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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 1212

[Document Number AMS–SC–18–0016]

Honey Packers and Importers Research, Promotion, Consumer Education and Industry Information Order; Change in Membership

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This rule changes the National Honey Board (Board) importer-handler member and alternate to an importer member and alternate. The Honey Packers and Importers Research, Promotion, Consumer Education and Industry Information Order (Order) is administered by the Board with oversight by the U.S. Department of Agriculture (USDA). This rule also updates the definition for the term Board to reflect current practices, and make clarifying and conforming changes to other provisions of the program.

DATES: *Effective Date:* March 6, 2019.

FOR FURTHER INFORMATION CONTACT: Patricia P. Petrella, Deputy Director, Promotion and Economics Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, Room 1406–S, Stop 0244, Washington, DC 20250–0244; telephone: (202) 260–9496; facsimile: (202) 205–2800; or electronic mail: *Patricia.Petrella@ams.usda.gov.*

SUPPLEMENTARY INFORMATION: This final rule affecting 7 CFR part 1212 (hereinafter referred to as the ''Order'') is authorized under the Commodity Promotion, Research, and Information Act of 1996 (1996 Act) (7 U.S.C. 7411–7425).

Executive Orders 12866, 13563, and 13771

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

Executive Order 12988

In addition, this final 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 final rule changes the importer-handler member and alternate to an importer member and alternate on the Board under the Honey Packers and Importers Research, Promotion, Consumer Education and Industry Information Order (Order). The Order is administered by the Board with oversight by USDA. Under the Order, assessments are collected from first handlers and importers and used for research and promotion projects designed to maintain and expand the market for honey and honey products in the United States and abroad. This rule will change the importer-handler representatives to importer representatives and make clarifying and conforming changes to other provisions of the program. This action was unanimously recommended by the Board in October 2017 and will allow more importers to be eligible to serve on the Board.

Section 1212.46 of the Order provides authority for the Board to recommend amendments to the Order. Section 1212.40 of the Order provides that the Board have ten members—three first handlers, two importers, one importer-handler, three producers, and one marketing cooperative representative. Each member shall have an alternate. Currently, the eligible importer-handler member and alternate must import at least 75 percent of the honey or honey products they market in the United States and handle at least 250,000 pounds annually. With this amendment, the total number of Board representatives will remain at ten, but importer representatives will increase from two to three representatives and the importer-handler member will be removed. Handlers will continue to be represented with three members on the Board. A corresponding adjustment will be made to the alternate representatives for each member. This action increases

the pool of importer nominees eligible to serve on the Board and reflects the current distribution of the industry.

U.S. honey imports have dramatically increased from 104,984 metric tons in 2008 to 203,534 metric tons in 2017. In comparison, U.S. honey production has decreased. USDA's National Agricultural Statistics Service estimates U.S. honey production from producers with 5 or more colonies at 164 million pounds in 2008 and at 148 million pounds in 2017.[1] The changes to the Board will reflect the distribution of the production of honey and the quantity of the honey and honey products imported into the United States.

Nominations to the Board are made by qualified national organizations and these organizations were consulted before the Board's recommendation. No qualified national organizations were opposed to the recommendation.

The Board met on October 26, 2017, and unanimously recommended that the importer-handler member and alternate become an importer member and alternate, allowing more importers to be eligible to serve on the Board. Section 1212.40 of the Order is revised accordingly. Conforming changes will be made to remove references to the importer-handler representative by removing § 1212.12 and revising §§ 1212.22, 1212.41, and 1212.42(b).

The current importer-handler member and alternate were appointed to the Board for a term that began on January 1, 2018 and ends on December 31, 2020. The importer-handler member and alternate will remain in their positions until their term expires on December 31, 2020. The following term beginning on January 1, 2021, will be filled by an importer member and importer alternate.

Finally, this action will revise the term Board as defined in § 1212.2 from the 'Honey Packers and Importers Board' to the 'National Honey Board' to reflect current practices. The term as it appears in § 1212.40 and in the undesignated heading preceding § 1212.40 will also be revised to read 'National Honey Board.'

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 the rule on small entities. 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 Small Business Administration (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 (first handlers and importers) as those having annual receipts of no more than $7.5 million.

The Board reported that there were about 785 importers and 40 first handlers of honey and honey products covered under the program during the 2017 fiscal period. Fourteen out of the 40 first handlers (35 percent) and 23 out of the 785 importers (3 percent) accounted for 91 and 90 percent of the assessments in their respective categories. Total assessments for 2017 were $8.87 million, of which $2.09 million (24 percent) were paid by first handlers and $6.78 million (76 percent) were paid by importers. This data can be used to compute an estimate of average annual revenue from honey sales from each of these categories, which in turn helps to estimate the number of large and small first handlers and importers. As mentioned above, 14 first handlers account for 91 percent of the domestic assessments. Multiplying first handler assessments in 2017 of $2,091,881 by 0.91 and then dividing by 14 yields an average annual assessment of $135,972 for the first handlers in this category. Dividing this figure ($135,972) by the assessment rate of 1.5 cents per pound ($0.015) yields an average quantity per first handler of 9.065 million pounds. Multiplying 9.065 million pounds by the average 2017 U.S. domestic price of $2.16 per pound[2] yields an average annual honey revenue per handler of $19.58 million, which is well above the SBA threshold of $7.5 million. It should be noted that this revenue estimate is based on the average price at the producer level, and the $19.58 million is an estimate of the total value at which the average size handler acquired the honey from producers. Therefore, most of the 14 first handlers that pay 91 percent of the domestic assessments are likely to be large firms according to the SBA definition.

An equivalent computation can be made for the 23 importers who paid 90 percent of the $6,778,147 in assessments in 2017. Of the 23 importers, the average assessment per importer was $265,741. Dividing the average assessment per importer by the assessment rate of $0.015 per pound yields an average quantity per importer estimate of 17.716 million pounds.

For honey imports, the equivalent of the season average price for domestic honey is referred to as a ''unit value.'' The unit value of $1.23 per pound is computed by dividing annual imported honey value of $550.16 million by average quantity of 448.72 million pounds.[3] Multiplying the $1.23 unit value by the average quantity of 17.716 million pounds yields average annual honey revenue per importer figure of $21.790 million, almost three times the SBA threshold figure of $7.5 million for a large firm. Therefore, the majority of the 23 importers that pay 90 percent of the assessments are large firms, according to the SBA definition.

Comparable computations can be made to determine the average 2017 honey revenue for the 26 first handlers and 762 importers that paid 9 and 10 percent, respectively, of the assessment in the first handler and importer categories. The first handler and importer average annual honey revenue figures are approximately $1,043,000 and $17,000, respectively, indicating that the vast majority are small businesses (in terms of honey sales), under the SBA large business threshold of $7.5 million in annual sales.

Based on the foregoing, the majority of first handlers and importers may be classified as small entities.

This rule changes the importer-handler Board member and alternate, as specified in section 1212.40 of the Order, to an importer member and alternate. The Order currently requires one importer-handler representative on the Board who must import at least 75 percent of the honey or honey products they market in the United States and handle at least 250,000 pounds annually. The U.S. honey industry has experienced dramatic increases in imported honey and honey products, as domestic production has decreased. Thus, the Board unanimously recommended that the importer-handler representative become an importer representative. This will allow for a greater pool of importer nominees to be eligible to serve on the Board. Conforming changes are being made to remove § 1212.12 and revise §§ 1212.22, 1212.41, and 1212.42(b). Finally, this rule updates the term Board to reflect current practices (§ 1212.2, the heading preceding §§ 1212.40 and 1212.40).

[1] USDA, National Agricultural Statistics Service, Honey, March 14, 2018, p. 3, *http://usda.mannlib.cornell.edu/usda/current/Hone/Hone-03-14-2018.pdf.*

[2] USDA, NASS, Honey, March 14, 2018, p. 3, *http://usda.mannlib.cornell.edu/usda/current/Hone/Hone-03-14-2018.pdf.*

[3] USDA, AMS, SCP, MND, National Honey Report, February 26, 2018, p. 10, *https://www.ams.usda.gov/mnreports/fvmhoney.pdf.*

Authority for this action is provided in § 1212.46(d) of the Order.

Relaxing the eligibility requirements for importer representatives on the Board is administrative in nature and would have no economic impact on entities covered under the program. This change will help increase the number of importers who would be eligible to serve on the Board. Eligible producers, first handlers, and importers interested in serving on the Board have to complete a background questionnaire. Those requirements are addressed later in this proposal in the section titled.

Reporting and Recordkeeping Requirements

Prior to arriving at this action, the Board consulted with the qualified national organizations that make the nominations to the Board. Alternatives that were considered included making no changes and adjusting the eligibility requirements. However, in considering the distribution of the production of honey and the quantity of honey and honey products imported into the United States, the Board concluded that revising the importer-handler representative to an importer representative would be an accurate reflection of the industry and would increase the pool of eligible importers.

Reporting and Recordkeeping Requirements

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the information collection requirements that are imposed by the part have been previously approved by OMB under OMB control number 0581–0093. Additionally, Board nominees (including producers) must submit a Background Information form (AD–755) to ensure they are qualified to serve on the Board. The time to complete that form is estimated at 30 minutes per response. The background form is approved under OMB control no. 0505–0001. This rule will not result in a change to the information collection and recordkeeping requirements previously approved and would impose no additional reporting requirements and recordkeeping burden on honey producers, first handlers, or importers.

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.

AMS is committed to complying with the E-Government Act, to promote the use of the internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

This action was discussed with the qualified national organizations. The Board met on October 26, 2017, and unanimously recommended changing the importer-handler representative to an importer representative. All of the Board's meetings are open to the public and interested persons are invited to participate and express their views.

A proposed rule concerning this action was published in the **Federal Register** on October 1, 2018 (83 FR 49314). A 30-day comment period ending on October 31, 2018, was provided to allow interested person to respond to the proposal. The proposed rule was included the Board's September newsletter. Notifications were sent to industry trade organizations and industry news publications. The proposal was also made available through the internet by USDA and the Office of the Federal Register. One comment was received, but it did not pertain to this proposal; therefore, no changes were made to the proposed rule.

List of Subjects in 7 CFR Part 1212

Administrative practice and procedure, Advertising, Consumer information, Honey Packer and Importer promotion, Marketing agreements, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR part 1212 is amended as follows:

PART 1212—HONEY PACKERS AND IMPORTERS RESEARCH, PROMOTION, CONSUMER EDUCATION AND INDUSTRY INFORMATION ORDER

■ 1. The authority citation for 7 CFR part 1212 continues to read as follows:

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

■ 2. Revise § 1212.2 to read as follows:

§ 1212.2 Board.

''Board'' or ''National Honey Board'' means the administrative body established pursuant to § 1212.40, or such other name as recommended by the Board and approved by the Department.

§ 1212.12 [Removed and Reserved]

■ 3. Remove and reserve § 1212.12.

■ 4. Revise § 1212.22 to read as follows:

§ 1212.22 Qualified national organization representing importer interests.

''Qualified national organization representing importer interests'' means an organization that the Secretary certifies as being eligible to nominate importer and alternate importer members of the Board under § 1212.42.

■ 5. Revise the undesignated center heading preceding § 1212.40 to read as follows:

National Honey Board

■ 6. Revise § 1212.40 to read as follows:

§ 1212.40 Establishment and membership.

The National Honey Board is established to administer the terms and provisions of this part. The Board shall have ten members, composed of three first handler representatives, three importer representatives, three producer representatives, and one marketing cooperative representative. In addition, each producer representative must produce a minimum of 50,000 pounds of honey in the United States annually based on the best three-year average of the most recent five calendar years, as certified by producers. The Secretary will appoint members to the Board from nominees submitted in accordance with § 1212.42. The Secretary shall also appoint an alternate for each member.

■ 7. Revise § 1212.41 to read as follows:

§ 1212.41 Term of office.

Each Board member and alternate will serve a three-year term or until the Secretary selects his or her successor. No member or alternate may serve more than two consecutive terms. Each term of office will end on December 31, with new terms of office beginning on January 1.

■ 8. Revise § 1212.42(b) to read as follows:

§ 1212.42 Nominations and appointments.

* * * * *

(b) All qualified national organizations representing importer interests will have the opportunity to participate in a nomination caucus and will, to the extent practical, submit as a group a single slate of nominations to the Secretary for importer positions and the importer alternate positions on the Board. If the Secretary determines that there are no qualified national organizations representing importer interests, individual importers who have paid assessments to the Board in the most recent fiscal period may submit nominations.

* * * * *

Dated: January 29, 2019.

Bruce Summers,

Administrator.

[FR Doc. 2019–00872 Filed 2–1–19; 8:45 am]

BILLING CODE 3410–02–P

FEDERAL DEPOSIT INSURANCE CORPORATION

12 CFR Parts 327 and 337

RIN 3064–AE89

Limited Exception for a Capped Amount of Reciprocal Deposits From Treatment as Brokered Deposits

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Final rule.

SUMMARY: The FDIC is amending its regulations that implement brokered deposits and interest rate restrictions to conform with recent changes to section 29 of the Federal Deposit Insurance Act made by section 202 of the Economic Growth, Regulatory Relief, and Consumer Protection Act related to reciprocal deposits, which took effect on May 24, 2018. The FDIC is also making conforming amendments to the FDIC's regulations governing deposit insurance assessments.

DATES: This rule will be effective March 6, 2019.

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SUPPLEMENTARY INFORMATION:

I. Policy Objectives

The policy objective of the final rule is to implement section 202 of the Economic Growth, Regulatory Relief, and Consumer Protection Act, codified in 12 U.S.C. 1831f, which took effect on May 24, 2018.[1] The main effect of the legislation and the final rule is to permit FDIC-insured financial institutions, under certain circumstances, to except certain amounts of reciprocal deposits from treatment as brokered deposits.

II. Background

The Economic Growth, Regulatory Relief, and Consumer Protection Act (the Act) was enacted on May 24, 2018.[2] Section 202 of the Act amends section 29 of the Federal Deposit Insurance Act (FDI Act)[3] to except a capped amount of reciprocal deposits from treatment as brokered deposits for certain insured depository institutions. In addition, section 202 ensures that the interest rate restrictions in section 29 remain applicable to *any* deposit, including reciprocal deposits, whether or not they meet the limited exception. Section 202 was effective immediately upon enactment.

As more fully discussed below, well-capitalized institutions are not restricted from accepting or soliciting brokered deposits and have no restrictions on the rates they pay on deposits. However, under section 29, less than well-capitalized institutions may generally not accept, renew, or roll-over brokered deposits and may not offer rates on any deposits that are significantly higher than the prevailing rates in the institution's normal market area. Section 29 defines the term ''deposit broker'' and provides a list of exclusions to that term. Funds obtained through a deposit broker are considered brokered deposits. Section 202 amends section 29 to provide that a capped amount of reciprocal deposits will not be considered funds obtained through a deposit broker for certain insured depository institutions, and thus such deposits will be non-brokered. Reciprocal deposits that do not meet the section 202 exception are brokered deposits under section 29.

A. Section 29 of the FDI Act

Under section 29 of the FDI Act, an insured depository institution that is less than well capitalized is restricted from accepting deposits by or through a deposit broker.[4] The FDIC may, however, waive this restriction if the insured depository institution is adequately capitalized; the restriction cannot be waived if the institution is less than adequately capitalized.[5] Section 29 also imposes restrictions on the deposit interest rates that an insured depository institution may offer if the institution is not well capitalized.[6] These interest rate restrictions cannot be waived. Section 337.6 of the FDIC's Rules and Regulations implements section 29 of the FDI Act.[7] Through this regulation, the FDIC has largely tracked the statutory definition of ''deposit broker'' and its exceptions.

A ''deposit broker,'' as defined by section 29 of the FDI Act, includes ''any person engaged in the business of placing deposits, or facilitating the placement of deposits, of third parties with insured depository institutions or the business of placing deposits with insured depository institutions for the purpose of selling interests in those deposits to third parties. . . .'' Under the FDIC's regulations, a ''brokered deposit'' is thus defined as a deposit accepted through a ''deposit broker.''[8] The definition of ''deposit broker'' is subject to nine statutory exceptions in section 29 and one regulatory exception.[9]

B. Reciprocal Deposits

The reciprocal deposit arrangement is based upon a network of banks that place funds at other participating banks in order for depositors to receive insurance coverage for the entire amount of their deposits.[10] In these arrangements, institutions within the network are both sending and receiving identical amounts of deposits simultaneously. Because reciprocal arrangements can be complex, and involve numerous banks, they are often managed by a third-party network sponsor. As a result of this arrangement, the institutions themselves (along with the third-party network sponsors) are ''in the business of placing deposits, or facilitating the placement of deposits, of third parties with insured depository institutions.''[11] The involvement of deposit brokers within the reciprocal network means the deposits are brokered deposits.[12]

For assessment purposes, reciprocal deposits have been treated more favorably than other types of brokered deposits. In 2009, through rulemaking, the FDIC amended its risk-based assessment rate methodology for small institutions (generally, insured depository institutions with less than $10 billion dollars in total assets).[13] In that rulemaking, the FDIC added an ''adjusted brokered deposit ratio'' that

[1] Public Law 115–174, 132 Stat. 1296–1368 (2018).

