudan [SUDAN].
96. PUBLIC CORPORATION FOR BUILDING AND CONSTRUCTION, P.O. Box 2110, Khartoum, Sudan [SUDAN].
97. PUBLIC CORPORATION FOR IRRIGATION AND EXCAVATION, P.O. Box 619, Khartoum, Sudan; P.O. Box 123, Wad Medani, Sudan [SUDAN].
98. PUBLIC CORPORATION FOR OIL PRODUCTS AND PIPELINES, Khartoum, Sudan [SUDAN].
99. PUBLIC ELECTRICITY AND WATER CORPORATION (a.k.a. CENTRAL ELECTRICITY AND WATER CORPORATION), P.O. Box 1380, Khartoum, Sudan [SUDAN].
100. RABAK OIL MILL, P.O. Box 2105, Khartoum, Sudan [SUDAN].
101. RAINBOW FACTORIES, P.O. Box 1768, Khartoum, Sudan [SUDAN].
102. RAM ENERGY COMPANY LIMITED, Altiyadh Street 131/Almashtal Street, Block 12, House No. 87, P.O. Box 802, Khartoum, Sudan [SUDAN].
103. REA SWEET FACTORY, P.O. Box 1027, Khartoum, Sudan [SUDAN].
104. RED SEA HILLS MINERALS COMPANY, P.O. Box 1034, Khartoum, Sudan; c/o SUDANESE MINING CORPORATION, undetermined [SUDAN].
105. RED SEA STEVEDORING, P.O. Box 215, Khartoum, Sudan; P.O. Box 17, Port Sudan, Sudan [SUDAN].
106. REFRIGERATION AND ENGINEERING IMPORT COMPANY, P.O. Box 1092, Khartoum, Sudan [SUDAN].
107. ROADS AND BRIDGES PUBLIC CORPORATION, P.O. Box 756, Khartoum, Sudan [SUDAN].
108. SACKS FACTORY (a.k.a. PLASTIC SACKS FACTORY), P.O. Box 2328, Khartoum, Sudan [SUDAN].
109. SENNAR SUGAR COMPANY LIMITED, P.O. Box 511, Khartoum, Sudan; Email Address *sukar@sudanmail.net* [SUDAN].
110. SHEIKAN INSURANCE AND REINSURANCE COMPANY LIMITED (a.k.a. SHEIKAN INSURANCE COMPANY), Al Souq Al Arabi, Sheikan Building, Khartoum SU001, P.O. Box 10037, Khartoum, Sudan; Email Address *sheikan@sudanmail.net* [SUDAN].
111. SHEREIK MICA MINES COMPANY (a.k.a. SHERIEK MICA PROJECT), P.O. Box 1034, Khartoum, Sudan; c/o SUDANESE MINING CORPORATION, undetermined [SUDAN].
112. SILOS AND STORAGE CORPORATION, P.O. Box 1183, Khartoum, Sudan [SUDAN].
113. SPINNING AND WEAVING CORPORATION, P.O. Box 795, Khartoum, Sudan [SUDAN].
114. SRC (a.k.a. SUDAN RAILWAYS CORPORATION), P.O. Box 43, Bara, Sudan; Babanousa, Sudan; Khartoum, Sudan; Kosti, Sudan; Port Sudan, Sudan [SUDAN].
115. SRDC (a.k.a. SUDAN RURAL DEVELOPMENT COMPANY LIMITED), P.O. Box 2190, Khartoum, Sudan [SUDAN].
116. STATE CORPORATION FOR CINEMA, P.O. Box 6028, Khartoum, Sudan [SUDAN].
117. STATE TRADING COMPANY (a.k.a. STATE TRADING CORPORATION), P.O. Box 211, Khartoum, Sudan [SUDAN].
118. SUDAN ADVANCED RAILWAYS, Khartoum, Sudan [SUDAN].
119. SUDAN AIR (a.k.a. SUDAN AIRWAYS), P.O. Box 253, Khartoum, Sudan; Bahrain; Chad; Egypt; Ethiopia; Germany; Greece; Italy; Kenya; Kuwait; Nigeria; Saudi Arabia; Uganda; United Arab Emirates; United Kingdom; 211 East 43rd Street, New York, NY 10017, United States; 199 Atlantic Avenue, Brooklyn, NY 11201–5606, United States [SUDAN].
120. SUDAN COTTON COMPANY, Khartoum, Sudan [SUDAN].
121. SUDAN COTTON COMPANY LIMITED, P.O. Box 1672, Khartoum, Sudan [SUDAN].
122. SUDAN DEVELOPMENT CORPORATION, Street 21, P.O. Box 710, Khartoum, Sudan [SUDAN].
123. SUDAN EXHIBITION AND FAIRS CORPORATION, P.O. Box 2366, Khartoum, Sudan [SUDAN].
124. SUDAN GEZIRA BOARD (a.k.a. GEZIRA SCHEME), Khartum Gezira Scheme Building, 39th Street, P.O. Box 884, Khartoum, Sudan [SUDAN].
125. SUDAN MASTER TECHNOLOGY (a.k.a. GIAD INDUSTRIAL CITY; a.k.a. GIAD INDUSTRIAL GROUP; a.k.a. SUDAN MASTER TECH), SMT Building, Gamhuria Street, GIAD Industrial Complex, P.O. Box 10782, Khartoum, SU001, Sudan; Web site *www.sudanmaster.com;* Email Address *info@sudanmaster.com* [SUDAN].
126. SUDAN NATIONAL BROADCASTING CORPORATION (a.k.a. SUDAN RADIO & TV CORP.; a.k.a. SUDAN RADIO AND TV CORP.; a.k.a. SUDAN T.V. CORPORATION), P.O. Box 1094, Omdurman, Sudan [SUDAN].
127. SUDAN OIL CORPORATION, P.O. Box 2, Khartoum North, Sudan [SUDAN].
128. SUDAN OIL SEEDS COMPANY LIMITED, P.O. Box 167, Khartoum, Sudan; Nyala, Sudan; Obied, Sudan; Port Sudan, Sudan; Tandalty, Sudan [SUDAN].
129. SUDAN SOAP CORPORATION, P.O. Box 23, Khartoum North, Sudan [SUDAN].
130. SUDAN TEA COMPANY, LTD., P.O. Box 1219, Khartoum, Sudan [SUDAN].
131. SUDAN TELECOMMUNICATIONS COMPANY LIMITED (a.k.a. SUDATEL), 9th

Floor, Sudatel Tower, Nile Street, Khartoum, Sudan; Sudatel Tower, Al Horriya Street, P.O. Box 11155, Khartoum, Sudan; Web site *www.sudatel.net/en;* Email Address *info@sudatel.net* [SUDAN].

132. SUDAN WAREHOUSING COMPANY, P.O. Box 215, Khartoum, Sudan; P.O. Box 17, Port Sudan, Sudan; El Obeid, Sudan; Gedarit, Sudan; Juba, Sudan; Kosti, Sudan; Sennar, Sudan; Wad Medani, Sudan [SUDAN].

133. SUDANESE COMPANY FOR BUILDING AND CONSTRUCTION LIMITED, P.O. Box 2110, Khartoum, Sudan [SUDAN].

134. SUDANESE ESTATES BANK, Al-Baladiya Avenue, P.O. Box 309, Khartoum, Sudan [SUDAN].

135. SUDANESE FREE ZONES AND MARKETS COMPANY (a.k.a. SFZ), P.O. Box 1789, Khartoum, Sudan; Chad; Saudi Arabia; Turkey; United Arab Emirates [SUDAN].

136. SUDANESE INTERNATIONAL TOURISM COMPANY, P.O. Box 7104, Khartoum, Sudan; c/o TOURISM AND HOTELS CORPORATION, undetermined [SUDAN].

137. SUDANESE MINING CORPORATION, P.O. Box 1034, Khartoum, Sudan [SUDAN].

138. SUDANESE PETROLEUM CORPORATION, 7th Floor, Al Kuwaitiah Building, El Nile Street, Khartoum, Sudan [SUDAN].

139. SUDANESE REAL ESTATE SERVICES COMPANY, Khartoum, Sudan [SUDAN].

140. SUDANESE SAVINGS BANK, P.O. Box 159, Wad Medani, Sudan [SUDAN].

141. SUDANESE SUGAR PRODUCTION COMPANY LIMITED (a.k.a. SUDANESE SUGAR COMPANY), El Gamaa Street (Aljama Street), Opposite the Authority of Electricity Building, P.O. Box 511, Khartoum, Sudan; P.O. Box 511, Building No. 3-Block No. 7, Alshatte Gharb-Gammaa Avenue, Khartoum, Sudan; Email Address *sukar@sudanmail.net* [SUDAN].

142. SUDAPET LTD. (a.k.a. SUDAN PETROLEUM COMPANY LIMITED; a.k.a. SUDAPET), El Nil Street, Khartoum, Sudan [SUDAN].

143. SUGAR AND DISTILLING INDUSTRY CORPORATION (a.k.a. SUGAR AND DISTILLING CORPORATION), New Mustafa El Amin Building, Barlaman Avenue, P.O. Box 511, Khartoum, Sudan [SUDAN].

144. TAHEER PERFUMERY CORPORATION, P.O. Box 2241, Khartoum, Sudan [SUDAN].

145. TAHREER PERFUMERY CORPORATION, EL, Omdurman, Sudan [SUDAN].

146. TEA PACKETING AND TRADING COMPANY, P.O. Box 369, Khartoum, Sudan [SUDAN].

147. TOURISM AND HOTELS CORPORATION, P.O. Box 7104, Khartoum, Sudan; Ed Damer, Sudan; El Fasher, Sudan; Khartoum Airport, Sudan; Port Sudan, Sudan [SUDAN].

148. WAD MADANI DUTY FREE SHOP, Wad Madani, Sudan [SUDAN].

149. WAFRA CHEMICALS & TECHNO–MEDICAL SERVICES LIMITED (a.k.a. WAFRA CHEMICALS AND TECHNO–MEDICAL SERVICES LIMITED), Khartoum, Sudan [SUDAN].

150. WAFRA PHARMA LABORATORIES (a.k.a. WAFRA PHARMACEUTICALS; a.k.a. WAFRAPHARMA LABORATORIES), Main Street, P.O. Box 2032, Omdurman, Sudan; Email Address *waframed@sudanmail.net* [SUDAN].

151. WAU FRUIT AND VEGETABLE CANNING FACTORY, P.O. Box 110, Wau, Sudan [SUDAN].

152. WHITE NILE BATTERY COMPANY, Khartoum, Sudan [SUDAN].

153. WHITE NILE BREWERY, P.O. Box 1378, Khartoum, Sudan [SUDAN].

154. WHITE NILE TANNERY, P.O. Box 4078, Khartoum, Sudan [SUDAN].

155. NILE CEMENT COMPANY LIMITED, P.O. Box 1502, Khartoum, Sudan; Factories at Rabak, St. 45–47, Khartoum Extension, Sudan [SUDAN].

156. NILE CEMENT FACTORY, Rabak, Sudan; P.O. Box 1502, Khartoum, Sudan [SUDAN].

157. FARMERS COMMERCIAL BANK (f.k.a. FARMERS BANK FOR INVESTMENT & RURAL DEVELOPMENT; a.k.a. FARMERS BANK FOR INVESTMENT AND RURAL DEVELOPMENT; f.k.a. SUDAN COMMERCIAL BANK), P.O. Box 1116, El Kasr Avenue, Khartoum, Sudan; P.O. Box 22, El Damazin, Sudan; El Fau, Sudan; P.O. Box 182, El Gadaref, Sudan; P.O. Box 1, El Hawata, Sudan; P.O. Box 8, El Nuhud, Sudan; P.O. Box 412, El Obeid, Sudan; P.O. Box 45153, El Suk Elarabi, Sudan; P.O. Box 1174, Gamhoria Avenue, Khartoum, Sudan; P.O. Box 1694, El Suk Elafrangi, Khartoum, Sudan; P.O. Box 384, Khartoum, Sudan; P.O. Box 86, Industrial Area, Khartoum, Sudan; P.O. Box 8127, Khartoum, Sudan; P.O. Box 899, Omdurman, Sudan; Wad Madani, Sudan; P.O. Box 36, New Halfa, Sudan; P.O Box 570, Port Sudan, Sudan [SUDAN].

**John E. Smith,**

*Director, Office of Foreign Assets Control.*

[FR Doc. 2017–23090 Filed 10–25–17; 8:45 am]

**BILLING CODE 4810–AL–P**

## DEPARTMENT OF THE TREASURY

### Agency Information Collection Activities; Submission for OMB Review; Comment Request; Multiple Alcohol and Tobacco Tax and Trade Bureau Information Collection Requests

**AGENCY:** Departmental Offices, U.S. Department of the Treasury.

**ACTION:** Notice.

**SUMMARY:** The Department of the Treasury will submit the following information collection requests to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. The public is invited to submit comments on these requests.

**DATES:** Comments should be received on or before November 27, 2017 to be assured of consideration.

**ADDRESSES:** Send comments regarding the burden estimate, or any other aspect of the information collection, including suggestions for reducing the burden, to (1) Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for Treasury, New Executive Office Building, Room 10235, Washington, DC 20503, or email at *OIRA_Submission@OMB.EOP.gov* and (2) Treasury PRA Clearance Officer, 1750 Pennsylvania Ave. NW., Suite 8142, Washington, DC 20220, or email at *PRA@treasury.gov*.

**FOR FURTHER INFORMATION CONTACT:** Copies of the submissions may be obtained from Jennifer Leonard by emailing *PRA@treasury.gov,* calling (202) 622–0489, or viewing the entire information collection request at *www.reginfo.gov*.

**SUPPLEMENTARY INFORMATION:**

### Alcohol and Tobacco Tax and Trade Bureau (TTB)

*Title:* Schedule of Tobacco Products, Cigarette Papers, or Tubes Withdrawn from the Market.

*OMB Control Number:* 1513–0034.

*Type of Review:* Extension without change of a currently approved collection.

*Abstract:* As provided by the IRC at 26 U.S.C. 5705, a manufacturer or importer is allowed credit or refund of the Federal excise tax paid on tobacco products, cigarette papers, or cigarette tubes withdrawn from the market when satisfactory proof of the withdrawal is provided to the Secretary. Under this authority, the TTB regulations prescribe the use of TTB F 5200.7 by manufacturers or importers to identify tobacco products, cigarette papers, or cigarette tubes to be withdrawn from the market and the location of those articles. The form also documents the taxpayer's planned disposition of the articles (destroyed, reduced to materials, or returned to bond), and TTB's decision to witness or not witness that disposition. Taxpayers file a completed TTB F 5200.7 to support their subsequent claim for credit or refund of the excise taxes paid on the withdrawn articles. The information collected on the form is necessary to protect the revenue; it provides TTB with certain information needed to determine whether a claim is valid.

*Form:* TTB F 5200.7.

*Affected Public:* Businesses or other for-profits.

*Estimated Total Annual Burden Hours:* 188.

*Title:* Tobacco Products Manufacturers—Supporting Records for

Removals for the Use of the United States.

*OMB Control Number:* 1513–0069.

*Type of Review:* Extension without change of a currently approved collection.

*Abstract:* Tobacco products and cigarette papers and tubes manufactured in or imported into the United States are subject to a Federal excise tax under the IRC at 26 U.S.C. 5701. However, pursuant to 26 U.S.C. 5704(b), manufacturers of tobacco products or cigarette papers and tubes may remove such articles, without payment of tax, ''for use of the United States'' under such regulations as the Secretary shall prescribe. In addition, under 26 U.S.C. 5741, all manufacturers and importers of tobacco products or cigarette papers and tubes are required to keep such records in such manner as the Secretary of the Treasury prescribes by regulation. Under these authorities, the TTB regulations require manufacturers to keep records related to the removals of tobacco products or cigarette papers or tubes for use of the United States, including the date of removal, the name and address of the Federal agency to which the products are shipped or delivered, the kind and quantity of products removed and, for large cigars, the sale price. Records must also be kept detailing any items removed for use of the United States and returned to the manufacturer. The required records are necessary to protect the revenue and prevent diversion of tobacco products by ensuring that the tax exemption is applied only to products that are delivered to a Federal agency for government use.

*Form:* None.

*Affected Public:* Businesses or other for-profits.

*Estimated Total Annual Burden Hours:* 205.

*Title:* Marks and Notices on Packages of Tobacco Products.

*OMB Control Number:* 1513–0101.

*Type of Review:* Extension without change of a currently approved collection.

*Abstract:* The IRC at 26 U.S.C. 5723(b) requires certain marks and notices be placed on packages of tobacco products and cigarette papers and tubes before removal. Under this authority, the TTB regulations require that packages of domestically manufactured or imported tobacco products bear certain marks to identify the product, its excise tax class, and the quantity or weight of the product, depending on the basis of the tax. The TTB regulations also require certain notices on packages of such articles intended for export or use of the United States. Tobacco products and cigarette papers and tubes for export or use of the United States are removed without payment of tax (or are exported after tax payment with benefit of drawback of the taxes paid), and the required notices on such packages (or shipping containers, under some circumstances) are intended to ensure the product is readily identifiable in order to prevent diversion of the products into the domestic market.

*Form:* None.

*Affected Public:* Businesses or other for-profits.

*Estimated Total Annual Burden Hours:* 1.

*Title:* Labeling of Major Food Allergens and Petitions for Exemption.

*OMB Control Number:* 1513–0121.

*Type of Review:* Revision of a currently approved collection.

*Abstract:* The Federal Alcohol Administration Act (FAA Act) at 27 U.S.C. 205(e) authorizes the Secretary to issue regulations regarding the labeling of wine, distilled spirits, and malt beverages in order to, among other things, prohibit consumer deception and ensure that labels provide consumers with adequate information as to the identity and quality of such products. Under this authority, the TTB regulations allow for the voluntary labeling of major food allergens (as defined in the Food Allergen Labeling and Consumer Protection Act of 2004 (118 Stat. 905)) used in the production of alcohol beverages. The regulations require that, if any one major food allergen is voluntarily declared, all major food allergens used in the product must be declared, except when TTB has approved a petition for exemption from such labeling. This information collection includes the labeling of allergens and petitions for exemption.

*Form:* None.

*Affected Public:* Businesses or other for-profits.

*Estimated Total Annual Burden Hours:* 527.

**Authority:** 44 U.S.C. 3501 *et seq.*

Dated: October 20, 2017.

**Spencer W. Clark,**

*Treasury PRA Clearance Officer.*

[FR Doc. 2017–23221 Filed 10–25–17; 8:45 am]

**BILLING CODE 4810–31–P**

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Part II

## Department of Justice

Drug Enforcement Administration

Lon F. Alexander, M.D.; Decision and Order; Notice

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

**[Docket No. 16–17]**

### Lon F. Alexander, M.D.; Decision and Order

On February 4, 2016, the Deputy Assistant Administrator, of the then Office of Diversion Control, issued an Order to Show Cause to Lon F. Alexander, M.D. (hereinafter, Respondent), of Hattiesburg, Mississippi. ALJ Ex. 1, at 1. The Show Cause Order proposed the denial of Respondent's application for a DEA Certificate of Registration as a practitioner, on the ground that his ''registration is inconsistent with the public interest.'' *Id.* (citing 21 U.S.C. 823(f)).

As for the Agency's jurisdiction, the Show Cause Order alleged that Respondent had previously held a registration which he surrendered for cause on January 16, 2014. *Id.* The Order further alleged that on January 9, 2015, Respondent applied for a new registration as a practitioner in schedules II through V, at the proposed registered address of 36 Bridgefield Turn, Hattiesburg, Mississippi. *Id.*

As for the substantive grounds for the proceeding, the Show Cause Order raised multiple allegations to the effect that, on numerous occasions in 2011 through 2013, Respondent violated federal and state law by issuing controlled substance prescriptions to his wife ''that were nontherapeutic, were for other than a legitimate medical purpose, and were issued outside of the usual course of [his] professional practice.'' *Id.* at 1–3. The Show Cause Order alleged that Respondent ''repeatedly issued'' prescriptions for schedule IV controlled substances which included zolpidem tartrate, alprazolam, and diazepam, ''when she was concurrently being issued prescriptions for the same or similar class of drugs by her own psychiatrist, which [he] did without [the] psychiatrist's knowledge or permission.'' *Id.* The Order further alleged that Respondent's ''actions dramatically increased the chances of [his] wife's dependency, overdose, or diversion of those controlled substances, while also potentially complicating her psychiatric condition.'' *Id.* (citing 21 CFR 1306.04; Miss. Admin. Code Part 2640, Ch. 1, r. 1.7, 1.10, and 1.16; Miss. Code Ann. Sec. 73–25–29(3) & (13)).[1]

The Show Cause Order also alleged that on various occasions from 2011 through 2013, Respondent violated federal and state law by issuing his wife prescriptions for hydrocodone, then a schedule III narcotic, as well as other controlled substances, which were also nontherapeutic, for other than a legitimate medical purpose, and were outside the usual course of professional practice. *Id.* at 2–3. Specifically, the Show Cause Order alleged that ''[o]n at least one occasion in 2011,'' Respondent issued prescriptions for hydrocodone and diazepam ''to [his] wife concurrently with another prescription [for clonazepam] issued by her . . . psychiatrist,'' and that he did so ''without her psychiatrist's knowledge or permission.'' *Id.* at 2. The Order again alleged that Respondent's ''actions dramatically increased the chances of [his] wife's dependency, overdose, or diversion of . . . controlled substance[s], while also potentially complicating her psychiatric condition.'' *Id.* (citing same authorities as above).

Next, the Show Cause Order alleged additional instances of non-therapeutic prescribing by Respondent to his wife in that, ''[o]n at least four different occasions in 2013,'' he ''repeatedly issued . . . prescriptions for hydrocodone . . . zolpidem tartrate . . . and alprazolam . . . when she was concurrently being issued other controlled substances prescriptions for the same or similar drugs, as well as amphetamines, by her . . . psychiatrist, which [he] did without his knowledge or permission.'' *Id.* at 2–3. As with the previous allegations, the Order alleged that Respondent's ''actions dramatically increased the chances of her dependency, overdose, or diversion of those controlled substances, while also potentially complicating her psychiatric condition.'' *Id.* at 3 (citing same authorities as above).

The Show Cause Order also alleged that ''[o]n at least fifteen different occasions between 2011 and 2013, [Respondent] violated state and federal law by issuing'' to his wife prescriptions for hydrocodone, and/or zolpidem, and/or alprazolam, ''without conducting any examination of [his] wife (or documenting such in her file) or noting the . . . prescriptions in her patient chart.'' *Id.* (citing same authorities as above). The Show Cause Order then alleged that ''[o]n at least nine occasions between 2011 and 2013, [Respondent] violated state and federal law by issuing'' to his wife prescriptions for these drugs, ''without conducting sufficient examinations of [her] (or documenting such in her file).'' *Id.* (citing same authorities as above).

Finally, the Show Cause Order alleged that Respondent ''engaged in conduct which may threaten public health and safety . . . by attempting to mislead DEA investigators.'' *Id.* (citing 21 U.S.C. 823(f)(5)). Specifically, the Government alleged that, ''on February 2, 2016, [Respondent] turned over to DEA in response to an administrative subpoena a record purporting to be the patient file'' of his wife. *Id.* The Order alleged that the file ''contained false entries'' in that it contained ''repeated reference to conversations with and attempts to contact [his wife's] treating psychiatrist'' and that ''DEA's investigation . . . indicate[s] that these statements and others presented as part of the purported patient file are false.'' *Id.*

Following service of the Show Cause Order, Respondent, through his counsel, requested a hearing on the allegations. ALJ Ex. 2. The matter was placed on the docket of the Office of Administrative Law Judges and assigned to ALJ Charles Wm. Dorman. Following pre-hearing procedures, the ALJ conducted an evidentiary hearing in Jackson, Mississippi on June 29–30, 2016, at which both parties elicited testimony from witnesses and submitted various documents for the record. Following the hearing, both parties submitted briefs of their proposed findings of fact, conclusions of law, and argument.

On September 20, 2016, the ALJ issued his Recommended Decision. Therein, with respect to Factors Two (Respondent's experience in dispensing controlled substances) and Four (compliance with applicable laws related to controlled substances), the ALJ found that the Government had proved that Respondent violated 21 CFR 1306.04, Mississippi Code Sec. 73–25–29(3) and 73–25–29(13), as well as Mississippi Administrative Rules 1.7, 1.10, and 1.16 when he issued numerous controlled substance prescriptions to his wife.

Specifically, the ALJ found that during 2011, Respondent issued nine zolpidem, two alprazolam, seven hydrocodone, and one diazepam prescription(s) in violation of these provisions. R.D. at 39–40. The ALJ also found that during 2012, Respondent issued five alprazolam prescriptions, and that during 2013, he issued 11 alprazolam prescriptions in violation of these provisions. *Id.* at 41–43. The ALJ further found that in 2013, Respondent issued five hydrocodone prescriptions and one zolpidem prescription in violation of these provisions. *Id.* at 44.

In addition to the above, the ALJ found that between 2011 and 2013,

[1] *See also* ALJ Ex. 1, at ¶¶ 5–6.

Respondent prescribed hydrocodone 11 times, zolpidem 12 times, and alprazolam five times without documenting the prescriptions or a prior examination in his wife's patient file in violation of various provisions of Mississippi law and administrative rules. *Id.* at 46. He also found that on nine occasions when Respondent did document a prescription in his wife's file, he failed to include information required by state rules such as a medical history, examination results, or a diagnosis. *Id.* at 47–48 (citing Miss. Admin. Rule 1.4). The ALJ further concluded that ''nothing in . . . Respondent's file for his wife necessarily indicates that [he] ever conducted any type of physical or mental status examination of his wife prior to prescribing controlled substances to her.'' *Id.* at 48. He thus found proved the ''allegation that the Respondent failed to conduct examinations and/or lacked adequate documentation of examinations of his wife'' in violation of various provisions of Mississippi law and administrative rules. *Id.* at 49.

Turning to Factor Five (such other conduct which may threaten public health or safety), the ALJ rejected the allegation that Respondent attempted to mislead DEA investigators by providing to them the patient file containing false entries to the effect that he had made his wife's psychiatrist aware of the prescriptions. *Id.* at 49–52. The ALJ reasoned that it appeared that Respondent created the file ''as he was treating his wife,'' that he ''did nothing more than turn over his file when ordered to do so by the . . . subpoena,'' and that there was ''[n]o evidence . . . that, after the DEA subpoenaed the file, [he] created false entries or altered the file he already maintained.'' *Id.* at 51.