[2] Public Law 115–174, 132 Stat. 1296–1368 (2018).

[3] *See* 12 U.S.C. 1831f.

[4] 12 U.S.C. 1831f(a).

[5] 12 U.S.C. 1831f(c).

[6] *See generally,* 12 U.S.C. 1831f.

[7] 12 U.S.C. 1831f(a).

[8] 12 CFR 337.6(a)(2).

[9] 12 U.S.C. 1831 f(g)(2), (i); 12 CFR 337.6(a)(5)(ii)(J); *see also,* 57 FR 23933–01 (June 5, 1992).

[10] *See* FDIC Advisory Opinion No. 03–03 (July 29, 2003).

[11] Excerpt of the definition of ''deposit broker.'' 12 U.S.C. 1831f.

[12] *See FDIC's 2011 Study on Core and Brokered Deposits,* issued July 2011, Sections IV.E. and VIII.E.

[13] 74 FR 9525 (Mar. 4, 2009).

applied to small institutions that were well capitalized and well rated. This ratio measured the extent to which significant reliance on brokered deposits helped to fund rapid asset growth. After consideration of comments received in response to the proposed rule, reciprocal deposits were not included as part of the adjusted brokered deposit ratio. In its final rule, the FDIC stated that ''[it] recognizes that reciprocal deposits may be a more stable source of funding for healthy banks than other types of brokered deposits and that they may not be as readily used to fund rapid asset growth.'' [14] When the FDIC updated its risk-based assessment rate methodology for established small institutions in 2016, it replaced the adjusted brokered deposit ratio with a new brokered deposit ratio.[15] The new ratio, which measures significant reliance on brokered deposits (rapid asset growth is considered as a separate measure) and applies to all established small institutions, continues to exclude reciprocal deposits for institutions that are both well capitalized and well rated.[16] Thus, for well capitalized, well rated institutions under $10 billion, reciprocal deposits continue to generally have no impact on assessments.

C. Notice of Proposed Rulemaking

Prior to enactment of the Act, all reciprocal deposits were classified as brokered deposits.[17] Section 202 of the Act amends section 29 of the FDI Act to except a capped amount of reciprocal deposits from treatment as brokered deposits for certain insured depository institutions. Section 202's amendments took effect upon enactment on May 24, 2018.

Section 202 defines ''reciprocal deposits'' as ''deposits received by an agent institution through a deposit placement network with the same maturity (if any) and in the same aggregate amount as covered deposits placed by the agent institution in other network member banks.'' Network member banks may receive other deposits through a network such as (1) deposits received without the institution placing into the network a deposit of the same maturity and same aggregate amount (sometimes referred to as ''one-way network deposits'') and (2) deposits placed by the institution into the network where the deposits were obtained, directly or indirectly, by or through a deposit broker. Such other network deposits meet the definition of brokered deposits but would not meet the definition of reciprocal deposits. Thus, these deposits would not be eligible to be excepted from an institution's brokered deposits under section 202.

On September 12, 2018, the FDIC Board authorized publication of a notice of proposed rulemaking (NPR) to implement section 202. The NPR was published in the **Federal Register** on September 26, 2018, with a 30-day comment period.[18] In the NPR, the FDIC proposed to implement section 202's limited exception by incorporating its provisions into § 337.6(e)(2) of the brokered deposit rules, without change. These provisions, and their definitions, must be satisfied in order for a capped amount of reciprocal deposits to be excepted from treatment as brokered deposits. The FDIC also proposed to conform its assessment regulations with section 202 and the proposed amendments to the brokered deposit regulations.

The FDIC received twelve comments from insured depository institutions, banking associations, bank service providers, and law firms writing on behalf of institutions. The commenters generally supported the proposed rule. After careful consideration of all comments received, the FDIC is adopting as proposed the amendments to 12 CFR part 337, which incorporate section 202 of the Act, and the conforming amendments to the assessment regulations in 12 CFR part 327. Comments are discussed in the relevant sections, below.

III. Discussion of Treatment of Reciprocal Deposits Under the Act and Final Rule

A. Deposit Placement Network, Covered Deposits, and Network Member Bank

The term ''deposit placement network'' is defined in section 202 as a network in which an insured depository institution participates, together with other insured depository institutions, for the processing and receipt of reciprocal deposits. Institutions that are members of the deposit placement network are ''network member banks.''

The deposits that an ''agent institution'' places at other banks in return for reciprocal deposits are termed ''covered deposits'' under section 202. The term covered deposit is defined as a deposit that (1) is submitted for placement through a deposit placement network and (2) does not consist of funds that were obtained for the agent institution, directly or indirectly, by or through a deposit broker before submission for placement through the deposit placement network.

One commenter requested that the FDIC clarify whether deposits placed at an insured depository institution in satisfaction of Section 29's ''primary purpose exception'' [19] would meet the definition of ''covered deposit'' and thus be eligible for the limited exception for reciprocal deposits.'' [20] The term ''deposit broker'' does not include an agent or nominee whose primary purpose is not the placement of funds with depository institutions.[21] Deposits placed at an insured depository institution by an entity that is not a deposit broker because it meets the primary purpose exception are not brokered. Thus, if such non-brokered deposits are submitted for placement through a deposit placement network, they may qualify as ''covered deposits'' eligible for the limited exception for reciprocal deposits, subject to the other requirements and definitions in section 202 and the Final Rule.

B. Agent Institution

Consistent with section 202, § 337.6(e)(2) defines ''agent institution'' as an insured depository institution that places a covered deposit through a deposit placement network at other insured depository institutions in amounts that are less than or equal to the standard maximum deposit insurance amount, and specifies the interest rate to be paid for such amounts, if the insured depository institution:

- Is well capitalized [22] and has a composite condition of outstanding (CAMELS ''1'') or good (CAMELS ''2'') when most recently examined under

[14] *Id.* at 9532.

[15] Generally, an established small bank is a small institution that has been federally insured for at least five years. *See* 12 CFR 327.8(v).

[16] *See* 12 CFR 327.16(a)(1)(ii).

[17] *See FDIC's 2011 Study on Core and Brokered Deposits,* issued July 2011, Section IV.

[18] 83 FR 48562 (Sept. 26, 2018).

[19] *See* 12 U.S.C. 1831f(g)(2)(I).

[20] Generally, deposits placed by a third party are brokered deposits, unless the third party meets one of the exceptions to the definition of deposit broker. The commenter specifically references the primary purpose exception with respect to certain broker-dealers that place a limited amount of customer free cash balances into deposit accounts at affiliated banks as agent for their customers. These deposits have not been viewed by staff, subject to certain conditions, as brokered deposits via an advisory opinion. Note that a staff advisory opinion is not binding on the FDIC's Board of Directors.

[21] 12 U.S.C. 1831f(g)(2)(I).

[22] *See generally,* 12 CFR part 325, subpart B, or 12 CFR part 324, subpart H (FDIC); 12 CFR part 208 (Board of Governors for the Federal Reserve System); 12 CFR part 6 (Office of the Comptroller of the Currency). 12 U.S.C. 1831*o.* ''Well capitalized'' is already defined in 12 CFR 337.6(a)(3)(i).

section 10(d) of the FDI Act (described as ''well rated'') [23];

• has obtained a waiver pursuant to section 29(c) of the FDI Act; or

□ does not receive an amount of reciprocal deposits that causes the total amount of reciprocal deposits held by the agent institution to be greater than the average of the total amount of reciprocal deposits held by the agent institution on the last day of each of the four calendar quarters preceding the calendar quarter in which the agent institution was found not to have a composite condition of outstanding or good or was determined to be not well capitalized.

C. Caps Applicable to Agent Institutions

Consistent with section 202, under the regulation, an ''agent institution'' can except reciprocal deposits from being classified as brokered deposits up to its applicable statutory caps, as explained below.

General Cap

An agent institution may except reciprocal deposits up to the lesser of the following amounts (referred to as the *general cap*) from being classified as brokered deposits: [24]

□ $5 billion or

□ An amount equal to 20 percent of the agent institution's total liabilities. Reciprocal deposits in excess of the *general cap,* as well as those reciprocal deposits that do not meet section 202's limited exception, are brokered deposits.

Special Cap

A *special cap* applies if the institution is either not well rated or not well capitalized. In this case, the institution may meet the definition of ''agent institution'' if it does not receive reciprocal deposits in excess of the *special cap,* which is the average amount of reciprocal deposits held at quarter-end during the last four quarters preceding the quarter that the institution fell below well capitalized or well rated. Thus, the *special cap* is applicable to agent institutions that were previously well capitalized and well rated. Section 202 does not provide a date by which an institution must demonstrate that its amount of reciprocal deposits are within the *special cap.*

The FDIC will calculate an institution's *special cap* based on information reported in its Call Reports as proposed. For an institution that falls below well rated or well capitalized, the FDIC will evaluate the institution's compliance with the *special cap* based on Call Report data submitted for the reporting date immediately following when the determination is made.

One commenter was concerned that it would not be possible to calculate a four quarter history of reciprocal deposits until March 31, 2019, because reciprocal deposits were not defined separately from brokered deposits before section 202 was enacted on May 24, 2018. However, reciprocal deposit data prior to the date of enactment is available because institutions have reported reciprocal deposits on Call Report Schedule RC–O since June 30, 2009.[25]

Application of Statutory Caps

Below are descriptions of how the two statutory caps will apply to an agent institution based upon its capital and composite ratings.[26]

1. Well capitalized and well rated. Institutions that are both well capitalized and well rated can have non-brokered reciprocal deposits up to the *general cap.* Any amount of reciprocal deposits over the *general cap* will not meet the limited exception and therefore that amount will be considered to be ''brokered deposits.'' Well capitalized institutions may accept brokered deposits, including reciprocal deposits that are brokered deposits, without restrictions.

2. *Not well capitalized or not well rated.* Institutions that are either not well capitalized or not well rated are subject to the lesser of either the *special cap* or the *general cap.* The amount of reciprocal deposits within the institution's *applicable cap* will not be considered brokered deposits. In no event, however, can an institution's non-brokered reciprocal deposits exceed the *general cap.* With respect to an institution that is well capitalized but not well rated, if it received reciprocal deposits above the *special cap,* it will no longer meet the definition of ''agent institution.''

Institutions that are less than well capitalized, however, are subject to restrictions on the acceptance of brokered deposits, including reciprocal deposits that are brokered deposits. Because only reciprocal deposits of an agent institution that are below the applicable cap are considered non-brokered, a less than well-capitalized agent institution may not accept reciprocal deposits in excess of the *special cap.* (An adequately capitalized institution's non-brokered reciprocal deposits may be above the *special cap* with a waiver from the FDIC, but can also never exceed the *general cap.*[27])

Comments on the Application of the Special Cap

Two commenters objected to the proposed rule's application of the special cap when an institution falls below well capitalized or is no longer well rated. They noted that while section 202 limits the amount an agent institution can ''receive,'' it does not limit amounts an agent institution can maintain, retain, or hold. Thus, according to commenters, an institution that falls below well capitalized or well rated should not be required to lower the amount of reciprocal deposits it holds within the special cap. Rather these institutions should be able to retain reciprocal deposits, even if above the special cap, so long as when those reciprocal deposits mature or roll off, the institution does not receive additional reciprocal deposits that cause its total to exceed the special cap (*i.e.,* the previous four-quarter average). One commenter argued that this interpretation is consistent with the FDIC's current interpretation of Section 29 of the Federal Deposit Insurance Act: If an institution drops to adequately capitalized, it does not need a waiver for deposits previously accepted when it was well capitalized. In this case, the adequately capitalized institution would continue to report such deposits as brokered.

The FDIC recognizes that the statute only limits the amount of reciprocal deposits an institution may ''receive'' in

[23] CAMELS refers to Capital adequacy, Asset quality, Management, Earnings, Liquidity, and Sensitivity to market risk. The effective date of a CAMELS composite rating is the date of written notification to the institution by its primary federal regulator or state authority of its supervisory rating. *See e.g.,* 12 CFR 327.4(f).

[24] *See* FFIEC Supplemental Instructions, Call Report Date, June 30, 2018 *https://www.fdic.gov/news/news/financial/2018/fil18039a.pdf.*

[25] Since June 30, 2009, institutions reported ''Reciprocal brokered deposits'' on Call Report Schedule RC–O. Until the passage of the Act, all reciprocal deposits were considered brokered deposits. As provided in the supplemental instructions to the September 30, 2018 Call Report, a new line item ''Total reciprocal deposits'' was proposed to be added to Schedule RC–E. In addition, the instructions note a one-time reporting line item of ''Total reciprocal deposits as of June 30, 2018'' (when the law was effective). These new line items track the new definition of ''reciprocal deposit'' in Section 202.

[26] For an example of Section 202's applicability, refer to the NPR at 83 FR 48564.

[27] 12 U.S.C. 1831f(c). Institutions that are adequately capitalized may seek a waiver from the FDIC to accept brokered deposits. Waivers under section 29(c) are only available (1) on a case-by-case basis, (2) upon application to the FDIC, (3) to adequately capitalized institutions, and (4) upon a finding that the acceptance of such deposits does not constitute an unsafe or unsound practice with respect to such institution. Less than adequately capitalized institutions (undercapitalized or significantly undercapitalized institutions) are not eligible to seek a waiver from the FDIC.

order to be considered an agent institution. Thus, an institution that is less than well capitalized or not well rated will still qualify as an agent institution if it holds a level of reciprocal deposits above the special cap, as long as (1) such deposits were received before the institution became less than well capitalized or not well rated, (2) such deposits are time deposits,[28] and (3) the institution satisfies all other qualifications necessary to be an agent institution. For example, an institution that is well capitalized but no longer well rated could continue to be an agent institution if it holds reciprocal time deposits that it received prior to its rating downgrade until those time deposits mature or roll off, but would no longer be an agent institution if it renewed or rolled over such deposits and doing so caused the total amount of reciprocal deposits to exceed the special cap. In this case, once the institution receives reciprocal deposits in excess of its special cap, it is no longer an agent institution. If an institution is not an agent institution, all of its reciprocal deposits should be reported as brokered deposits.

Another commenter noted that an institution that is well capitalized but not well rated may be treated the same or worse under section 202 and the proposed rule than adequately capitalized or undercapitalized institutions. This is because, under section 29(c) of the FDI Act, only an adequately capitalized institution may be an agent institution pursuant to a waiver. Thus, according to the commenter, a well-capitalized but not well-rated institution would be treated the same as an undercapitalized institution, both of which are not eligible for a waiver under section 29(c) and could only qualify as an agent institution through application of the special cap. The commenter suggested that the FDIC amend the regulation to alleviate this discrepancy in relative treatment, arguing that this would better reflect congressional intent.

Amending the final rule in the manner that the commenter suggests would be inconsistent with section 29 of the FDI Act, as well as section 202 of the Act. Section 202 unambiguously defines ''agent institution'' to include an institution that has obtained a waiver pursuant to paragraph (c) of section 29. Section 29 of the FDI Act only allows the FDIC to grant a waiver for adequately capitalized institutions.

[28] Transactional reciprocal deposits are viewed as being ''received'' daily.

D. Treatment of De Novo Institutions

Several commenters objected that the regulation would not allow *de novo* institutions to benefit from the limited exception for reciprocal deposits because they would not have a composite condition rating for 12 to 14 months after being in operation and would not be eligible for the special cap because they would not have a prior four quarter average of reciprocal deposits. Commenters therefore proposed that the FDIC allow *de novo* institutions to be treated as agent institutions subject to the general cap. Some commenters suggested that the FDIC treat a *de novo* institution's pre-opening activities and approval of its business plan from both the FDIC and the chartering authority as substitute for a composite condition rating of outstanding or good. Another commenter argued that in the absence of a four quarter average of reciprocal deposits that precedes an adverse rating or an adverse capital determination, no amount of reciprocal deposits would cause its total amount of reciprocal deposits to exceed the special cap, and therefore qualifies as an agent institution.