The ALJ nonetheless concluded that ''Factors Two and Four weigh substantially in favor of denying . . . Respondent's application because he prescribed controlled substances to his wife for illegitimate and nontherapeutic purposes, outside the scope of professional practice, and because he did not appropriately document examinations of, any prescriptions to, his wife.'' *Id.* at 52. The ALJ thus found ''that the Government has made a *prima facie* case . . . that the Respondent's registration would be inconsistent with the public interest.'' *Id.*

The ALJ acknowledged that ''[t]o rebut the Government's *prima facie* case, the Respondent must both accept responsibility for his actions and demonstrate that he will not engage in future misconduct.'' *Id.* (citation omitted). The ALJ explained that a ''[a] respondent *must* express remorse for all acts of documented misconduct, and *may* be required to acknowledge the scope of his misconduct.'' R.D. 52 (citations omitted); *see also id.* at 54. The ALJ also explained that ''[a]cceptance of responsibility and remedial measures are assessed in the context of the egregiousness of the violations and the [DEA's] interest in deterring similar misconduct by [the] Respondent in the future as well as on the part of others.'' *Id.* at 52 (internal quotations and citations omitted).

The ALJ concluded that ''Respondent's misconduct was egregious'' in that he ''repeatedly and wrongfully prescribed addictive, dangerous, and potentially harmful controlled substances to his wife for approximately three years,'' which ''interfered with his wife's treatment and could have caused her to overdose, lose consciousness, or die.'' *Id.* at 53. The ALJ nonetheless concluded that Respondent had accepted responsibility for his misconduct in prescribing outside the usual course of practice because, by ''[s]imply acknowledging that he failed to properly document his treatment of his wife, [he] admitted to practicing outside the usual scope of professional practice.'' *Id.* at 54.

The ALJ also acknowledged Respondent's testimony ''that he did not think that his actions increased his wife's chances of dependency, overdose, or diversion,'' and that ''[t]he Government's argument that that Respondent did not accept responsibility for putting his wife at risk is also understandable.'' *Id.* The ALJ reasoned, however, that ''a respondent is not required to admit to every single component of an allegation in order to accept responsibility.'' *Id.* The ALJ then noted that in a proceeding before the Mississippi Board, ''Respondent acknowledged that his prescriptions were probably hurting his wife and keeping her from getting appropriate treatment.'' *Id.*

As for the Government's contention that Respondent did not specifically acknowledge his misconduct in ''failing to conduct examinations and/or conduct insufficient examinations prior to issuing'' the prescriptions, the ALJ noted that this ''is technically correct.'' *Id.* at 54–55. The ALJ, however, rejected the Government's contention, reasoning that ''the Government overlooks the central concern of this case, which is that the Respondent wrote prescriptions for his wife when he should not have.'' *Id.* at 55. The ALJ then explained that ''[i]n his view, the Respondent's acceptance of responsibility for failing to examine his wife before writing her a prescription is subsumed in his general acceptance of responsibility.'' *Id.*

While the ALJ acknowledged that Respondent declined ''to admit that he violated federal laws because he did not want to speculate on what statutes he might have violated'' and ''testif[ied] that he did not know whether the prescriptions were outside the scope of his professional practice as the DEA defines those terms,'' the ALJ reasoned that Respondent was not required to ''identify the specific federal code provisions he violated, or interpret federal laws and apply them to his circumstances.'' *Id.* at 56. The ALJ further explained that he found Respondent's remorse to be ''sincere and that his commitment to adhere to all regulations governing controlled substances is genuine.'' *Id.* at 56–57.

The ALJ further found that Respondent had undertaken ''reasonable and appropriate'' remedial measures. *Id.* at 59. As for the Agency's interest in specific deterrence, the ALJ suggested that it ''might be negligible,'' reasoning that Respondent ''thoroughly understands that if he engages in any further misconduct he will face immediate sanctions from the'' Physicians Health Program and the State Board ''that will end his medical career.'' *Id.* at 59. And while the ALJ noted that ''Respondent's conduct was egregious,'' he reasoned that the circumstances were unique because ''every allegation of misconduct . . . involved . . . Respondent prescribing to only his wife.'' *Id.* at 60. The ALJ then explained that Respondent's testimony in a State Board proceeding to the effect that his prescribing ''was not a matter of judgment but a matter of the heart[] merits some consideration.'' *Id.* The ALJ thus recommended that Respondent's application be granted subject to various conditions. *Id.* at 61–62.

The Government filed Exceptions to the Recommended Decision. In its Exceptions, the Government contended that the ALJ committed error in concluding that Respondent has sufficiently accepted responsibility for his misconduct. Exceptions, at 3–15. The Government also contended that the ALJ committed error in concluding that Respondent is entitled to a new registration notwithstanding the egregiousness of his misconduct. *Id.* at 16–20. The Government thus argues that I should deny Respondent's application. *Id.* at 20. Respondent did not file a response to the Government's Exceptions.

Thereafter, the ALJ forwarded the record to me for final agency action. Having considered the record in its

entirety including the Recommended Decision, the parties post-hearing briefs and the Government's Exceptions, I adopt the ALJ's findings of fact (while making several additional findings as to prescriptions) and legal conclusions with respect to paragraphs two through ten of the Show Cause Order. I conclude, however, that the Government's Exception to the ALJ's legal conclusion that Respondent has sufficiently accepted responsibility for his misconduct is well taken. Accordingly, I deny his application. I make the following factual findings.

**Findings of Fact**

*Respondent's Registration and Licensure Status*

Respondent is a neurosurgeon licensed by the Mississippi State Board of Medical Licensure. R.D. 3 (citing Stipulation of Fact No. 4); Tr. 481–82. Respondent also previously held a DEA Certificate of Registration, pursuant to which he was authorized to dispense schedule II through V controlled substances as a practitioner. GX 1, at 1. However, on January 17, 2014, Respondent surrendered this registration for cause. *Id.* According to Respondent, he agreed to surrender his registration at the time of the State Board hearing that suspended his medical license. Tr. 485. On January 9, 2015, Respondent applied for a new practitioner's registration seeking authority to dispense controlled substances in schedules II through V, at a registered address in Hattiesburg, Mississippi. R.D. 3 (citing Stipulation of Fact No. 1).

In 2008, Respondent referred himself to the Betty Ford Center, ''when [he] realized [he] had a problem with prescription medicines'' and spent 90 days in treatment. Tr. 487. According to Respondent, ''[o]nce [he] went to the Betty Ford Center, [he] disclosed to the MPHP [Mississippi Physician's Health Program] and ultimately the [B]oard of [M]edicine that [he] was now a participant.'' *Id.* at 488.

In May 2008, Respondent entered into a Recovery Contract Agreement (hereinafter, recovery contract, contract, or RCA) with the MPHP. GE 14, at 13. The RCA's terms included that he completely abstain from mood-altering addictive substances, that he not treat himself or his family, that he undergo random drug screens, and that he be honest. *Id.; see also* R.D. at 4.[2]

In March 30, 2012, Respondent tested positive for Tramadol. He then returned to the Betty Ford Center for one month, after which he was discharged with a diagnosis of opioid dependence. GE 14, at 14–16. The MPHP did not, however, withdraw its advocacy on his behalf, and on June 11, 2012, Respondent entered into a new RCA which contained the same terms as the previous RCA, including the prohibition on prescribing to family members. *Id.* at 16–17.

On September 10, 2012, Respondent met with the Mississippi Professionals Health Committee due to its concerns that he had ''missed callings for random drugs screens,'' had failed to attend Caduceus meetings, failed to continued his aftercare therapy, failed to pay his bill for the drug screen testing, and had ''fail[ed] to turn in his support group attendance records.'' *Id.* at 19–20. According to Dr. Hambleton's testimony at the second State Board hearing, the committee ''warned [Respondent] very carefully that any future noncompliance would result in [the] potential loss of [the] MPHP['s] advocacy'' and ''that this was really his last chance to demonstrate that he could do what was necessary to prove that he's safe.'' *Id.*

While Respondent was compliant with the issues raised by the committee, the committee was unaware that Respondent had been violating his RCA by writing controlled substance prescriptions for his wife. *Id.* at 20–21. According to Dr. Hambleton, he did not know that Respondent had been calling in controlled substance prescriptions for his wife until the State Board informed him on October 7, 2013. *Id.* Dr. Hambleton also testified in the State Board proceeding that Respondent did not disclose this information to his ''treatment providers at Betty Ford, to our committee, or [to] our staff at MPHP.'' *Id.*

On October 15, 2013, the MPHP, having concluded that Respondent's ''continued practice of medicine represent[ed] a definite threat to the public health'' withdrew its advocacy on behalf of Respondent. GE 14, at 23. Eight days later, the Board issued Respondent an order of prohibition which barred him from practicing medicine until further notice. GE 13, at 5.

Thereafter, Respondent was charged with two counts of violating the State's Medical Practice Act, including violating an existing Board Order, Stipulation or Agreement, *see* Miss. Code Ann. Sec. 73–25–29(13), and engaging in unprofessional conduct, by engaging in dishonorable or unethical conduct. GE 14, at 5; *see also* Miss. Code Ann. Sec. 73–25–29(8)(d) (unprofessional conduct includes ''[b]eing guilty of any dishonorable or unethical conduct likely to deceive, defraud or harm the public'').

On January 16, 2014, the Board held a hearing on the allegations at which Respondent appeared. As the record of the hearing shows, the allegations were based on Respondent's violations of his RCA, particularly in his prescribing of controlled substances to his wife. Also at issue was his lack of honesty in failing to disclose his prescribing to his treatment providers as well as the MPHP committee and the MPHP's staff. GE 14, at 21.

Following the hearing, the Board found Respondent guilty on both counts and suspended his medical license for one year, after which he was entitled to petition the Board for reinstatement of his license. *Id.* at 91. The Board ordered that he ''successfully complete multidisciplinary treatment at a treatment facility approved in advance by the MPHP,'' as well ''establish a provisional contract [and] take those steps necessary to obtain affiliation and advocacy with the MPHP.'' GE 13, at 7–8.

On January 15, 2015, Respondent appeared before the Board seeking reinstatement. At the hearing, Dr. Hambleton (the MPHP Medical Director) testified in support of Respondent's petition, stating that he ''complied with all of our requirements and he's begun the treatment process at Acumen.'' *Id.* at 13. Dr. Hambleton further expressed his ''belief . . . that he will comply with his contract.'' *Id.* At the conclusion of the testimony, the Board reinstated Respondent's medical license. *Id.* at 15.

**The DEA Investigation**

At some point not clearly established on the record, a DEA Diversion Investigator (DI) assigned to the Jackson, Mississippi office opened an investigation into Respondent's

[2] The ALJ noted that these facts, which are based on the testimony of Dr. Hambleton, the Director of the MPHP, at Respondent's January 15, 2015 Board Hearing, are ''*not* necessarily proven by a preponderance of the evidence.'' R.D. 4. The Director was, however, placed under oath in the State Board proceeding. GE 14, at 11. He also testified in this proceeding and explained that with the exception of its duration, the terms of Respondent's current RCA (which ''is his fourth contract'') are the same as they were for his previous contracts. Tr. 452. Notably, his current contract requires that, ''[o]ther than cases of medical emergencies, I agree to abstain from the use of any mood-altering, addictive, or potentially addictive prescription medication, including amphetamine preparations, without written permission from MPHP.'' RX C, at 2. The RCA's terms also state that ''I agree not to prescribe, dispense or administer to family members or myself any drug having addiction-forming or addiction-sustaining liability.'' *Id.*

prescribing practices.[3] Tr. 31, 90. As the DI explained, Respondent's ''history with the Medical Board . . . gave us pause, so we began an investigation into . . . his prescribing habits.'' *Id.* The DI testified that he had access to the Board's investigation, Tr. 22 & 32, and obtained reports from the State's Prescription Monitoring Program showing Respondent's controlled substance prescribing. *Id.* at 22–23. Specifically, the DI obtained a ''Prescriber Activity Report'' showing Respondent's prescriptions from January 1, 2011 through December 31, 2013. Tr. 24; GX 10. The DI also obtained a PMP report using the various names of Respondent's wife for the same period. Tr. 29; GX 11. Of note, however, GX 10 contains a number of prescriptions which Respondent issued to his wife which are not listed on GX 11.[4]

In reviewing the PMP reports, the DI found it suspicious that Respondent was prescribing controlled substances to his wife as ''she was seeing a psychiatrist, Dr. Mark Webb, during that timeframe.'' Tr. 30. The DI ''noticed multiple prescriptions'' which Respondent authorized for drugs that his wife ''was receiving'' from Dr. Webb. *Id.* at 31. The DI further explained that he was ''aware that [Respondent] was married to . . . Ms. Alexander, so [I] knew there was a pretty good assumption that he was aware that she was receiving these medications, because she had seen Dr. Webb for such a long time.'' *Id.* at 32. According to the DI, during a phone conversation with Respondent's wife ''[s]he advised that she needed the medications'' and that Respondent had written ''her some prescriptions, but that she didn't feel like that was a problem.'' *Id.* at 33. Respondent's wife also told the DI that ''she didn't know if her husband had patient files . . . for her [but] that he did prescribe some prescriptions to her.'' [5] *Id.* at 34.

Thereafter, the DI visited Dr. Webb and ''asked him if he was aware'' that Respondent's wife was ''receiving these prescriptions from'' Respondent. *Id.* Dr. Webb ''said that he was not'' and asked the DI to ''look into it further.'' *Id.* Following the visit, the DI served a subpoena on Dr. Webb and obtained his patient file for Respondent's wife. *Id.* at 35; GX 3, at 1–2. Dr. Webb's file for Respondent's wife was entered into evidence as GX 5. Tr. 68–75.

The DI also obtained some of ''the hard copy prescriptions from several different pharmacies throughout'' the State.[6] Tr. 35–36. The DI presented the prescriptions to Dr. Webb and asked him: ''were these authorized? Did you know?'' *Id.* at 36. Dr. Webb ''again maintained that he did not'' know about the prescriptions. *Id.*

The DI also served a subpoena on Respondent for ''[a]ny and all charts, files and/or documents, written, typed or computerized, relating to'' his wife. GX 4, at 1. A ten-page exhibit of Respondent's Medical Progress Notes for his wife was entered into evidence as GX 6. Tr. 67.

*Dr. Webb's Testimony*

The Government called Dr. Mark Webb as a fact witness. Dr. Webb testified that he has practiced psychiatry in Mississippi since 1990 and that Respondent's wife has been his patient since November 2000. *Id.* at 102, 105. Dr. Webb acknowledged that he prescribes both controlled and non-controlled substances and that for most of the patients who are treated with controlled substances, he prescribes only ''two weeks' worth of medications'' so that ''it's a tighter leash.'' *Id.*

According to Dr. Webb, he has ''known [Respondent] for a long time'' and the two ''referred patients back and forth in the 90s and the early 2000[s].'' *Id.* at 110. Dr. Webb testified that he saw Respondent's wife at his request. *Id.* He also testified that during the 2011 through 2013 period, his medication regimen for Respondent's wife was to prescribe ''an anti-depressant,'' an Attention Deficit Disorder (ADD) medication such as Adderall XR, a sleeping medication such as Ambien or Restoril, and an anxiety medication such as Xanax or Clonazepam. *Id.* at 204.

Dr. Webb testified that while he and Respondent ''talked a lot in the 90s and the early 2000s,'' they have ''talked less and less over the last 10 years.'' *Id.* at 110. Dr. Webb testified that his records show that he had talked to Respondent ''about four times'' in the period from January 2011 to December 2013. *Id.* at 111; *see also* GX 7, at 1 (memo prepared by Dr. Webb memorializing meeting with DEA noting that he had talked with Respondent on Dec. 20, 2011, Feb. 20, 2012, Sept. 4, 2012, and Aug. 5, 2013).

According to Dr. Webb, Respondent ''would call me whenever he felt [his wife] was in a crisis . . . to give me that information and to . . . garner some help from me to her.'' Tr. 110. Dr. Webb testified that he never had a discussion with Respondent about the latter's prescribing controlled substances to his wife. *Id.; see also id.* at 138. When then asked if Respondent had contacted him and told him that he had prescribed because his wife had ''run out'' and ''need[ed] some'' medication on a temporary basis, Dr. Webb answered ''no'' and explained that ''that would not make a lot of sense,'' because he (Dr.Webb) ''would be the person authorized that needed to call that in.'' *Id.* at 111. While Dr. Webb testified that there was an instance during which he ''walked out to the car with [Respondent's wife] . . . and [Respondent] was in the car with their newborn son,'' and they ''chit-chatted [for] two seconds,'' there was no discussion of Respondent's prescribing of controlled substances to his wife. *Id.* at 111–12; *see also* R.D. 16 (ALJ Finding of Fact No. 28). Dr. Webb also testified that he did not have a conversation with Respondent's wife about Respondent's prescribing to her until either late in 2015 or 2016. Tr. 174–75.

Dr. Webb testified that DEA Investigators showed him the ten pages of notes Respondent created with respect to the prescriptions he issued for his wife and that he compared them with the patient file he maintained on Respondent's wife. *Id.* at 116. However, ''none of'' the dates in the records created by Respondent ''correspond[ed] to [Dr. Webb's] treatment records.'' *Id.* at 16 (quoting GX 9 (memo created by Dr. Webb re: Feb. 25, 2016 meeting with DEA)). In his testimony, Dr. Webb adhered to his statement in the memo that he ''did not speak to [Respondent] on these times in question and certainly would not have authorized him to call in medication for my patient.'' GX 9; Tr. 117. As he testified, ''[t]here's no reason for somebody else to call in the

[3] Earlier in his testimony, the DI stated that the investigation was prompted by Respondent's 2015 application. Tr. 31. Yet later in his testimony, the DI stated that the case was opened earlier, after the Board provided DEA ''with documentation regarding his history with them.'' Tr. 90. The DI explained that ''[w]hen we obtain information from the Medical Board, whether or not somebody's applied for a DEA license or not, we have to document that information . . . the different allegations that the Board has made[,] or evidence that they may have against a physician.'' *Id.* at 90–91.

[4] According to the DI, when calling in the prescriptions, Respondent used ''several different variations of'' his wife's name. Tr. 38.

[5] According to the DI, during this conversation, he told Respondent's wife (who holds a DEA registration as a Nurse Practitioner) that she appeared to be obtaining controlled substances ''from multiple doctors, including her husband'' and that he ''would potentially be asking her to surrender her DEA license because of that.'' Tr. 33–34. The DI testified that shortly after this conversation, he was contacted by Respondent's counsel, who advised that he was also representing Respondent's wife and was told ''not to contact her anymore unless there, you know.'' *Id.* at 34. The DI did not clarify what conditions Respondent's counsel asserted during this conversation. *Id.* The DI did not subsequently speak to Respondent's wife. *Id.*

[6] According to the DI, he provided the pharmacies with the prescription numbers, Respondent's wife's name, and her date of birth. Tr. 38.

prescriptions. That's my job.'' Tr. 117. Subsequently, Dr. Webb reiterated that he did not authorize Respondent to issue any prescriptions to his wife during the relevant time frame. *Id.* at 119.

*Respondent's Prescriptions for His Wife*

The evidence shows that between January 1, 2011 and October 14, 2013 (when his medical license was suspended), Respondent issued the following controlled substances prescriptions for his wife.[7]

1. January 9, 2011, eight tablets of alprazolam (Xanax) 1 mg, one tablet to be taken twice day, a four-day supply. GE 10, at 85; GE 11, at 14; GE 29, at 1–2. The record does not establish when Dr. Webb had last prescribed alprazolam to Respondent's wife.[8] Respondent did not document the prescription in the patient file he maintained for his wife. *See generally* GE 6. Nor did he inform Dr. Webb that he had issued the prescription.

2. January 31, 2011, 30 tablets of zolpidem tartrate (Ambien) 10 mg, a 15-day supply. GE 10, at 19; GE 11, at 14. Notably, on January 8, 2011, Respondent's wife had refilled a prescription issued by Dr. Webb on August 31, 2010 for 60 tablets, this being a 30-day supply. GE 11, at 14. Thus, if taken as directed, the refill of Dr. Webb's prescription should have last Respondent's wife until February 7, 2011. On February 3, 2011 (only three days later), Dr. Webb prescribed 60 units of zolpidem 10 to Respondent's wife. GE 11, at 13. GE 5, at 112. Respondent did not document the prescription in the patient file he maintained for his wife. GE 6. Nor did he inform Dr. Webb that he issued the prescription.

3. February 7, 2011, 20 tablets of hydrocodone/acetaminophen (Lorcet) 7.5–650, a three-day supply. GE 10, at 23; GE 11, at 13; *see generally* Tr. 373–74 (testifying that her husband prescribed hydrocodone for her once in 2011). Other than on one occasion in June/July 2013, which is discussed below, Dr. Webb did not prescribe hydrocodone to Respondent's wife. Moreover, the PMP report does not list any hydrocodone prescriptions that were issued by any other provider until November 30, 2011. GE 11, 11. Respondent did not document this prescription in the patient file he maintained on his wife. *See generally* GE 6. He also did not disclose the prescription to Dr. Webb.

4. March 30, 2011, 30 tablets of zolpidem tartrate (Ambien) 10 mg, with a dosing instruction of one tablet at bedtime but ''may repeat for early,'' a 15–30-day supply. GE 10, at 85; GE 11, at 13; GE 30, at 1–2. Notably, the zolpidem prescription which Dr. Webb issued on February 3, 2011 (RX #949559) provided for multiple refills, as it was refilled by Respondent's wife on April 9, 2011, May 23, 2011, and July 7, 2011. GE 11, at 13; Tr. 254–55. Respondent did not document the prescription in the patient file he maintained on his wife. GE 6. Nor did he inform Dr. Webb that he issued the prescription.

5. April 8, 2011, 15 tablets of hydrocodone/acetaminophen (Lorcet) 10–650, one tablet every six hours as needed, a three-day supply. GE 10, at 85; GE 11, at 13; GE 31, at 1–2. As explained above, other than in June/July 2013, Dr. Webb did not prescribe this drug to Respondent's wife, and no other physician prescribed hydrocodone to her until November 30, 2011. Respondent did not document the prescription in the patient file. GE 6. He also did not disclose the prescription to Dr. Webb.

6. May 6, 2011, 30 tablets of zolpidem tartrate (Ambien) 10 mg, one tablet at bedtime but ''may repeat,'' a 30-day supply. GE 10, at 85; GE 11, at 13; GE 32, at 1–2. As discussed above, Respondent's wife still had refills available for 60 dosage units based on the prescription issued by Dr. Webb on February 3, 2011, and eventually refilled the prescription on May 23, 2011. GE 11, at 13; Tr. 255. Respondent did not document the prescription in the patient file. *See generally* GE 6. Nor did he disclose the prescription to Dr. Webb.

7. May 14, 2011, 14 tablets of hydrocodone/acetaminophen (Lorcet) 10–650, a two-day supply. GE 10, at 19; GE 11, at 13. As explained above, other than in June/July 2013, Dr. Webb did not prescribe this drug to Respondent's wife, and no other physician prescribed hydrocodone to her until November 30, 2011. Respondent did not document the prescription in the patient file. GE 6. Nor did he disclose the prescription to Dr. Webb.

8. June 28, 2011, 30 tablets of zolpidem tartrate (Ambien) 10 mg, a 30-day supply. GE 10, at 84; GE 11, at 12. Respondent's wife still had a refill available for 60 dosage units based on the prescription issued by Dr. Webb on February 3, 2011, and eventually refilled the prescription on July 7, 2011. GE 11, at 12. Respondent did not document the prescription in the patient file. *See generally* GE 6. Nor did he disclose it to Dr. Webb.

9. July 15, 2011, prescription (assigned RX # 4002009 by the pharmacy) for 28 tablets of hydrocodone-acetaminophen (Lorcet) 10–650, a five-day supply. GE 10, at 64. This prescription also authorized a refill, which Respondent's wife obtained on July 29, 2011. *Id.* As explained above, other than in June/July 2013, Dr. Webb did not prescribe this drug to Respondent's wife, and no other physician prescribed hydrocodone to her until November 30, 2011. Respondent did not document the prescription in the patient file. GE 6. Nor did he disclose the prescription to Dr. Webb.

10. July 31, 2011, 12 tablets of zolpidem 10 mg, one tablet at bedtime, a 12-day supply, with one refill. GE 10, at 84; GE 11, at 12; GE 33, at 1–2. As found above, on July 7, 2011, Respondent's wife obtained a refill of a prescription for 60 zolpidem issued by Dr. Webb, which, if taken as directed, should have lasted her until August 6, 2011 (this being in addition to the 30 zolpidem prescription Respondent issued on June 28, 2011). GE 11, at 12; Tr. 251–53. Respondent did not document the prescription in the patient file. *See generally* GE 6. Nor did he disclose the prescription to Dr. Webb.

11. August 13, 2011, 20 tablets of alprazolam (Xanax) 1 mg, one-half to one tablet, to be taken twice a day, a 10–20-day supply. GE 22, at 1–2.[9] Notably, on August 4, 2011, Respondent's wife had refilled a prescription issued by Dr. Webb for 45 alprazolam 2 mg, a 15 day supply. GE 11, at 12. Thus, if taken as directed, this refill should have lasted Respondent's wife until August 19, 2011. Moreover, on August 16, 2011, Dr. Webb issued Respondent's wife a new prescription for 90 alprazolam 2mg, a 30-day supply. *Id.* Respondent did not document the prescription in his wife's patient file. *See generally* GE 6.[10] Nor

[7] The ''fill dates'' are used to identify these prescriptions because some of the prescriptions are not dated or bear illegible dates.

[8] The ALJ found that this prescription overlapped with a 30-day prescription for zolpidem tartrate (Ambien) from Dr. Webb, which was filled on January 8, 2011. R.D. 16. Given that Dr. Webb testified that he was prescribing both Xanax for anxiety and Ambien for sleep to Respondent's wife simultaneously, the record does not establish that these were overlapping prescriptions.

[9] Although this prescription was filled on August 13, 2011, *see* GE–22, at 2, it does not appear on Mrs. Alexander's PMP. *See* GE–11, at 12. However, a copy of the prescription and the fill sticker is in the record. GE 22.

[10] The Respondent's patient file for his wife mentions a prescription for 20 tablets of Xanax, 2 mg, dated July 13, 2011. *See* GE–6, at 1. The patient file says he prescribed Xanax because ''Jill out of Xanax—in Philadelphia—Has had twitching—[illegible] Dr. Webb has not called back.'' GE–6, at 1. Dr. Webb, however, had no notes in his file about any attempt by the Respondent to contact him on July 13, 2011. *See* Tr. 126. However, neither the

did he disclose the prescription to Dr. Webb.

12. August 28, 2011, 12 tablets of zolpidem tartrate (Ambien) 10 mg, a 12-day supply. GE 10, at 19. Notably, on August 16, 2011, Respondent's wife had obtained and filled a new prescription from Dr. Webb for 60 zolpidem, a 30-day supply. GX 11, at 12. If taken as directed, Dr. Webb's prescription should have lasted Respondent's wife until September 15, 2011. Moreover, as found above, Respondent had also provided a refill when he issued the July 31, 2011 prescription (RX# 443737), and this refill was still available to his wife on August 28, 2011. GE 11, at 12. Respondent did not document the prescription in the patient file. *See generally* GE 6. He also did not disclose the prescription to Dr. Webb.

13. September 6, 2011, 12 tablets of zolpidem tartrate (Ambien) 10 mg, a 12-day supply, this being a refill authorized by Respondent's July 31, 2011 prescription. GE 11, at 12. As discussed in the preceding paragraph, Dr. Webb's August 16, 2011 prescription should have lasted Respondent's wife until September 15, 2011. In addition, Respondent's August 28, 2011 prescriptions provided his wife with additional medication in excess of what Dr. Webb had prescribed. As found above, Respondent did not document the original prescription in the patient file nor disclose it to Dr. Webb. *See generally* GE 6.

14. September 28, 2011, 16 tablets of hydrocodone/apap 10/650, a four-day supply with one refill. *See* GE 10, at 64. As explained above, other than in June/July 2013, Dr. Webb did not prescribe this drug to Respondent's wife, and no other physician prescribed hydrocodone to her until November 30, 2011. Respondent did not document the prescription in the patient file. *See* GE 6. Nor did he disclose the prescription to Dr. Webb.

15. October 11, 2011, 20 tablets of zolpidem tartrate (Ambien) 10 mg, one tablet at bedtime, a 20-day supply. GE 10, at 84; GE 11, at 11; GE 34, at 1–2; Tr. 249. Of note, on September 19, 2011, Respondent's wife had refilled Dr. Webb's August 16, 2011 prescription and obtained 60 tablets, a 30-day supply. GE 11, at 12. If taken as directed, the September 19 refill should have lasted Respondent's wife until October 19. GE 11, at 12; Tr. 248–49. Respondent did not document the prescription in the patient file. *See generally* GE 6. Nor did he disclose it to Dr. Webb.

16. October 20, 2011, 16 tablets of hydrocodone-acetaminophen (Lorcet) 10–650, a four-day supply, this being a refill of the September 28, 2011 prescription. GE 10, at 64. As explained above, other than in June/July 2013, Dr. Webb did not prescribe this drug to Respondent's wife, and no other physician prescribed hydrocodone to her until November 30, 2011. As found above, Respondent did not document the prescription or the refill in the patient file. *See* GE 6. Nor did he disclose the prescription to Dr. Webb.

17. November 13, 2011, 18 tablets of clonazepam 2mg, a six-day supply. GE 10, at 19. Notably, on November 3, 2011, Respondent's wife had refilled a prescription issued by Dr. Webb on October 19, 2011 for 45 dosage units, a 15 day supply. GE 11, at 11. If taken as directed, the November 3 refill should have lasted Respondent's wife until November 18, 2011. Moreover, on November 15, 2011, only two days after filling the prescription she obtained from her husband, Respondent's wife obtained a further refill of Dr. Webb's prescription for 45 dosage units of clonazepam. GE 11, at 11. Respondent did not document the prescription in the patient file. *See generally* GE 6. Nor did he disclose it to Dr. Webb.

18. November 25, 2011, 10 tablets of clonazepam 2 mg, a three-day supply. GE 10, at 63. If taken as directed, by itself, the November 15, 2011 refill should have lasted Respondent's wife until November 30, 2011. Respondent did not document the prescription in the patient file. GE 6. Nor did he disclose it to Dr. Webb.

19. November 29, 2011, four tablets of hydrocodone/acetaminophen (Lorcet) 10–650 mg, one tablet to be taken four to six times a day, a one-day supply. GE 26. Respondent did not document the prescription in the patient file. GE 6. He also did not disclose the prescription to Dr. Webb.

20. Also on November 29, 2011, one Diastat Acudial, 5–7.5–10 mg kit. GE 10, at 92; GE 11, at 11; GE 28, at 1. Diastat Acudial is a rectal suppository of diazepam, which is also a benzodiazepine and a schedule IV controlled substance.[11] Tr. 260–61; 21 CFR 1308.14(c). Respondent did not document the prescription in the patient file. *See* GX 6. Nor did he disclose it to Dr. Webb.

21. December 5, 2011, 10 tablets of hydrocodone-acetaminophen (Lorcet) 10–650, a three-day supply. GE 10, at 63. Respondent did not document the prescription in the patient file. *See generally* GE 6. Nor did he disclose it to Dr. Webb.

22. December 27, 2011,[12] 30 tablets of zolpidem tartrate (Ambien) 10 mg, one tablet a day at bedtime, a 30-day supply. GE 10, at 80; GE 21, at 1–2. However, on December 16, 2011, Respondent's wife had obtained a refill of Dr. Webb's August 16, 2011 prescription for 60 dosage units, a 30-day supply. GE 11, at 11. Thus, if taken as directed, the December 16 refill should have lasted Respondent's wife until January 15, 2012. In Respondent's patient file for his wife, he documented: ''Jill not sleeping. Holiday schedule at Mississippi Neuropsychiatric—stress of house repossession and moving in with mother-in-law. Erratic. Bugs. Ambien 10 mg #30 [one to two orally at bedtime]. No response on-call dr.'' GE 6, at 1. Respondent did not disclose the prescription to Dr. Webb.

23. January 7, 2012, 28 tablets of zolpidem 10 mg, a 28-day supply. GE 10, at 63. As found above, on December 16, 2011, Respondent's wife had obtained a refill of Dr. Webb's prescription and obtained medication that should have lasted her until January 15, 2012. Moreover, on December 27, 2011, she filled the prescription Respondent wrote her for 30 more tablets. Respondent's patient file for his wife does not document the issuance of a zolpidem prescription on this date, but rather on January 10, 2012. *See generally* GE 6. That entry states: ''Jill Philadephia at M-I-L house,'' ''Pills discarded—tension—No vehicles (Bankruptcy).'' GE 6, at 2. The entry then lists a prescription for 30 Ambien 10 mg, with a dosing instruction of one tablet by mouth per day. *Id.* Moreover, Respondent did not disclose the prescription to Dr. Webb.

24. January 16, 2012, 30 tablets of alprazolam (Xanax) 2 mg, to be taken ''as directed.''[13] GE 23, at 1–2. However, on January 5, 2012, Respondent's wife had refilled a prescription (Rx# 976879) issued by Dr. Webb for 45 tablets, a 15-

PMP reports, nor the copies of the prescriptions, support a finding that Respondent issued an alprazolam prescription on or about this date.

[11] Dr. Chambers, the Government's Expert testified that this prescription ''is a bit puzzling because it's clear she's taking oral meds and usually that's reserved for people who can't take'' the oral form of the drug. Tr. 259.

[12] The Government established that this was a Tuesday. Tr. 190.

[13] While neither PMP report contains an entry for an alprazolam prescription issued by Respondent for his wife on this date, Government Exhibit 23 contains a copy of the prescription and the fill sticker showing that on January 16, 2012, Respondent issued, and his wife filled a prescription for 30 alprazolam 2 mg. Notwithstanding that the prescription appears to be dated ''1/16/11,'' the fill sticker states that the prescription was written on ''01/16/12.'' GX 23, at 1–2.

day supply, and that prescription had an additional refill remaining which Respondent's wife obtained on February 14, 2012. GE 11, at 10. In his wife's patient file, Respondent wrote: ''Dr. Webb wants Jill to come in. Difficult [with] transportation—Will Rx 10 day supply til 1/26/12—Webb aware—Xanax 2 mg #30 [two orally three times a day].'' GE 6, at 2. Dr. Webb testified, however, that neither Respondent nor Respondent's wife ever told him about any prescription issued by Respondent.[14] Tr. 115–17, 119, 138, 174–75; *see also* R.D. 16 (Finding of Fact No. 28).

25. February 26, 2012, 20 tablets of diazepam 5 mg, a six-day supply. GX 11, at 10. Of note, on February 23, 2012, Respondent's wife had obtained and filled a new prescription from Dr. Webb for 45 alprazolam 2 mg, a 15-day supply; this prescription (Rx# 982872) also authorized three refills. *Id.* at 10–11. Diazepam and alprazolam are both benzodiazepines and are used to treat anxiety. Tr. 259. Dr. Webb did not prescribe diazepam to Respondent's wife. *See generally* GE 11; Tr. 204; GX 5. Respondent did not document the prescriptions in his wife's patient file. *See* GE 6. Nor did he disclose the prescription to Dr. Webb.

26. March 4, 2012, 30 tablets of zolpidem10 mg, a 30-day supply. GE 10, at 13; GE 11, at 10. Of note, on February 23, 2012, Respondent's wife obtained and filled a prescription from Dr. Webb for 30 zolpidem, a 15-day supply. GE 11, at 10. If taken as directed, Dr. Webb's prescription should have lasted Respondent's wife until March 9, 2012. Moreover, Dr. Webb's Feb. 23 prescription provided for two refills, the first of which Respondent's wife obtained on March 19, 2012, respectively. GE 11, at 10. Respondent did not document the prescription in the patient file. *See generally* GE 6. Nor did he disclose the prescription to Dr. Webb.

27. March 12, 2012, 12 tablets of alprazolam (Xanax) 2 mg, one tablet to be taken three times a day, a four-day supply. GE 10, at 80; GE 20. As found above, on February 23, 2012, Dr. Webb issued a prescription for 45 tablets of alprazolam 2 mg, a 15-day supply, which authorized three refills. GE 11, at 9–10. In the patient file, Respondent wrote: ''Out of Xaax [sic] x 5 days—Jerky & twitching—feels like Extreme anxiety—digging at arms [-] delusional parasitosis? Will give 4 day supply—[illegible] talk to Dr. Webb—Xaax [sic] 2 mg #12,'' followed by the dosage instruction of one tablet by mouth, three times a day.'' GE 6, at 3. Respondent's wife had available a refill of Dr. Webb's February 23 prescription which she could have filled on this date (without being early) but which she did not fill until March 19, 2012. GE 11, at 10. Respondent did not disclose the prescription to Dr. Webb.

28. March 12, 2012, 30 tablets of zolpidem 10 mg, 30-day supply. GE 10, at 80. As found above, on March 4, 2012, Respondent prescribed 30 zolpidem (a 30-day supply) for his wife which she filled the same day. GE 11, at 10. If taken as directed, Respondent's March 4 prescription should have lasted until April 3, 2012. Also, Dr. Webb's Feb. 23, 2012 prescription (for 30 tablets) authorized multiple refills and Respondent's wife obtained a refill on March 19, 2012. *Id.* Respondent did not document the prescription in his wife's patient file. *See* GE 6. Nor did he disclose the prescription to Dr. Webb.

29. April 1, 2012, 24 tablets of zolpidem tartrate (Ambien) 10 mg, a 24-day supply. GE 10, at 13; GE 11, at 10. Putting aside that Respondent's March 4 prescription should have lasted through April 3, 2012, as found above, Respondent's wife obtained 30 tablets on March 12 when she filled his prescription and another 30 tablets on March 19, when she refilled Dr. Webb's Feb. 2, 2012 prescription. GE 11, at 10. Respondent did not document the prescription in his wife's patient file. *See* GE 6. Nor did he disclose the prescription to Dr. Webb.

30. April 2, 2012, 120 units of hydrocodone-homatropine syrup (Hycodan), one teaspoon every four to six hours as needed. GE 19, at 1–2.[15] Respondent did not document the prescription in his wife's patient file. *See* GE 6. Nor did he disclose the prescription to Dr. Webb.

31. June 18, 2012, 20 tablets of alprazolam (Xanax) 2 mg, one tablet to be taken twice a day, a 10-day supply. GE 10, at 75; GE 11, at 9; GE 15, at 1–2; Tr. 262. Respondent's wife still had a refill remaining on Dr. Webb's Feb. 23, 2012 prescription for 45 alprazolam, which she filled on July 5, 2012. GE 11, at 9. Respondent did not document the prescriptions in his wife's patient file. *See generally* GE 6. Nor did he disclose the prescription to Dr. Webb.

32. July 17, 2012, 20 tablets of alprazolam (Xanax) 2 mg, one tablet twice a day, a 10-day supply. GE 10, at 13; GE 11, at 9; *see* Tr. 262–63. As noted above, on July 5, 2012, Respondent's wife obtained 45 tablets (15 days) of alprazolam when she refilled Dr. Webb's prescription. GE 11, at 9. In a note (dated July 14, 2012) in his wife's patient file, Respondent wrote: ''she had done very well without medicine—even though extremely stressful living conditions. . . . 4 month no meds—depressed, crying, jittery—Has been in contact [with] Dr. Webb. . . . She feels self harm—but no SI. Xanax 2 mg #20 6 day supply.'' GE 6, at 4; Tr. 130. Respondent did not disclose the prescription to Dr. Webb, and Dr. Webb did not talk to the Respondent's wife on July 14, 2012. *See generally* GE 5; Tr. 131. Dr. Webb also testified that neither Respondent nor Respondent's wife ever told him about any prescription issued by Respondent. Tr. 115–17, 119, 138, 174–75; *see also* R.D. 16 (Finding of Fact No. 28).

33. August 13, 2012, 30 tablets of hydrocodone/acetaminophen, 10–650, one tablet every four hours, a five-day supply. GE 10, at 80; GE 11, at 9; GE 16, at 1. Respondent did not document the prescription in his wife's patient file. *See* GE 6. Nor does the PMP report show that any other doctor prescribed hydrocodone to Respondent's wife between December 22, 2011 and December 16, 2012. GE 11, at 8–10. Respondent did not disclose the prescription to Dr. Webb.

34. October 5, 2012, 12 tablets of alprazolam (Xanax) 2 mg, a four-day supply. GE 10, at 22; GE 11, at 9. On September 24, 2012, Dr. Webb prescribed and Respondent's wife filled a prescription for 45 alprazolam 2 mg, a 15-day supply, which also provided for two refills. GE 11, at 9. If taken as directed, Dr. Webb's prescription should have lasted until October 9, 2012. In his wife's patient file, Respondent wrote: ''Dr. Webb Rx Xanax—She is out 2 days early—Laceration/cutting—severe anxiety & depression—arms excoriated No return call from weekend MD—I have to leave to work out of town Xanax 2 mg #12 Walgreens 3–4 day supply through weekend.'' GE 6, at 5. While the note also appears to state ''aware -,'' Dr. Webb did not have any notes in his file regarding any calls from Respondent on October 5, 2012, Tr. 131, and I find that Respondent did not disclose the prescription to Dr. Webb. I also find that Respondent's wife did not disclose the prescription. Tr. 174–75.

35. December 22, 2012, 15 capsules of Dextroamphetamine-Amphetamine ER 20 mg, a five-day supply. GE 11, at 8. While Dr. Webb had prescribed this drug to Respondent's wife, *see id.,* Respondent did not disclose the prescription to Dr. Webb. Nor did

[14] January 16, 2012 was a Monday. Tr. 190.

[15] Although this prescription does not appear on either of the PMP reports, the Government produced both the prescription and the fill sticker showing that the drug was dispensed on April 2, 2012. *See* GE 19, at 2.

Respondent document the prescription in his wife's patient file. *See* GE 6.

36. January 11, 2013, 10 tablets of alprazolam (Xanax) 2 mg, a three-day supply. GE 10, at 21; GE 11, at 8. According to the PMP report, on January 10, 2013, Respondent's wife refilled a prescription issued by Dr. Webb [16] (Rx #996307) for 45 tablets of alprazolam 2 mg, a 15-day supply. *Id.* If taken as directed, the January 10 refill provided enough medication to last Respondent's wife until January 25. The PMP report also shows that on December 30, 2012, Respondent's wife had refilled a different prescription issued by Dr. Webb [17] (RX #2703928) for 45 tablets of alprazolam 2 mg, a 15-day supply. *Id.* If taken as directed, the December 30 refill provided enough medication to last Respondent's wife until January 14, 2013. Respondent did not document the prescription in his wife's patient file. *See generally* GE 6. Nor did he disclose the prescription to Dr. Webb.

37. January 11, 2013, six capsules of temazepam, a three-day supply. GE 11, at 8. According to the PMP report, on January 10, 2013, Respondent's wife refilled a prescription issued by Dr. Webb for 30 capsules of the drug, a 30-day supply. *Id.* If taken as directed, the January 10 refill provided enough medication to last Respondent's wife until February 9, 2013. Respondent did not document the prescription in his wife's patient file. *See* GE 6. Nor did he disclose the prescription to Respondent.

38. January 23, 2013, 15 tablets of alprazolam 2 mg, to be taken ''as directed.'' [18] GE 17; GE 10, at 79; GE 11, at 7. An entry in Respondent's file (dated January 20, 2013) states ''Jill has opened sore on nose,'' ''arms—del. parastosis [sic]—arms,'' ''cutting—Anxiety/depression,'' ''Out of her Xanax—inconsolable,'' ''weekend—No return from on-call,'' ''Xanax #15,'' ''will contact Dr. Webb in Am,'' ''No HI/SI,'' and a dosing instruction of ''TID prn.'' GE 6, at 5. Dr. Webb's patient file for his wife does not document a call from the Respondent on or near this date. *See* GE 5; Tr. 131–32. I therefore find that Respondent did not disclose the prescription to Dr. Webb.

39. January 23, 2013, 30 tablets of hydrocodone/apap 10–650, a five-day supply. GE 11, at 7. Respondent's wife had obtained prescriptions on December 16, 2012 for 20 tablets for hydrocodone/apap 7.5/500 (a two-day supply) and on December 18, 2012 for 20 tablets of hydrocodone/apap 10/500 (a five-day supply) from Dr. Pecunia. GE 11, at 8. However, she was not regularly being prescribed hydrocodone. *See generally* GE 11. Respondent did not document the prescription in his wife's patient file. *See* GE 6. Nor did he disclose the prescription to Dr. Webb.

40. February 5, 2013, eight tablets of alprazolam 2 mg, a two-day supply. GE 10, at 86; GE 11, at 7; GE 40, at 2. In his wife's patient file, Respondent wrote: ''Agitated—open sore on nose & hair line—Back from attempted trip—weathered out—returned with tons of anxiety—ran out of meds while OOT [19]—Minneapolis.'' GE 6, at 6. The note further states: ''Xanax #8 CVS Hattiesburg Zoloft #7'' and ''Filled Dr. Webb in on Travel—Jill did.'' GE 6, at 6. Respondent did not, however, disclose the prescriptions to Dr. Webb.

41. February 27, 2013, 10 tablets of alprazolam 2 mg, a three-day supply. GE 6, at 6; GE 10, at 86; GE 11, at 7. On February 19, 2013, Respondent's wife filled a prescription written by Dr. Webb for 45 alprazolam 2 mg, a 15-day supply. GE 5, at 70; GE 11, at 7. If taken as directed, Dr. Webb's prescription should have provided Respondent's wife with enough medication to last until March 6, 2013. In his wife's patient file, Respondent wrote: ''Anxious about marital situation—sores on nose/forehead will not heal—No HI/SI—out of her meds early—Out of Xanax,'' ''Xanax #10 [one orally three times a day] CVS Hardy St (enough for weekend) (Monday: Dr. Webb refilled for her).'' GE 6, at 6.

42. March 27, 2013, 14 tablets of alprazolam (Xanax) 2 mg, one tablet to be taken three times a day as needed, a five-day supply, which was filled the next day.[20] GE 36; GE 10, at 86; GE 11, at 7. On March 19, 2013, Respondent's wife had refilled a prescription issued by Dr. Webb for 45 alprazolam 2 mg, a 15-day supply. GE 11, at 7. If taken as directed, the refill of Dr. Webb's prescription should have provided Respondent's wife with enough medication to last until April 3, 2013. A note dated ''3/28/13'' in his wife's patient file, states: ''Marital/physical/mental stress. Sky high Marriage Workshop in Montana just accentuated—depilitating hairline—[illegible] meds needs plastic surg[ery] to fix—Out of Xanax early—rebound anxieties—self-harm—Xanax #14—CVS Hardy St.'' GE 6, at 7. The note also includes the following addendum: ''Dr. Webb aware—he called in Restoril/Zoloft & the Xanax (3/30/13).'' *Id.* Dr. Webb, however, was not aware of this prescription. Tr. 132–33; 174–75. Further, Dr. Webb's file contains no documentation of any contact by Respondent around March 28 through 30. Tr. 133; *see generally* GE 5; GE 7–9. Notably, Respondent did not note what dose of Xanax he prescribed or the dosing instructions. *See* GE 6, at 7; *see* Tr. 266, 287–88.

43. May 10, 2013, 14 tablets of alprazolam (Xanax) 2 mg, one tablet to be taken three times a day as needed, a four-day supply. GE 10, at 86; GE 11, at 7; GE 37, at 1–2. On April 30, 2013, Respondent's wife obtained a refill of a prescription issued by Dr. Webb for 45 alprazolam 2 mg, a 15-day supply. GE 11, at 7; Tr. 267. If taken as directed, the refill of Dr. Webb's prescription should have provided Respondent's wife with enough medication to last until May 15, 2013. Respondent did not document the prescription in his wife's patient file. GE 6. Nor did he disclose the prescription to Dr. Webb.

44. May 13, 2013, 12 tablets of alprazolam (Xanax) 2 mg, one tablet to be taken three times a day, a four-day supply. GE 10, at 21; GE 11, at 7; GE 41, at 1–2. Respondent wrote in his wife's patient file: ''Out of Xanax 2 days early—she says repeated [illegible] calls—no answer—No healing on face/arm—repeated re-openings. I am scheduled OOT next 4 days—Xanax #12 [once orally three times a day].'' GE 6, at 8. Respondent had already prescribed a four-day supply of Xanax to his wife on May 10; additionally, Respondent's wife still should have had two days' worth of Xanax left from Dr. Webb's April 30 refill. GE 11, at 7; Tr. 267. Respondent did not disclose the prescription to Dr. Webb. While the note also states that Respondent prescribed ''Ambien 10 for sleep,'' GE 6, at 8, the record does not contain a zolpidem prescription with this date.

45. May 20, 2013, 20 tablets of zolpidem 10 mg, one tablet at bedtime, a 20-day supply. GE 10, at 85; GE 11, at 7; GE 38, at 1–2. Respondent's patient file contains no note for a prescription issued on this date. GE 6, at 8. On May 23, 2013, Dr. Webb prescribed 30 du of another sleep medication, Restoril 30 mg (temazepam), with five refills, to Respondent's wife. GE 5, at 102; GE 11, at 6; Tr. 133–34. Moreover, the PMP report shows that Dr. Webb had been prescribing temazepam with refills to Respondent's wife beginning on July 26,

[16] The prescription was originally issued on July 26, 2012 and provided five refills. GE 11, at 8.

[17] The prescription was originally issued on November 6, 2012. GE 11, at 8.

[18] Both the prescription label and the PMP report list this as being a 30-day supply. *See* GE 17; GE 10, at 79. However, according to Respondent's note in the file, the dosing instruction was take the drug three times a day as needed.

[19] The ALJ presumed, with reason, that ''OOT'' is an abbreviation for ''out of town.'' R.D. 22 n.32.

[20] Although the PMP entry (as well as Respondent's note) are dated March 28, 2013, the prescription was written on March 27. *See* GE 36, at 1.

2012 and had not issued a zolpidem prescription to her since February 23, 2012, which she last refilled more than a year earlier on April 12, 2012. GE 11, at 7–10. Respondent did not discuss the prescription with Dr. Webb. Tr. 133. In an entry dated ''5/23,'' Respondent wrote: ''Dr Webb—started Zoloft & Buspar—And [R]estoril[.] Ambien discarded—only Restoril.'' GE 6, at 8. As also found above, Respondent had previously prescribed temazepam for his wife on January 11, 2013. GE 11, at 8.

46. July 1, 2013, 20 tablets of hydrocodone/acetaminophen (Lorcet), 10–650, a five-day supply.[21] GE 10, at 93; GE 11, at 6; GE 27, at 1. In his wife's patient file, Respondent wrote: ''Her mother in hospital in Jackson—dying—in ICU/hospice—she had *seizure*—injured shoulder/rib finger. Fractured teeth. Would not go to ER—Lorcet 10/650 #20,'' which was followed by illegible handwriting. GE 6, at 9; Tr. 134. Respondent did not discuss those injuries with Dr. Webb at any point; further, Respondent's wife had an appointment with Dr. Webb on July 1. Tr. 134. While Dr. Webb did not prescribe any medications to Respondent's wife at this visit, she did fill a prescription for 90 capsules of Adderall XR 20 (amphetamine), which Dr. Webb issued on June 28, 2013. GE 11, at 6; Tr. 273. Also, on June 28, 2013, she had obtained from Dr. Webb and filled new prescriptions for 45 alprazolam 2 mg, a 15-day supply, and 30 temazepam 30 mg, a 30-day supply. GE 11, at 6.

47. July 7, 2013, 12 tablets of alprazolam (Xanax) 2 mg, one tablet to be taken twice a day, a six-day supply. GE 35, at 1–4; *see* GE 10, at 41; GE 11, at 6; Tr. 268–69. However, if taken as directed, the June 28 alprazolam prescription from Dr. Webb should have provided enough medication to last Respondent's wife until July 13, 2013. In his wife's patient file, Respondent wrote: ''She is out of her Xanax early. Dr. Webb is aware of the tremendous stress of her mother's illness. No return call on-call MS Neuro [illegible] Xanax #12/Lorcet #12 Walgreens.'' GE 6, at 9; Tr. 135. Dr. Webb's file for Respondent's wife does not document a call from Respondent on this date. *See generally* GE 5; GE 7–9; Tr. 135.

48. July 7, 2013, 12 tablets of hydrocodone/apap 10–650 mg, one tablet to be taken four to six times a day, a two-day supply. Respondent's note in his wife's patient file does not discuss his reason for prescribing hydrocodone. *See* GE 6, at 9. Respondent did not disclose the prescription to Dr. Webb.

49. July 25, 2013, 12 tablets of hydrocodone/apap, 10–650, one tablet every six hours as needed, a three-day supply. GE 10, at 21; GE 11, at 5; GE 42, at 1–2. Respondent did not document this prescription in his wife's patient file. *See generally* GE 6. He also did not disclose the prescription to Dr. Webb.

50. July 29, 2013, eight tablets of alprazolam 2 mg, one tablet to be taken three times a day as needed, a two-day supply. GE 10, at 85; GE 11, at 5; GE 39, at 1–2. The PMP shows that on July 19, 2013, Respondent's wife had obtained a refill of a prescription issued by Dr. Webb for 45 alprazolam 2 mg, a 15-day supply. GE 11, at 6. If taken as directed, the refill should have provided Respondent's wife with enough medication to last until August 3, 2017. In his wife's patient file, Respondent wrote: ''Out of Xanax—buried her mother—funeral—Dr. Webb back Thursday. Xanax #8 [once orally three times a day].'' GE 6, at 9; Tr. 136. Dr. Webb testified that he did not receive any message or have any contact with Respondent on this day, Tr. 136, and there is nothing in Dr. Webb's file for Respondent's wife that indicates that he was contacted by Respondent around July 29, 2013. *See* GE 5; GE 7–9. I find that Respondent did not disclose the prescription to Dr. Webb.