De novo institutions may be eligible for the limited exception for reciprocal deposits once they meet the definition of agent institution under the statute and Final Rule, which adopts the exact language of section 202. The FDIC considered treating a *de novo* institution as well rated as commenters suggested, but section 202 specifically requires that an institution ''when most recently examined under section 10(d) was found to have a composite condition of outstanding or good.'' Pre-opening activities are not examinations under section 10(d) of the FDI Act.[29] In addition, a *de novo* institution that does not have a preceding four quarter average of reciprocal deposits would also not be able to qualify as an agent institution under the special cap prong.

De novo institutions that do not qualify as ''agent institutions'' are not prohibited from accepting reciprocal deposits, but would need to report them as brokered.

Although *de novo* institutions may not be eligible for the limited exception for reporting reciprocal deposits as non-brokered until they receive their first rating under section 10(d) of the FDI Act, the FDIC will make every effort to accelerate the timing of a *de novo* state nonmember bank's first examination. To this end, the FDIC will update examiner instructions to make clear to open and operating *de novo* state nonmember banks that wish to make use of the limited exemption for not reporting reciprocal deposits as brokered that they may request an accelerated on-site examination in order to obtain an examination rating. The FDIC will work with the other federal banking agencies to encourage similar supervisory treatment.

[29] Section 10(d) requires the appropriate Federal banking agency to ''conduct a full-scope, on-site examination of each insured depository institution.'' 12 U.S.C. 1820(d).

E. Conforming Assessments Amendments

The FDIC is finalizing as proposed the conforming amendments to its assessments regulations to be consistent with the statutory definition of reciprocal deposits. Prior to enactment of section 202, all reciprocal deposits as defined in the assessment regulations met the definition of brokered deposits. Because section 202 excepts certain reciprocal deposits from treatment as brokered deposits, the FDIC is replacing the current definition of ''reciprocal deposits'' in § 327.8(q) with a new term, ''brokered reciprocal deposit.'' A ''brokered reciprocal deposit'' is a ''reciprocal deposit'' as defined under section 202, and § 337.6(e)(2)(v), that does not meet the statute's limited exception (for example, deposits over the applicable caps discussed above). The FDIC is also making conforming amendments to § 327.16(a)(1)(ii) and (e)(3), which reference reciprocal deposits.

For assessment purposes, ''brokered reciprocal deposits'' will continue to be excluded from the brokered deposit ratio for established small institutions that are well capitalized and well rated.[30] For new small banks and large and highly complex banks that are less than well capitalized or not well rated, ''brokered reciprocal deposits'' will continue to be included in an institution's total brokered deposits for the brokered deposit adjustment.[31]

[30] The brokered deposit ratio may increase assessment rates for established small banks with brokered deposits greater than 10 percent of total assets. Since 2009, when the ratio was first used as one of the financial measures used to determine an established small bank's assessment rate, the ratio has excluded reciprocal deposits from brokered deposits if the bank is well capitalized and well rated. *See* 12 CFR 327.16(a)(1)(ii).

[31] The brokered deposit adjustment applies to all new small institutions in Risk Categories II, III, and IV, and all large and all highly complex institutions, except large and highly complex institutions (including new large and new highly complex institutions) that are well capitalized and have a CAMELS composite rating of 1 or 2. The brokered deposit adjustment can increase assessments for institutions that have brokered deposits in excess of 10 percent of domestic deposits. *See* 12 CFR 327.16(e)(3).

The FDIC notes that the statutory definition of ''reciprocal deposit'' is substantially similar to the current regulatory definition in part 327, with one difference. Section 202's definition of ''reciprocal deposits'' is limited to funds obtained from a deposit placement network in exchange for funds placed into the network that meet the definition of ''covered deposits,'' which excludes funds that were obtained, directly or indirectly, by or through a deposit broker before submission for placement through the deposit placement network. As such, funds that do not meet the statutory definition of ''reciprocal deposit'' because they are obtained in exchange for funds that the institution acquired by or through a deposit broker are ''brokered deposits'' and would not meet the definition of ''brokered reciprocal deposits.''

One commenter supported the amendments to the assessment rules to conform to the changes in the treatment of certain reciprocal deposits. Another commenter suggested adding the term ''non-brokered reciprocal deposits'' to the assessment regulations in order to allow all well capitalized institutions to benefit from the reciprocal deposit limited exception. The FDIC believes this addition is unnecessary. Under the Final Rule, all institutions that qualify under section 202 will be allowed to exclude reciprocal deposits from brokered deposits for both the brokered deposit ratio and the brokered deposit adjustment. The assessments regulations, amended as proposed, only include brokered reciprocal deposits for the brokered deposit adjustment, and, for institutions that are well capitalized and well rated, exclude brokered reciprocal deposits from the brokered deposit ratio. Non-brokered reciprocal deposits would not be included in either the brokered deposit adjustment or the brokered deposit ratio by definition.

F. Interest Rates

Section 202 applies the statutory interest rate restrictions under section 29 to all reciprocal deposits. More specifically, section 202 amends section 29(e) of the FDI Act by ensuring that the interest rate restrictions apply to less than well capitalized banks that accept reciprocal deposits.[32] As a result, section 202 confirms that the current statutory and regulatory rate restrictions for less than well capitalized institutions continue to apply to *any* deposit, including a reciprocal deposit that is a covered deposit.[33] To ensure consistent treatment of the interest rate restrictions under section 202, the FDIC is adopting conforming amendments to § 337.6(b)(2)(ii) of its rules and regulations as proposed. The FDIC did not receive comments objecting to the adoption of these conforming changes.

G. Other Brokered Deposit Comments

Several commenters suggested that the FDIC eliminate all limits on the acceptance of reciprocal deposits and two commenters suggested that the FDIC treat all reciprocal deposits as core deposits. However, section 202 did not change the definition of deposit broker in section 29 of the FDI Act and only allows a limited amount of reciprocal deposits to be excepted from being treated as brokered deposits in certain circumstances (where the institution qualifies as an agent institution). Thus, the statute does not provide a blanket exception for all reciprocal deposits to be treated as nonbrokered.

Commenters also responded to a question about whether reciprocal deposits that are no longer considered brokered deposits under section 202 would be viewed by a potential acquiring institution in the same way it views traditional retail deposits. Commenters indicated that reciprocal deposits increase franchise value. In light of these comments that taking non-brokered reciprocal deposits in failed bank transactions may provide a benefit to some acquiring banks, the FDIC will include nonbrokered reciprocal deposits in the calculation of the deposit premium paid by the assuming institution of a failed bank.

A number of commenters addressed general brokered deposit issues not specifically related to the limited exception for reciprocal deposits under section 202. For example, some commenters discussed the FDIC's interpretation of ''deposit broker'' and the need to update the calculation of the national rate cap. The FDIC is planning to publish an advanced notice of proposed rulemaking (ANPR) seeking comment on all parts of the brokered deposit regulation (§ 337.6) and will consider these comments when reviewing comments on the ANPR. The FDIC encourages interested parties to submit comments about the brokered deposit regulations when the ANPR is published.

IV. Expected Effects

As noted previously, section 202 of the Act took effect upon enactment, and the rule will conform part 337 with the legislation and align the assessment rules with the statute's definition of ''reciprocal deposits.'' The rule applies to all FDIC-insured depository institutions. As of March 31, 2018, there were 5,616 FDIC-insured institutions.[34] Of these, 2,528 institutions reported having brokered deposits, which totaled $980 billion. Of the institutions reporting brokered deposits, 1,185 institutions also reported having reciprocal deposits, totaling $48 billion.

Benefits

The rule could affect deposit insurance assessments for a small number of FDIC-insured institutions. As discussed in Section II: Background, the brokered deposit ratio is one of the financial measures used to determine assessment rates for established small banks. The brokered deposit ratio may increase assessment rates for established small banks with brokered deposits greater than 10 percent of total assets.[35] Among these banks, those that are well capitalized and well rated can already deduct reciprocal deposits from brokered deposits and generally would not be affected by the final rule, for assessment purposes.[36] Furthermore, the final rule will not affect the assessment rates of any banks that do not have reciprocal deposits or whose brokered deposits comprise less than 10 percent of total assets. The FDIC estimates that fewer than ten (0.178 percent) small FDIC-insured institutions that are either not well capitalized or not well rated (or both) could have a lower assessment rate under the final rule if their reciprocal deposits are excepted from brokered deposits.[37] For large institutions, generally insured depository institutions with greater than $10 billion in total assets, the final rule may alter the core deposit ratio, resulting in a change in the bank's assessment.[38] The FDIC estimates that 20 (0.356 percent) FDIC-insured institutions could have a lower assessment due to the effect of the final rule on their core deposit ratio for assessment purposes, if their reciprocal

[32] 12 U.S.C. 1831f(h).

[33] 12 U.S.C. 1831f(g)(3) and (e).

[34] The FDIC is analyzing expected effects based on March 31, 2018 Call Report data, which is the last available Call Report data prior to enactment of section 202 on May 24, 2018.

[35] All else equal, a higher brokered deposit ratio will result in a higher assessment rate.

[36] *See* 12 CFR 327.16(a)(1)(ii).

[37] FDIC Call Report, March 31, 2018.

[38] The core deposit ratio applies to large and highly-complex institutions and is measured as domestic deposits, excluding brokered deposits and uninsured non-brokered time deposits, divided by total liabilities. Reciprocal deposits that are brokered reciprocal deposits will continue to be excluded from the ratio. *See* 12 CFR 327.16(b) and 12 CFR part 327, appendix B to subpart A.

deposits are excepted from treatment as brokered. Based on data as of March 31, 2018, the FDIC estimates that no more than 30 institutions would have reduced assessment rates, all else equal, and the FDIC's aggregate assessment revenue would be reduced by an estimated $4.3 million annually.

Adequately capitalized institutions may also benefit from the final rule through a reduction in administrative costs. Before this rule change, these institutions must have sought and received a regulatory waiver from the FDIC in order to accept brokered deposits.[39] The Final Rule allows these institutions that previously accepted reciprocal deposits to continue to receive reciprocal deposits up to the lesser of the *general* or *special cap* without requesting a waiver. This allowance results in a de minimis savings of administrative expenses for affected institutions. The number of institutions that may benefit from this reduction in administrative costs is difficult to accurately estimate with available data because it depends on the specific financial conditions of each bank, fluctuating market conditions for reciprocal deposits, and future management decisions.

Undercapitalized institutions also benefit from the final rule by being allowed to accept reciprocal deposits up to the lesser of either the *general* or *special cap,* even though they are otherwise prohibited from receiving brokered deposits.[40] Before this rule change, undercapitalized institutions could not solicit or accept any reciprocal deposits because all reciprocal deposits were treated as brokered deposits. Because the final rule excepts a certain amount of reciprocal deposits from treatment as brokered, undercapitalized institutions that, when better capitalized, previously accepted reciprocal deposits may now be allowed to receive reciprocal deposits up to the lesser of the *general* or *special cap* despite being undercapitalized. If undercapitalized institutions can receive reciprocal deposits, the result may be increased utilization of reciprocal deposits in the future. However, this effect is difficult to estimate with available data because the decision to receive reciprocal deposits depends on the specific financial conditions of each bank, fluctuating market conditions for reciprocal deposits, and future management decisions.

As of March 31, 2018, there were 2,528 (45 percent) institutions that reported holding some amount of brokered deposits and 1,185 (21 percent) that reported holding some amount of reciprocal deposits. The changes could affect some metrics that rely on the amount of brokered deposits reported on the Call Report, such as:

- Net Noncore Funding Dependence Ratio
- Brokered Deposits maturing in less than one year to Brokered Deposits Ratio
- Brokered Deposits to Deposits Ratio
- Listing Service and Brokered Deposits to Deposits Ratio
- Reciprocal Brokered Deposits to Total Brokered Deposits Ratio

Costs

With regard to the difference in the previous regulatory definition of ''reciprocal deposits'' for assessment purposes, which was added pursuant to the FDIC's assessment authority under section 7 of the FDI Act, and the statutory definition of reciprocal deposits that was added to section 29 of the FDI Act, the FDIC notes that banks do not report data on the amount (if any) of deposits that were obtained, directly or indirectly, by or through a deposit broker before submission for placement through the deposit placement network. As a result, the FDIC cannot estimate whether this change to align the assessment regulation definition of ''reciprocal deposits'' with the statutory definition of that term in section 29 of the FDI Act would affect the amount of reciprocal deposits that a bank would report or whether it would affect any bank's assessment rate.

With regard to costs to the Deposit Insurance Fund, the FDIC estimates that, assuming all currently reported reciprocals align with the statutory definition, all else equal, the FDIC's aggregate assessment revenue would be reduced by an estimated $4.3 million annually. Additional reduced assessment revenue could occur if institutions shift their funding mix in ways that affect assessment rates, such as less use of traditional brokered deposits, and increased use of reciprocal deposits. Historically, when resolving failed institutions, the FDIC has found that potential acquiring institutions have generally been unwilling to pay a premium for reciprocal deposits, typically treating them consistent with other brokered deposits. It is not clear whether reciprocal deposits that are no longer treated as brokered as a result of section 202 would be viewed by potential acquiring institutions as more akin to traditional retail deposits for purposes of warranting a premium. Additionally, the final rule could pose some additional regulatory costs associated with changes to internal systems or processes, or changes to reporting requirements.

V. Alternatives

The FDIC considered alternatives but believes that the final rule represents the most appropriate option. In particular, the FDIC considered whether a rulemaking implementing section 202 was necessary or appropriate, because section 202's amendments to section 29 became effective upon the Act's enactment on May 24, 2018. However, the FDIC believes that conforming § 337.6 with section 202's amendments will remove confusion that might arise if interested parties only consult § 337.6 for requirements related to brokered deposits.

Section 202 did not address the assessment rules in part 327 with respect to reciprocal deposits. The definition of ''reciprocal deposits'' in part 327 varies with the definition of that term in section 202. As an alternative, the FDIC considered whether it should continue to use the existing definition of ''reciprocal deposits'' for assessment purposes. However, the FDIC was concerned that having two different definitions of ''reciprocal deposits'' could cause confusion as well as undue burden in the industry, particularly for reporting purposes.

VI. Regulatory Analysis and Procedure

A. Plain Language

Section 722 of the Gramm-Leach-Bliley Act, Public Law 106–102, 113 Stat. 1338, 1471 (Nov. 12, 1999), requires the Federal banking agencies to use plain language in all proposed and final rules published after January 1, 2000. The FDIC requested comments on this issue but received none.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.,* generally requires an agency, in connection with a rule, to prepare and make available for public comment an initial regulatory flexibility analysis that describes the impact of a proposed rule on small entities.[41] However, a regulatory flexibility analysis is not required if the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. The Small Business Administration (SBA) has defined ''small entities'' to include banking organizations with total

[39] 12 U.S.C. 1831f(c); 12 CFR 337.6(c).

[40] 12 CFR 337.6(b).

[41] 5 U.S.C. 601 *et seq.*

assets of less than or equal to $550 million.[42]

As of March 31, 2018, there were 5,616 FDIC-insured institutions, of which 4,177 are considered small entities for the purposes of RFA.[43]

The rule could affect deposit insurance assessments for a small number of FDIC-insured, small entities. As discussed in Section II: Background, the brokered deposit ratio is one of the financial measures used to determine assessment rates for established small banks. The brokered deposit ratio may increase assessment rates for established small banks with brokered deposits greater than 10 percent of total assets.[44] Among these banks, those that are well capitalized and well rated can already deduct reciprocal deposits from brokered deposits and generally would not be affected by the proposed rule, for assessment purposes.[45]

Furthermore, the rule will not affect the assessment rates of small banks that do not have reciprocal deposits or whose brokered deposits comprise less than 10 percent of total assets. The FDIC estimates that seven (0.2 percent) small, FDIC-insured entities that are either not well capitalized or not well rated (or both) could have a lower assessment rate under the proposed rule if their reciprocal deposits are excepted from brokered deposits.[46]

There are 611 (14.6 percent) small entities that report holding some amount of reciprocal deposits and 1,499 (35.9 percent) that report holding some amount of brokered deposits. These changes could affect some metrics that rely on the amount of brokered deposits reported on the Call Report, such as:

- Net Noncore Funding Dependence Ratio
- Brokered Deposits maturing in less than one year to Brokered Deposits Ratio
- Brokered Deposits to Deposits Ratio
- Listing Service and Brokered Deposits to Deposits Ratio
- Reciprocal Brokered Deposits to Total Brokered Deposits Ratio

Based on available information, it is difficult to determine whether additional regulatory costs or costs to the Deposit Insurance Fund could result. Nonetheless, the rule could pose some additional regulatory costs associated with changes to internal systems or processes, or changes to reporting requirements. Based on the information above, the FDIC certifies that the rule will not have a significant economic impact on a substantial number of small entities.