51. August 15, 2013, 14 tablets of hydrocodone/apap 10–650, one tablet every four to six hours as needed, a two-day supply. GE 10, at 21; GE 11, at 5; GE 43, at 1–2. Respondent did not document the prescription in his wife's patient file. *See generally* GE 6. Nor did he disclose the prescription to Dr. Webb.

52. August 22, 2013, 15 tablets of alprazolam (Xanax), 2 mg, one tablet to be taken three times a day, a five-day supply. GE 10, at 67; GE 11, at 5; GE 24, at 1–2. According to the PMP report, Dr. Webb issued his last alprazolam prescription to Respondent's wife on July 31, 2013 for 45 tablets, a 15-day supply, and the PMP report contains no entry for any refill of this prescription. GE 11, at 1–5. The PMP report further shows that on August 5, 2013, Dr. Webb had re-commenced prescribing clonazepam, a different benzodiazepine. GE 11, at 5; *see also* GE 5, at 71. In an entry in his wife's patient file dated ''8/24/13,'' Respondent wrote: ''Following [her mother's] death, she has been very labile. Dr. Webb has tried multiple medications. Jill is very morose, often cannot stop crying. Denies SI/HI—No self-harm this month.'' GE 6, at 10. Continuing, the note states: ''Multiple Rx & calls to Dr. Webb. Could not reach this weekend—Rx: Xanax #12 [once orally three times a day]'' and ''[w]ill update Dr. Webb.'' GE 6, at 10; Tr. 136–37. However, there is nothing in Dr. Webb's file for Respondent's wife that indicates that he was contacted by the Respondent around August 22, 2013 and Dr. Webb testified that Respondent never disclosed any of the prescriptions. *See* GE 5; Tr. 137. I find that Respondent did not disclose the prescription to Dr. Webb.

53. September 5, 2013, 24 tablets of alprazolam (Xanax), 2 mg, an eight-day supply. GE 10, at 21; GE 11, at 5. The Respondent recorded in his wife's patient file: ''Will not leave room—depressed—needs to get back with Dr. Webb—anorexic—very anxious/depressed—Xanax #20 [once orally three times a day].'' GE 6, at 10. Respondent did not disclose the prescription to Dr. Webb.

*Dr. Webb's Testimony Regarding Respondent's Prescriptions*

Asked if there were ''any risks'' in Respondent's wife ''receiving prescriptions from someone other'' than himself, Dr. Webb testified that ''this particular patient . . . has some severe problems[,] and takes a high dose of medication. . . . my concern is that I'm keeping a close tab on it, but if there's somebody out there writing that I don't know about, that's dangerous.'' *Id.* at 120. Dr. Webb explained that Respondent's prescribing was dangerous because ''you're going above the maximum dose that should be prescribed and more medicines can lead to sedation, more sedation, difficulty, death, loss of balance, falls, poor judgment, things like that.'' *Id.* at 121.

Dr. Webb also explained that the prescriptions ''interfered with [my] treatment for her, because I wasn't seeing the real patient, because there's a ghost writer out there that I don't know about.'' *Id.* Dr. Webb testified that ''I have certain timed prescriptions and if that timed prescription is getting gapped . . . by another prescription, it's distracting me from my decisionmaking.'' *Id.* He also testified that this would ''[m]ost definitely'' interfere with his decisionmaking, in that ''[if] she was out of . . . my medicines, then I would hear a distressed phone call . . . and I would need to reorient my treatment for her [by] put[ting] her in the hospital.'' *Id.* at 122.

In a July 13, 2011 entry in Respondent's wife patient file, which documents a prescription for 20 Xanax 2mg, but for which there is no corresponding prescription in either the PMP reports or the other exhibits,

[21] *See* GE–14, at 59 (admitting to calling in a prescription for Lorcet in July).

Respondent wrote: ''Dr. Webb has not called back.'' GX 6, at 1. Regarding this entry, Dr. Webb testified that there are ''five other [ ]'' practitioners that work at his clinic and the phones are covered 24 hours a day, seven days a week. Tr. 124. Moreover, his clinic has an answering service for after office hours and weekends. *Id.* at 125. Dr. Webb testified that Respondent's note did not state what time the call to him had been placed and he maintained that he ''always called patients back.'' *Id.* at 126.

Dr. Webb further testified that the file did not contain a note ''from the answering service or the secretary that on [this date] a message was left.'' *Id.* Dr. Webb then testified that his ''file contains every telephone message notation that is given to our office'' and that ''the actual notes written by the office staff are kept,'' and that there are no notes for this date.[22] *Id.* The closest phone message by date are two messages on July 21, 2011 from Respondent's wife; the earlier message states ''please call asap'' and the later message states ''urgent out of med.'' GE 5, at 137. Notably, the PMP shows that on the same day, Dr. Webb issued to Respondent's wife a new prescription for 45 alprazolam 2 mg. GE 11, at 12.

The Government also asked Dr. Webb about Respondent's note dated ''1/16/12'' (prescription No. 24). The note appears as follows:

Dr. Webb wants Jill to come in
Difficult s transportation
Will Rx 10 day supply til
1/26/12—Webb aware—
Xanax 2 mg # 30
[ ] po TID prn

GX 6, at 2, Tr. 126. Dr. Webb testified that he was not sure if the prescription referenced in the note was ''attached to the January 16 or January 26th note.'' Tr. 127. He then testified that he had no contact with Respondent's wife on January 16, 2012,[23] but that on January 26, 2012, he called in a prescription for 45 Xanax 2 mg, three tablets a day. *Id.* at 127–28; *see also* GX 5, at 69. He also had no contact with Respondent on January 26, 2012.[24] Tr. 128.

The Government also asked Dr. Webb about an entry Respondent made on July 7, 2013, which states in part: ''She's out of her Xanax early. Dr. Webb is aware of the tremendous stress of her mother's illness. No return on call.'' GX 6, at 9; *see also* Tr. 135. As found above, on this date, Respondent prescribed to his wife 12 Xanax and 12 Lorcet. GX 6, at 9; GX 11, at 6. Notably, the PMP report shows that Respondent's wife had refilled a prescription issued by Dr. Webb on May 23, 2013 for 45 Xanax (15 day supply) on June 21, 2013, and had obtained and filled a new prescription for 45 Xanax (15 day supply) on June 28, 2013.[25] GX 11, at 6. After again noting that there was no record of any call to the clinic or its answering service by Respondent on this date, Dr. Webb testified that the fact that Respondent's wife was out of her Xanax early would concern him ''[b]ecause it lets me know that she's using more than prescribed and would . . . ha[ve] me wondering whether we need to put her in the hospital, to monitor her, or [if] there [are] other issues going on.'' Tr. 135–36.

An entry in Respondent's file dated July 29, 2013 states: ''Out of Xanax—buried her mother—funeral—Dr Webb back Thursday Xanax #8'' and includes dosing instructions of ''po TID.'' GX 6, at 9. As found above, the PMP report shows that Respondent issued his wife a prescription for eight Xanax 2 mg. GX 11, at 5. The PMP report also shows, however, that Respondent's wife refilled prescriptions for 45 Xanax (15 day supply) issued by Dr. Webb on both July 10 and 19, 2013. GX 11, at 6. *Id.* Dr. Webb testified that he spoke with Respondent's wife on July 30, 2013, and prescribed more Xanax to her and referred her to a psychologist. Tr. 136. According to the PMP report, Dr. Webb issued Respondent's wife a prescription for 45 Xanax on July 31, 2013. GX 11, at 5.

Dr. Webb testified that in his view ''gap filling . . . means that there's a prescription that is used to get [the patient] to the next authorized refill.'' Tr. 138. Dr. Webb then cited stolen medication as an example of when a gap fill would be appropriate. *Id.* Dr. Webb also testified that if a doctor sets up a regimen of refills, the patient ''needs to follow that timeline. And so, if they're short on set refills, that's a problem.'' *Id.* at 139.

On cross-examination, Respondent's counsel asked Dr. Webb about a statement he wrote in a memo he prepared following a January 11, 2016 meeting with DEA personnel in which he noted that Respondent's ''prescriptions consisted of large quantities of controlled medications such as Xanax, [h]ydrocodone, [and] Ambien.'' Tr. 151; *see also* GX 8. Asked how he concluded that the prescriptions were for large quantities, Dr. Webb explained that ''[t]hey appeared to be more than just a day or so'' and that while ''some were less than 10 . . . my recollection was that more, most of them were more than 10'' tablets. Tr. 151.

Dr. Webb subsequently explained that he had Respondent's wife ''up to max doses of all prescriptions . . . that I had her on'' and that ''[a]nything over was a potentially large impact.'' *Id.* at 152. He added that ''[m]aybe the number isn't large, but the potential impact is large.'' *Id.* Asked by Respondent's counsel if he ''agree[d] that compared to [his] prescribing, the number of controlled substances prescribed by [Respondent] was relatively small,'' Dr. Webb answered ''correct,'' but then added that it was ''[m]ore than I prescribe and moving into . . . above my max and serious harm.'' [26] *Id.* at 152–53.

[22] On cross-examination, Dr. Webb acknowledged that the clinic's answering service would not necessarily page the on-call doctor just for a patient ''who needs a normal refill.'' Tr. 156. However, Dr. Webb maintained that if a patient was out of medicine early and in distress, the answering service would pass this message on to the doctor. *Id.* at 157, 182. He also testified that ''[i]t's our policy to call everybody back.'' *Id.* at 183.

Dr. Webb further testified that to the best of his recollection, all of the phone call messages ''should be'' in the patient file for Respondent's wife. *Id.* at 159. Dr. Webb testified that he did not ''find it odd'' that there was ''only [in the words of Respondent's counsel] a handful of . . . call notes in her file.'' *Id.* at 160. Putting aside that there are 48 such notes in the patient file, Dr. Webb explained that Respondent's wife ''typically kept pretty good contact. Knowing that I'd be in the daytime, she's in the medical field, she knows night time phone calls . . . aren't very productive . . . [b]ecause you're unlikely to have your doctor on call.'' *Id.* He also testified that Respondent's wife had not expressed any dissatisfaction with her being able to reach him other than when he was not on call during a weekend. *Id.* at 184.

Dr. Webb further testified that his practice has not received complaints about the clinic's ''on call service'' and ''the inability to connect with a doctor'' or to ''get a request fulfilled by a doctor.'' *Id.* at 161. The ALJ specifically found that Dr. Webb's testimony was credible. R.D. 8.

[23] With respect to Respondent's wife, Dr. Webb testified that early in his treatment of her, she lost a bottle of Xanax which prompted him ''to shorten the leash and give smaller amounts.'' *Id.* at 162.

[24] Dr. Webb also identified other instances in which Respondent made notes in his wife's file documenting phone calls but Dr. Webb's file contained no record that the call was made to his office. *See* Tr. 129–33,137. These include notations for Feb. 18, 2012 (''called answering service for Dr. Webb No response—weekend Dr''); Oct. 5, 2012 (''No return call from weekend doctor''); Jan. 20, 2013 (''No return from on call'' and ''Will contact Dr. Webb in AM''); Mar. 28, 2013 (''Dr. Webb aware.''); Aug. 24, 2013 (''Will update Dr. Webb''). The record, however, does not establish whether these notations were intended to document that Respondent or his wife had placed the call and/or notified, or intended to notify Dr. Webb.

[25] Respondent's wife also obtained a refill of the June 28, 2013 prescription for 45 Xanax on July 10, 2013, and a refill of the May 23, 2011 prescription (which also was for 45 Xanax) on July 19, 2013. GX 11, at 6; Tr. 144.

[26] As found above, the evidence shows that Respondent issued a number of prescriptions, especially for zolpidem, that provided quantities that were for periods considerably longer than two to three days. Specifically, Respondent authorized prescriptions on May 20, 2013, for 20 dosage units (du) of zolpidem (a 20 day supply); on April 1,

Continued

Dr. Webb testified that he had been ''very careful in regimenting'' the prescriptions he issued for Respondent's wife based on his ''years of working with her'' and her visit in either 2002 or 2009 (or both years) when ''she went to Sierra Tucson'' to be evaluated for Xanax abuse. Tr. 146–47. According to Dr. Webb, Sierra Tucson did not diagnose her as being addicted or abusing controlled substances. *Id.* at 164. While he ''was not aware'' that she was ''overtly abusing,'' Dr. Webb testified that she ''[s]he had been early . . . sometimes on her prescriptions.'' *Id.* at 185. Dr. Webb also cited ''the severity of her illness'' as a reason for why he generally limited the prescriptions to 15 days.[27] *Id.*

Dr. Webb subsequently testified that ''[s]ince I did not know about the other prescriptions out there, it did not appear to be as big of an issue. She was early a day or two here and there. But, yes, substance dependence was on the radar.'' *Id.* at 194. On still further questioning by the Government, Dr. Webb testified that if he had known about Respondent's prescriptions to his wife during the 2011–2013 period, this ''would have'' changed his opinion as to whether she was abusing controlled substances. *Id.* at 196–97. On questioning by the ALJ, Dr. Webb testified that ''[k]nowing what [he] know[s] today . . . I would have suggested'' that she undergo ''in-patient'' treatment to address both ''her primary . . . and secondary problem[s].'' *Id.* at 197.

Asked about the notes he maintained for his phone conversations with Respondent's wife, which typically were no more than one or two lines, Dr. Webb maintained that he and Respondent's wife ''always had in-depth conversations'' and that ''[t]hey were usually fairly long, like 20, 30, 45 minute phone conversations.'' *Id.* at 169. He also testified that his notes met the standard for documentation. Dr. Webb acknowledged, however, that he is ''not perfect'' and that there may have been some phone calls that he had with Respondent's wife ''that were not noted.'' *Id.* at 203.

Dr. Webb acknowledged that psychiatrists do not typically prescribe opioids such as hydrocodone; he testified that he had ''written maybe less than five [prescriptions] in my last 20 years.'' *Id.* at 170–71. Asked why he issued the June 28, 2013 prescription for 10 tablets of hydrocodone/acetaminophen 10/650 mg, *see* GX 11, at 6, Dr. Webb testified that the prescription was filled ''at Beemon, so potentially she had come up from Hattiesburg.'' Tr. 171. Continuing, Dr. Webb testified: ''[t]hat was right around her mother's death, mother's sickness, and maybe she told me she was out of her medicine potentially. I'd want to see my note if I put it in there.'' *Id.* Subsequently, Dr. Webb added that Respondent's wife had undergone a procedure by a different doctor and received hydrocodone about nine or ten days earlier, but he could not otherwise recall the circumstances. *Id.* at 172. Dr. Webb then admitted that this prescription ''certainly could'' interfere with the treatment being provided by the other doctor. *Id.* However, he explained that Respondent's wife ''was out of town from her treating . . . physician, and out of her opiate for pain relief.'' *Id.* at 186. Moreover, this was the only instance in which he prescribed hydrocodone or any other opioid to her. *Id.* at 200–01.

Dr. Webb testified that he did not have a conversation with Respondent's wife about Respondent's prescribing controlled substances to her until either late 2015 or 2016, after he was contacted by the Diversion Investigator. *Id.* at 175. Dr. Webb testified that he ''believe[d] at times'' that Respondent was trying to help his wife and that ''[t]hey have had lots of difficulty.'' *Id.* at 177. Based on the four phone calls he had with Respondent during the 2011 through 2013 period and because Respondent would ''[t]ypically call if there would be a crisis,'' Dr. Webb acknowledged that Respondent's wife was often in crisis. *Id.* at 178.

On subsequent questioning, Respondent's counsel suggested that just as the other doctors in his practice can appropriately prescribe gap fills to his patients because they can access the patient's file and see ''abuse issues in the patient file . . . someone living with the patient can assess that person.'' *Id.* at 196. Dr. Webb took issue with this suggestion, explaining that ''the difficulty with living with someone is that you're not potentially an expert.'' *Id.*

Dr. Webb testified that Respondent's notes did not contain a patient history and specific diagnosis. *Id.* at 188. As for whether the notes contained evidence of an examination, Dr. Webb explained that, ''other than the subjective notes that are listed, no.'' *Id.*

*The Testimony of the Government's Expert*

The Government called R. Andrew Chambers, M.D., to testify as an expert in psychiatry, the proper prescribing of controlled substances and their effects on patients, and on addiction; the ALJ accepted Dr. Chambers as an expert in these areas. Tr. 246. Dr. Chambers obtained his B.S. degree in Chemical Physics from Centre College, Danville, Kentucky in 1991 and his M.D. degree from the Duke University School of Medicine in 1996. GX 12, at 1. Thereafter, he completed a residency in psychiatry at the Yale University School of Medicine in 2002 and a fellowship in addiction psychiatry at the Indiana University (IU) School of Medicine in 2012. *Id.* From 2002 through 2003, he served as an Assistant Professor of Psychiatry, Division of Substance Abuse at Yale; from 2003 through 2009, he served as an Assistant Professor of Psychiatry at the Indiana University School of Medicine; and since 2010, he has been an Associate Professor of Psychiatry with Tenure at the IU School of Medicine. *Id.* Also since 2012, Dr. Chambers has been the Director of the Fellowship Training Program in Addiction Psychiatry at the IU School of Medicine. *Id.*

Dr. Chambers has had appointments in the Department of Psychiatry at various hospitals including the West Haven (Connecticut) VA Hospital, Yale New-Haven Hospital, Connecticut Mental Health Center, and Indiana University Health Hospitals. GX 12, at 2. He is board certified in general adult psychiatry and addiction psychiatry. Tr. 227–28. He has also been published in the areas of psychiatry and addiction ''on the order of 50 times'' in peer-reviewed journals, published in multiple textbooks, and made a number of presentations to professional conferences. *Id.* at 229–30; GX 12, at 3–7, 11–18.

Dr. Chambers testified that treating patients with mental illness and addiction is his ''bread and butter work.'' Tr. 231. He testified that he is ''familiar with and utilize[s] a broad range of pharmacotherapies for both mental illness and addiction, as well as psychotherapies for both mental illness and addiction'' and that ''the vast majority of [his] patients have both mental illness and addiction.'' *Id.* at 231–32. He testified that he is familiar with the prescribing of controlled

2012, for 24 du of zolpidem (24 days); on March 4, 2012, for 30 zolpidem (30 days); on October 11, 2011, for 20 du of zolpidem (20 days); on July 31, 2011, for 12 du (12 days) plus a refill; on June 28, 2011, for 30 du (30 days); on May 6, 2011, for 30 du (30 days); on March 30, 2011, for 30 du (15 days), and on January 31, 2011, also for 30 du (15 days). GX 11, at 7, 10–14. He also authorized prescriptions on July 7, 2013, for 12 du of alprazolam (6 day supply); on March 28, 2013, for 14 du of alprazolam (5 days); and on both July 17, 2012 and June 18, 2012, for 20 du of alprazolam (10 days). GX 11, at 6–7, 11.

[27] Dr. Webb testified that he ''feel[s] that . . . she's primarily a psychiatric disorder first, and then medication difficulty second, rather than the other way around.'' *Id.* at 165; *id.* at 194–95.

substances to psychiatric patients, the risks of controlled substances, and the typical practices undertaken by psychiatrists to mitigate the risks or dangers of the diversion of controlled substances. *Id.* He further testified that he is familiar with the standards for prescribing controlled substances in Mississippi, as well the circumstances under which a doctor may fail to conduct himself in a manner that comports with a legitimate medical purpose or is within the course of proper professional practice. *Id.* at 233.

While Dr. Chambers had never previously testified in a proceeding based on the Mississippi law and the State Board's rules, *id.* at 240, he testified that he had reviewed the State's laws and rules. *Id.* at 236. He further testified that the Mississippi provisions on prescribing controlled substances are ''fairly universal.'' *Id.* at 237. Dr. Chambers explained ''that the codes around the country are informed by the medical profession . . . and there are universal, fairly universal ethical standards, evidence-based standards that are scientific that then inform the code.'' *Id.* at 240. Dr. Chambers subsequently cited the Patient Record provisions of the State Board's Rule 1.4 as one such standard that is accepted across the medical profession. *Id.* at 244.

Turning to Respondent's October 11, 2011 prescription for 20 zolpidem (No. 15 above), Dr. Chambers noted that the refill obtained by Respondent's wife on September 19 was for 30 days and should have lasted until October 19. *Id.* at 249. Dr. Chambers testified that Respondent's October 11 prescription was ''a problem.'' *Id.* As to why, Dr. Chambers explained: ''[t]his is a prescription for a controlled substance that is coming from a separate source that's occurring on top of a prescription from the primary psychiatrist, and the combination of these kinds of controlled substances could have serious consequences.'' *Id.* Dr. Chambers further explained that ''Ambien and other benzoate medications have central nervous system effects that can cause oversedation, memory disturbances, and, if taken in combination with other drugs, especially opioids, death.'' *Id.* at 250. While Dr. Chambers testified that 10 milligrams (the dose prescribed by Respondent) ''is not the maximum dose of Ambien that can be prescribed,'' a patient obtaining the drug from another source ''would be of concern.'' *Id.* Dr. Chambers explained that the concern would be driven by the ''the size of the dose, the nature of the drug,'' as well as ''the fact the primary physician who is prescribing the drug . . . would not . . . necessarily [be] aware'' that the patient was obtaining the drug ''from a separate source.'' *Id.*

According to Dr. Chambers, when a patient is obtaining a drug from other sources, ''it can create a great deal of confusion on the part of the primary prescriber about the effects or side effects of the drug and the mental status of the patient.'' *Id.* at 250–51. Continuing, Dr. Chambers testified that ''there are also synergistic overdose risks of being on both doses at the same time. . . . It's obviously not the dose that the primary prescriber wants because they would have prescribed that dose if that's what they wanted.'' *Id.* at 251. Dr. Chambers then explained that ''the same concerns'' were raised by the zolpidem prescription Respondent wrote on July 31, 2011 because the refill his wife obtained on July 7, 2011 of Dr. Webb's prescription for 30 days of zolpidem should have lasted for another week. *Id.* at 252.

Dr. Chambers identified several instances in which Dr. Webb's prescriptions ''overlapped'' with those of Respondent.[28] These included the zolpidem prescription (for 30 tablets/30 days) which Respondent issued on May 6, 2011 and the refills obtained on both April 9, 2011 and May 23, 2011 by Respondent's wife of Dr. Webb's Feb. 3, 2011 prescription for 60 tablets (a 30-day supply). Tr. 255. Dr. Chambers testified that while ''[t]he one before is a relatively minor overlap[,] about one or two days, which is fairly insignificant, . . . the secondary overlap is more significant.'' *Id.* The prescriptions presented the same concerns of danger to the patient and confusion for the doctor. *Id.*

Dr. Chambers subsequently testified that it does not matter whether Dr. Webb's prescriptions were new prescriptions or refills because the prescription ''is essentially an instruction both to the pharmacist and the patient for the daily dosing and the number of days that the patient should follow that dosing.'' *Id.* at 257. Dr. Chambers then testified that ''[r]efills is [sic] just a way to communicate to the patient and the pharmacist . . . that you're allotting the schedule out in monthly, usually monthly allotments, and then it starts over.'' *Id.* Continuing, Dr. Chambers explained that ''the bottom line is that when the doctor writes the prescription and the pharmacist records it . . . there's a complete understanding of what's expected. There should be no haziness on the part of the doctor or the pharmacist or the patient . . . about the expected rate of consumption . . . from the start to finish, whether it be a 30-day supply or a 30-day supply with two refills.'' *Id.* at 257–58.

Next, the Government questioned Dr. Chambers about the combination of prescriptions/refills that Respondent's wife filled on November 28–29, 2011. *Id.* at 258–59. Specifically, on November 28, 2011, she refilled a prescription issued by Dr. Webb for 45 clonazepam (15 days) as well as filled a new prescription issued by Webb for 90 capsules of Adderall. GX 11, at 11. The next day, she filled prescriptions for a one-day supply of Diastat Acudial (a rectal suppository of diazepam) and a one-day supply (four tablets) of hydrocodone/apap 10/650. *Id.*

Dr. Chambers noted that the Diastat prescription ''is a bit puzzling because it's clear [Respondent's wife] is taking oral meds and usually [Diastat] [is] reserved for people who can't take [drugs] oral[ly].'' *Id.* He then testified that ''it's a very high risk and potentially lethal combination one day after receiving a 15-day supply of'' clonazepam and ''also a stimulant'' from Dr. Webb. *Id.* Dr. Chambers then testified that ''[t]he combination of an opioid and a benzodiazepine is causing an unprecedented epidemic of death in the United States . . . because when the two drugs are together they synergistically suppress consciousness and breathing and the central nervous system.'' *Id.*

Addressing the prescriptions which Respondent issued on both June 18 and July 17, 2012, for 20 du of alprazolam 2 mg (both being for a 10-day supply),[29] each of which was filled on the date of issuance, as well as the refill she obtained on July 5, 2012 of Dr. Webb's prescription for 45 du (15 days), Dr. Chambers testified that the prescriptions had different dosing instructions and overlapped. *Id.* at 262–63. Dr. Chambers then testified that ''we don't know what she was actually taking, but if she was actually taking the dose per both doctor's directions, she would be taking 10 milligrams of [alprazolam] a day . . . which would render me unconscious.'' *Id.* at 263. As another example of Respondent's issuance of an alprazolam

[28] This particular overlap involved Respondent's zolpidem prescription of March 30, 2011 for 30 tablets (a 15-day supply) (Rx No. 4 above) and an April 9 dispensing of a zolpidem prescription. Tr. 254–55. Dr. Chambers testified that ''on April 9, 2011, Dr. Webb issue[d] the same med for a 30-day supply. So now you have an example of Webb unknowingly overlapping a controlled substance with Dr. Alexander that happened on 3–30.'' *Id.* at 255. The PMP report shows, however, that the latter event did not involve the issuance of a new prescriptions but a refill of Dr. Webb's February 3, 2011 prescription. *See* GE 11, at 13. Nonetheless, Respondent's prescription still created an overlap.

[29] *See* prescription Nos.31 and 32 above.

prescription which resulted in ''nearly a week of overlap of the same dose by two different doctors'' and raised ''the same concern,'' Dr. Chambers identified Respondent's March 28, 2013 prescription for 14 dosage units (three tablets a day), which overlapped with a refill his wife obtained on March 19, 2013 for 45 tablets (also three tablets a day).[30] *Id.* at 266.