C. Small Business Regulatory Enforcement Fairness Act

The Office of Management and Budget has determined that the final rule is not a ''major rule'' within the meaning of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121, Title II).

D. Paperwork Reduction Act

In accordance with the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521) (PRA), the FDIC may not conduct or sponsor, and a respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number. The FDIC has reviewed the rule and determined that it revises certain reporting requirements that have been previously cleared by the OMB under various control numbers.[47]

On May 24, 2018, the Act amended various statutes administered by the Agencies and affected regulations issued by the Agencies.[48] As described above, certain amendments made by the Act took effect on the day of the Act's enactment and immediately impacted institutions' regulatory reports. In response to emergency review requests, the Agencies received approval from OMB to revise the reporting of information in the Call Reports including the reciprocal deposits provisions described in this rule. As a result of OMB's emergency approval of revisions to the information collections affected by the above statutory changes, the expiration date of these collections has been revised to February 28, 2019. The Agencies have begun the regular PRA process for revising and extending these information collections for three years and they published the required 60-day notice in the **Federal Register** on September 28, 2018.[49]

E. Riegle Community Development and Regulatory Improvement Act

The Riegle Community Development and Regulatory Improvement Act of 1994 (RCDRIA), 12 U.S.C. 4701, requires that each Federal banking agency, in determining the effective date and administrative compliance requirements for new regulations that impose additional reporting, disclosure, or other requirements on insured depository institutions, consider, consistent with principles of safety and soundness and the public interest, any administrative burdens that such regulations would place on depository institutions, including small depository institutions, and customers of depository institutions, as well as the benefits of such regulations.[50] In addition, new regulations that impose additional reporting, disclosures, or other new requirements on insured depository institutions generally must take effect on the first day of a calendar quarter that begins on or after the date on which the regulations are published in final form.

The changes relating to ''reciprocal deposits'' and section 29 are effective upon enactment of section 202, and as described previously, institutions have already begun reporting reciprocal deposits as per the new law. This final rule relating to the amendments to part 337 of the FDIC's regulations is effective 30 days after publication in the **Federal Register**. The rule also includes changes to conform section 202's statutory definition of ''reciprocal deposit'' with the current definition of ''reciprocal deposit'' in the FDIC's assessments regulations in part 327. The FDIC requested comments on any administrative burdens that the changes would place on depository institutions, including small depository institutions and customers of depository institutions and received one comment; that comment supported the change in the assessment rule. Consistent with RCDRIA, changes to the assessment

[42] The SBA defines a small banking organization as having $550 million or less in assets, where ''a financial institution's assets are determined by averaging the assets reported on its four quarterly financial statements for the preceding year.'' See 13 CFR 121.201 (as amended, effective December 2, 2014). ''SBA counts the receipts, employees, or other measure of size of the concern whose size is at issue and all of its domestic and foreign affiliates.'' See 13 CFR 121.103. Following these regulations, the FDIC uses a covered entity's affiliated and acquired assets, averaged over the preceding four quarters, to determine whether the covered entity is ''small'' for the purposes of RFA.

[43] FDIC Call Report, March 31, 2018.

[44] All else equal, a higher brokered deposit ratio will result in a higher assessment rate.

[45] *See* 12 CFR 327.16(a)(1)(ii).

[46] FDIC Call Report, March 31, 2018.

[47] The reporting requirements are found in the three Consolidated Reports of Condition and Income (Call Reports) promulgated by the Federal Financial Institutions Examination Council (FFIEC). The Call Reports are designated FFIEC 031 (Consolidated Report of Condition and Income for a Bank with Domestic and Foreign Offices); FFIEC 041 (Consolidated Report of Condition and Income for a Bank with Domestic Offices Only); and FFIEC 051 (Consolidated Report of Condition and Income for a Bank with Domestic Only and Total Assets of Less than $1 Billion). The FFIEC constituent bank regulatory agencies (the Board of Governors of the Federal Reserve System (the Board), the Office of the Comptroller of the Currency (the OCC) and the FDIC) (the Agencies) have each obtained information collection clearances from OMB under the following Control Numbers: 7100–0036 (Board); 1557–0081 (OCC); and 3064–0052 (FDIC).

[48] Public Law 115–174, 132 Stat. 1296 (2018).

[49] 83 FR 49160 (Sept. 28, 2018).

[50] 12 U.S.C. 4802.

regulations are effective on the first day of the calendar quarter that begins after the date on which this final rule is published.

List of Subjects

12 CFR Part 327

Bank deposit insurance, Banks, banking, Savings associations.

12 CFR Part 337

Banks, banking, Reporting and recordkeeping requirements, Securities, Savings associations.

Authority and Issuance

For the reasons stated in the preamble, the FDIC amends 12 CFR parts 327 and 337 as follows:

PART 327—ASSESSMENTS

■ 1. The authority citation for 12 CFR part 327 continues to read as follows:

Authority: 12 U.S.C. 1441, 1813, 1815, 1817–19, 1821.

■ 2. Amend § 327.8 by revising paragraph (q) to read as follows:

§ 327.8 Definitions.

* * * * *

(q) *Brokered reciprocal deposits.* Reciprocal deposits as defined in § 337.6(e)(2)(v) that are not excepted from the institution's brokered deposits pursuant to § 337.6(e).

* * * * *

■ 3. Amend § 327.16 by:

■ a. In the table in paragraph (a)(1)(ii)(A), revising the entry for ''Brokered Deposit Ratio''; and

■ b. In paragraph (e)(3) introductory text, removing ''reciprocal deposits as defined in § 327.8(p)'' and adding in its place ''brokered reciprocal deposits as defined in § 327.8(q)''.

The revision reads as follows:

§ 327.16 Assessment pricing methods—beginning the first assessment period after June 30, 2016, where the reserve ratio of the DIF as of the end of the prior assessment period has reached or exceeded 1.15 percent.

(a) * * *

(1) * * *

(ii) * * *

(A) * * *

DEFINITIONS OF MEASURES USED IN THE FINANCIAL RATIOS METHOD

Variables	Description
*	* * * * * *
Brokered Deposit Ratio	The ratio of the difference between brokered deposits and 10 percent of total assets to total assets. For institutions that are well capitalized and have a CAMELS composite rating of 1 or 2, brokered reciprocal deposits as defined in § 327.8(q) are deducted from brokered deposits. If the ratio is less than zero, the value is set to zero.
*	* * * * * *

* * * * *

PART 337—UNSAFE AND UNSOUND BANKING PRACTICES

■ 4. The authority citation for 12 CFR part 337 continues to read as follows:

Authority: 12 U.S.C. 375a(4), 375b, 1463(a)(1),1816, 1818(a), 1818(b), 1819, 1820(d), 1828(j)(2), 1831, 1831f, 5412.

■ 5. Amend § 337.6 by revising paragraph (b)(2)(ii) introductory text, redesignating paragraph (e) as paragraph (f), and adding a new paragraph (e) to read as follows:

§ 337.6 Brokered deposits.

* * * * *

(b) * * *

(2) * * *

(ii) Any adequately capitalized insured depository institution that has been granted a waiver to accept, renew or roll over a brokered deposit, or is an agent institution that receives a reciprocal deposit (under § 337.6(e)(2)(i)(C)), may not pay an effective yield on any such deposit which, at the time that such deposit is accepted, renewed or rolled over, exceeds by more than 75 basis points:

* * * * *

(e) *Limited exception for reciprocal deposits*—(1) *Limited exception.* Reciprocal deposits of an agent institution shall not be considered to be funds obtained, directly or indirectly, by or through a deposit broker to the extent that the total amount of such reciprocal deposits does not exceed the lesser of:

(i) $5,000,000,000; or

(ii) An amount equal to 20 percent of the total liabilities of the agent institution.

(2) *Additional definitions that apply to the limited exception for reciprocal deposits.* (i) *Agent institution* means an insured depository institution that places a covered deposit through a deposit placement network at other insured depository institutions in amounts that are less than or equal to the standard maximum deposit insurance amount, specifying the interest rate to be paid for such amounts, if the insured depository institution:

(A)(*1*) When most recently examined under section 10(d) of the Federal Deposit Insurance Act (12 U.S.C. 1820(d)) was found to have a composite condition of outstanding or good; and

(*2*) Is well capitalized;

(B) Has obtained a waiver pursuant to paragraph (c) of this section; or

(C) Does not receive an amount of reciprocal deposits that causes the total amount of reciprocal deposits held by the agent institution to be greater than the average of the total amount of reciprocal deposits held by the agent institution on the last day of each of the four calendar quarters preceding the calendar quarter in which the agent institution was found not to have a composite condition of outstanding or good or was determined to be not well capitalized.

(ii) *Covered deposit* means a deposit that:

(A) Is submitted for placement through a deposit placement network by an agent institution; and

(B) Does not consist of funds that were obtained for the agent institution, directly or indirectly, by or through a deposit broker before submission for placement through a deposit placement network.

(iii) *Deposit placement network* means a network in which an insured depository institution participates, together with other insured depository institutions, for the processing and receipt of reciprocal deposits.

(iv) *Network member bank* means an insured depository institution that is a

member of a deposit placement network.

(v) *Reciprocal deposits* means deposits received by an agent institution through a deposit placement network with the same maturity (if any) and in the same aggregate amount as covered deposits placed by the agent institution in other network member banks.

* * * * *

Dated at Washington, DC, on December 18, 2018.

By Order of the Board of Directors.

Federal Deposit Insurance Corporation.

Valerie Best,

Assistant Executive Secretary.

[FR Doc. 2018–28137 Filed 2–1–19; 8:45 am]

BILLING CODE 6714–01–P

FARM CREDIT ADMINISTRATION

12 CFR Part 622

RIN 3052–AD33

Rules of Practice and Procedure; Adjusting Civil Money Penalties for Inflation

AGENCY: Farm Credit Administration.

ACTION: Final rule.

SUMMARY: This regulation implements inflation adjustments to civil money penalties (CMPs) that the Farm Credit Administration (FCA) may impose or enforce pursuant to the Farm Credit Act of 1971, as amended (Farm Credit Act), and pursuant to the Flood Disaster Protection Act of 1973, as amended by the National Flood Insurance Reform Act of 1994 (Reform Act), and further amended by the Biggert-Waters Flood Insurance Reform Act of 2012 (Biggert-Waters Act).

DATES: *Effective date:* This regulation is effective on February 4, 2019. *Applicability date:* The inflation-adjusted CMP were applicable beginning January 15, 2019.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Objective

The objective of this regulation is to adjust the maximum CMPs for inflation through a final rulemaking to retain the deterrent effect of such penalties.

II. Background

A. Introduction

The Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996 (1996 Act) and the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (2015 Act) (collectively, 1990 Act, as amended), requires all Federal agencies with the authority to enforce CMPs to evaluate and adjust, if necessary, those CMPs each year to ensure that they continue to maintain their deterrent value and promote compliance with the law. Section 3(2) of the 1990 Act, as amended, defines a civil monetary penalty [1] as any penalty, fine, or other sanction that: (1) Either is for a specific monetary amount as provided by Federal law or has a maximum amount provided for by Federal law; (2) is assessed or enforced by an agency pursuant to Federal law; and (3) is assessed or enforced pursuant to an administrative proceeding or a civil action in the Federal courts.[2]

The FCA imposes and enforces CMPs through the Farm Credit Act [3] and the Flood Disaster Protection Act of 1973, as amended. FCA's regulations governing CMPs are found in 12 CFR parts 622 and 623. Part 622 establishes rules of practice and procedure applicable to formal and informal hearings held before the FCA, and to formal investigations conducted under the Farm Credit Act. Part 623 prescribes rules regarding persons who may practice before the FCA and the circumstances under which such persons may be suspended or debarred from practice before the FCA.

B. CMPs Issued Under the Farm Credit Act

The Farm Credit Act provides that any Farm Credit System (System) institution or any officer, director, employee, agent, or other person participating in the conduct of the affairs of a System institution who violates the terms of a cease-and-desist order that has become final pursuant to section 5.25 or 5.26 of the Farm Credit Act must pay up to a maximum daily amount of $1,000 [4] during which such violation continues. This CMP maximum was set by the Farm Credit Amendments Act of 1985, which amended the Farm Credit Act. Orders issued by the FCA under section 5.25 or 5.26 of the Farm Credit Act include temporary and permanent cease-and-desist orders. In addition, section 5.32(h) of the Farm Credit Act provides that any directive issued under sections 4.3(b)(2), 4.3A(e), or 4.14A(i) of the Farm Credit Act ''shall be treated'' as a final order issued under section 5.25 of the Farm Credit Act for purposes of assessing a CMP.

Section 5.32(a) of the Farm Credit Act also states that ''[a]ny such institution or person who violates any provision of the [Farm Credit] Act or any regulation issued under this Act shall forfeit and pay a civil penalty of not more than $500 [5] per day for each day during which such violation continues.'' This CMP maximum was set by the Agricultural Credit Act of 1987, which was enacted in 1988, and amends the Farm Credit Act. Current, inflation-adjusted CMP maximums are set forth in existing § 622.61 of FCA regulations.[6]

The FCA also enforces the Flood Disaster Protection Act of 1973,[7] as amended by the National Flood Insurance Reform Act of 1994,[8] which requires FCA to assess CMPs for a pattern or practice of committing certain specific actions in violation of the National Flood Insurance Program. The existing maximum CMP for a violation under the Flood Disaster Protection Act of 1973 is $2,000.[9] [10]

C. Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015

1. In General

The 2015 Act required all Federal agencies to adjust the CMPs yearly, starting January 15, 2017.

Under Section 4(b) of the 1990 Act, as amended, annual adjustments are to be

[1] *Note:* While the 1990 Act, as amended by 1996 and 2015 Acts, uses the term ''civil monetary penalties'' for these penalties or other sanctions, the Farm Credit Act and the FCA Regulations use the term ''civil money penalties.'' Both terms have the same meaning. Accordingly, this rule uses the term civil money penalty, and both terms may be used interchangeably.

[2] *See* 28 U.S.C. 2461 *note.*

[3] Public Law 92–181, as amended.

[4] The inflation-adjusted CMP in effect on January 15, 2018, for a violation of a final order is $2,269 per day, as set forth in § 622.61(a)(1) of FCA regulations.

[5] The inflation-adjusted CMP in effect on January 15, 2018, for a violation of the Farm Credit Act or a regulation issued under the Farm Credit Act is $1,026 per day, as set forth in § 622.61(a)(2) of FCA regulations.

[6] Prior adjustments were made under the 1990 Act.

[7] 42 U.S.C. 4012a.

[8] Public Law 103–325, title V, 108 Stat. 2160, 2255–87 (September 23, 1994).

[9] Public Law 112–141, 126 Stat. 405 (July 6, 2012).

[10] The inflation-adjusted CMP in effect on January 15, 2018, for a flood insurance violation is $2,133, as set forth in § 622.61(b)of FCA regulations.

made yearly no later than January 15 of each year.[11] Section 6 of the 1990 Act, as amended, states that any increase to a civil monetary penalty under this 1990 Act applies only to civil monetary penalties, including those whose associated violation predated such increase, which are assessed after the date the increase takes effect.

Section 5(b) of the 1990 Act, as amended, defines the term ''cost-of-living adjustment'' as the percentage (if any) for each civil monetary penalty by which (1) the Consumer Price Index (CPI) for the month of October of the calendar year preceding the adjustment, exceeds (2) the CPI for the month of October 1 year before the month of October referred to in (1) of the calendar year in which the amount of such civil monetary penalty was last set or adjusted pursuant to law.[12]

The increase for each CMP adjusted for inflation must be rounded using a method prescribed by section 5(a) of the 1990 Act, as amended, by the 2015 Act.[13]

2. Other Adjustments

If a civil monetary penalty is subject to a cost-of-living adjustment under the 1990 Act, as amended, but is adjusted to an amount greater than the amount of the adjustment required under the Act within the 12 months preceding a required cost-of-living adjustment, the agency is not required to make the cost-of-living adjustment to that CMP in that calendar year.[14]

III. Yearly Adjustments

A. Mathematical Calculations of 2019 Adjustments

The adjustment requirement affects two provisions of section 5.32(a) of the Farm Credit Act. For the 2019 yearly adjustments to the CMPs set forth by the Farm Credit Act, the calculation required by the 2018 White House Office of Management and Budget (OMB) guidance [15] is based on the percentage by which the CPI for October 2018 exceeds the CPIs for October 2017. The OMB set forth guidance, as required by the 2015 Act,[16] with a multiplier for calculating the new CMP values.[17] The OMB multiplier for the 2019 CMPs is 1.02522.