Addressing Respondent's July 7, 2013 prescriptions (Nos. 46 and 47) for 12 du of hydrocodone/apap 10/650 (two-day supply) and 12 alprazolam 2 mg (six-day supply), Dr. Chambers characterized the latter prescription as ''remarkable,'' explaining that ''it's prescribed at the same time [Respondent] also prescribed hydrocodone, an opioid medication, also on the same day, again introducing the risk of a potentially lethal overdose.'' *Id.* at 268–69. Dr. Chambers noted that Respondent's prescribing was ''also occurring in the context of'' an amphetamine (Adderall XR) prescription for 30 days issued by Dr. Webb ''six days'' earlier. *Id.* at 269. Dr. Chambers then testified that if Respondent's wife was ''taking as prescribed, she's doing what street people call a speedball, which is essentially an amphetamine/opioid combination with a . . . benzodiazepine garnish.'' *Id.* Dr. Chambers also noted that on July 1, 2013, the same day that Respondent's wife filled the Adderall[31] prescription, Respondent had also issued her a prescription for 20 hydrocodone/apap 10/650, which she filled that day. *Id.* at 269–70. Dr. Chambers noted that this hydrocodone prescription was ''a higher dose than what Dr. Webb did.'' *Id.* at 273. He explained that ''there's a combination of multiple overlaps of multiple classes of addictive substances that can produce overdose and severe psychiatric disturbances from two different physicians who are apparently in no communication.'' *Id.* Continuing, he explained that ''in [his] experience, when you see all three of those [classes of] drugs represented and you have multiple physicians contributing to it . . . that indicates a patient who is in serious trouble iatrogenically . . . meaning harmed being caused through medical practice.'' *Id.* at 274.

Asked if he had ''reach[ed] a conclusion'' as to whether Respondent's prescriptions were issued ''within the usual course of professional conduct,'' Dr. Chambers testified:

> I did. It is not [the] usual course of clinical conduct for someone with mental illness or someone without mental illness to be prescribed these combinations of drugs and to have these combinations being prescribed by different individuals who—one of who—where there's not communication or awareness that it's happening. So it's not only not usual clinical practice, but the reason it's not usual is because it's dangerous for patients and harmful. So it's actually not only is it not usual, it's essentially malpractice.

*Id.* at 275. On further questioning, Dr. Chambers testified that the Respondent's prescribing was not ''legitimate medical practice'' and the prescriptions were ''non-therapeutic.'' *Id.* Dr. Chambers further testified that ''[b]ased on the entirety of the evidence [he] reviewed,'' Respondent's prescribing did not comply with either the Controlled Substances Act or the standards of the Mississippi Administrative Code, including the State's requirements for patient records. *Id.* at 276, 278.

Addressing the patient file Respondent maintained on his wife, Dr. Chambers testified that ''there is a paucity of data to support the diagnosis or the prescription . . . that the note is built around. There's a lack of physical or mental status exam that normally would be in a note like this to justify and direct the use of controlled substances.'' *Id.* at 277. Dr. Chambers further observed that in comparing the patient file with the PMP data, ''about 40 percent of the prescriptions'' had ''no corresponding note at all. There's no data. There's no diagnosis, no detailing of what was prescribed.'' *Id.* He also observed that ''there are instances where the dosing or type of the drug is left out of the record.'' *Id.* at 278.

Dr. Chambers identified Respondent's entry dated January 16, 2012 (Prescription No. 24) as one such example. Tr. 278. As found above, on this date, Respondent prescribed 30 alprazolam 2 mg ''to be taken as directed'' and wrote in the note: ''Dr. Webb wants Jill to come in. Difficult [with] transportation—will Rx 10 day supply till 1/26/12—Webb aware—Xanax 2 mg'' with a dosing instruction of ''po TID.'' GE 6, at 2.

Dr. Chambers testified that ''this note does not have a diagnosis. It doesn't have an examination to justify . . . why that prescription happened at that dose . . . was he aware of what the prescription was from another doctor? Was he continuing? Was there any plan to taper it?'' Tr. 279. Dr. Chambers added that ''he's kind of writing as if the reason he's doing it is because the patient can't get to Dr. Webb, and he's documenting that Webb is aware . . . but in review of Webb's chart, there no indication that Webb was ever aware that this kind of stuff was going on.'' *Id.* When then asked if a 10-day supply is ''unusual for . . . a gap fill,'' Dr. Chambers answered:

> . . . I think it's unusual for one doctor to be gap filling another regardless of what the duration is, especially when there's no knowledge that that's happening. So any duration is odd, I think. I guess the longer the number of days the more concerning it is because you're dispensing bigger doses. I mean, she's got 30 tabs. That's quite a bit.

*Id.* at 280.

Addressing Respondent's note of February 18, 2012, Dr. Chambers acknowledged that it contained ''a little bit more of what you could call a clinical assessment'' in that Respondent described his wife's symptoms. *Id.* at 281. Dr. Chambers observed, however, that the note did not indicate ''how many he prescribe[d].'' *Id.* As for Respondent's statement that his wife was ''[o]ut of her Xanax for . . . 10 days'' and ''[o]ut of her Ambien for a week,'' GE 6, at 3, Dr. Chambers testified:

> It's not clear exactly what that means, but I take it to mean that he is prescribing because she's been out. And so, first of all, why is she out? Is it because she's using it too rapidly? It's just not clear. But he is filling the gap with an unclear amount and then suggesting by my read . . . [that] he's documenting he's contacting Dr. Webb,

[30] Other examples of overlapping prescriptions involved Respondent's May 10 and May 13, 2013 prescriptions (Nos. 43 and 44 above) for 14 and 12 dosage units of alprazolam 2 mg, which overlapped with the refill his wife obtained on April 30, 2013 of Dr. Webb's prescriptions for 45 du (15 days) of alprazolam 2 mg. Tr. 267. According to Dr. Chambers, even Respondent's May 10 and May 13 prescriptions overlapped, and that on May 13, ''what you actually have here is a triple compounding of the dosing based on the disposition dates and the way the drugs were instructed to be taken.'' *Id.* Dr. Chambers then explained that ''that is a very dangerous dose that would normally never be prescribed outside an intensive care unit.'' *Id.* at 267–68.

Another such example is Respondent's July 29, 2013 alprazolam prescription which provided eight tablets (TID). Dr. Chambers testified that Respondent's prescription provided a dosing instruction of eight milligrams a day, Tr. 271, which is supported by the PMP report which lists the prescription as providing a two-day supply. GE 11, at 5. However, the dosing instruction on the actual prescription was TID, or one tablet, three times a day. GX 39, at 1–2. Nonetheless, the prescription overlapped with the refill Respondent's wife obtained on July 19, 2013 for Dr. Webb's prescription for 45 tablets (15 days), and on July 31, 2013, she obtained a new prescription from Dr. Webb for 45 tablets (15 days). GE 11, at 5. However, even if Respondent's prescription only had a dosing instruction of 3 tablets a day, if she took the medications as prescribed by both Dr. Webb and Respondent for the period in which the prescriptions overlapped, she would have taken six tablets a day or 12 milligrams. Tr. 272.

[31] Dr. Chambers explained that while Adderall is ''used for a number of clinical indications, including attention deficit disorder [and] narcolepsy . . . [i]t also has significant street value'' and is ''basically a cousin of methamphetamine.'' Tr. 270.

informing them of this gap fill, the best I could tell.

But what's beginning to emerge here in this note and does come in later is that he is becoming—Dr. Alexander is becoming aware that she's running out and I assume prematurely because when you look at the PDMP data from Dr. Webb, Dr. Webb is not creating gaps. . . . He is not leaving her hanging with no medication a whole lot of times.

*Id.* at 281–82.

Continuing on to the next note (March 12, 2012), Dr. Chambers testified that this was ''the first time I've seen a diagnosis in the chart.'' *Id* at 282. He then explained that ''delusional parasitosis is a non-specific psychotic symptom,'' and that while it can be caused by ''a primary delusional illness . . . more commonly [it] is a sign of severe drug withdrawal'' including ''benzodiazepine . . . or even opiate withdrawal.'' *Id.* at 282–83. Dr. Chambers testified that the behavior documented in the chart (jerking, twitching, and delusional parasitosis) ''suggests extreme discomfort'' and ''could suggest vital sign changes [and] impending catastrophic withdrawal.'' [32] *Id.* at 283. Dr. Chambers observed, however, that Respondent did not obtain his wife's blood pressure and pulse or perform a mental status exam. *Id.* at 284.

Respondent's note of July 14, 2012 documents a prescription for 20 alprazolam 2 mg, a ''6 day supply,'' and states, among other things, that his wife had been off medications for four months and had been staying with her mother-in-law. GE 6, at 4. Regarding the note, Dr. Chambers testified that ''I don't know that she's even around when this prescription happens. It's just not clear where . . . she [is]. There's no evidence that she's even in front of him on July 14, and that's also a concern.'' Tr. 285.

Dr. Chambers observed that, in the October 5, 2012 note (''[s]he is out 2 days early''), Respondent documented that his wife was ''actually overusing the prescription that Dr. Webb ha[d] provided her. So he's documenting evidence that she's demonstrating abuse of these drugs and then he . . . say[s], '[s]he's lacerating and cutting herself, severe anxiety and depression, arms excoriated. No return call from a weekend doctor. I have to leave to work out of town.''' *Id.* After criticizing Respondent for ''abandoning the patient,'' who was self-mutilating and in a ''potentially life threatening withdrawal,'' Dr. Chambers testified that Respondent's ''leaving for the weekend and leaving her with more medication unsupervised'' is ''of grave concern.'' *Id.*

Dr. Chambers offered similar testimony regarding Respondent's May 13, 2012 note. *See id.* 288 (''So again he's now creating a track record in his . . . notation that the patient is essentially out of control and abusing Xanax and injuring herself. His response is to attempt to prescribe a combo of Xanax and Ambien . . . .).

Respondent's February 27, 2013 note states that his wife was ''[a]nxious about marital situation.'' As to the note, Dr. Chambers testified that ''it's not considered a normal medical practice'' to treat family members and ''that when it comes to controlled substances it's a whole different ball game'' when the prescription is ''for a family member.'' [33] *Id.* at 286–87.

Dr. Chambers offered similar testimony with respect to Respondent's March 28, 2012 note, which states: ''Marital/physical/mental stress sky high—Marriage workshop in Montana just accentuated'' and ''Out of Xanax early—rebound anxiety—self harm.'' GE 6, at 7. Dr. Chambers testified that he found that entry was ''interesting because the marital, physical and mental stress . . . involves him, and he's prescribing this medication to somebody who is in acute distress that's ultimately related to the medication.'' Tr. 287. Dr. Chambers also testified that Respondent's notation of a prescription for ''Xanax # 14'' ''is incomplete'' because it does not state ''the dose'' or the patient's instructions. *Id.*

Subsequently, the Government asked Dr. Chambers to address ''the situation where'' a primary care doctor is prescribing to a patient who is also being treated by a psychiatrist. *Id.* at 291. Dr. Chambers testified that in his ''own practice,'' if a new patient is receiving psychoactive medication from another physician, he ''will call them to stop that because you can't have two chefs in the kitchen.'' *Id.* Dr. Chambers then explained:

> If you have two chefs in the kitchen, this is the kind of stuff that can happen as you get chaos and harm and polypharmacy and no one understanding what is the illness versus what is [sic] the side effects of the medications, and it can lead to escalation of mental illness, addiction, and even death.

*Id.*

Finally, on direct examination, Dr. Chambers testified that ''[a] competent psychiatrist would document [in the patient's chart] if they knew that another doctor was prescribing controlled substances that were overlapping or representing a threat.'' *Id.* at 298. A competent psychiatrist would also ''take action to stop it or to stop their practice.'' *Id.*

On cross-examination, Dr. Chambers agreed that ''[i]n many cases,'' Respondent prescribed the same drugs to his wife as were prescribed by Dr. Webb. *Id.* at 307. Dr. Chambers also acknowledged that he had not examined Respondent's wife and that ''someone who sees her in person'' is in a better position to evaluate her than a person who only reads her chart. *Id.* at 310. After accusing Dr. Chambers of making a ''serious allegation []'' when he testified that Respondent's ''wife was going through withdrawal'' and which ''could be interpreted as she was abusing controlled substances,'' Respondent's counsel asked Dr. Chambers whether he or Dr. Webb was in a better position to make that determination. *Id.* Dr. Chambers answered that Dr. Webb was, but noted that he ''was looking at data from'' Respondent and ''had the ability to look at two charts.'' *Id.* at 310–11; *see also id.* at 319 (Q. You don't know if she was exhibiting physical characteristics that correspond to drug addiction. A. I can only go on what I've read.'').

Asked by Respondent's counsel if ''providing gap fills necessarily mean[s] there's a drug abuse issue,'' Dr. Chambers answered that ''[i]t can mean.'' *Id.* at 311. After Respondent's counsel asserted that ''[i]t can . . . it's not definitive,'' Dr. Chambers answered: ''I don't see gap filling happen[ing] in this case. There is no gap filling going on. There's overlaying.'' *Id.* After Respondent's counsel asserted that Dr. Webb ''ha[d] categorized the same

[32] Dr. Chambers further criticized Respondent because ''the standard of care for the treatment of acute withdrawal'' requires as part of ''the basic response to get a blood pressure or a pulse,'' and ''[i]f these measures aren't taken, people die routinely.'' *Id.* at 284.

[33] Dr. Chambers also testified that there is a prohibition against a psychiatrist treating a spouse for two reasons. Tr. 293. According to Dr. Chambers, the first reason is that the practice of psychiatry requires ''getting inside the mind of the patient'' and ''is a very invasive process'' and that ''romantic and sexual . . . motives will contaminate the clarity of the practitioner. . . . A psychiatrist who is falling in love with his patient will begin to take actions that benefit . . . him or her rather than the patient.'' *Id.* at 293–94. The second reason is that ''there is an implicit power differential'' between ''a psychiatrist and a patient'' and that ''to exploit that power differential on a patient who's vulnerable with mental illness through romantic or erotic counter-transference is regarded fairly much as a cardinal sin in psychiatry.'' *Id.* at 294. Continuing, Dr. Chambers testified that in ''many cases, these are patients who have already suffered physical and sexual abuse previously'' and are ''susceptible'' to more abuse ''later on.'' Thus, if a ''psychiatrist engages in a sexual relationship with a patient . . . the very real danger is [that] there could . . . be a revictimization . . . of the patient.'' *Id.* at 295.

Dr. Chambers also testified, however, that ''[t]his standard is actually not true for other branches of medicine'' such as family practice. *Id.* at 294.

evidence . . . as gap filling,'' Dr. Chambers testified: ''[i]t would surprise me if he's seen the same evidence . . . It would surprise me because that's not what I see in the data.'' [34] *Id.*

Assuming facts not in evidence, Respondent's counsel then asked Dr. Chambers if ''somebody who sees [the patient] regularly five or six times a week as a patient [35] or someone who's paid to review her patient file'' is ''in a better position'' to diagnose a patient as a substance abuser. *Id.* While Dr. Chambers agreed that a psychiatrist who saw the patient is in a better position to evaluate a patient, in response to the question of whether ''it would not surprise [him] that Dr. Webb concluded that [Respondent's wife] didn't have a substance abuse issue,'' Dr. Chambers explained that ''[i]t wouldn't'' because Dr. Webb is ''not an addiction psychiatrist.'' *Id.* at 312–13. When subsequently asked by Respondent's counsel if he ''disagree[d] . . . with the doctor that's seen her for 15 years five to six times a week with his diagnosis,'' Dr. Chambers answered that he did.[36] *Id. See also id.* at 319 (Q. ''So it's better to leave it to the psychiatrist who sees her five to six times a week over a 15-year period to make that decision.'' A. ''Well, not always. Not always, right.'').

Dr. Chambers acknowledged that Respondent's and Dr. Webb's dosing of alprazolam were ''often in the same ballpark.'' *Id.* at 317. However, Dr. Chambers explained that, while ''taken separately both of the [doctors'] dose ranges might be acceptable, . . . if they're . . . overlapping, that's when you get into the danger.'' *Id.* Dr. Chambers acknowledged, however, that ''[n]o one'' knows how much of the drug Respondent's wife was taking. *Id.* at 318.

Respondent's counsel then asked Dr. Chambers if ''you're saying that she was addicted or . . . was abusing controlled substances . . . wouldn't . . . the individual who prescribed her over 1500 doses of controlled substance in one year . . . be more responsible for that versus the individual who prescribed 200 doses of controlled substances a year?'' *Id.* at 320. Dr. Chambers answered: ''but what we're seeing here, that's not what happened. We're seeing two people prescribing [to] one person.'' *Id.* Continuing, Dr. Chambers explained that ''it could be a totally different picture if . . . only Dr. Webb'' was prescribing but he had ''no idea what that whole trajectory would look like'' and whether ''[s]he might be more stable.'' *Id.* Dr. Chambers held to his earlier testimony that having two physicians prescribe to Respondent's wife was ''creating chaos that could actually cause the treatment to get even worse'' and ''to evolve in the wrong direction.'' *Id.* at 321.

After Dr. Chambers acknowledged that ''Dr. Webb prescribed a significant amount of controlled substances, Respondent's counsel asked him if he ''was aware that in 2011 [Respondent] only prescribed 128 dosage units to her?'' [37] *Id.* at 321. After answering ''yes,'' Dr, Chambers added that ''Dr. Alexander prescribed about 20 percent of the controlled prescriptions and Dr. Webb about 70 percent on average over three years. *Id.*

Following questions about the relative amounts of controlled substances prescribed by Dr. Webb and Respondent, Respondent's counsel asked Dr. Chambers if Respondent's wife had ''a substance abuse issue, . . . isn't it logical that Dr. Webb would have as much, if not more, responsibility for that?'' *Id.* at 322. Dr. Chambers disagreed, explaining: ''not necessarily because Dr. Webb is not aware that . . . two doctors [were] putting drugs into one person.'' *Id.* While Dr. Chambers acknowledged that there is evidence in Dr. Webb's chart ''that he had discussions'' with Respondent about his wife, he found ''no evidence at all . . . that [Dr. Webb] knew that [Respondent] was also prescribing controlled substances.'' *Id.*

Dr. Chambers testified that he did not see any notation in Dr. Webb's patient file that he was aware that Respondent's wife ''was running out early and that [Dr. Webb] was filling earlier.'' *Id.* at 328. Asked if he would be surprised that Dr. Webb testified that he was aware that Respondent's wife was getting early refills, Dr. Chambers answered that he ''would be'' and explained that PMP ''data doesn't really reflect [that] there was a great deal of early refill activity going on from Webb by himself,'' and while ''[t]here may be a few instances of it, [it was] not very frequent.'' *Id.* at 329. Dr. Chambers explained that Dr. Webb's ''prescribing shows a relative lack of overlap of his . . . prescriptions for controlled substances. And when I say 'relative lack,' I mean maybe a day or two,'' which is ''not really significant because people have got to go to the pharmacy.'' *Id.*

Respondent's counsel then questioned Dr. Chambers about the alprazolam prescriptions which were issued by Dr. Webb and filled by Respondent's wife on May 14, June 10, July 4, July 21, August 4, and August 16, 2011, and whether the overlap between the prescriptions concerned him. *Id.* at 331. Dr. Chambers acknowledged that the June 10, 2011 filling created an overlap of three/four days and was ''on the margin'' as did the August 16, 2011 filling. *Id.* at 331–32. Dr. Chambers also acknowledged that the July 21 prescription ''would concern me.'' *Id.* at 332. Dr. Chambers offered similar testimony with respect to several alprazolam prescriptions that Respondent's wife filled on February 14 and 23, 2012, finding that the latter fill was ''five days early'' and ''[t]hat's when the red flag begins to go up.'' *Id.* at 332–33. Of note, however, several of these fills were actually refills of prescriptions written much earlier, *see* Tr. 333, and in any event, to the extent that Dr. Webb should have been aware that a previous prescription he issued had provided sufficient refills such that there was no reason to issue a new prescription on a particular date, Dr. Webb is not the respondent in this proceeding.[38] Likewise, while Respondent's counsel raised a series of questions as to whether the pharmacies that filled the prescriptions should not have dispensed various early refills, *id.* at 334–336, the

[34] As found above, while Dr. Webb testified that gap filling ''means a prescription that is used to get you to the next authorized refill'' and gave various examples, including ''something that would speak to a need for more medication,'' his testimony was clear that with the exception of a prescription issued by ''one of my on call doctors,'' a gap fill by another provider was not appropriate. Tr. 138–39, 192, 195–96.

[35] Dr. Webb's patient file contains progress notes for 10 visits by Respondent's wife during the years 2011 through 2013. GX 5, at 42–53. Thus, contrary to the premise of the question, there is no evidence that Dr. Webb saw Respondent's wife ''five or six times a week as a patient.'' Tr. 311.

[36] While the ALJ admitted only Dr. Webb's chart for Respondent's wife during the years 2011 through 2013, Tr. 74, here again, there is no evidence in the entire record that Dr. Webb saw Respondent's wife five to six times a week.

[37] This, too, is a misstatement of the evidence. Rather, the evidence shows that during 2011, Respondent issued prescriptions for 206 dosage units of zolpidem, 151 dosage units of hydrocodone, 28 dosage units of clonazepam, 28 dosage units of alprazolam, and one kit of Diastat acudial.

Respondent's counsel also misstated the evidence when he asked Dr. Chambers if he was ''aware [that] in 2012 Dr. Webb prescribed approximately 1720 dosage units of controlled substances versus the 132 that [Respondent] prescribed] to'' is wife. Tr. 321. Rather, the evidence shows that Respondent prescribed 112 du of zolpidem, 94 du of alprazolam, 20 du of diazepam, 30 du of hydrocodone, 15 du of Adderall, as well as Hycodan cough syrup.

[38] Specifically, Dr. Webb's February 3, 2011 alprazolam prescription, which was for a 30-day supply, see GE 5, at 111, authorized five refills, and Respondent's wife obtained refills which were authorized by this prescription on June 10 and July 4, 2011. *See* GE 11, at 12. However, on May 2, 2011, Dr. Webb issued Respondent's wife an additional prescription for 30 days of alprazolam. GE 11, at 13; GE 5, at 111.

ALJ properly ruled that the conduct of the pharmacies is irrelevant. *Id.* at 336.

Respondent's counsel subsequently asked Dr. Chambers if the hydrocodone prescription which Dr. Webb issued on June 28, 2013 concerned him. *Id.* at 338. Dr. Chambers testified that he did ''have a concern in that [Dr. Webb] is concurrently prescribing two other benzodiazepines at the same time,'' these being temazepam and alprazolam. *Id.* at 338–39. Dr. Chambers also acknowledged that the Adderall prescription issued by Dr. Webb on this date created ''a speedball.'' *Id.* at 339. Continuing, Dr. Chambers testified:

> So that is a concern. When you step back from the record and you look at where—the opiate is the main threat actually, and when you look at the predominance of opiate prescribing over three years, the majority of it came from Dr. Alexander. So the number of opiates that were prescribed were quite rare. The incidents you're putting in there—you're pointing out is a concern, but . . . the relative frequency of which Webb did that was much, much, much lower than when Dr. Alexander [did] it, and that's interesting because, as you pointed out, Dr. Webb is prescribing . . . three or four times more number of prescriptions. So it's a matter of degree as well.

*Id.* at 340.

Asked if it is within the usual course of professional practice for a psychiatrist to prescribe an opiate, Dr. Chambers testified that a psychiatrist ''may treat pain on occasion.'' *Id.* at 341. While Dr. Chambers then testified that he was surprised that Dr. Webb had testified that that he had written the June 28, 2013 hydrocodone prescription knowing that another physician was prescribing the drug to Respondent's wife and did so without consulting that physician, when Respondent's counsel asked Dr. Chambers if this called into question Dr. Webb's treatment of her, the ALJ properly sustained the Government's objection. *Id.* at 341–42.

Addressing the prescription for Diastat Acudial, a rectal suppository form of diazepam, Dr. Chambers testified that while Dr. Webb's file shows that Respondent's wife suffers from seizures, he did not see how administering Diastat would ''be consistent with treating someone who was having a seizure.'' *Id.* at 345. While Dr. Chambers testified that Valium (diazepam) and benzodiazepines ''can be used to treat seizure disorder[s],'' he added that these drugs ''can also cause seizure disorders.'' *Id.* at 346. Dr. Chambers subsequently testified that a rectal suppository might be used ''to treat a seizure disorder if someone can't take [the drug] orally, meaning [the patient] would be in status epilepticus, like actively seizing and not conscious.'' *Id.*

*Respondent's Testimony at the State Board Hearing Regarding His Reasons for Issuing the Prescriptions*

At the January 2014 Board hearing which resulted in the suspension of his medical license, Respondent was asked to explain why he issued the prescriptions. GE 14, at 56. Respondent explained that his wife has a ''fragile'' psychiatric condition, which ''became even more fragile'' in ''about November or December of last year.'' *Id.* He testified that while ''[t]here were times [that his wife] would run out of medicine and not decompensate . . . there was never a decompensation where she had her medicines.'' *Id.* at 57. Respondent testified that ''[w]ith [his] history, there was no way to call anyone else'' and ask them to prescribe Xanax to his wife because anyone he knows would ''be immediately suspicious that it was for me.'' *Id.* at 58. According to Respondent, ''as regards my wife herself, I would phone in usually a two- or three-day stop gap supply of medicines. And if you'll look at the numbers dispensed, it's usually 12, which would be a three-day supply for'' her. *Id.*

Continuing, Respondent testified that ''[w]e tried to . . . contact [Dr.] Webb, but . . . you can't get him at night, on weekends, and I don't blame him. And as he always tells [my wife], this is a matter that she shouldn't be running out prematurely.'' *Id.* Respondent maintained that ''[t]his happened . . . in December, in January, in February. I don't think it happened in April or May.'' *Id.* He further asserted that ''[i]t was sporadic'' and ''was always for a confined number of pills, a small amount, that bridged her gap between obviously when she was in crisis and didn't have any medicine.'' *Id.* Respondent also testified that ''we've got a baby here,'' ''I may be working out of town,'' and ''I've got to do something to calm this situation down.'' *Id.* Respondent added that he ''felt as if [he] was in an emergency situation.'' *Id.*

Apparently referring to the prescriptions he issued for hydrocodone, Respondent testified that ''[w]hen that changes—there were two occasions in general'' when he ''called in.'' *Id.* Respondent then related that a plastic surgeon had drained an abscess in his wife's thigh and testified that he ''noticed that there was one prescription for Lorcet then for a few, and it happened again in July of last year'' when his wife's mother died and his wife ''had a seizure [and] fell,'' suffering various injuries. *Id.* While Respondent testified that ''there was pain medicines [sic] then,'' he added that ''in general, the majority of the medicine were Xanax, two milligrams, three days' supply were common.'' *Id.* at 59–60. Respondent then maintained that his wife ''would get in with Dr. Webb the following Monday morning, and he will refill everything.'' *Id.* He further testified that ''I think the record reflects that I filled in in times where I just didn't think I had no other choice. I didn't know what to do.'' *Id.*

Continuing, Respondent testified that ''I have never denied that I called things in for Jill . . . I always thought that if called to task for it, the context would not speak for itself but would be evidenced by number, etcetera.'' *Id.* at 61. Respondent then testified that he was monitored by the Board and that ''[t]here's not been any diversion. There has not been any suggestion of that and, fortunately, got a lot of urine tests that were negative. I only ever did what I did when I perceived I had no other options having exhausted anything else that I knew to do.'' *Id.*

Asked about the December 2012 Adderall prescription, Respondent stated that he did not ''recall ever writing'' the prescription and that his wife ''was in the hospital in Hattiesburg at the time.'' *Id.* at 62. Continuing, Respondent stated that ''that one prescription doesn't seem to fit for me. I don't think that's mine, but I would be glad if somebody had a copy of it to look at it.'' *Id.* at 62–63. The prescription is, however, in the record of this proceeding. GE 18, at 102. It shows Respondent as the prescriber and Respondent offered no testimony in this proceeding disputing that he issued it. *Id.*

Respondent also told the Board that his prescribing was ''not a matter of judgment'' but ''a matter of heart.'' GE 14, at 63. He further told the Board that:

> I never did anything that I didn't think at the moment . . . was necessary, and I think if you look at the record you can see that. There can be no more. There can be no more. You know, if I have to call 911 every time, then I am Jill's husband. I am not—I was never her doctor. I stopped gapped, but I can't even do that anymore. I mean, I know that is a matter of fact going forward.

*Id.* at 63–64.

During cross-examination at the Board proceeding, Respondent admitted that he did not disclose that he had been issuing the prescriptions until he was asked by the Board. *Id.* at 64–65. He further asserted that he did not ''come up with [his wife's] regimen,'' that he ''didn't change her regime,'' and that he only ''mirrored what her treating psychiatrist had done.'' *Id.* at 65.

However, after a Board member identified multiple hydrocodone and Xanax prescriptions that he issued in July 2013 and asked if he thought ''that's wise,'' Respondent stated that ''I have to alter what I said. She also has a treating neurologist'' (Dr. Bell) who ''also does musculoskeletal medicine'' and that when his wife ''had a seizure'' she saw the neurologist. *Id.* at 66. Respondent then explained that ''[w]hen I say psychiatrist, that's what Dr. Bell had given her for pain, and she ran out, and she was sitting constantly in the . . . [h]ospital.'' *Id.* Respondent asserted that ''that was an isolated incident there.'' *Id.*

During the Board proceeding, Respondent acknowledged that he had violated his RCA and an agreement with the Board. *Id.* at 68. He further asserted that he never issued the prescriptions ''out of defiance[,] . . . self will, power, or arrogance'' and that ''[i]t was always done in a short stop gap times [sic] when I believed again . . . that there were no other options.'' *Id.* at 69.

Before the Board, Respondent further asserted that he did not notify Dr. Webb about the prescriptions because his wife ''assured [him] that [Webb] was apprised of every situation.'' *Id.* at 78. However, when a Board member noted that ''[c]ommon sense would dictate as a physician [that] the next morning you pick up the phone and call this psychiatri[st] that's taken care of [her] for 18 years and knows her probably better than any healthcare professional'' and tell him ''this is what happened last night, and this is what I did,'' Respondent answered: ''Not with every time.'' *Id.* at 79. Asked more specifically why he did not talk to Dr. Webb, Respondent maintained that his wife told him that ''[w]ith your Betty Ford attitude, he's going to take me off my Xanax'' and ''I don't want you to talk to him.'' *Id.* at 80. While Respondent testified that he should ''have overridden her concerns and intruded . . . upon her doctor/patient relationship,'' he then added that ''[i]n retrospect, I should have done that, more than the few times that I did do it. I certainly did it sometimes. I didn't do it with every issuance herein.'' *Id.*

The same Board member noted that ''there's an insinuation that [Dr. Webb] knew something had happened and that weekend or something had happened and that emergency medicine had been called in'' and asked ''is that correct?'' *Id.* Respondent answered: ''I certainly know that certain times he did. I don't know that at every time he did.'' *Id.* Respondent added that he was ''certain that the answering service's message was, '[c]all Dr. Alexander.' '' *Id.* at 80–81. Respondent subsequently testified that ''no, I didn't do it every time. I have had the discussion with him.'' *Id.* at 81.

Respondent testified that when he would call Dr. Webb's answering service, he would ''ask [ ] for a call back from Dr. Webb or the doctor on call.'' *Id.* at 84. When asked if he ''communicate[d] to the answering service the gravity of the situation,'' he admitted that he did not. *Id.* at 85. He then explained that ''I think I communicated that it was a medicine shortfall and that we needed someone to remedy that.'' *Id.*

*Respondent's Case*

Respondent's first witness was his wife. Tr. 357–401. Of consequence, the ALJ found ''that her testimony was not helpful in resolving the issues in this case.'' R.D. 9. Specifically, the ALJ found that ''her testimony was confusing, lacked specificity, and, at times, was internally inconsistent'' and that ''she could not remember many details of the underlying events about which she was testifying.'' *Id.* (citing Tr. 373–74, 376–77, 382, 384, 391). The ALJ also ''found her responses to some questions to be evasive, and her demeanor to be somewhat combative.'' *Id.* The ALJ also provided extensive reasons for why he gave ''little credence to her testimony, and where it [was] contradicted by other evidence,'' he did not find her testimony as credible.

These included:

She could not recall the number of times she had called Dr. Webb's answering service and had not received a return phone call. Tr. 360–62. She could not provide an adequate explanation of why she continued to be Dr. Webb's patient even though she was dissatisfied with his failure to return her phone calls. Tr. 361–62, 382, 391. In explaining her difficulty in recalling details from 2011 to 2013, she said she could not recall because that was ''seven years ago.'' Tr. 372. She testified that she did not have appointments with Dr. Webb between 2011 and 2013, yet Dr. Webb's treatment notes document several appointments during that period. *Compare* GE 5, at 42–46, 49–53, *with* Tr. 386. She testified that she told Dr. Webb that she would only get her prescriptions from him, and that that had been her practice for the past three years, but later testified that she had this discussion with Dr. Webb in 2016. Tr. 363, 368, 398–99. She testified that she only used one pharmacy, but her PMP report shows she filled prescriptions at numerous pharmacies. GE 11; Tr. 369. She did not give a direct answer to the question of whether she had told Dr. Webb that the Respondent had provided her with prescriptions, and when she provided an example of when she had passed that information to Dr. Webb, the example was outside of the time range of the Respondent's alleged violations. Tr. 360–63, 398–99.

R.D. 9.

Respondent's wife testified that she is known by various names including Mona Jill Graham Alexander, Mona Jill Graham, Mona Jill G. Alexander, and Jill Alexander. Tr. 357–58. She testified that she has been a patient of Dr. Webb for 16 years and she would usually see Dr. Webb three times a year and speak on the phone two to three times a month for 30 minutes to one hour. *Id.* at 359.

Respondent's wife testified that during the 2011 through 2013 time period, she ''would tell'' Dr. Webb that Respondent was prescribing controlled substances for her, ''especially if I got out of medication.'' *Id.* at 360. I do not find this credible. Nor apparently did the ALJ. R.D. 16 (FoF #28: ''Dr. Webb did not know that the Respondent was simultaneously prescribing controlled substances to Mrs. Alexander.'') (citations omitted). While Respondent's wife also testified that when she called after hours, ''[n]o one would ever . . . call me back,'' that this ''was very frustrating'' to her, and that she expressed her frustration to Dr. Webb, Tr. 360–61, the ALJ did not find this testimony credible. R.D. 15 n.21. Indeed, the ALJ specifically found credible Dr. Webb's testimony that Respondent's wife ''never told [him] that she was dissatisfied with her ability to contact him or his office.'' R.D. 15 (FOF #23.). I agree with these findings.

Respondent's wife testified that ''[t]he only conversation we [she and Dr. Webb] ever had about [her husband's prescribing] was to let me be the only one that prescribes you this medicine.'' Tr. 363. She initially testified that this conversation ''probably [occurred] towards the end'' of 2013, *id.* at 391, only to testify that the conversation occurred ''after [she] got discharged from the hospital'' in March 2016. *Id.* at 398–99. She also testified that during the 2011 through 2013 time period, she was hurting herself and that to the best of her recollection, she shared this with Dr. Webb. *Id.* at 364.

Regarding the Diastat prescription, Respondent's wife testified that she uses the drug because she has seizures and because ''I've had seizures, I just always try to travel with it and keep some on me.'' *Id.* at 366. Asked by the ALJ if she was using this medication in the 2011–2013 time period, Respondent's wife answered: ''I always keep it with me. It's something that I'll try not to ever run out.'' *Id.* She also subsequently testified that the Diastat was not prescribed by Dr. Webb but by her ''neurologist.'' *Id* at 393.

Respondent's wife testified that she believed her husband prescribed the controlled substances because he was trying to help her. *Id.* at 367. She further

testified that her husband ''never prescribed medicines that weren't prescribed for [sic] Dr. Webb when I got—until we could get in touch with him.'' *Id. See also id.* at 383 (''[B]ut he never prescribed anything that I hadn't already been prescribed by Dr. Webb.'').

She also testified that when her husband wrote a prescription for her, she was in crisis, and that her husband had never provided her with a controlled substance prescription when she was not in crisis. *Id.* at 367–68, 376. She further maintained that she ''would try to get in touch with Dr. Webb, and in the interim of a two- or three-day fill-in, I did get medicine from'' my husband. *Id.* at 371. When later asked why her husband would have to prescribe to her when she was in crisis, she maintained that ''[t]here would be occasional times I might run out a day early on a weekend . . . and he would see me very upset, crying, very emotional, and I feel like his intent was never to harm me. He was just trying to help me.'' *Id.* at 379. *See also id.* at 381 (''I don't know if I told him I need more or if he just knew that I just needed just two, three, four to get back to Dr. Webb because no one would call us back.''). However, when asked if Respondent had ever given her a prescription for a longer time period than two to four days, she answered: ''Not to my knowledge. I do not remember.'' *Id.* at 384.

On cross-examination, she also admitted that Respondent had written a hydrocodone prescription for her but maintained that he did so when her mother ''was dying in the hospital'' and she developed back pain because she sat at her ''mother's bedside waiting for her to die.'' *Id.* at 374. Respondent's wife then maintained that she did not recall her husband as having written ''[m]ore than one'' hydrocodone prescription. *Id.*

However, as found above, Respondent issued numerous hydrocodone prescriptions to her well before Dr. Webb issued the single hydrocodone prescription on June 28, 2013. Also, a substantial number of the prescriptions (especially those for zolpidem) were for quantities that far exceeded the amount necessary to provide medication until she was able to get a new prescription from Dr. Webb. Moreover, in a number of instances, Respondent issued the prescription notwithstanding that his wife had either recently refilled a prescription for the same drug or had refills outstanding which were authorized by an existing prescription issued by Dr. Webb.

On questioning by the ALJ, Respondent's wife maintained that during the period of 2011 and 2013, she ''usually [did] not'' get a call back from Respondent's office when she would leave a message. Tr. 387. Not only did the ALJ not find her testimony credible, her medical file contains evidence of only two phone calls she made during this period in which Dr. Webb did not document that he called back or Dr. Webb did not issue a prescription either the same day or the following day.[39]

Respondent called as a witness Peter Graham, Ph.D. Dr. Graham is a psychologist who works with Acumen Assessments, which provides clinical evaluations of physicians who are referred to it by physician health programs and state boards, and the Acumen Institute, which provides treatment, education and coaching to ''licensed professionals who are in the process of being rehabilitated for one or another professional reason.'' Tr. 403–04. Dr. Graham testified that the main focus of Acumen's evaluations is not whether a physician is competent to practice medicine, but whether the physician's ''mental status, personality variables, [and] character traits . . . may impact on decision-making, ethical judgment, self-regulation, ability to remain responsible and maintain the duties of licensure.'' *Id.* at 416–17.

Dr. Graham testified that Respondent was referred to him ''for evaluation of his fitness secondary to having engaged in conduct that was contrary to his [recovery] contract,'' that being writing the prescriptions for his wife. *Id.* at 417. According to Dr. Graham, the evaluation determined ''that there was an interaction between certain personality factors that affected his judgment and the way he was deciding to comply or not with his contract, as well as anxiety and situational stress related to'' his home life that ''affect[ed] his mental status.'' *Id.* at 419. The evaluation recommended to the MPHP that Respondent ''undergo treatment designed for professionals who have made ethical misjudgments or engaged in some kind of misconduct . . . with a focus on examining his ethical decision-making'' and how his ''personality traits'' affected his behavior. *Id.* at 420.

Respondent subsequently underwent treatment, which included both a three-week inpatient and one-week follow-up visits at three and six months, individual psychotherapy in his home community, and a three-day wrap up visit at the one-year mark. *Id.* at 421–22. According to Dr. Graham, Respondent's treatment team has determined that he can ''return to supervised and monitored practice.'' *Id.* at 425.

Respondent also called as a witness, Scott Hambleton, M.D., the medical director of the MPHP. *Id.* at 435–37. Dr. Hambleton testified that ''the heart of [Respondent's recovery] contract concerns abstinence from any mood-altering or addictive substances, which would increase the risk of a relapse to substance use and active addition.'' *Id.* at 443. He further testified that Respondent is subject to random testing approximately 30 times a year for both drug and alcohol use, that he is subject to a workplace monitor, and in the event he needs to take controlled substances, he ''is required to use a medication monitor'' and all such prescriptions must be approved by the MPHP ''in advance.'' *Id.* at 443–44. Dr. Hambleton also testified that Respondent is required to attend 12-step and Caduceus meetings for physicians in recovery. *Id.* at 445. In addition, according to Dr. Hambleton, a Board investigator visits Respondent on a random basis at least once a quarter to witness a drug screen and evaluate his appearance. *Id.* at 446–47. Dr. Hambleton further stated that Respondent's contract will last for as long as he has an active medical license. *Id.* at 447.

As for how the MPHP monitors the provision in Respondent's contract that prohibits prescribing to family members and himself, Dr. Hambleton testified that this is done by the Board's investigators. *Id.* at 448. Dr. Hambleton testified that if the MPHP found out that Respondent had prescribed controlled substances to himself or a family member it ''would withdraw advocacy immediately.'' *Id.* at 449. Dr. Hambleton further testified that he had no reservations about Respondent returning to the unrestricted practice of medicine. *Id.* at 450. The record does not establish, however, what ''the unrestricted practice of medicine'' entails in light of Respondent's recovery contract.

On cross-examination, Dr. Hambleton acknowledged that Respondent had violated his first two recovery contracts.[40] *Id.* at 452. He also

[39] The first of these was on August 25, 2011. GX 5, at 140. Notably, Respondent's wife had an office visit with Dr. Webb on August 16, 2011, during which he wrote her prescriptions for 30-day quantities of Adderall 20 mg, zolpidem 10 mg, and 90 alprazolam 2 mg. *Id.* at 49; GX 11, at 12. While the phone messages states ''Having problems,'' GX 5, at 140, Respondent did not issue a prescription until August 28, 2011, when he authorized 12 zolpidem.

The second of these occurred on July 10, 2013. GX 5, 133. However, the same day, Respondent's wife refilled a prescription for 45 alprazolam 2 mg (15 days). GX 11, at 6.

[40] Dr. Hambleton explained that Respondent had been subject to a ''provisional contract'' during the period of his license suspension ''to establish a

Continued

acknowledged that at some point when Respondent had a job opportunity in Tennessee, the MPHP had written to that State's Board recommending against granting a license to Respondent. *Id.* at 475.

Dr. Hambleton testified that he supported Respondent's return to the unrestricted practice of medicine because the Board's suspension of his license was ''a profound experience, especially for a neurosurgeon, with that amount of training,'' and ''[t]hat type of intervention has a powerful effect on the recovery process.'' *Id.* at 470. He also testified that ''Acumen has more expertise in dealing with personality issues'' and ''[s]o that treatment in itself . . . represents a profound event that makes it possible to provide advocacy.'' *Id.* at 470–71.

Dr. Hambleton further testified that Respondent's ''treatment has been effective'' and that ''[h]e's gaining insight, sensitivity, demonstration of more regard for others, responsibility, authenticity, the markers of recovery.'' *Id.* at 471.

However, on questioning by the ALJ, Dr. Hambleton testified that his ''frequency of contact'' with Respondent ''is not what allows me to make that assessment of him.'' *Id.* at 472. Rather, Dr. Hambleton explained that his assessment was based on reports he received from other participants in Respondent's Caduceus group, ''from another facilitator of the group,'' his cases manager's reports, and ''watching him interact with other physicians during'' the MPHP's ''annual Caduceus retreat.'' *Id.* at 472. Dr. Hambleton then acknowledged that when he ''provides advocacy, [his] interaction with participants is very limited'' and that he ''provide[s] advocacy based on the constellation of collateral sources of information [and] their drug testing'' results. *Id.* at 473.

Dr. Hambleton testified that ''[i]n the event that there is evidence of substance abuse, we will withdraw advocacy immediately, and it [will] be the end of his medical career.'' *Id.* at 477. He also testified that ''[i]n the event that he prescribes inappropriately . . . our medical board investigators will monitor it closely'' and the Board would ''issue an immediate prohibition on practice.'' *Id.* Dr. Hambleton was ''not sure'' as to how the Board found out about Respondent's prescribing to his wife, but based on ''conversations'' he has ''had with investigators,'' he asserted that ''now it is part of their policy to do regular PMP checks'' on the MPHP's participants.'' *Id.* at 477–78. The MPHP does not, however, have that authority. *Id.* at 478.

Respondent also testified on his own behalf. *Id.* at 481. After discussing his background, training and current employment, *id.* at 481–82, Respondent testified that he ''[a]bsolutely'' prescribed controlled substances to his wife and did so when she was under the care of another physician. *Id.* at 484.

Asked if his prescribing of controlled substances to his wife ''violated his obligations as a licensed doctor in . . . Mississippi,'' Respondent answered: ''I know it violated my contract with the professionals healthcare program.'' *Id.* Asked if he believed that his prescribing ''in the manner that'' he did ''violated [his] obligations as a DEA registrant,'' Respondent testified: ''I don't know the specific legalities of DEA registration, but I'm here to tell you what I did was wrong, period, without any equivocation.'' *Id.*

Respondent testified that when he testified before the State Board, he accepted responsibility for prescribing to his wife. *Id.* at 486. He then testified that he is under a lifetime monitoring contract, and that he is monitored by both the MPHP and the Board. *Id.*

Asked why the Agency should entrust him with a DEA registration, Respondent testified:

> even . . . if I don't know the letter or spirt of any law that I transgressed, I do know that becoming involved in a loved one's care is foolish. There is no subjectivity there. I can be Jill's husband, but that's all I can be to her, period. There can't be any clinical judgment, or any family member for that matter.
>
> As I testified in my [2014] board hearing . . . , regardless of what it had come from, I thought I'd hit a brick wall. And there are no other options for me. If I can't practice medicine, conforming to every jot, tittle, to the letter of the law, I can't practice medicine. There are no more get-out-of-jail cards for me. There aren't.

*Id.* at 489–90. Continuing, Respondent testified:

> I have tried to—perhaps I made enough missteps, I can provide a beacon of some sort to younger physicians that might think it's okay to prescribe outside the bounds of normal patients. I don't know what else I possibly could do at this point to convince Your Honor what more I could do to be—that I am worthy to be entrusted with a DEA registration. I will do it. If someone suggests something to me, I will gladly do it, but —.

*Id.* at 491.

On cross-examination, the Government asked Respondent if he understood that ''DEA is alleging something slightly different than prescribing outside the contract.'' *Id.* at 494. After the ALJ overruled the objection of Respondent's counsel that the question was outside the scope of direct examination, Respondent testified that he was ''not certain that [he] understand[s] that fully.'' *Id.* at 495. The Government then asked Respondent if he understood that ''DEA is asserting that with respect to the prescriptions you issued for your wife that you violated Mississippi and federal law.'' *Id.* Respondent answered: ''I understand that you just asserted that, but my understanding would only stop there.'' *Id.*

The Government followed-up by asking: ''so . . . you are not admitting that you violated either federal or state law with respect to the prescriptions you issued to your wife?'' *Id.* Respondent testified: ''I think my answer is I'm uncertain as to every component, specifically of the federal, to be able to answer that as honestly as I want to.'' *Id.*

The Government asked Respondent if he understood that what he had been charged with in the DEA proceeding ''had nothing to do with'' his recovery contract. *Id.* at 497. Respondent testified: ''I understand that you just represented half of what I understand'' and added that ''I was found guilty of two things one, violation of a previous order . . . Number two, the unethical behavior, which in my interpretation is subsumed by the number of things that you have cited as far as Mississippi conduct, et cetera.'' *Id.*

After noting that Respondent was only ''admitting responsibility to what the Board found'' and that was not what DEA had charged him with, the Government explained that it was ''trying to get a clarification as to what you're accepting responsibility for?'' *Id.* at 497–98. Respondent testified:

> . . . as I've said already . . . I wrote prescriptions. I shouldn't have written prescriptions. It violated my contract. It violated my duty to my wife. It violated—in this one instance, in all my years of practice, that's the only time I've ever been called into question, but it violated as a layperson everything I think I should have done, regardless of why I thought at the time it might—erroneously thought it could be proper.
>
> As far as me as a physician testifying to what statutes I may or may not have transgressed, I can't. That would be speculative at least on some level for me.

*Id.*

After the ALJ sustained Respondent's objection to the Government's attempt to question him about both his testimony before the State Board and the patient file he maintained on his wife, the Government asked Respondent if he

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period of compliance and recovery.'' Tr. 452. Respondent did not violate this contract, which ended when he entered his current (fourth) contract. *Id.* at 453.

''accept[ed] that the prescriptions that you issued to your wife were outside the course of professional practice as defined by the DEA?'' *Id.* at 501. Respondent answered:

> I think I've answered that already. I don't know precisely how the DEA defines it, and to be scrupulously honest, I can't. I will once again accept the responsibility that what I did was wrong and I should not have done it. And I have done everything in my power to remediate that. But I do not know again . . . the specifics of the—of what I'm being charged with by DEA now, three years after I have assiduously striven to do everything I can to clean up and do everything right, and then you come along and ask me about new things.
>
> What hope is there for any other physician that follows me for redemption if we do everything we can. . . . What more, I mean, that's—I'm sorry. I'm getting emotional.

*Id.* at 501. Then asked if he had been treated unfairly by DEA, Respondent testified that ''I'm not certain I have a well-founded opinion of that. I know that I have done everything I humanly can and will continue to do so and provide the DEA and every other regulatory body with anything I can to ensure that I am safe for the public.'' *Id.* at 502.

The Government then attempted to ask Respondent if he accepted responsibility for failing maintain patient files in compliance with Mississippi law. *Id.* at 502–03. The ALJ disallowed the question, explaining that Respondent's ''counsel has decided not to ask him if he wants to accept responsibility for that.'' *Id.*

After both the Government and Respondent's counsel stated they had ''[n]othing further,'' the ALJ observed that he was ''was just a little bit puzzled as to [Respondent's] answer about acceptance of responsibility.'' *Id.* at 503. While the ALJ stated that he found Respondent ''generally very credible,'' he then explained that ''[w]hat puzzles me is how you could come to this hearing without knowing what the charges against you by DEA are?'' *Id.* Respondent answered that he ''presumed . . . that they would parallel that which the state charged me with. I mean, I knew we were having a hearing.'' *Id.* Respondent then testified that when he ''first applied for re-registration,'' he was told by a DI that ''it was all about my past history with addiction'' but that when he ''had the temerity to get an attorney, it morphed into something else,'' so he ''wasn't sure if'' he was to talk about his ''recovery or other things.'' *Id.* at 503–04.

After the ALJ asked if he had read the Show Cause Order and pointed out that it ''didn't say anything about [his] failure in recovery,'' Respondent acknowledged that ''[i]t didn't'' and asserted ''that's why [he] was confused.'' *Id.* at 504. Noting that the allegations involved his prescribing to his wife and his failure to make adequate notes in his wife's record, the ALJ again expressed his puzzlement as to what Respondent was ''accepting responsibility for.'' *Id.* at 504–05. Respondent replied that he knew ''exactly what the State . . . said I did'' and ''I think I believe that the DEA mimicked that . . . [or] paralleled that.'' *Id.* at 505. Continuing, Respondent stated: ''And if those two specifications or charges are the same, then, yes, I do accept responsibility for what DEA says.'' *Id.*

The ALJ then explained that he was not sure what Respondent meant; Respondent stated that it went to his ''understanding of what I was charged and found guilty with by the State,'' which included violating his Recovery Contract and ''basically unethical behavior.'' *Id.* Respondent added that he ''assumed that that was also what DEA was doing here . . . [and] that I was being called to task for the same things.'' *Id.* at 506.

Thereafter, the ALJ stated to Respondent's counsel that if he was ''getting into an area that you don't want me to ask about, don't hesitate to object because I know I'm going beyond what your direct examination was.'' *Id.* The ALJ further stated that he ''want[ed] to respect the relationship between you and your client and your client's rights in this hearing,'' and that if he asked a question that Respondent's counsel ''vigorously object[ed] to,'' he expected Respondent's counsel ''to say so.'' *Id.* Respondent's counsel then stated that ''[t]here are lines that I'm concerned about here and based on the history here of whether or not a full-throated, yes, I violated this statute was going to result in, you know additional action against'' Respondent. *Id.* The ALJ then offered Respondent's counsel the opportunity to further question his client. *Id.* at 507.

Respondent's counsel resumed questioning Respondent and asked him to ''clarify . . . what specific actions [he was] accepting responsibility for?'' *Id.* Respondent testified: ''Violating the previous order, right? Writing prescriptions for my wife when I wasn't a treating physician, which I think is not proper document, not fully proper documentation of those things.'' *Id.* Respondent's counsel then asked if ''it matter[ed] . . . what provisions that the violations fall under?'' *Id.* at 508. Respondent answered:

> . . . I have found me guilty, and so if someone shows me—and perhaps . . . what I was saying that I'm ignorant of the specifics of a DEA charge. But if I meet the criteria and I accept I did it, then I did it. From my hearing in January of 2014, I never said I didn't. I sat there and said, yes, this is what happened. There are some prescriptions errors in that record, but in general, yes, this is what happened.

*Id.* Respondent further testified on re-direct that he was, in the words of his counsel, ''accepting responsibility for inappropriate prescribing practices related to [his] wife.'' *Id.*

On re-cross, the Government asked Respondent ''[w]hat portion of the prescribing to [his] wife [was] inappropriate?'' *Id.* Respondent answered:

> Through my education with Dr. Webb—well, first of all, prescribing for family members is a bad idea in general. I think the contract specifies it because commonly that means there's diversion going on, and I'm prescribing for someone, and they're kicking it back to me, but that's not a question, and I think my urine tests show that didn't happen.
>
> I think that in general the objectivity required even in exigent circumstances must be called into question when it's a loved one.

*Id.* at 508–09.