The adjustment also affects the CMPs set by the Flood Disaster Protection Act of 1973, as amended. The adjustment multiplier is the same for all FCA enforced CMPs, set at 1.02522. The maximum CMPs for violations were created in 2012 by the Biggert-Waters Act, which amended the Flood Disaster Protection Act of 1973.

1. New Penalty Amount in § 622.61(a)(1)

The inflation-adjusted CMP currently in effect for violations of a final order occurring on or after January 15, 2017, is a maximum daily amount of $2,269.[18] Multiplying the $2,269 CMP by the 2018 OMB multiplier, 1.02522, yields a total of $2,326.22. When that number is rounded as required by section 5(a) of the 1990 Act, as amended, the inflation-adjusted maximum increases to $2,326. Thus, the new CMP maximum is $2,326.

2. New Penalty Amount in § 622.61(a)(2)

The inflation-adjusted CMP currently in effect for violations of the Farm Credit Act or regulations issued under the Farm Credit Act occurring on or after January 15, 2018, is a maximum daily amount of $1,026.[19] Multiplying the $1,026 CMP maximum by the 2018 OMB multiplier, 1.02522, yields a total of $1,051.88. When that number is rounded as required by section 5(a) of the 1990 Act, as amended the inflation-adjusted maximum increases to $1,052. Thus, the new CMP maximum is $1,052.

3. New Penalty Amounts for Flood Insurance Violations Under § 622.61(b)

The existing maximum CMP for a pattern or practice of flood insurance violations pursuant to 42 U.S.C. 4012a(f)(5) is $2,133. Multiplying $2,133 by the 2018 OMB multiplier, 1.02522, yields a total of $2,186.79. When that number is rounded as required by section 5(a) of the 1990 Act, as amended, the new maximum assessment of the CMP for violating 42 U.S.C. 4012a(f)(5) is $2,187. Thus, the new CMP maximum is $2,187.

IV. Notice and Comment Not Required by Administrative Procedure Act

The 1990 Act, as amended, gives Federal agencies no discretion in the adjustment of CMPs for the rate of inflation. Further, these revisions are ministerial, technical, and noncontroversial. For these reasons, the FCA finds good cause to determine that public notice and an opportunity to comment are impracticable, unnecessary, and contrary to the public interest pursuant to the Administrative Procedure Act, 5 U.S.C. 553(b)(B), and adopts this rule in final form.

V. Regulatory Flexibility Act

Pursuant to section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the FCA hereby certifies that this final rule will not have a significant economic impact on a substantial number of small entities. Each of the banks in the System, considered together with its affiliated associations, has assets and annual income in excess of the amounts that would qualify them as small entities. Therefore, System institutions are not ''small entities'' as defined in the Regulatory Flexibility Act.

List of Subjects in 12 CFR Part 622

Administrative practice and procedure, Crime, Investigations, Penalties.

For the reasons stated in the preamble, part 622 of chapter VI, title 12 of the Code of Federal Regulations is amended as follows:

PART 622—RULES OF PRACTICE AND PROCEDURE

■ 1. The authority citation for part 622 continues to read as follows:

Authority: Secs. 5.9, 5.10, 5.17, 5.25–5.37 of the Farm Credit Act (12 U.S.C. 2243, 2244, 2252, 2261–2273); 28 U.S.C. 2461 note; and 42 U.S.C. 4012a(f).

■ 2. Revise § 622.61 to read as follows:

§ 622.61 Adjustment of civil money penalties by the rate of inflation under the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended.

(a) The maximum amount of each civil money penalty within FCA's jurisdiction is adjusted in accordance with the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended (28 U.S.C. 2461 *note*), as follows:

(1) Amount of civil money penalty imposed under section 5.32 of the Act for violation of a final order issued under section 5.25 or 5.26 of the Act: The maximum daily amount is $2,326 for violations that occur on or after January 15, 2019.

(2) Amount of civil money penalty for violation of the Act or regulations: The maximum daily amount is $1,052 for each violation that occurs on or after January 15, 2019.

(b) The maximum civil money penalty amount assessed under 42 U.S.C.

[11] Public Law 114–74, sec. 701(b)(1).

[12] The CPI is published by the Department of Labor, Bureau of Statistics, and is available at its website: *ftp://ftp.bls.gov/pub/special.requests/cpi/cpiai.txt.*

[13] Pursuant to section 5(a)(3) of the 2015 Act, any increase determined under the subsection shall be rounded to the nearest $1.

[14] Pursuant to section 4(d) of the 1990 Act, as amended.

[15] OMB Circular M–19–04, Implementation of Penalty Inflation Adjustments for 2019, Pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015.

[16] 28 U.S.C. 2461 *note,* section 7(a).

[17] OMB Circular M–19–04, Implementation of Penalty Inflation Adjustments for 2019, Pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015.

[18] 12 CFR 622.61(a)(1).

[19] 12 CFR 622.61(a)(2).

4012a(f) is $2,187 for each violation that occurs on or after January 15, 2019, with no cap on the total amount of penalties that can be assessed against any single institution during any calendar year.

Dated: January 29, 2019.

Dale Aultman,

Secretary, Farm Credit Administration Board.

[FR Doc. 2019–00789 Filed 2–1–19; 8:45 am]

BILLING CODE 6705–01–P

BUREAU OF CONSUMER FINANCIAL PROTECTION

12 CFR Part 1026

RIN 3170–AA93

Truth in Lending Act (Regulation Z) Adjustment to Asset-Size Exemption Threshold

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Final rule; official interpretation.

SUMMARY: The Bureau of Consumer Financial Protection (Bureau) is amending the official commentary that interprets the requirements of the Bureau's Regulation Z (Truth in Lending) to reflect a change in the asset-size threshold for certain creditors to qualify for an exemption to the requirement to establish an escrow account for a higher-priced mortgage loan based on the annual percentage change in the average of the Consumer Price Index for Urban Wage Earners and Clerical Workers (CPI–W). Based on the 2.6 percent increase in the average of the CPI–W for the 12-month period ending in November 2018, the exemption threshold is adjusted to increase to $2.167 billion from $2.112 billion. Therefore, creditors with assets of less than $2.167 billion (including assets of certain affiliates) as of December 31, 2018, are exempt, if other requirements of Regulation Z also are met, from establishing escrow accounts for higher-priced mortgage loans in 2019.

DATES: *Effective date:* This rule is effective February 4, 2019. *Applicability date:* This rule is applicable on January 1, 2019, consistent with relevant statutory or regulatory provisions.

FOR FURTHER INFORMATION CONTACT: Monique Chenault, Paralegal Specialist, Office of Regulations, at (202) 435–7700. If you require this document in an alternative electronic format, please contact *CFPB_Accessibility@cfpb.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 129D of the Truth in Lending Act (TILA) contains a general requirement that an escrow account be established by a creditor to pay for property taxes and insurance premiums for certain first-lien higher-priced mortgage loan transactions. TILA section 129D also generally permits an exemption from the higher-priced mortgage loan escrow requirement for a creditor that meets certain requirements, including any asset-size threshold the Bureau may establish.

In the 2013 Escrows Final Rule,[1] the Bureau established such an asset-size threshold of $2 billion, which would adjust automatically each year, based on the year-to-year change in the average of the CPI–W for each 12-month period ending in November, with rounding to the nearest million dollars.[2] In 2015, the Bureau revised the asset-size threshold for small creditors and how it applies. The Bureau included in the calculation of the asset-size threshold the assets of the creditor's affiliates that regularly extended covered transactions secured by first liens during the applicable period and added a grace period to allow an otherwise eligible creditor that exceeded the asset limit in the preceding calendar year (but not in the calendar year before the preceding year) to continue to operate as a small creditor with respect to transactions with applications received before April 1 of the current calendar year.[3] For 2018, the threshold was $2.112 billion.

During the 12-month period ending in November 2018, the average of the CPI–W increased by 2.6 percent. As a result, the exemption threshold is increased to $2.167 billion for 2019. Thus, if the creditor's assets together with the assets of its affiliates that regularly extended first-lien covered transactions during calendar year 2018 are less than $2.167 billion on December 31, 2018, and it meets the other requirements of § 1026.35(b)(2)(iii), it will be exempt from the escrow-accounts requirement for higher-priced mortgage loans in 2019 and will also be exempt from the escrow-accounts requirement for higher-priced mortgage loans for purposes of any loan consummated in 2020 with applications received before April 1, 2020. The adjustment to the escrows asset-size exemption threshold will also increase the threshold for small-creditor portfolio and balloon-payment qualified mortgages under Regulation Z. The requirements for small-creditor portfolio qualified mortgages at § 1026.43(e)(5)(i)(D) reference the asset threshold in § 1026.35(b)(2)(iii)(C). Likewise, the requirements for balloon-payment qualified mortgages at § 1026.43(f)(1)(vi) reference the asset threshold in § 1026.35(b)(2)(iii)(C). Under § 1026.32(d)(1)(ii)(C), balloon-payment qualified mortgages that satisfy all applicable criteria in § 1026.43(f)(1)(i) through (vi) and (f)(2), including being made by creditors that have (together with certain affiliates) total assets below the threshold in § 1026.35(b)(2)(iii)(C), are also excepted from the prohibition on balloon payments for high-cost mortgages.

II. Procedural Requirements

A. Administrative Procedure Act

Under the Administrative Procedure Act (APA), notice and opportunity for public comment are not required if the Bureau finds that notice and public comment are impracticable, unnecessary, or contrary to the public interest. 5 U.S.C. 553(b)(B). Pursuant to this final rule, comment 35(b)(2)(iii)–1 in Regulation Z is amended to update the exemption threshold. The amendment in this final rule is technical and merely applies the formula previously established in Regulation Z for determining any adjustments to the exemption threshold. For these reasons, the Bureau has determined that publishing a notice of proposed rulemaking and providing opportunity for public comment are unnecessary. Therefore, the amendment is adopted in final form.

Section 553(d) of the APA generally requires publication of a final rule not less than 30 days before its effective date, except (1) a substantive rule which grants or recognizes an exemption or relieves a restriction; (2) interpretive rules and statements of policy; or (3) as otherwise provided by the agency for good cause found and published with the rule. 5 U.S.C. 553(d). At a minimum, the Bureau believes the amendments fall under the third exception to section 553(d). The Bureau finds that there is good cause to make the amendments effective on February 4, 2019. The amendment in this final rule is technical and non-discretionary, and it applies the method previously established in the agency's regulations

[1] 78 FR 4726 (Jan. 22, 2013).

[2] *See* 12 CFR 1026.35(b)(2)(iii)(C).

[3] *See* 80 FR 59943, 59951 (Oct. 2, 2015). The Bureau also issued an interim final rule in March 2016 to revise certain provisions in Regulation Z to effectuate the Helping Expand Lending Practices in Rural Communities Act's amendments to TILA (Pub. L. 114–94, section 89003, 129 Stat. 1312, 1800–01 (2015)). The rule broadened the cohort of creditors that may be eligible under TILA for the special provisions allowing origination of balloon-payment qualified mortgages and balloon-payment high-cost mortgages, as well as for the escrow exemption. *See* 81 FR 16074 (Mar. 25, 2016).

for automatic adjustments to the threshold.

B. Regulatory Flexibility Act

Because no notice of proposed rulemaking is required, the Regulatory Flexibility Act does not require an initial or final regulatory flexibility analysis.[4]

C. Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995,[5] the agency reviewed this final rule. No collections of information pursuant to the Paperwork Reduction Act are contained in the final rule.

D. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Bureau will submit a report containing this rule and other required information to the United States Senate, the United States House of Representatives, and the Comptroller General of the United States prior to the rule taking effect. The Office of Information and Regulatory Affairs (OIRA) has designated this rule as not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 12 CFR Part 1026

Advertising, Appraisal, Appraiser, Banking, Banks, Consumer protection, Credit, Credit unions, Mortgages, National banks, Reporting and recordkeeping requirements, Savings associations, Truth in lending.

Authority and Issuance

For the reasons set forth above, the Bureau amends Regulation Z, 12 CFR part 1026, as set forth below:

PART 1026—TRUTH IN LENDING (REGULATION Z)

■ 1. The authority citation for part 1026 continues to read as follows:

Authority: 12 U.S.C. 2601, 2603–2605, 2607, 2609, 2617, 3353, 5511, 5512, 5532, 5581; 15 U.S.C. 1601 *et seq.*

■ 2. In supplement I to part 1026, under *Section 1026.35—Requirements for Higher-Priced Mortgage Loans, 35(b)(2) Exemptions, Paragraph 35(b)(2)(iii)* is revised to read as follows:

Supplement I to Part 1026—Official Interpretations

* * * * *

Subpart E—Special Rules for Certain Home Mortgage Transactions

* * * * *

Section 1026.35—Requirements for Higher-Priced Mortgage Loans

* * * * *

35(b)(2) Exemptions.

* * * * *

Paragraph 35(b)(2)(iii).

1. *Requirements for exemption.* Under § 1026.35(b)(2)(iii), except as provided in § 1026.35(b)(2)(v), a creditor need not establish an escrow account for taxes and insurance for a higher-priced mortgage loan, provided the following four conditions are satisfied when the higher-priced mortgage loan is consummated:

i. During the preceding calendar year, or during either of the two preceding calendar years if the application for the loan was received before April 1 of the current calendar year, a creditor extended a first-lien covered transaction, as defined in § 1026.43(b)(1), secured by a property located in an area that is either ''rural'' or ''underserved,'' as set forth in § 1026.35(b)(2)(iv).

A. In general, whether the rural-or-underserved test is satisfied depends on the creditor's activity during the preceding calendar year. However, if the application for the loan in question was received before April 1 of the current calendar year, the creditor may instead meet the rural-or-underserved test based on its activity during the next-to-last calendar year. This provides creditors with a grace period if their activity meets the rural-or-underserved test (in § 1026.35(b)(2)(iii)(A)) in one calendar year but fails to meet it in the next calendar year.

B. A creditor meets the rural-or-underserved test for any higher-priced mortgage loan consummated during a calendar year if it extended a first-lien covered transaction in the preceding calendar year secured by a property located in a rural-or-underserved area. If the creditor does not meet the rural-or-underserved test in the preceding calendar year, the creditor meets this condition for a higher-priced mortgage loan consummated during the current calendar year only if the application for the loan was received before April 1 of the current calendar year and the creditor extended a first-lien covered transaction during the next-to-last calendar year that is secured by a property located in a rural or underserved area. The following examples are illustrative:

1. Assume that a creditor extended during 2016 a first-lien covered transaction that is secured by a property located in a rural or underserved area. Because the creditor extended a first-lien covered transaction during 2016 that is secured by a property located in a rural or underserved area, the creditor can meet this condition for exemption for any higher-priced mortgage loan consummated during 2017.

2. Assume that a creditor did not extend during 2016 a first-lien covered transaction secured by a property that is located in a rural or underserved area. Assume further that the same creditor extended during 2015 a first-lien covered transaction that is located in a rural or underserved area. Assume further that the creditor consummates a higher-priced mortgage loan in 2017 for which the application was received in November 2017. Because the creditor did not extend during 2016 a first-lien covered transaction secured by a property that is located in a rural or underserved area, and the application was received on or after April 1, 2017, the creditor does not meet this condition for exemption. However, assume instead that the creditor consummates a higher-priced mortgage loan in 2017 based on an application received in February 2017. The creditor meets this condition for exemption for this loan because the application was received before April 1, 2017, and the creditor extended during 2015 a first-lien covered transaction that is located in a rural or underserved area.

ii. The creditor and its affiliates together extended no more than 2,000 covered transactions, as defined in § 1026.43(b)(1), secured by first liens, that were sold, assigned, or otherwise transferred by the creditor or its affiliates to another person, or that were subject at the time of consummation to a commitment to be acquired by another person, during the preceding calendar year or during either of the two preceding calendar years if the application for the loan was received before April 1 of the current calendar year. For purposes of § 1026.35(b)(2)(iii)(B), a transfer of a first-lien covered transaction to ''another person'' includes a transfer by a creditor to its affiliate.

A. In general, whether this condition is satisfied depends on the creditor's activity during the preceding calendar year. However, if the application for the loan in question is received before April 1 of the current calendar year, the creditor may instead meet this condition based on activity during the next-to-last calendar year. This provides creditors with a grace period if their activity falls at or below the threshold in one calendar year but exceeds it in the next calendar year.

B. For example, assume that in 2015 a creditor and its affiliates together extended 1,500 loans that were sold, assigned, or otherwise transferred by the creditor or its affiliates to another person, or that were subject at the time of consummation to a commitment to be acquired by another person, and 2,500 such loans in 2016. Because the 2016 transaction activity exceeds the threshold but the 2015 transaction activity does not, the creditor satisfies this condition for exemption for a higher-priced mortgage loan consummated during 2017 if the creditor received the application for the loan before April 1, 2017, but does not satisfy this condition for a higher-priced mortgage loan consummated during 2017 if the application for the loan was received on or after April 1, 2017.