Subsequently asked by the Government if ''there [was] anything else wrong with your prescriptions to your wife, aside from the fact that she's a family member,'' Respondent answered:

> Let me think on that a minute. I'm a little almost frightened to answer because at no time do I want anyone in this courtroom thinking, exigent or not, that I'm saying it was right or that you'd have done it too if you were there. There's not a complete patient file. I mean, is that what you're asking me?

*Id.* at 510. After the Government again asked Respondent what he thought he ''did wrong with respect to the prescriptions,'' Respondent answered: ''again, I shouldn't have written. I violated the contract. Prompt me . . . I'm not trying to minimize anything. I'm blanking, frankly.'' *Id.*

The Government then asked Respondent if he ''admit[ted] that the prescriptions you issued to your wife were outside the usual course of professional practice?'' *Id.* at 511. Respondent answered:

> As I understand that term of art . . . if the documentation is substandard, that that renders it outside the course of professional practice, then I would accept that, if I'm—any hesitancy previously has been based on that. I mean, you know, as a physician, I don't understand that term. When you say outside the course of medical practice, it makes me think that someone just gave rat poison or something absurd like that. But when you lay the predicate about proper documentation, for instance, then, yes, I would have to accept that.

*Id.* at 511–12. The Government subsequently asked Respondent if he ''believe[d] that [his] actions increased the chances of [his] wife's dependency, overdose, or diversion of controlled substances?'' *Id.* at 512. Respondent answered ''[n]o.'' *Id.*

On still a further round of re-direct, Respondent acknowledged that he is ''not a psychiatrist'' and that ''[t]hese medicines are . . . chiefly used in psychiatric conditions. *Id.* at 513. Respondent's counsel further asked him if he understood that the DEA had alleged that he ''prescrib[ed] controlled substances to someone who was under the care of another physician for those same ailments.'' *Id.* Respondent testified that he understood that and ''accept[ed] that'' it was wrong for him to do that. *Id.* at 513–14.

Respondent's counsel then asked if could ''be trusted to not engage in such prescribing in the future?'' *Id.* at 514. Respondent testified:

> I will first say strongly, absolutely. I have spent the last three years trying to redeem this situation, to show everyone exactly how driven I am. And, Your Honor, I'm not trying to avoid anything. If someone shows me I've done something wrong, I will admit it. I'm not even bringing up the subtext. I did wrong. I throw myself upon the mercy of the process. I have done everything that I know to do to try to remedy this situation and I can do no more than give my sworn oath that this will not happen again.

*Id.*

Respondent's counsel concluded his examination by asking Respondent if his acceptance of responsibility included his ''prescribing to [his wife] while she was under the care of another doctor, perhaps providing medications too soon in terms of early refills, providing gap fills, [and] not having an adequate medical file?'' *Id.* at 515. Respondent answered ''[y]es.'' *Id.*

## Discussion

Section 303(f) of the Controlled Substances Act (CSA) provides that ''[t]he Attorney General may deny an application for [a practitioner's] registration . . . if the Attorney General determines that the issuance of such registration . . . would be inconsistent with the public interest.'' 21 U.S.C. 823(f). With respect to a practitioner, the Act requires the consideration of the following factors in making the public interest determination:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing . . . controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.

*Id.*

''[T]hese factors are . . . considered in the disjunctive.'' *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (2003). It is well settled that ''I may rely on any one or a combination of factors, and may give each factor the weight [I] deem [] appropriate in determining whether . . . an application for registration [should be] denied.'' *Paul H. Volkman,* 73 FR 30630, 30641 (2008) (citing *id.*), *pet. for rev. denied, Volkman* v. *DEA,* 567 F.3d 215, 222 (6th Cir. 2009); *see also MacKay* v. *DEA,* 664 F.3d 808, 816 (10th Cir. 2011); *Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005). Moreover, while I am required to consider each of the factors, I ''need not make explicit findings as to each one.'' *MacKay,* 664 F.3d at 816 (quoting *Volkman,* 567 F.3d at 222 (quoting *Hoxie,* 419 F.3d at 482)).[41]

The Government has the burden of proving, by a preponderance of the evidence, that the requirements for denial of an application pursuant to 21 U.S.C. 823(f) are met. 21 CFR 1301.44(d). However, once the Government has made a *prima facie* showing that issuing a new registration to the applicant would be inconsistent with the public interest, an applicant must then present sufficient mitigating evidence to show why he can be entrusted with a new registration. *Medicine Shoppe-Jonesborough,* 73 FR 364, 387 (2008) (citing cases)); *see also MacKay,* 664 F.3d at 817.

Having considered all of the factors, I find that the Government's evidence with respect to Factors Two and Four satisfies its *prima facie* burden of showing that granting Respondent's application would be inconsistent with the public interest.[42] I further find that Respondent has failed to produce sufficient evidence to rebut the Government's *prima facie* case.

[41] In short, this is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest; what matters is the seriousness of the registrant's misconduct. *Jayam Krishna-Iyer,* 74 FR 459, 462 (2009). Accordingly, as the Tenth Circuit has recognized, findings under a single factor can support the revocation of a registration or the denial of an application. *MacKay,* 664 F.3d at 821.

[42] As to factor one, while the Mississippi Board has taken disciplinary action against Respondent based on his issuance of the prescriptions, the Board has not made a recommendation to the Agency with respect to whether his application should be granted. To be sure, as a result of the Board's subsequent restoration of his medical license without restriction of his controlled substance prescribing authority under Mississippi law, Respondent satisfies the CSA's prerequisite for obtaining a new practitioner's registration. *See* 21 U.S.C. 823(f)(1); *see also id.* 802(21). (defining ''the term 'practitioner' [to] mean[ ] a . . . physician . . . or other person licensed, registered or otherwise permitted, by . . . the jurisdiction in which he practices . . . to distribute, dispense, [or] administer . . . a controlled substance in the course of professional practice''). However, the restoration of Respondent's state authority is not dispositive of the public interest inquiry. *See Mortimer Levin,* 57 FR 8680, 8681 (1992) (''[T]he Controlled Substances Act requires that the Administrator . . . make an independent determination [from that made by state officials] as to whether the granting of controlled substance privileges would be in the public interest.'').

To be sure, the Agency's case law contains some older decisions which can be read as giving more than nominal weight in the public interest determination to a State Board's decision (not involving a recommendation to DEA) either restoring or maintaining a practitioner's state authority to dispense controlled substances. *See, e.g., Gregory D. Owens,* 67 FR 50461, 50463 (2002) (expressing agreement with ALJ's conclusion that the board's placing dentist on probation instead of suspending or limiting his controlled substance authority ''reflects favorably upon [his] retaining his . . . [r]egistration, and upon DEA's granting of [his] pending renewal application''); *Vincent J. Scolaro,* 67 FR 42060, 42065 (2002) (concurring with ALJ's ''conclusion that'' state board's reinstatement of medical license ''with restrictions'' established that ''[b]oard implicitly agrees that the [r]espondent is ready to maintain a DEA registration upon the terms set forth in'' its order).

Of note, these cases cannot be squared with the Agency's longstanding holding that ''[t]he Controlled Substances Act requires that the Administrator . . . make an independent determination [from that made by state officials] as to whether the granting of controlled substance privileges would be in the public interest.'' *Levin,* 57 FR at 8681. Indeed, neither of these cases even acknowledged the existence of *Levin,* let alone attempted to reconcile the weight it gave the state board's action with *Levin.* While in other cases, the Agency has given some weight to a Board's action in allowing a practitioner to retain his state authority even in the absence of an express recommendation, *see Tyson Quy,* 78 FR 47412, 47417 (2013), the Agency has repeatedly held that a practitioner's retention of his/her state authority is not dispositive of the public interest inquiry. *See, e.g., Paul Weir Battershell,* 76 FR 44359, 44366 (2011) (citing *Edmund Chein,* 72 FR 6580, 6590 (2007), *pet. for rev. denied, Chein* v. *DEA,* 533 F.3d 828 (D.C. Cir. 2008)).

As to factor three, I acknowledge that there is no evidence that Respondent has been convicted of an offense under either federal or Mississippi law ''relating to the manufacture, distribution or dispensing of controlled substances.'' 21 U.S.C. 823(f)(3). However, there are a number of reasons why even a person who has engaged in criminal misconduct may never have been convicted of an offense under this factor, let alone prosecuted for one. *Dewey C. MacKay,* 75 FR 49956, 49973 (2010), *pet. for rev. denied, MacKay* v. *DEA,* 664 F.3d at 822. The Agency has therefore held that ''the absence of such a conviction is of considerably less consequence in the public interest inquiry'' and is therefore not dispositive. *Id.*

As for factor five, because the Government did not file exceptions to the ALJ's legal conclusions with respect to this factor, I deem it unnecessary to make any findings.

*Factors Two and Four—Respondent's Experience in Dispensing Controlled Substances and Record of Compliance With Applicable Controlled Substance Laws*

Under a longstanding DEA regulation, a prescription for a controlled substance is not ''effective'' unless it is ''issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.'' 21 CFR 1306.04(a). *See also* Miss. Code Ann. Sec. 41–29–137 (''a 'valid prescription' means a prescription that is issued for a legitimate medical purpose in the usual course of professional practice'').

Under the CSA, it is fundamental that a practitioner must establish a bonafide doctor-patient relationship in order to act ''in the usual course of . . . professional practice'' and to issue a prescription for a ''legitimate medical purpose.'' *See United States* v. *Moore,* 423 U.S. 122, 142–43 (1975); *United States* v. *Lovern,* 590 F.3d 1095, 1100–01 (10th Cir. 2009); *United States* v. *Smith,* 573 F.3d 639, 657 (8th Cir. 2009); *see also* 21 CFR 1306.04(a) (''an order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription within the meaning and intent of [21 U.S.C. 829] and . . . the person issuing it, shall be subject to the penalties provided for violations of the provisions of law related to controlled substances''). As the Supreme Court has explained, ''the prescription requirement . . . ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse. As a corollary, [it] also bars doctors from peddling to patients who crave the drugs for those prohibited uses.'' *Gonzales* v. *Oregon,* 546 U.S. 243, 274 (2006) (citing *Moore,* 423 U.S. 122, 135, 143 (1975)).

Both this Agency and the federal courts have held that ''establishing a violation of the prescription requirement 'requires proof that the practitioner's conduct went ''beyond the bounds of any legitimate medical practice, including that which would constitute civil negligence.'' ' '' *Laurence T. McKinney,* 73 FR 43260, 43266 (2008) (quoting *United States* v. *McIver,* 470 F.3d 550, 559 (4th Cir. 2006)). *See also United States* v. *Feingold,* 454 F.3d 1001, 1010 (9th Cir. 2006) (''[T]he *Moore* Court based its decision not merely on the fact that the doctor had committed malpractice, or even intentional malpractice, but rather on the fact that his actions completely betrayed any semblance of legitimate medical treatment.''); *Jack A. Danton,* 76 FR 60900, 60904 (2011) (finding violations of 21 CFR 1306.04(a), in the absence of expert testimony, ''where a physician has utterly failed to comply with multiple requirements of state law for evaluating her patients and determining whether controlled substances are medically indicated and thus has 'completely betrayed any semblance of legitimate medical treatment' '') (quoting *McKinney,* 73 FR at 43266 (quoting *Feingold,* 454 F.3d at 1010)).[43]

Under the Mississippi Board's Rule 1.4:

> Patient Record. A physician who prescribes, dispenses, or administers a controlled substance shall maintain a complete record of his or her examination, evaluation and treatment of the patient which must include documentation of the diagnosis and reasons for prescribing, dispensing or administering of any controlled substance; the name, dose, strength, quantity of the controlled substance and the date that the controlled substance was prescribed, dispensed or administered. The record required by this rule shall be maintained in the patient's medical records, provided that such medical records are maintained at the office of the physician . . . .
>
> No physician shall prescribe, administer or dispense any controlled substance or other drug having addiction-forming or addiction-sustaining liability without a good faith prior examination and medical indication therefore.

Miss. Admin. Code part 2640, Ch.1 r. 1.4. Continuing, Rule 1.4 explains that:

> A determination as to whether a ''good faith prior examination and medical indication therefore'' exists depends upon the facts and circumstances in each case. One of the primary roles of a physician is to elicit detailed information about the signs and symptoms which a patient presents in order that he or she may recommend a course of treatment to relieve the symptoms and cure the patient of his or her ailment or maintain him or her in an apparent state of good health. In order for a physician to achieve a proper diagnosis and treatment plan, a history and physical examination consistent with the nature and complaint are necessary. . . . The paramount importance of a complete medical history in establishing a correct diagnosis is well established. Standards of proper medical practice require that, upon any encounter with a patient, in order to establish proper diagnosis and regimen of treatment, a physician must take three steps: (a) take and record an appropriate medical history, (b) carry out an appropriate physical examination, and (c) record the results. The observance of these principles as a function of the ''course of legitimate professional practice'' is particularly of importance in cases in which controlled substances are to play a part in the course of treatment. It is the responsibility of the physician to dispense, prescribe or administer such drugs with proper regard for the actual and potential dangers.

*Id.*

Rule 1.4 further notes that ''[a] determination of proper 'medical indication'[ ] also requires a careful examination of the nature of the drug and all circumstances surrounding dispensation.'' *Id.* The Rule also specifically notes that ''repeated refills over relatively short periods of time or the issuance of prescriptions at a time when the patient should not have finished taking the same medication from a prior prescription had the prescription directions been properly followed or the correct dosage taken'' is a factor indicating a lack of good faith on the part of a physician. *Id.* Also, the Board's Rule 1.16 specifically provides that ''[t]he prescribing, administering or dispensing of any controlled substance in violation of the above rules shall constitute the administering, dispensing or prescribing of any narcotic drug or other drug having addiction-forming or addiction-sustaining liability otherwise than in the course of legitimate professional practice, in violation of Mississippi Code [ ] Section 73–25–29(3). '' Miss. Admin. Code part 2640, Ch. 1, r. 1.16).

Here, the ALJ found that that Respondent acted outside of the usual course of professional practice and lacked a legitimate medical purpose when he issued numerous prescriptions for controlled substances included alprazolam, diazepam, hydrocodone, zolpidem, and Adderall (amphetamine). R.D. 39–44. I agree with the ALJ that Respondent violated 21 CFR 1306.04(a) in issuing the prescriptions. I further find that in issuing each of the prescriptions enumerated above (Nos. 1 through 53), Respondent acted outside of the usual course of professional practice and lacked a legitimate medical purpose in doing so.

Dr. Chambers provided unrefuted testimony that it is not within the usual

[43] However, as the Agency has held in multiple cases, ''the Agency's authority to deny an application [and] to revoke an existing registration . . . is not limited to those instances in which a practitioner intentionally diverts a controlled substance.'' *Bienvenido Tan,* 76 FR 17673, 17689 (2011) (citing *Paul J. Caragine, Jr.,* 63 FR 51592, 51601 (1998)); *see also Dewey C. MacKay,* 75 FR at 49974. As *Caragine* explained: ''[j]ust because misconduct is unintentional, innocent, or devoid of improper motive, [it] does not preclude revocation or denial. Careless or negligent handling of controlled substances creates the opportunity for diversion and [can] justify'' the revocation of an existing registration or the denial of an application for a registration. 63 FR at 51601.

''Accordingly, under the public interest standard, DEA has authority to consider those prescribing practices of a physician, which, while not rising to the level of intentional or knowing misconduct, nonetheless create a substantial risk of diversion.'' *MacKay,* 75 FR at 49974; *see also Patrick K. Chau,* 77 FR 36003, 36007 (2012).

course of professional practice to prescribe a controlled substance to a patient with mental illness when the patient is being treated by a primary prescriber and the second physician does not communicate to the primary physician that he has issued the prescription. Tr. 275. Dr. Chambers testified as to the serious risks created by such prescribing, including oversedation, memory disturbance, overdose and potentially death, especially if the patient is also taking opioids. *Id.* at 250; *see also id.* at 268–69. Dr. Chambers also explained that when a patient is obtaining drugs from other sources and the primary prescriber is unaware, this ''can create a great deal of confusion on the part of the primary prescriber about the effects or side effects of the drug and the mental status of the patient.'' *Id.* at 251; *see also id.* at 291 (''If you have two chefs in the kitchen, this is the kind of stuff that can happen as you get chaos and harm and polypharmacy and no one understanding what is the illness versus what is [sic] the side effects of the medications, and it can lead to escalation of mental illness, addiction, and even death.'').

Dr. Chambers also offered unrefuted testimony that Respondent's prescribing resulted in ''a combination of multiple overlaps of multiple classes of addictive substances that can produce overdose and severe psychiatric disturbances.'' *Id.* at 273. And while Respondent is not a psychiatrist, Dr. Chambers offered unrefuted testimony that within the practice of psychiatry, there is a prohibition against treating a spouse. *Id.* at 293. Dr. Chambers further offered unrefuted testimony that Respondent's prescribing was not for legitimate medical practice and was non-therapeutic. I thus find that Respondent violated 21 CFR 1306.04(a) with respect to each of the prescriptions set forth above.

Respondent's failure to maintain adequate records to support the prescriptions provides additional support for this conclusion, as well as the conclusion that Respondent violated Mississippi Board Rule 1.4's provisions with respect to patient records.[44] As found above, there was no documentation at all to support 36 of the prescriptions. Moreover, even with respect to the entries Respondent did make, Dr. Chambers found that ''there is a paucity of data to support the diagnosis or the prescriptions . . . that the note is built around. There's a lack of physical or mental status exam that normally would be in a note like this to justify and direct the use of controlled substances.'' Tr. 277. Dr. Chambers also observed that ''there are instances where the dosing or type of the drug is left out of the record.'' *Id.* at 278. *See also* GE 6, at 6 (entry for 2/5/13); *id.* at 7 (entry for 3/28/13); *id.* at 8 (5/13/13 no dosing for Ambien); *id.* at 9 (entries for 7/1/13 no dosing for Lorcet and 7/7/13 no dosing for Lorcet and Xanax); *id.* at 10 (no drug strength for Xanax prescriptions of 8/24/13 and 9/5/13).

Before the State Board, Respondent testified that his prescribing ''was sporadic'' and ''was always for a confined number of pills, a small amount, that bridged her gap between obviously when she was in crisis and didn't have any medicine.'' GE 14, at 58. He maintained that ''the majority of the medicine were Xanax, two milligrams, [and that a] three day supply were [sic] common.'' *Id.* at 59–60. Also before the State Board, he maintained that ''I think the record reflects that I filled in in times where I just didn't think I had no other choice.'' *Id.* He further asserted that his writing of the prescriptions ''was always done in a short stop gap times [sic] when I believed again . . . that there were no other options.'' *Id.* at 69.

Although the Government introduced into evidence the transcript of the January 2014 state board proceeding, it did not submit the Board's order prohibiting him from practice and/or the charging document, any of the exhibits submitted in the Board proceeding which may have shown what prescriptions were at issue in the proceeding, or even the Board's order suspending his license after the January 2014 proceeding. However, while it may have been the case that Respondent's explanation as to his reasons for prescribing during the 2014 board proceeding was consistent with the evidence presented at that proceeding, it is not consistent with much of the evidence submitted in this proceeding.

As found above, the record contains numerous prescriptions which are not fairly characterized as two to three-day gap fills. With respect to Respondent's prescribing of zolpidem, they include fourteen prescriptions which clearly were not short-term gap fills. These prescriptions include numbers 2, 4, 6, 8, 22, 26, 28 (each for 30 du [45]), 23 (28 du), 29 (24 du), 15, 45 (each for 20 du), and 10, 12, 13 (each for 12 du).

With respect to Respondent's prescribing of alprazolam, they include prescription numbers 11 (20 du, a 10 to 20-day supply), 34 (30 du, a 10-day supply [46]), 53 (24 du, an eight-day supply), 31, 32 (each for 20 du, each for a 10-day supply), 38, 52 (15 du, a five-day supply) 42, 43 (14 du, a 4–5 day supply), and 44, 47 (12 du, one a four-day supply, the other a six-day supply). Respondent also issued a prescription for 18 tablets of clonazepam (a six-day supply), 15 capsules of Dextroamphetamine-Amphetamine 5 mg (a five-day supply), and 20 tablets of diazepam (a six-day supply). With respect to the diazepam prescription, Dr. Webb did not even prescribe this drug to Respondent's wife. Of note, before the State Board, Respondent testified that he did not change his wife's treatment regimen and only ''mirrored what [Dr. Webb] had done.'' GE 14, at 65.

Likewise before the State Board, Respondent initially offered testimony regarding his prescribing of hydrocodone which addressed only the prescriptions he wrote after a plastic surgeon had drained an abscess in his wife's thigh and when his wife had a seizure and fell. Moreover, when on cross-examination a Board member identified the multiple hydrocodone prescriptions Respondent issued in July 2013, Respondent testified that ''that was an isolated incident there.'' *Id.* at 66. The evidence in this proceeding shows, however, that during 2011, Respondent issued seven hydrocodone prescriptions (Nos. 3, 5, 7, 9, 14, 16, 19) for his wife prior to any other doctor prescribing the drug to her. *See* GE 11, at 11 (hydrocodone Rx written on Nov. 30, 2011 by Dr. Bell, who Respondent identified as his wife's neurologist). Respondent has offered no explanation in either proceeding as to why he issued these seven prescriptions, as well as the hydrocodone prescriptions he issued on December 5, 2011 (No. 21), Aug. 13, 2012 (No. 33) and Jan. 23, 2013 (No. 39).[47]

Also, in a number of instances, Respondent issued prescriptions even though his wife had refills available under prescriptions that were previously issued by Dr. Webb. For example, on March 30, 2011, Respondent issued a prescription for 30 zolpidem. (Rx No. 4). However, Dr. Webb's February 3, 2011 zolpidem

[44] *See supra* findings for RXs No. 1–21, 25, 26, 28–31, 33, 35–37, 39, 43, 45, 49, and 51.

[45] While some of Respondent's prescriptions for 30 du of zolpidem had a dosing instruction of two tablets, the dosing instructions generally provided for one tablet.

[46] This is based on Respondent's note for the prescription.

[47] While Dr. Bell (his wife's neurologist) issued hydrocodone prescriptions to Respondent's wife on November 30, 2011 and June 19, 2013, Respondent's testimony before the Board addressed only his July 2013 prescriptions. GE 14, at 86.

provided for multiple refills, which Respondent's wife filled on April 9, 2011, May 23, 2011, and July 7, 2011. Moreover, Respondent issued new prescriptions for 30 zolpidem to his wife on May 6, 2011 and June 28, 2011 (Rx No. 6 & 8). Respondent's prescriptions of March 30, May 6, and June 28 were clearly not ''gap fills.''

Moreover, when Respondent issued the July 31, 2011 prescription for 12 zolpidem, he also authorized a refill, which was available to his wife on August 28, 2011 (which she did not fill until September 6, 2011), when Respondent issued her a new prescription for 12 zolpidem. *See* Rx No. 10 & 12. (Dr. Webb had also issued a 60 du zolpidem prescription on August 16, 2011 which provided multiple refills.). Even ignoring the prescription she obtained from Dr. Webb, Respondent's August 28, 2011 prescription was not a gap fill given that she had a refill available on Respondent's July 31, 2011 prescription.

So too, Respondent's October 11, 2011 prescription for 20 zolpidem, a 20-day supply, (Rx No. 16) was issued notwithstanding that Dr. Webb's August 16, 2011 zolpidem prescription provided for five refills, one of which his wife filled on October 19, 2011. *See* GE 11, at 10–12. Even if Respondent's wife had run out of medication early because she failed to follow Dr. Webb's dosing instruction, she did not need this quantity of drugs to last her to the day on which she could refill Dr. Webb's prescription.

Another such example involves Respondent's December 27, 2011 prescription for 30 zolpidem and his January 7, 2012 prescription for 28 zolpidem. (Nos. 22 & 23). Respondent's wife had obtained a refill of Dr. Webb's August 16, 2011 prescription for 60 du on December 16, 2011, only 11 days earlier (Dec. 16). Thus, there was no gap to fill. Nor was there a gap to fill on January 7, 2012, when he issued the prescription for an additional 28 dosage units given the quantity of drugs his wife had recently obtained.

Still more examples are provided by the zolpidem prescriptions Respondent issued on March 4 and 12 (both for a 30-day supply), as well April 1, 2012 (for a 24-day supply). During this period, Respondent's wife obtained a prescription for 30 du (a 15-day supply) on February 23, 2012, which provided for two refills, the first of which she obtained on March 19, 2012. Here again, the only potential gap was likely created by the failure of Respondent's wife to follow Dr. Webb's dosing instructions on the February 23rd prescription. Moreover, the March 12, 2012 prescription was not a gap fill given that Respondent issued the March 4, 2012 prescription, which provided a 30-day supply. Nor was the April 1, 2012 prescription a gap fill given Respondent's issuance of the March 12 prescription and the refill she obtained on March 19, 2012 pursuant to Dr. Webb's Feb. 23 prescription.

Similarly, the evidence shows that on January 11, 2013, Respondent issued a prescription for 10 du of alprazolam (*see* No. 36). While this prescription provided only a three-day supply, the evidence shows that Respondent's wife had refilled a prescription issued by Dr. Webb for 45 du of alprazolam the day before. GE 11, at 8. Thus, this was not a gap fill. Nor was Respondent's January 11, 2013 temazepam prescription (No. 37) a gap fill as the evidence shows that his wife had also refilled a prescription for a 30-day supply of this drug the day before. GE 11, at 8.

As one further example, on May 20, 2013, Respondent issued a prescription for 20 tablets of zolpidem (No. 45). The evidence shows, however, that Dr. Webb had not issued a zolpidem prescription since February 23, 2012, which his wife last refilled in April 2012. Here again, this was not a gap fill.

Had Respondent's prescribing been limited to a few instances of small (two to three day) gap fills, his conduct would be considerably less egregious given the circumstances of his wife's illness. The evidence shows, however, that his illicit prescribing went on for nearly three years. Even more disturbing is that the evidence shows that many of the prescriptions were not for gap fills at all, let alone for gap fills for two to three day periods as he testified before the State Board.

Notably, in this proceeding, Respondent has personally offered no explanation as to why he issued the prescriptions. Moreover, the only evidence he offered was the discredited testimony of his wife that there occasionally were times when she ''might run out a day early on a weekend'' and only needed a short term supply until Dr. Webb got back to her and that Respondent had never given her a prescription for a time period longer than two to four days. Tr. 379, 381, 384.

I thus conclude that the Government's evidence with respect to Factors Two and Four makes out a *prima facie* case to deny Respondent's application as ''inconsistent with the public interest.'' 21 U.S.C. 823(f). I further find that Respondent's misconduct was egregious.