C. For purposes of § 1026.35(b)(2)(iii)(B), extensions of first-lien covered transactions, during the applicable time period, by all of a creditor's affiliates, as ''affiliate'' is defined in § 1026.32(b)(5), are counted toward the threshold in this section. ''Affiliate'' is defined in § 1026.32(b)(5) as any company that controls, is controlled by, or is under common control with another company, as set forth in the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*). Under the Bank Holding Company Act, a company has

[4] 5 U.S.C. 603(a), 604(a).

[5] 44 U.S.C. 3506; 5 CFR part 1320.

control over a bank or another company if it directly or indirectly or acting through one or more persons owns, controls, or has power to vote 25 per centum or more of any class of voting securities of the bank or company; it controls in any manner the election of a majority of the directors or trustees of the bank or company; or the Federal Reserve Board determines, after notice and opportunity for hearing, that the company directly or indirectly exercises a controlling influence over the management or policies of the bank or company. 12 U.S.C. 1841(a)(2).

iii. As of the end of the preceding calendar year, or as of the end of either of the two preceding calendar years if the application for the loan was received before April 1 of the current calendar year, the creditor and its affiliates that regularly extended covered transactions secured by first liens, together, had total assets that are less than the applicable annual asset threshold.

A. For purposes of § 1026.35(b)(2)(iii)(C), in addition to the creditor's assets, only the assets of a creditor's ''affiliate'' (as defined by § 1026.32(b)(5)) that regularly extended covered transactions (as defined by § 1026.43(b)(1)) secured by first liens, are counted toward the applicable annual asset threshold. *See* comment 35(b)(2)(iii)–1.ii.C for discussion of definition of ''affiliate.''

B. Only the assets of a creditor's affiliate that regularly extended first-lien covered transactions during the applicable period are included in calculating the creditor's assets. The meaning of ''regularly extended'' is based on the number of times a person extends consumer credit for purposes of the definition of ''creditor'' in § 1026.2(a)(17). Because covered transactions are ''transactions secured by a dwelling,'' consistent with § 1026.2(a)(17)(v), an affiliate regularly extended covered transactions if it extended more than five covered transactions in a calendar year. Also consistent with § 1026.2(a)(17)(v), because a covered transaction may be a high-cost mortgage subject to § 1026.32, an affiliate regularly extends covered transactions if, in any 12-month period, it extends more than one covered transaction that is subject to the requirements of § 1026.32 or one or more such transactions through a mortgage broker. Thus, if a creditor's affiliate regularly extended first-lien covered transactions during the preceding calendar year, the creditor's assets as of the end of the preceding calendar year, for purposes of the asset limit, take into account the assets of that affiliate. If the creditor, together with its affiliates that regularly extended first-lien covered transactions, exceeded the asset limit in the preceding calendar year—to be eligible to operate as a small creditor for transactions with applications received before April 1 of the current calendar year—the assets of the creditor's affiliates that regularly extended covered transactions in the year before the preceding calendar year are included in calculating the creditor's assets.

C. If multiple creditors share ownership of a company that regularly extended first-lien covered transactions, the assets of the company count toward the asset limit for a co-owner creditor if the company is an ''affiliate,'' as defined in § 1026.32(b)(5), of the co-owner creditor. Assuming the company is not an affiliate of the co-owner creditor by virtue of any other aspect of the definition (such as by the company and co-owner creditor being under common control), the company's assets are included toward the asset limit of the co-owner creditor only if the company is controlled by the co-owner creditor, ''as set forth in the Bank Holding Company Act.'' If the co-owner creditor and the company are affiliates (by virtue of any aspect of the definition), the co-owner creditor counts all of the company's assets toward the asset limit, regardless of the co-owner creditor's ownership share. Further, because the co-owner and the company are mutual affiliates the company also would count all of the co-owner's assets towards its own asset limit. *See* comment 35(b)(2)(iii)–1.ii.C for discussion of the definition of ''affiliate.''

D. A creditor satisfies the criterion in § 1026.35(b)(2)(iii)(C) for purposes of any higher-priced mortgage loan consummated during 2016, for example, if the creditor (together with its affiliates that regularly extended first-lien covered transactions) had total assets of less than the applicable asset threshold on December 31, 2015. A creditor that (together with its affiliates that regularly extended first-lien covered transactions) did not meet the applicable asset threshold on December 31, 2015 satisfies this criterion for a higher-priced mortgage loan consummated during 2016 if the application for the loan was received before April 1, 2016 and the creditor (together with its affiliates that regularly extended first-lien covered transactions) had total assets of less than the applicable asset threshold on December 31, 2014.

E. Under § 1026.35(b)(2)(iii)(C), the $2,000,000,000 asset threshold adjusts automatically each year based on the year-to-year change in the average of the Consumer Price Index for Urban Wage Earners and Clerical Workers, not seasonally adjusted, for each 12-month period ending in November, with rounding to the nearest million dollars. The Bureau will publish notice of the asset threshold each year by amending this comment. For calendar year 2019, the asset threshold is $2,167,000,000. A creditor that together with the assets of its affiliates that regularly extended first-lien covered transactions during calendar year 2018 has total assets of less than $2,167,000,000 on December 31, 2018, satisfies this criterion for purposes of any loan consummated in 2019 and for purposes of any loan consummated in 2020 for which the application was received before April 1, 2020. For historical purposes:

1. For calendar year 2013, the asset threshold was $2,000,000,000. Creditors that had total assets of less than $2,000,000,000 on December 31, 2012, satisfied this criterion for purposes of the exemption during 2013.

2. For calendar year 2014, the asset threshold was $2,028,000,000. Creditors that had total assets of less than $2,028,000,000 on December 31, 2013, satisfied this criterion for purposes of the exemption during 2014.

3. For calendar year 2015, the asset threshold was $2,060,000,000. Creditors that had total assets of less than $2,060,000,000 on December 31, 2014, satisfied this criterion for purposes of any loan consummated in 2015 and, if the creditor's assets together with the assets of its affiliates that regularly extended first-lien covered transactions during calendar year 2014 were less than that amount, for purposes of any loan consummated in 2016 for which the application was received before April 1, 2016.

4. For calendar year 2016, the asset threshold was $2,052,000,000. A creditor that together with the assets of its affiliates that regularly extended first-lien covered transactions during calendar year 2015 had total assets of less than $2,052,000,000 on December 31, 2015, satisfied this criterion for purposes of any loan consummated in 2016 and for purposes of any loan consummated in 2017 for which the application was received before April 1, 2017.

5. For calendar year 2017, the asset threshold was $2,069,000,000. A creditor that together with the assets of its affiliates that regularly extended first-lien covered transactions during calendar year 2016 had total assets of less than $2,069,000,000 on December 31, 2016, satisfied this criterion for purposes of any loan consummated in 2017 and for purposes of any loan consummated in 2018 for which the application was received before April 1, 2018.

6. For calendar year 2018, the asset threshold was $2,112,000,000. A creditor that together with the assets of its affiliates that regularly extended first-lien covered transactions during calendar year 2017 had total assets of less than $2,112,000,000 on December 31, 2017, satisfied this criterion for purposes of any loan consummated in 2018 and for purposes of any loan consummated in 2019 for which the application was received before April 1, 2019.

iv. The creditor and its affiliates do not maintain an escrow account for any mortgage transaction being serviced by the creditor or its affiliate at the time the transaction is consummated, except as provided in § 1026.35(b)(2)(iii)(D)(*1*) and (*2*). Thus, the exemption applies, provided the other conditions of § 1026.35(b)(2)(iii) are satisfied, even if the creditor previously maintained escrow accounts for mortgage loans, provided it no longer maintains any such accounts except as provided in § 1026.35(b)(2)(iii)(D)(*1*) and (*2*). Once a creditor or its affiliate begins escrowing for loans currently serviced other than those addressed in § 1026.35(b)(2)(iii)(D)(*1*) and (*2*), however, the creditor and its affiliate become ineligible for the exemption in § 1026.35(b)(2)(iii) on higher-priced mortgage loans they make while such escrowing continues. Thus, as long as a creditor (or its affiliate) services and maintains escrow accounts for any mortgage loans, other than as provided in § 1026.35(b)(2)(iii)(D)(*1*) and (*2*), the creditor will not be eligible for the exemption for any higher-priced mortgage loan it may make. For purposes of § 1026.35(b)(2)(iii), a creditor or its affiliate ''maintains'' an escrow account only if it services a mortgage loan for which an escrow account has been established at least through the due date of the second periodic payment under the terms of the legal obligation.

* * * * *

Dated: December 20, 2018.

Kathleen Kraninger,

Director, Bureau of Consumer Financial Protection.

[FR Doc. 2018–28374 Filed 1–31–19; 4:15 pm]

BILLING CODE 4810–AM–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 11

[Docket No. RM11–6–000]

Annual Update to Fee Schedule for the Use of Government Lands by Hydropower Licensees

AGENCY: Federal Energy Regulatory Commission.

ACTION: Final rule.

SUMMARY: In accordance with the Commission's regulations, the Commission, by its designee, the Executive Director, issues this document of the annual update to the fee schedule, which lists per-acre rental fees by county (or other geographic area) for use of government lands by hydropower licensees.

DATES: This rule is effective February 4, 2019 and updates Appendix A to Part 11 with the fee schedule of per-acre rental fees by county (or other geographic area) from October 1, 2018, through September 30, 2019 (Fiscal Year 2019).

FOR FURTHER INFORMATION CONTACT: Norman Richardson, Financial Management Division, Office of the Executive Director, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, (202) 502–6219, *Norman.Richardson@ferc.gov.*

SUPPLEMENTARY INFORMATION:

Annual Update to Fee Schedule

(Issued January 18, 2019)

Section 11.2 of the Commission's regulations provides a method for computing reasonable annual charges for recompensing the United States for the use, occupancy, and enjoyment of its lands by hydropower licensees.[1] Annual charges for the use of government lands are payable in advance, and are based on an annual schedule of per-acre rental fees published in Appendix A to Part 11 of the Commission's regulations.[2] This document updates the fee schedule in Appendix A to Part 11 for fiscal year 2019 (October 1, 2018, through September 30, 2019).

Effective Date

This Final Rule is effective February 4, 2019. The provisions of 5 U.S.C. 804, regarding Congressional review of final rules, do not apply to this Final Rule because the rule concerns agency procedure and practice and will not substantially affect the rights or obligations of non-agency parties. This Final Rule merely updates the fee schedule published in the Code of Federal Regulations to reflect scheduled adjustments, as provided for in section 11.2 of the Commission's regulations.

List of Subjects in 18 CFR Part 11

Public lands.

By the Executive Director.

Issued: January 18, 2019.

Anton C. Porter,

Executive Director, Office of the Executive Director.

In consideration of the foregoing, the Commission amends part 11, chapter I, title 18, *Code of Federal Regulations,* as follows.

PART 11—[AMENDED]

■ 1. The authority citation for part 11 continues to read as follows:

Authority: 16 U.S.C. 792–828c; 42 U.S.C. 7101–7352.

■ 2. Appendix A to part 11 is revised to read as follows:

Appendix A to Part 11—Fee Schedule for FY 2019

State	County	Fee/acre/yr.
Alabama	Autauga	$64.31
	Baldwin	112.02
	Barbour	63.64
	Bibb	59.03
	Blount	102.24
	Bullock	61.29
	Butler	68.36
	Calhoun	85.74
	Chambers	73.25
	Cherokee	96.22
	Chilton	82.54
	Choctaw	52.70
	Clarke	57.56
	Clay	69.62
	Cleburne	77.26
	Coffee	74.20
	Colbert	79.37
	Conecuh	56.04
	Coosa	58.33
	Covington	63.47
	Crenshaw	57.10
	Cullman	117.54
	Dale	70.64
	Dallas	51.65
	DeKalb	106.67
	Elmore	89.36
	Escambia	63.92
	Etowah	100.16
	Fayette	59.77

[1] *Annual Charges for the Use of Government Lands,* Order No. 774, 78 FR 5256 (January 25, 2013), FERC Stats. & Regs. ¶ 31,341 (2013).

[2] 18 CFR part 11 (2018).

State	County	Fee/acre/yr.
	Franklin	59.21
	Geneva	60.83
	Greene	57.13
	Hale	58.86
	Henry	62.90
	Houston	73.28
	Jackson	73.53
	Jefferson	126.86
	Lamar	41.58
	Lauderdale	83.59
	Lawrence	86.09
	Lee	106.25
	Limestone	114.48
	Lowndes	48.59
	Macon	69.17
	Madison	104.56
	Marengo	50.17
	Marion	62.52
	Marshall	106.71
	Mobile	114.34
	Monroe	55.38
	Montgomery	73.85
	Morgan	105.05
	Perry	49.39
	Pickens	58.19
	Pike	64.10
	Randolph	79.09
	Russell	63.64
	Shelby	118.17
	St. Clair	108.04
	Sumter	40.04
	Talladega	81.87
	Tallapoosa	67.94
	Tuscaloosa	83.45
	Walker	72.54
	Washington	47.53
	Wilcox	47.35
	Winston	73.21
Alaska	Aleutian Islands	1.06
	Statewide	38.08
Arizona	Apache	3.18
	Cochise	23.11
	Coconino	3.44
	Gila	5.40
	Graham	9.53
	Greenlee	25.75
	La Paz	21.20
	Maricopa	93.40
	Mohave	7.96
	Navajo	4.27
	Pima	8.60
	Pinal	39.24
	Santa Cruz	25.20
	Yavapai	26.00
	Yuma	119.10
Arkansas	Arkansas	59.42
	Ashley	65.07
	Baxter	59.75
	Benton	99.34
	Boone	57.62
	Bradley	78.23
	Calhoun	55.08
	Carroll	56.95
	Chicot	59.70
	Clark	41.38
	Clay	71.62
	Cleburne	61.32
	Cleveland	87.25
	Columbia	48.33
	Conway	57.96
	Craighead	71.85
	Crawford	67.23
	Crittenden	62.22
	Cross	56.95

State	County	Fee/acre/yr.
	Dallas	35.84
	Desha	62.47
	Drew	56.45
	Faulkner	73.44
	Franklin	51.02
	Fulton	35.87
	Garland	82.60
	Grant	50.46
	Greene	76.55
	Hempstead	45.86
	Hot Spring	57.51
	Howard	52.81
	Independence	46.90
	Izard	39.56
	Jackson	56.36
	Jefferson	64.96
	Johnson	53.87
	Lafayette	45.30
	Lawrence	59.86
	Lee	62.64
	Lincoln	62.61
	Little River	37.66
	Logan	50.32
	Lonoke	62.30
	Madison	60.87
	Marion	45.11
	Miller	44.49
	Mississippi	63.81
	Monroe	53.84
	Montgomery	56.14
	Nevada	42.50
	Newton	49.42
	Ouachita	49.90
	Perry	54.60
	Phillips	58.46
	Pike	47.77
	Poinsett	68.74
	Polk	59.39
	Pope	61.49
	Prairie	56.03
	Pulaski	77.00
	Randolph	45.14
	Saline	78.82
	Scott	49.22
	Searcy	37.35
	Sebastian	59.64
	Sevier	52.30
	Sharp	40.71
	St. Francis	53.00
	Stone	43.71
	Union	56.76
	Van Buren	55.58
	Washington	92.09
	White	57.60
	Woodruff	55.89
	Yell	50.88
California	Alameda	46.62
	Alpine	36.24
	Amador	33.24
	Butte	64.21
	Calaveras	27.57
	Colusa	45.90
	Contra Costa	71.19
	Del Norte	73.65
	El Dorado	69.52
	Fresno	70.02
	Glenn	38.81
	Humboldt	21.83
	Imperial	59.17
	Inyo	6.58
	Kern	37.48
	Kings	50.97
	Lake	51.45
	Lassen	16.29

State	County	Fee/acre/yr.
	Los Angeles	105.28
	Madera	64.34
	Marin	52.63
	Mariposa	17.78
	Mendocino	33.91
	Merced	65.38
	Modoc	14.55
	Mono	23.81
	Monterey	41.34
	Napa	184.23
	Nevada	91.55
	Orange	184.67
	Placer	90.11
	Plumas	15.01
	Riverside	86.30
	Sacramento	60.29
	San Benito	24.03
	San Bernardino	113.70
	San Diego	151.80
	San Francisco	1,065.68
	San Joaquin	85.26
	San Luis Obispo	35.60
	San Mateo	95.48
	Santa Barbara	62.24
	Santa Clara	56.72
	Santa Cruz	104.70
	Shasta	23.67
	Sierra	12.71
	Siskiyou	17.23
	Solano	46.96
	Sonoma	123.54
	Stanislaus	81.43
	Sutter	55.93
	Tehama	25.16
	Trinity	9.63
	Tulare	63.67
	Tuolumne	39.14
	Ventura	132.00
	Yolo	47.68
	Yuba	48.95
Colorado	Adams	26.76
	Alamosa	27.15
	Arapahoe	31.39
	Archuleta	40.01
	Baca	10.36
	Bent	8.66
	Boulder	106.47
	Broomfield	36.51
	Chaffee	56.33
	Cheyenne	14.48
	Clear Creek	51.11
	Conejos	28.27
	Costilla	20.47
	Crowley	6.38
	Custer	28.36
	Delta	61.83
	Denver	1,010.22
	Dolores	26.87
	Douglas	93.57
	Eagle	73.38
	El Paso	22.49
	Elbert	20.89
	Fremont	43.57
	Garfield	51.74
	Gilpin	52.77
	Grand	42.59
	Gunnison	52.49
	Hinsdale	98.60
	Huerfano	16.09
	Jackson	19.42
	Jefferson	102.32
	Kiowa	12.71
	Kit Carson	21.10
	La Plata	34.60

State	County	Fee/acre/yr.
	Lake	54.33
	Larimer	57.42
	Las Animas	7.54
	Lincoln	8.90
	Logan	16.18
	Mesa	62.73
	Mineral	80.90
	Moffat	13.60
	Montezuma	20.63
	Montrose	53.49
	Morgan	26.57
	Otero	12.16
	Ouray	52.91
	Park	24.80
	Phillips	33.72
	Pitkin	104.28
	Prowers	12.81
	Pueblo	13.67
	Rio Blanco	24.75
	Rio Grande	44.04
	Routt	41.31
	Saguache	27.69
	San Juan	23.85
	San Miguel	27.15
	Sedgwick	23.68
	Summit	61.92
	Teller	37.38
	Washington	18.21
	Weld	36.86
	Yuma	25.52
Connecticut	Fairfield	326.76
	Hartford	340.21
	Litchfield	306.68
	Middlesex	378.65
	New Haven	337.96
	New London	277.96
	Tolland	267.06
	Windham	205.21
Delaware	Kent	223.90
	New Castle	278.10
	Sussex	219.80
Florida	Alachua	106.97
	Baker	128.83
	Bay	103.19
	Bradford	83.09
	Brevard	107.59
	Broward	455.41
	Calhoun	42.21
	Charlotte	100.71
	Citrus	131.58
	Clay	69.95
	Collier	89.08
	Columbia	90.15
	Dade	505.22
	DeSoto	93.33
	Dixie	78.35
	Duval	137.82
	Escambia	96.98
	Flagler	84.24
	Franklin	38.60
	Gadsden	88.04
	Gilchrist	66.23
	Glades	60.74
	Gulf	83.14
	Hamilton	57.36
	Hardee	81.98
	Hendry	80.63
	Hernando	166.81
	Highlands	58.38
	Hillsborough	179.90
	Holmes	56.09
	Indian River	76.63
	Jackson	66.92
	Jefferson	83.71

State	County	Fee/acre/yr.
	Lafayette	81.95
	Lake	149.82
	Lee	188.49
	Leon	109.33
	Levy	118.69
	Liberty	53.76
	Madison	66.92
	Manatee	111.09
	Marion	185.86
	Martin	130.79
	Monroe	377.14
	Nassau	95.12
	Okaloosa	72.09
	Okeechobee	91.27
	Orange	166.24
	Osceola	78.45
	Palm Beach	140.90
	Pasco	134.39
	Pinellas	599.02
	Polk	108.90
	Putnam	109.87
	Santa Rosa	156.45
	Sarasota	130.29
	Seminole	94.55
	St. Johns	70.33
	St. Lucie	95.66
	Sumter	106.32
	Suwannee	79.76
	Taylor	75.62
	Union	71.02
	Volusia	121.97
	Wakulla	69.60
	Walton	57.16
	Washington	57.11
Georgia	Appling	63.06
	Atkinson	71.88
	Bacon	78.01
	Baker	73.94
	Baldwin	65.92
	Banks	147.98
	Barrow	147.94
	Bartow	119.32
	Ben Hill	68.31
	Berrien	71.45
	Bibb	88.01
	Bleckley	62.69
	Brantley	77.91
	Brooks	88.95
	Bryan	78.99
	Bulloch	65.22
	Burke	60.67
	Butts	93.84
	Calhoun	59.02
	Camden	58.72
	Candler	64.17
	Carroll	119.46
	Catoosa	152.69
	Charlton	54.95
	Chatham	139.05
	Chattahoochee	56.03
	Chattooga	82.93
	Cherokee	255.51
	Clarke	152.12
	Clay	44.54
	Clayton	150.10
	Clinch	72.99
	Cobb	329.55
	Coffee	70.91
	Colquitt	79.12
	Columbia	132.25
	Cook	74.11
	Coweta	133.13
	Crawford	83.06
	Crisp	56.29

State	County	Fee/acre/yr.
	Dade	85.18
	Dawson	209.62
	Decatur	76.97
	DeKalb	74.88
	Dodge	59.32
	Dooly	63.16
	Dougherty	88.28
	Douglas	177.54
	Early	57.84
	Echols	71.08
	Effingham	74.85
	Elbert	95.28
	Emanuel	57.44
	Evans	69.70
	Fannin	175.21
	Fayette	164.57
	Floyd	104.98
	Forsyth	296.15
	Franklin	145.79
	Fulton	182.62
	Gilmer	165.42
	Glascock	49.76
	Glynn	105.65
	Gordon	129.22
	Grady	82.89
	Greene	86.90
	Gwinnett	278.38
	Habersham	154.78
	Hall	221.21
	Hancock	92.22
	Haralson	113.46
	Harris	129.36
	Hart	139.56
	Heard	93.53
	Henry	154.47
	Houston	83.43
	Irwin	68.48
	Jackson	149.19
	Jasper	93.26
	Jeff Davis	89.46
	Jefferson	53.80
	Jenkins	50.60
	Johnson	48.38
	Jones	85.55
	Lamar	103.36
	Lanier	91.78
	Laurens	55.25
	Lee	77.51
	Liberty	56.90
	Lincoln	74.68
	Long	66.33
	Lowndes	95.28
	Lumpkin	242.25
	Macon	60.50
	Madison	77.20
	Marion	69.53
	McDuffie	69.02
	McIntosh	151.28
	Meriwether	85.42
	Miller	66.40
	Mitchell	77.03
	Monroe	91.85
	Montgomery	46.53
	Morgan	117.74
	Murray	115.49
	Muscogee	138.38
	Newton	113.77
	Oconee	194.54
	Oglethorpe	87.24
	Paulding	176.26
	Peach	107.71
	Pickens	180.87
	Pierce	64.14
	Pike	98.31

State	County	Fee/acre/yr.
	Polk	97.14
	Pulaski	70.50
	Putnam	102.42
	Quitman	57.44
	Rabun	190.63
	Randolph	52.12
	Richmond	71.38
	Rockdale	188.08
	Schley	61.21
	Screven	57.47
	Seminole	72.79
	Spalding	140.84
	Stephens	142.02
	Stewart	52.86
	Sumter	60.97
	Talbot	56.13
	Taliaferro	59.32
	Tattnall	74.81
	Taylor	54.54
	Telfair	51.24
	Terrell	63.67
	Thomas	90.06
	Tift	85.55
	Toombs	63.87
	Towns	159.25
	Treutlen	48.32
	Troup	107.24
	Turner	64.21
	Twiggs	67.37
	Union	162.02
	Upson	85.12
	Walker	105.25
	Walton	144.58
	Ware	66.46
	Warren	54.38
	Washington	55.69
	Wayne	73.97
	Webster	47.74
	Wheeler	40.20
	White	184.94
	Whitfield	130.54
	Wilcox	65.69
	Wilkes	74.81
	Wilkinson	57.47
	Worth	69.59
Hawaii	Hawaii	173.22
	Honolulu	437.59
	Kauai	164.87
	Maui	213.39
Idaho	Ada	64.25
	Adams	18.52
	Bannock	22.01
	Bear Lake	17.30
	Benewah	19.33
	Bingham	27.21
	Blaine	34.79
	Boise	17.27
	Bonner	53.16
	Bonneville	28.22
	Boundary	41.64
	Butte	18.75
	Camas	18.06
	Canyon	64.92
	Caribou	17.06
	Cassia	28.52
	Clark	17.73
	Clearwater	22.92
	Custer	28.03
	Elmore	24.91
	Franklin	24.44
	Fremont	27.18
	Gem	33.62
	Gooding	46.63
	Idaho	16.98

State	County	Fee/acre/yr.
	Jefferson	31.90
	Jerome	46.75
	Kootenai	50.39
	Latah	21.95
	Lemhi	27.06
	Lewis	17.08
	Lincoln	31.96
	Madison	40.34
	Minidoka	42.22
	Nez Perce	20.48
	Oneida	14.46
	Owyhee	14.94
	Payette	36.78
	Power	18.41
	Shoshone	72.81
	Teton	40.09
	Twin Falls	37.62
	Valley	30.10
	Washington	12.16
Illinois	Adams	140.78
	Alexander	94.22
	Bond	184.38
	Boone	195.18
	Brown	113.64
	Bureau	208.96
	Calhoun	108.33
	Carroll	194.86
	Cass	159.38
	Champaign	226.88
	Christian	215.91
	Clark	140.00
	Clay	135.76
	Clinton	166.64
	Coles	200.91
	Cook	298.41
	Crawford	142.42
	Cumberland	155.03
	De Witt	204.83
	DeKalb	223.78
	Douglas	216.84
	DuPage	197.99
	Edgar	187.16
	Edwards	114.67
	Effingham	165.18
	Fayette	127.00
	Ford	216.05
	Franklin	105.69
	Fulton	149.58
	Gallatin	125.21
	Greene	160.66
	Grundy	217.09
	Hamilton	103.16
	Hancock	163.19
	Hardin	100.78
	Henderson	176.40
	Henry	194.68
	Iroquois	193.82
	Jackson	112.21
	Jasper	144.38
	Jefferson	102.70
	Jersey	168.03
	Jo Daviess	138.36
	Johnson	86.14
	Kane	252.89
	Kankakee	188.44
	Kendall	247.44
	Knox	195.71
	La Salle	224.85
	Lake	296.27
	Lawrence	139.57
	Lee	215.66
	Livingston	204.83
	Logan	204.69
	Macon	223.21

State	County	Fee/acre/yr.
	Macoupin	177.19
	Madison	181.85
	Marion	119.73
	Marshall	197.31
	Mason	166.61
	Massac	101.95
	McDonough	200.27
	McHenry	229.98
	McLean	233.12
	Menard	180.22
	Mercer	173.06
	Monroe	147.59
	Montgomery	169.74
	Morgan	190.44
	Moultrie	219.08
	Ogle	197.56
	Peoria	197.21
	Perry	116.02
	Piatt	246.62
	Pike	140.10
	Pope	74.24
	Pulaski	114.63
	Putnam	179.36
	Randolph	127.07
	Richland	125.25
	Rock Island	177.69
	Saline	120.19
	Sangamon	209.96
	Schuyler	124.75
	Scott	165.90
	Shelby	172.06
	St. Clair	179.93
	Stark	211.96
	Stephenson	193.82
	Tazewell	211.99
	Union	101.03
	Vermilion	200.70
	Wabash	151.36
	Warren	197.24
	Washington	147.62
	Wayne	127.39
	White	127.74
	Whiteside	194.96
	Will	223.21
	Williamson	125.61
	Winnebago	180.36
	Woodford	220.86
Indiana	Adams	165.00
	Allen	175.83
	Bartholomew	167.39
	Benton	183.91
	Blackford	120.40
	Boone	175.76
	Brown	113.99
	Carroll	194.41
	Cass	154.15
	Clark	120.40
	Clay	124.10
	Clinton	190.03
	Crawford	72.94
	Daviess	184.51
	Dearborn	115.95
	Decatur	151.55
	DeKalb	126.13
	Delaware	150.94
	Dubois	127.38
	Elkhart	229.76
	Fayette	132.36
	Floyd	151.83
	Fountain	136.63
	Franklin	130.37
	Fulton	143.08
	Gibson	151.76
	Grant	158.88

State	County	Fee/acre/yr.
	Greene	112.28
	Hamilton	183.05
	Hancock	162.83
	Harrison	104.84
	Hendricks	166.14
	Henry	141.05
	Howard	180.92
	Huntington	155.29
	Jackson	130.51
	Jasper	174.65
	Jay	186.97
	Jefferson	100.82
	Jennings	110.96
	Johnson	173.48
	Knox	160.80
	Kosciusko	167.07
	LaGrange	212.10
	Lake	161.55
	LaPorte	173.26
	Lawrence	90.35
	Madison	171.66
	Marion	182.91
	Marshall	148.17
	Martin	114.99
	Miami	144.36
	Monroe	137.59
	Montgomery	159.06
	Morgan	140.19
	Newton	161.59
	Noble	137.66
	Ohio	101.39
	Orange	99.32
	Owen	96.72
	Parke	118.73
	Perry	85.40
	Pike	121.64
	Porter	170.67
	Posey	136.63
	Pulaski	146.74
	Putnam	119.54
	Randolph	144.89
	Ripley	116.16
	Rush	173.41
	Scott	102.28
	Shelby	174.44
	Spencer	110.22
	St. Joseph	174.87
	Starke	124.81
	Steuben	127.77
	Sullivan	118.97
	Switzerland	100.46
	Tippecanoe	191.70
	Tipton	208.01
	Union	141.12
	Vanderburgh	120.51
	Vermillion	135.31
	Vigo	110.39
	Wabash	147.17
	Warren	167.75
	Warrick	138.31
	Washington	94.59
	Wayne	147.45
	Wells	180.28
	White	194.73
	Whitley	146.31
Iowa	Adair	133.52
	Adams	122.50
	Allamakee	121.43
	Appanoose	84.72
	Audubon	190.14
	Benton	206.01
	Black Hawk	227.41
	Boone	215.36
	Bremer	220.10

State	County	Fee/acre/yr.
	Buchanan	209.26
	Buena Vista	208.36
	Butler	194.88
	Calhoun	219.32
	Carroll	214.71
	Cass	155.93
	Cedar	204.65
	Cerro Gordo	189.24
	Cherokee	211.82
	Chickasaw	204.26
	Clarke	96.39
	Clay	210.75
	Clayton	136.59
	Clinton	202.69
	Crawford	197.41
	Dallas	191.99
	Davis	83.97
	Decatur	85.26
	Delaware	205.65
	Des Moines	159.06
	Dickinson	201.51
	Dubuque	173.87
	Emmet	207.76
	Fayette	196.31
	Floyd	182.68
	Franklin	189.67
	Fremont	175.26
	Greene	198.70
	Grundy	229.20
	Guthrie	165.45
	Hamilton	231.77
	Hancock	198.55
	Hardin	210.75
	Harrison	166.20
	Henry	140.66
	Howard	188.14
	Humboldt	217.67
	Ida	193.67
	Iowa	172.73
	Jackson	152.14
	Jasper	177.44
	Jefferson	131.03
	Johnson	195.99
	Jones	191.17
	Keokuk	142.23
	Kossuth	217.10
	Lee	121.79
	Linn	191.85
	Louisa	163.88
	Lucas	82.01
	Lyon	235.30
	Madison	139.91
	Mahaska	160.46
	Marion	127.35
	Marshall	188.99
	Mills	180.25
	Mitchell	210.40
	Monona	156.71
	Monroe	90.50
	Montgomery	160.10
	Muscatine	179.47
	O'Brien	243.64
	Osceola	200.87
	Page	143.58
	Palo Alto	214.68
	Plymouth	209.83
	Pocahontas	217.89
	Polk	201.27
	Pottawattamie	200.69
	Poweshiek	173.51
	Ringgold	97.60
	Sac	211.75
	Scott	231.66
	Shelby	193.27