**Sanction**

Where, as here, the Government has met its *prima facie* burden of showing that issuing a new registration to the applicant would be inconsistent with the public interest, a respondent must come forward with ''sufficient mitigating evidence'' to show why he can be entrusted with a new registration. *Medicine Shoppe-Jonesborough,* 73 FR 364, 387 (2008) (quoting *Samuel S. Jackson,* 72 FR 23848, 23853 (2007) (quoting *Leo R. Miller,* 53 FR 21931, 21932 (1988))). ''Moreover, because 'past performance is the best predictor of future performance,' *ALRA Labs, Inc.* v. *DEA,* 54 F.3d 450, 452 (7th Cir.1995), [DEA] has repeatedly held that where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for [his] actions and demonstrate that [he] will not engage in future misconduct.'' *Medicine Shoppe,* 73 FR at 387; *see also Jackson,* 72 FR at 23853; *John H. Kennedy,* 71 FR 35705, 35709 (2006); *Prince George Daniels,* 60 FR 62884, 62887 (1995). *See also MacKay* v. *DEA,* 664 F.3d at 820; *Hoxie* v. *DEA,* 419 F.3d at 483 (''admitting fault'' is ''properly consider[ed]'' by DEA to be an ''important factor[]'' in the public interest determination).

Moreover, the egregiousness and extent of a registrant's misconduct are significant factors in determining the appropriate sanction. *See Jacobo Dreszer,* 76 FR 19386, 19387–88 (2011) (explaining that a respondent can ''argue that even though the Government has made out a *prima facie* case, his conduct was not so egregious as to warrant revocation''); *Paul H. Volkman,* 73 FR 30630, 30644 (2008); *see also Paul Weir Battershell,* 76 FR 44359, 44369 (2011) (imposing six-month suspension, noting that the evidence was not limited to security and recordkeeping violations found at first inspection and ''manifested a disturbing pattern of indifference on the part of [r]espondent to his obligations as a registrant''); *Gregory D. Owens,* 74 FR 36751, 36757 n.22 (2009).

Finally, the Agency has also held that '' '[n]either *Jackson,* nor any other agency decision, holds . . . that the Agency cannot consider the deterrent value of a sanction in deciding whether a registration should be [suspended or] revoked' '' or an application should be denied. *Wesley Pope,* 82 FR 14944, 14985 (2017) (quoting *Joseph Gaudio,* 74 FR 10083, 10094 (2009) (quoting *Southwood Pharmaceuticals, Inc.,* 72 FR 36487, 36504 (2007))). *See also Robert Raymond Reppy,* 76 FR 61154, 61158

(2011); *Michael S. Moore,* 76 FR 45867, 45868 (2011). This is so, both with respect to the respondent in a particular case and the community of registrants. *See Pope,* 82 FR at 14985 (quoting *Gaudio,* 74 FR at 10095 (quoting *Southwood,* 71 FR at 36503)). *Cf. McCarthy* v. *SEC,* 406 F.3d 179, 188–89 (2d Cir. 2005) (upholding SEC's express adoptions of ''deterrence, both specific and general, as a component in analyzing the remedial efficacy of sanctions'').

The ALJ acknowledged that ''to rebut the Government's *prima facie* case, the Respondent must both accept responsibility for his actions and demonstrate that he will not engage in future misconduct.'' R.D. at 52 (citing *Patrick W. Stodola,* 74 FR 20727, 20734–35 (2009)). The ALJ then explained that ''[t]he Respondent may accept responsibility by providing evidence of his remorse, his efforts at rehabilitation, and his recognition of the severity of his misconduct.'' [48] *Id.* (citing *Robert A. Leslie,* 68 FR 15227, 15228 (2003)). He also explained that ''[t]o accept responsibility, a respondent must show 'true remorse' for wrongful conduct,'' which includes an ''acknowledgment of wrongdoing.'' *Id.* (citing *Michael S. Moore,* 76 FR 45867, 45877 (2011) and *Wesley G. Harline,* 65 FR 5665, 5671 (2000)).

However, there are also numerous cases, that were not discussed in the Recommended Decision, which hold that where the Government has proved that a respondent committed knowing or intentional misconduct, he must unequivocally acknowledge his misconduct. *See Daniel A. Glick,* 80 FR 74800, 74800–01 (2015) (rejecting exception to ''CALJ's conclusion that [r]espondent has not unequivocally acknowledged his misconduct'' and holding that ''[a] registrant's acceptance of responsibility must be unequivocal''); *Annicol Marrocco,* 80 FR 28695, 28706 (2015) (denying application, holding that respondent's ''equivocal testimony provided substantial evidence to support a finding that she does not accept responsibility for her misconduct''); *Arthur H. Bell,* 80 FR 50035, 50041 (2015) (denying application finding that physician's ''acceptance of responsibility is equivocal at best'' and ''his failure to accept responsibility for [intentional] misconduct is reason alone to conclude that he cannot be entrusted with a new registration''); *Michael A. White,* 79 FR 62957, 62598, 62967–68 (2014) (revoking registration adopting ALJ's finding that physician did not accept responsibility when his ''acceptance of responsibility was tenuous at best,'' ''not once during the hearing did [he] unequivocally admit fault for his improper . . . prescriptions,'' and he ''minimized the severity of his misconduct''); *The Medicine Shoppe,* 79 FR 59504, 59510 (2014) (revoking registration where respondent ''offered generalized acceptance of responsibility'' but then denied filling any unlawful prescriptions); *Ronald Lynch,* 75 FR 78745, 78754 (2010) (revoking registration agreeing with ALJ's finding that respondent did not accept responsibility noting that he ''repeatedly attempted to minimize his [egregious] misconduct).[49]

I disagree with the ALJ's conclusion that Respondent is entitled to a finding that he has accepted responsibility for his misconduct. To the contrary, I find that his testimony was equivocal and that he repeatedly attempted to minimize his misconduct. Indeed, even after the ALJ granted Respondent a second chance to explain what he was accepting responsibility for, he still did not unequivocally acknowledge his misconduct.

In this matter, Respondent was specifically charged with violating 21 CFR 1306.04(a), the CSA's prescription regulation which requires that a controlled substance prescription ''be issued for a legitimate medical purpose by [a] practitioner acting in the usual course of professional practice.'' ALJ Ex. 1, at 1–3 (¶¶ 3–9). Indeed, the Government specifically alleged that the prescriptions ''were nontherapeutic, were for other than a legitimate medical purpose, and were outside the course of professional practice.'' *Id.* The Government also alleged that the prescriptions violated the counterpart provision of State law. *See id.* (citing Board Rule 1.16 and Miss. Code Sec. 73–25–29–(3)). The Government further alleged that Respondent violated provisions of State regulations prohibiting the prescribing of controlled substances ''without conducting any examination of [his] wife (or documenting such in her file) or noting the . . . prescriptions in her patient chart,'' as well as ''without conducting sufficient examinations of [his] wife (or documenting such in her file).'' *Id.* at 3 (citing, *inter alia,* Board Rules 1.4 and 1.16, Miss. Code Ann. Sec. 73–25–29(3)).

Notwithstanding that the Show Cause Order clearly set forth these violations, and that Dr. Chambers offered unrefuted testimony that Respondent's prescribing was outside of the ''usual course of clinical conduct,'' ''was dangerous and harmful,'' ''non-therapeutic,'' not for a ''legitimate medical practice,'' that there was ''a paucity of data to support the diagnosis or the prescriptions'' and there was ''a lack of physical or mental status exam'' documented in the noted to justify the prescriptions, Respondent repeatedly refused to acknowledge that he violated 21 CFR 1306.04(a).

While Respondent testified that he violated his contract with the State PHP (which was not a charge in this proceeding), when asked by his counsel if he violated his obligations as a DEA registrant, he asserted that he did not ''know the specific legalities of DEA registration'' but was willing ''to tell you what I did was wrong, . . . without any equivocation.'' Tr. 484–85. While he

[48] To the extent the ALJ's statement suggests that a respondent can satisfy his burden of production on the issue of acceptance of responsibility by only producing evidence of efforts at rehabilitation, this is not the Agency's rule. Indeed, *Leslie* makes it clear that it was describing the total showing that is required to refute the Government's *prima facie* case. *See Leslie,* 68 FR at 15228 (discussing previous agency decision involving respondent and stating that ''[t]he agency also found that although he was free to offer evidence that he would never again engage in the sort of conduct that resulted in his conviction, [r]espondent did not avail himself of that opportunity and offered no evidence of remorse for his misconduct, efforts at rehabilitation, or recognition of the severity of his conduct'').

The Agency has explained that where the Government has proved that a respondent has committed knowing or intentional misconduct, a respondent must fully acknowledge the misconduct that has been proved on the record to be deemed to have accepted responsibility, and absent such a showing, his evidence of remedial measures is irrelevant. *See Hatem M. Ataya,* 81 FR 8221, 8242–43 (2016) (''the Agency has held that proof of remedial measures is rendered irrelevant where a respondent fails to accept responsibility for his knowing or intentional misconduct'').

[49] More recently, in *Roberto Zayas,* 82 FR 21410, 21429 (2017), I rejected the reasoning of *Jeffrey Martin Ford,* 68 FR 10750 (2003), which granted a new registration to a respondent who had a history of substance abuse and had been convicted of several drug felonies. In *Zayas,* I noted that the *Ford* ''decision apparently excused the respondent's failure to unequivocally accept responsibility based on his having attended drug rehabilitation and remained sober for more than 10 years, as well [as] having satisfied the conditions for reinstatement of his state license.'' 82 FR 21429. I also noted that ''the decision [did] not even address whether [the respondent] accepted responsibility for his criminal conduct.'' *Id.* I further explained that I found ''the reasoning of this case unpersuasive, [and] were a case with similarly egregious misconduct presented to me, I would not grant a registration absent a clear and unequivocal acceptance of responsibility for all of the misconduct that was proven on the record.'' *Id. See also Jones Total Health Care,* 81 FR 79188, 79200–01 (2016) (''[W]here the Government has proved that a registrant has engaged in intentional or knowing misconduct, revocation is warranted in the absence of the registrant's unequivocal acceptance of responsibility for its misconduct.''); *Joe W. Morgan,* 78 FR 61961, 61963 (2013) (''Given [r]espondent's multiple statements in which he blamed others for his troubles, that he never once acknowledged that he prescribed in violation of the CSA and Florida law, and that he attempted unpersuasively to minimize his culpability, the overwhelming weight of the evidence fully supports the ALJ's conclusion that [r]espondent is sorry only because he was caught.'').

also acknowledged that ''becoming involved in a loved one's care is foolish,'' he then stated that he did not ''know the letter or spirit of any law that I transgressed.'' *Id.* at 489. And when asked why the Agency should entrust him with a new registration, he testified that ''[i]f I can't practice medicine, conforming to every jot, tittle, to the letter of the law, I can't practice medicine,'' but he offered no explanation as to how he would conform ''to the letter of the law'' given his acknowledgment that he does not ''know the letter of or spirit of any law that [he] transgressed.'' *Id.* at 489–90.

Indeed, throughout his testimony, Respondent asserted that he thought the charges in this proceeding simply involved the same charges that he was found guilty of in the State Board proceeding. He doggedly denied that he violated the CSA's prescription requirement, asserting that that it ''would be speculative . . . on some level'' for him to testify as ''to what statutes I may or may not have transgressed.'' *Id.* at 498. And when asked if he accepted that the prescriptions he issued to his wife ''were outside the course of professional practice,'' he asserted that he did not know how DEA defined the term ''outside the course of professional practice'' and maintained that I ''do not know again . . . the specifics of . . . of what I'm being charged with by DEA now.'' [50] *Id.* at 501.

Given that the Show Cause Order provided fair notice to Respondent that he was charged with violating 21 CFR 1306.04(a) and that he heard the evidence against him and put up no defense, he was not required to speculate as to ''what statutes [he] may or may not have transgressed.'' Moreover, the CSA's requirement that ''a prescription for a controlled substance . . . must be issued for a legitimate medical purposes by [a] practitioner acting in the usual course of professional practice'' is hardly a ''jot'' or a ''tittle'' of the Act.[51] To the contrary, the rule is one of the Act's fundamental features, as one of its purposes is to ''ensure [] patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse.'' *Gonzales,* 546 U.S. at 274.

Notably, even after the ALJ repeatedly expressed his puzzlement as to what Respondent was accepting responsibility for, Respondent testified that he was accepting responsibility for what the State said he did and again asserted that he thought the charges in the DEA proceeding were the same as the charges which he was found guilty of by the State Board. Tr. 503–05. While the ALJ subsequently gave Respondent several chances to answer this question, his testimony continued to manifest equivocation, minimization and an unwillingness to acknowledge that he violated the CSA's prescription requirement.

For example, when asked to ''clarify . . . what specific actions [he was] accepting responsibility for,'' Respondent answered: ''[v]iolating the previous order, right? Writing prescriptions for my wife when I wasn't a treating physician, which I think is not proper document, not fully proper documentation of those things.'' Tr. 507. He subsequently testified that ''if someone shows me . . . what I was saying that I'm ignorant of the specifics of a DEA charge. *But if I meet the criteria and I accept I did it, then I did it.*'' *Id.* at 508 (emphasis added). *See also id.* at 514 (''If someone shows me I've done something wrong, I will admit it.'')

However, as found above, the unrefuted evidence, including the testimony of Dr. Chambers, establishes that Respondent's prescribing did ''meet the criteria'' for a violation of 21 CFR 1306.04(a). Yet even when confronted with this evidence, Respondent still was unwilling to accept that he ''did it.'' *Id.*

On further cross-examination, Respondent was again asked what he thought was ''wrong with respect to the prescriptions.'' *Id.* at 510. While he answered that ''I shouldn't have written'' and ''I violated the contract,'' he then stated: ''[p]rompt me. I'm not trying to minimizing anything.'' *Id.*

Minimizing is, however, exactly what Respondent was engaged in. And when the Government again asked Respondent if he was admitting that the prescriptions were issued outside the usual course of professional practice, Respondent maintained that ''as a physician, I don't understand that term'' and he was only willing to admit to acting outside of the usual course to the extent that his documentation was ''substandard.'' *Id.* at 511. He then denied that his prescribing had increased the chances of his wife's becoming dependent, overdosing or diverting controlled substances.

While it is true that on a still further round of re-direct examination, Respondent testified that it was wrong for him to ''prescribe controlled substances to someone who was under the care of another physician for those same ailments,'' this is not a full acknowledgment of his illegal behavior. Indeed, the mere fact that a physician prescribes controlled substances to someone who is under care of another physician for the same ailments would not necessarily give rise to liability under 1306.04(a). Such prescribing would be entirely lawful under the CSA in bona fide emergency situations provided the prescriptions were limited to what was medically necessary to treat a patient before the primary physician could resume care.

Here, however, Respondent has admitted to acting outside of the usual course of professional practice only to the extent he maintained ''substandard records.'' Notwithstanding Dr. Chambers' testimony, Respondent has failed to acknowledge that his prescribing increased the risks of his wife become dependent, overdosing, or diverting controlled substances, his failure to conduct appropriate examinations, as well as his failure to notify Dr. Webb that he had prescribed the drugs.

Moreover, before the State Board, Respondent maintained that his prescribing ''was sporadic,'' ''was always for a confined number of pills,'' that they were simply short gap fills which ''mirrored what [Dr. Webb] had done.'' However, as found above, many of the prescriptions provided substantially more medication than was necessary for a two to three-day period. These include 14 zolpidem prescriptions, each of which provided at least a 12-day supply (with 11 of the prescriptions providing 20 to 30 dosage units, most of which for a 20 to 30-day supply) and five of the alprazolam prescriptions, four of which were for a ten-day supply, the other being for an eight-day supply. There were also the seven hydrocodone prescriptions and a diazepam prescription, which although they were for small amounts, did not ''mirror what [Dr. Webb or any other doctor] had done,'' and are unsupported by the findings of an examination and a diagnosis.

Respondent personally offered no explanation in this proceeding (or before the State Board) as to why he issued these prescriptions, which clearly provided more drugs than were medically necessary to address a two- to three-day period.[52] Indeed, while

[50] Yet in his Pre-hearing Statement, Respondent stated that he ''will acknowledge the allegations raised by DEA in the Order to Show Cause.'' ALJ Ex. 5, at 3.

[51] *See Webster's Third New International Dictionary,* at 1221 (1976) (defining ''jot'' as ''the least bit: IOTA''); *see also id.* at 2401(defining ''tittle,'' in part, as ''a very small part'').

[52] In his Pre-hearing Statement, Respondent also stated ''he will discuss the circumstances in which

Continued

Respondent maintained that he could ''absolutely'' be trusted to not engage in such prescribing in the future, that he was ''not trying to avoid anything'' and that ''I have done everything that I know to do to try to remedy this situation,'' he has not been forthcoming in this matter. Thus, I disagree with the ALJ that Respondent has ''express[ed] remorse to the full extent of [his] wrongful conduct.'' R.D. at 56.

The ALJ also gave weight to Respondent's testimony during the second State Board hearing that he was ''committed to 'absolute and complete adherence' to applicable rules and regulations,'' *id.* at 55 (citing GE 13, at 9–10), and further asserted ''that his commitment to adhere to all regulations governing controlled substances is genuine.'' *Id.* at 56–57. The ALJ did not explain how Respondent would accomplish this given his repeated assertions in this proceeding that he did not ''know the specific legalities of DEA registration,'' did not ''know the letter or spirit of any law that [he] transgressed,'' that he does not ''know precisely how the DEA defines'' the term ''outside the course of professional practice,'' and ''as a physician, [he does not] understand [the] term.'' Tr. 511.

The ALJ also rejected as only ''technically correct'' the Government's argument that Respondent did not accept responsibility for failing to conduct examinations and/or conducting insufficient examinations prior to issuing the prescriptions. R.D. 54–55. While the ALJ found that Respondent did not ''specifically acknowledge that it was wrong of him to issue a prescription without first conducting an examination,'' the ALJ faulted the Government for not asking this question of Respondent. *Id.* at 55. The ALJ further reasoned that the Government ''overlook[ed] the central concern of this case, which is that the Respondent wrote prescriptions for his wife when he should not have.'' *Id.* In the ALJ's ''view, the Respondent's acceptance of responsibility for failing to examine his wife before writing her a prescription is subsumed in his general acceptance of responsibility.'' *Id.* (citing Tr. 515).

I cannot agree with this reasoning. As for the ALJ's faulting of the Government for not asking Respondent if he accepted responsibility for his failure to conduct examinations or conducting inadequate examinations, Respondent, and not the Government, had the burden of production on this issue. As for the ALJ's assertion that ''the central concern of this case . . . is that the Respondent wrote prescriptions for his wife when he should not have,'' the central concern of this case is what the Government alleged in the Show Cause Order and proved at the hearing.[53] The proof fully supported the allegations, which included that he issued controlled substance prescriptions that ''were nontherapeutic, were for other than a legitimate medical purpose, and were outside the usual course of professional practice,'' that he issued the prescriptions when his wife was ''being issued prescriptions for the same or similar class of drugs by her . . . psychiatrist, which [he] did without her psychiatrist's knowledge or permission,'' and that his ''actions dramatically increased the chances of [his] wife's dependency, overdose or diversion.'' ALJ Ex. 1, at 1–3 (¶¶ 3–7). Moreover, the Government's allegations that Respondent violated state and federal law by issuing controlled substance prescriptions ''without conducting any examination,'' *Id.* at 3 (¶ 8), or ''without conducting sufficient examinations,'' *id.* (¶ 9), were not simply additional factual allegations to support the charges in paragraphs three to seven of the Show Cause Order but were stand-alone charges.

With respect to the proven misconduct, Respondent admitted that he acted outside of the usual course of professional practice only to the extent that he failed to maintain proper records. As for the ALJ's further assertion that his acceptance of responsibility for failing to conduct examinations was ''subsumed in his general acceptance of responsibility,'' the cited testimony does not support this, as the question, which was asked by his counsel, made no reference to his failing to conduct examinations. Tr. 515.

The ALJ acknowledged that ''[i]t is true . . . that Respondent did not plainly and expressly accept responsibility for violating specific federal regulations.'' R.D. 56. Indeed, at no point did Respondent admit that he violated 21 CFR 1306.04(a) with respect to any of the prescriptions, including those which clearly were not two to three day ''gap fills.'' Nor did he ever admit that any of the prescriptions were non-therapeutic or lacked a legitimate medical purpose. And he denied that his prescribing increased the risks of his wife become dependent, overdosing, or diverting controlled substances. Respondent has therefore failed to ''express remorse to the full extent of [his] wrongful conduct.'' [54] R.D. 56.

The ALJ further explained that he found Respondent's remorse to be sincere and that his acceptance of responsibility was ''credible.'' R.D. 56–57. This case, however, is less about Respondent's credibility (although there is ample reason to question it given his testimony regarding what he thought he had been charged with in this proceeding) [55] and more about the weight to be given to his testimony. Moreover, the ALJ failed to apply the Agency's extensive case law which requires that an acceptance of responsibility be unequivocal, as well as that which requires a full acknowledgment of the proven misconduct.

While I appreciate that the ALJ closely examined Respondent's testimony both at this hearing and before the state board (as have I), I find it particularly disturbing that Respondent has never offered an explanation in any proceeding [56] for the

he prescribed controlled substances to his wife.'' ALJ Ex. 5, at 3. Respondent, however, offered no such testimony.

[53] Based on the Board's order and his recovery contract, Respondent ''should not have'' written the prescriptions. Yet, as the ALJ recognized when he expressed his puzzlement (multiple times) at to what Respondent was accepting responsibility for, the Government did not allege that Respondent violated his recovery contract or a Board Order; it alleged specific violations of federal and state laws and regulations.

[54] Earlier in his Recommended Decision, the ALJ asserted that my decision in *Arvinder Singh,* 81 FR 8247 (2016), ''states only that a registrant *may* be required to acknowledge the scope of his misconduct,'' thus suggesting that a respondent's acknowledgment of the scope of his misconduct is optional and that he is not required to ''accept responsibility for the consequences of his acts.'' R.D. 54 (citing 81 FR at 8250–51). This is mistaken, as the case clearly stated that the respondent ''was required to acknowledge . . . the full scope of his criminal behavior and the risk of diversion it created.'' 81 FR at 8250. The risk of diversion was, of course, a consequence of the respondent's acts, which involved pre-signing prescriptions for controlled substances which were subsequently issued by nurses who were not lawfully authorized to prescribe controlled substances and the respondent did not see the patients. *Id.* at 8248–49.

The ALJ also gave weight to Respondent's having ''expressed remorse and accepted responsibility for writing those prescriptions during the first three weeks of his treatment at Acumen'' as well as his testimony during the second Board hearing. R.D. 55. However, whether Respondent accepted responsibility for writing the prescriptions during his treatment at Acumen is wholly irrelevant. Likewise, because the Agency was not a party in the State Board's proceedings, the weight to be given to Respondent's testimony before the Board is substantially diminished. What matters is whether he accepted responsibility for the misconduct alleged and proved in this proceeding.

[55] While Respondent professed that he did not understand what he was charged with in this proceeding, the Show Cause Order was clear on its face. Respondent was also represented and if he truly did not understand the allegations, he should have asked his counsel.

[56] While I have noted Respondent's testimony in the State Board proceeding as to why he issued the prescriptions, so that there is no lack of clarity for future matters, a respondent is required to present his evidence in the Agency's proceeding.

many prescriptions he issued which clearly were not for short-term gap fills, an issue which is not even discussed in the Recommended Decision. Thus, I conclude that Respondent does not recognize the full extent of his misconduct. *See MacKay* v. *DEA,* 664 F.3d 808, 820 (10th Cir. 2011); *see also Samuel Jackson,* 72 FR 23848, 23852 (2007) (noting a respondent's burden to produce sufficient evidence to assure the Administrator that he/she can be entrusted with the responsibility carried by such a registration'').

I therefore find that Respondent has failed to produce sufficient evidence to support a finding that he accepts responsibility for his misconduct. While there are cases in which the Agency has imposed a sanction less than denial or revocation where a respondent has failed to meet his burden on acceptance of responsibility, those cases have involved considerably less egregious misconduct than the knowing and intentional diversion of controlled substances which occurred here. Because Respondent engaged in egregious misconduct which he has failed to fully acknowledge, his evidence of remedial measures cannot rebut the Government's *prima facie* showing that his registration ''would be inconsistent with the public interest.'' 21 U.S.C. 823(f). Accordingly, I will deny his application.

## Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 28 CFR 0.100(b), I order that the application of Lon F. Alexander, M.D., for a DEA Certificate of Registration as a practitioner, be, and it hereby is, denied. This Order is effective immediately.

Dated: October 17, 2017.

**Robert W. Patterson,**

*Acting Administrator.*

[FR Doc. 2017–23339 Filed 10–25–17; 8:45 am]

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# FEDERAL REGISTER

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Part III

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Proclamation 9663—Minority Enterprise Development Week, 2017

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# Presidential Documents

**Title 3—**

**The President**

**Proclamation 9663 of October 20, 2017**

## Minority Enterprise Development Week, 2017

**By the President of the United States of America**

**A Proclamation**

Since our earliest days, hardworking entrepreneurs have driven our Nation's prosperity. During Minority Enterprise Development Week, we recognize the contributions that minority-owned businesses make to our economy and our way of life, and we strive to ensure that small business owners have access to the resources they need to achieve the American Dream.

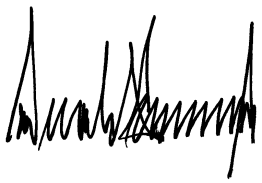
The United States is entering upon a new period of economic revival. Unemployment is at a 16-year low, businesses are expanding, and wages are rising. Ensuring that minority-owned businesses remain strong and vibrant is vital to the growth of our great Nation. Minority-owned firms employ eight million people and generate more than $1 trillion in annual economic output. They export their products at a greater rate than non-minority businesses and provide a great boost to our global competitiveness.

My Administration is committed to creating a business climate in which minority business enterprises can thrive and expand. The Unified Framework for Fixing Our Broken Tax Code, my Administration's basic plan for tax cuts and tax reform, calls for a steep reduction to the corporate tax rate from 35 to 20 percent. This reform will lift up our entrepreneurs, our businesses, and our families. The Framework also caps the top tax rate for millions of family-owned and small- and mid-sized businesses at 25 percent—the lowest it has been in more than 80 years. We also want Americans to be able to invest in capital to build their businesses, so for 5 years, we will allow them to deduct 100 percent of their capital investments. By eliminating needless regulations, promoting fair and reciprocal trade relationships, lowering taxes, and increasing the flow of capital, the United States will further cement its status as a global economic powerhouse.

During Minority Enterprise Development Week, we recommit to empowering every hardworking American to write our next great chapter. Let us work together to ensure that every American citizen can flourish and give back to our country and our communities.

NOW, THEREFORE, I, DONALD J. TRUMP, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim October 22 through October 28, 2017, as National Minority Enterprise Development Week. I call upon all Americans to celebrate this week with programs, ceremonies, and activities to recognize the many contributions of American minority business enterprises.

IN WITNESS WHEREOF, I have hereunto set my hand this twentieth day of October, in the year of our Lord two thousand seventeen, and of the Independence of the United States of America the two hundred and forty-second.



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