State	County	Fee/acre/yr.
	Sioux	259.84
	Story	223.67
	Tama	185.57
	Taylor	109.23
	Union	98.21
	Van Buren	99.17
	Wapello	117.72
	Warren	145.94
	Washington	174.30
	Wayne	92.25
	Webster	209.83
	Winnebago	192.56
	Winneshiek	170.05
	Woodbury	170.48
	Worth	175.37
	Wright	205.72
Kansas	Allen	39.17
	Anderson	43.70
	Atchison	60.43
	Barber	34.09
	Barton	43.98
	Bourbon	40.61
	Brown	91.78
	Butler	49.38
	Chase	38.05
	Chautauqua	32.40
	Cherokee	52.25
	Cheyenne	44.43
	Clark	25.53
	Clay	59.23
	Cloud	55.87
	Coffey	42.82
	Comanche	25.85
	Cowley	40.19
	Crawford	46.99
	Decatur	42.79
	Dickinson	56.60
	Doniphan	100.97
	Douglas	80.06
	Edwards	59.86
	Elk	35.60
	Ellis	37.38
	Ellsworth	37.21
	Finney	40.37
	Ford	34.16
	Franklin	65.13
	Geary	54.39
	Gove	36.09
	Graham	37.00
	Grant	37.38
	Gray	37.45
	Greeley	41.73
	Greenwood	39.52
	Hamilton	28.37
	Harper	42.58
	Harvey	72.10
	Haskell	38.65
	Hodgeman	30.16
	Jackson	49.38
	Jefferson	62.78
	Jewell	54.15
	Johnson	121.76
	Kearny	36.40
	Kingman	40.09
	Kiowa	34.58
	Labette	41.70
	Lane	36.09
	Leavenworth	90.76
	Lincoln	41.91
	Linn	49.38
	Logan	33.11
	Lyon	43.77
	Marion	59.16
	Marshall	75.54

State	County	Fee/acre/yr.
	McPherson	63.34
	Meade	34.23
	Miami	87.85
	Mitchell	62.85
	Montgomery	43.42
	Morris	41.21
	Morton	23.74
	Nemaha	79.19
	Neosho	42.01
	Ness	29.21
	Norton	37.17
	Osage	45.63
	Osborne	38.44
	Ottawa	52.82
	Pawnee	51.13
	Phillips	35.11
	Pottawatomie	53.52
	Pratt	44.89
	Rawlins	48.92
	Reno	50.40
	Republic	74.38
	Rice	44.82
	Riley	51.31
	Rooks	36.82
	Rush	36.40
	Russell	32.05
	Saline	55.45
	Scott	42.58
	Sedgwick	66.67
	Seward	32.30
	Shawnee	69.82
	Sheridan	53.83
	Sherman	47.91
	Smith	45.52
	Stafford	49.59
	Stanton	31.07
	Stevens	38.47
	Sumner	50.29
	Thomas	59.83
	Trego	36.82
	Wabaunsee	41.24
	Wallace	35.39
	Washington	65.48
	Wichita	38.09
	Wilson	40.33
	Woodson	38.61
	Wyandotte	134.91
Kentucky	Adair	72.68
	Allen	83.89
	Anderson	88.47
	Ballard	96.60
	Barren	83.61
	Bath	55.40
	Bell	55.22
	Boone	175.17
	Bourbon	120.84
	Boyd	66.22
	Boyle	96.67
	Bracken	59.48
	Breathitt	40.60
	Breckinridge	68.10
	Bullitt	103.48
	Butler	57.42
	Caldwell	77.65
	Calloway	84.25
	Campbell	124.71
	Carlisle	80.31
	Carroll	74.88
	Carter	49.90
	Casey	57.67
	Christian	98.05
	Clark	93.19
	Clay	45.21
	Clinton	73.64

State	County	Fee/acre/yr.
	Crittenden	61.11
	Cumberland	48.48
	Daviess	110.26
	Edmonson	67.53
	Elliott	38.54
	Estill	52.45
	Fayette	258.71
	Fleming	59.51
	Floyd	41.81
	Franklin	104.58
	Fulton	99.08
	Gallatin	85.92
	Garrard	70.16
	Grant	86.88
	Graves	92.06
	Grayson	64.45
	Green	64.31
	Greenup	50.25
	Hancock	79.85
	Hardin	99.51
	Harlan	37.55
	Harrison	77.51
	Hart	62.99
	Henderson	103.66
	Henry	94.90
	Hickman	98.80
	Hopkins	82.40
	Jackson	51.60
	Jefferson	245.08
	Jessamine	155.37
	Johnson	49.68
	Kenton	123.78
	Knott	38.40
	Knox	49.65
	Larue	97.17
	Laurel	97.91
	Lawrence	40.21
	Lee	54.01
	Leslie	123.39
	Letcher	65.65
	Lewis	41.70
	Lincoln	70.66
	Livingston	60.40
	Logan	95.07
	Lyon	57.49
	Madison	85.67
	Magoffin	42.09
	Marion	76.44
	Marshall	86.80
	Martin	142.91
	Mason	73.18
	McCracken	87.37
	McCreary	50.82
	McLean	106.75
	Meade	92.09
	Menifee	50.75
	Mercer	95.93
	Metcalfe	64.06
	Monroe	66.97
	Montgomery	77.86
	Morgan	36.23
	Muhlenberg	65.97
	Nelson	95.46
	Nicholas	61.29
	Ohio	69.49
	Oldham	177.37
	Owen	65.48
	Owsley	38.29
	Pendleton	67.22
	Perry	34.25
	Pike	37.87
	Powell	45.14
	Pulaski	82.23
	Robertson	51.32

State	County	Fee/acre/yr.
	Rockcastle	57.70
	Rowan	60.54
	Russell	87.44
	Scott	129.82
	Shelby	138.58
	Simpson	118.18
	Spencer	88.97
	Taylor	79.00
	Todd	104.76
	Trigg	84.04
	Trimble	89.61
	Union	116.51
	Warren	102.38
	Washington	72.68
	Wayne	64.55
	Webster	90.67
	Whitley	61.54
	Wolfe	42.23
	Woodford	231.53
Louisiana	Acadia	59.72
	Allen	56.56
	Ascension	94.71
	Assumption	82.03
	Avoyelles	61.07
	Beauregard	67.22
	Bienville	64.03
	Bossier	90.51
	Caddo	73.28
	Calcasieu	69.08
	Caldwell	66.65
	Cameron	47.34
	Catahoula	65.34
	Claiborne	67.76
	Concordia	62.11
	De Soto	72.91
	East Baton Rouge	154.67
	East Carroll	73.72
	East Feliciana	80.25
	Evangeline	57.10
	Franklin	61.37
	Grant	57.43
	Iberia	84.38
	Iberville	48.52
	Jackson	76.17
	Jefferson	102.39
	Jefferson Davis	61.17
	La Salle	69.04
	Lafayette	128.39
	Lafourche	57.80
	Lincoln	89.57
	Livingston	154.70
	Madison	66.42
	Morehouse	63.73
	Natchitoches	65.34
	Orleans	416.91
	Ouachita	78.50
	Plaquemines	33.98
	Pointe Coupee	73.85
	Rapides	68.44
	Red River	52.59
	Richland	61.81
	Sabine	85.60
	St. Bernard	44.75
	St. Charles	58.31
	St. Helena	90.07
	St. James	94.75
	St. John the Baptist	78.33
	St. Landry	64.74
	St. Martin	66.55
	St. Mary	67.49
	St. Tammany	196.90
	Tangipahoa	110.83
	Tensas	59.15
	Terrebonne	60.36

State	County	Fee/acre/yr.
	Union	78.29
	Vermilion	69.95
	Vernon	85.06
	Washington	95.42
	Webster	93.74
	West Baton Rouge	100.94
	West Carroll	57.47
	West Feliciana	71.03
	Winn	65.07
Maine	Androscoggin	68.92
	Aroostook	38.38
	Cumberland	131.93
	Franklin	58.40
	Hancock	90.56
	Kennebec	77.05
	Knox	102.09
	Lincoln	93.79
	Oxford	68.35
	Penobscot	54.17
	Piscataquis	46.10
	Sagadahoc	101.58
	Somerset	56.96
	Waldo	50.14
	Washington	42.04
	York	130.89
Maryland	Allegany	97.78
	Anne Arundel	324.18
	Baltimore	264.30
	Calvert	211.00
	Caroline	171.03
	Carroll	228.01
	Cecil	203.12
	Charles	180.66
	Dorchester	145.90
	Frederick	212.64
	Garrett	117.80
	Harford	231.37
	Howard	306.89
	Kent	190.73
	Montgomery	284.77
	Prince George's	220.87
	Queen Anne's	208.41
	Somerset	153.18
	St. Mary's	184.85
	Talbot	185.13
	Washington	167.46
	Wicomico	175.93
	Worcester	167.18
Massachusetts	Barnstable	874.93
	Berkshire	172.34
	Bristol	357.84
	Dukes	240.46
	Essex	510.89
	Franklin	149.25
	Hampden	180.16
	Hampshire	198.05
	Middlesex	469.52
	Nantucket	654.13
	Norfolk	595.70
	Plymouth	282.42
	Suffolk	5,029.90
	Worcester	229.12
Michigan	Alcona	67.41
	Alger	57.25
	Allegan	132.48
	Alpena	67.28
	Antrim	99.12
	Arenac	76.96
	Baraga	51.10
	Barry	110.07
	Bay	111.11
	Benzie	115.29
	Berrien	154.64
	Branch	98.29

State	County	Fee/acre/yr.
	Calhoun	101.67
	Cass	109.52
	Charlevoix	101.88
	Cheboygan	68.66
	Chippewa	44.87
	Clare	78.41
	Clinton	120.17
	Crawford	91.48
	Delta	53.97
	Dickinson	61.16
	Eaton	102.95
	Emmet	87.43
	Genesee	106.96
	Gladwin	77.99
	Gogebic	72.56
	Grand Traverse	147.48
	Gratiot	124.73
	Hillsdale	95.24
	Houghton	49.02
	Huron	143.88
	Ingham	112.81
	Ionia	115.33
	Iosco	73.91
	Iron	55.00
	Isabella	105.27
	Jackson	105.72
	Kalamazoo	128.67
	Kalkaska	84.18
	Kent	162.00
	Keweenaw	69.59
	Lake	71.84
	Lapeer	126.46
	Leelanau	186.17
	Lenawee	112.22
	Livingston	134.10
	Luce	63.47
	Mackinac	57.46
	Macomb	152.74
	Manistee	79.51
	Marquette	56.35
	Mason	78.96
	Mecosta	82.62
	Menominee	55.49
	Midland	99.56
	Missaukee	83.66
	Monroe	125.91
	Montcalm	92.27
	Montmorency	62.85
	Muskegon	141.88
	Newaygo	98.39
	Oakland	237.09
	Oceana	89.09
	Ogemaw	73.29
	Ontonagon	46.84
	Osceola	70.14
	Oscoda	72.70
	Otsego	69.87
	Ottawa	178.59
	Presque Isle	59.32
	Roscommon	72.63
	Saginaw	105.55
	Sanilac	121.31
	Schoolcraft	44.91
	Shiawassee	98.94
	St. Clair	103.33
	St. Joseph	131.47
	Tuscola	125.63
	Van Buren	122.93
	Washtenaw	140.91
	Wayne	205.84
	Wexford	78.75
Minnesota	Aitkin	50.16
	Anoka	171.67
	Becker	77.30

State	County	Fee/acre/yr.
	Beltrami	48.34
	Benton	97.75
	Big Stone	111.02
	Blue Earth	182.49
	Brown	157.02
	Carlton	53.29
	Carver	164.84
	Cass	54.36
	Chippewa	147.06
	Chisago	123.90
	Clay	100.14
	Clearwater	47.77
	Cook	135.00
	Cottonwood	156.34
	Crow Wing	73.64
	Dakota	161.50
	Dodge	174.95
	Douglas	87.58
	Faribault	160.04
	Fillmore	130.55
	Freeborn	155.20
	Goodhue	154.17
	Grant	102.91
	Hennepin	234.35
	Houston	98.25
	Hubbard	64.14
	Isanti	105.97
	Itasca	53.61
	Jackson	173.88
	Kanabec	65.31
	Kandiyohi	136.78
	Kittson	49.91
	Koochiching	33.47
	Lac qui Parle	124.83
	Lake	93.49
	Lake of the Woods	42.40
	Le Sueur	157.87
	Lincoln	110.35
	Lyon	147.91
	Mahnomen	57.91
	Marshall	60.01
	Martin	174.56
	McLeod	153.25
	Meeker	118.39
	Mille Lacs	78.33
	Morrison	78.94
	Mower	170.39
	Murray	160.61
	Nicollet	184.66
	Nobles	168.40
	Norman	85.16
	Olmsted	155.74
	Otter Tail	71.29
	Pennington	51.69
	Pine	57.41
	Pipestone	149.41
	Polk	82.60
	Pope	104.34
	Ramsey	261.10
	Red Lake	49.80
	Redwood	180.00
	Renville	172.32
	Rice	163.10
	Rock	200.06
	Roseau	33.79
	Scott	177.22
	Sherburne	122.41
	Sibley	170.57
	St. Louis	53.50
	Stearns	111.02
	Steele	170.71
	Stevens	127.14
	Swift	145.60
	Todd	67.27

State	County	Fee/acre/yr.
	Traverse	126.57
	Wabasha	133.68
	Wadena	50.76
	Waseca	167.37
	Washington	234.43
	Watonwan	173.92
	Wilkin	111.06
	Winona	133.36
	Wright	152.57
	Yellow Medicine	130.27
Mississippi	Adams	59.77
	Alcorn	51.40
	Amite	92.68
	Attala	49.61
	Benton	43.97
	Bolivar	66.62
	Calhoun	50.78
	Carroll	51.75
	Chickasaw	50.89
	Choctaw	54.33
	Claiborne	55.40
	Clarke	64.93
	Clay	45.14
	Coahoma	69.48
	Copiah	62.97
	Covington	81.01
	DeSoto	72.75
	Forrest	94.09
	Franklin	70.58
	George	92.58
	Greene	59.91
	Grenada	50.34
	Hancock	109.17
	Harrison	170.73
	Hinds	63.14
	Holmes	57.77
	Humphreys	60.84
	Issaquena	52.81
	Itawamba	55.29
	Jackson	104.04
	Jasper	55.02
	Jefferson	58.36
	Jefferson Davis	54.67
	Jones	87.83
	Kemper	47.86
	Lafayette	61.77
	Lamar	99.22
	Lauderdale	65.76
	Lawrence	74.06
	Leake	73.75
	Lee	52.68
	Leflore	55.57
	Lincoln	82.56
	Lowndes	58.46
	Madison	72.13
	Marion	81.70
	Marshall	54.33
	Monroe	48.17
	Montgomery	48.99
	Neshoba	84.87
	Newton	57.36
	Noxubee	59.53
	Oktibbeha	60.66
	Panola	52.99
	Pearl River	88.14
	Perry	78.84
	Pike	97.85
	Pontotoc	50.09
	Prentiss	43.21
	Quitman	55.47
	Rankin	82.35
	Scott	69.62
	Sharkey	63.14
	Simpson	75.43

State	County	Fee/acre/yr.
	Smith	81.42
	Stone	100.67
	Sunflower	53.74
	Tallahatchie	61.94
	Tate	55.29
	Tippah	44.83
	Tishomingo	51.02
	Tunica	74.40
	Union	57.08
	Walthall	82.42
	Warren	51.71
	Washington	58.56
	Wayne	80.25
	Webster	49.75
	Wilkinson	61.90
	Winston	59.84
	Yalobusha	50.13
	Yazoo	57.84
Missouri	Adair	68.72
	Andrew	99.69
	Atchison	136.26
	Audrain	107.12
	Barry	71.11
	Barton	58.99
	Bates	63.54
	Benton	58.57
	Bollinger	56.43
	Boone	102.11
	Buchanan	96.71
	Butler	89.22
	Caldwell	63.75
	Callaway	91.56
	Camden	60.98
	Cape Girardeau	87.78
	Carroll	87.81
	Carter	46.59
	Cass	92.96
	Cedar	51.07
	Chariton	83.30
	Christian	87.53
	Clark	74.36
	Clay	120.01
	Clinton	96.05
	Cole	81.61
	Cooper	79.62
	Crawford	58.29
	Dade	61.44
	Dallas	65.19
	Daviess	78.01
	DeKalb	78.95
	Dent	44.91
	Douglas	45.50
	Dunklin	105.64
	Franklin	104.31
	Gasconade	68.69
	Gentry	73.87
	Greene	103.19
	Grundy	64.52
	Harrison	69.88
	Henry	59.51
	Hickory	54.40
	Holt	106.45
	Howard	71.11
	Howell	52.75
	Iron	45.12
	Jackson	113.14
	Jasper	65.50
	Jefferson	95.49
	Johnson	74.12
	Knox	83.54
	Laclede	61.65
	Lafayette	118.39
	Lawrence	71.81
	Lewis	81.09

State	County	Fee/acre/yr.
	Lincoln	109.29
	Linn	67.71
	Livingston	81.72
	Macon	69.43
	Madison	51.56
	Maries	54.68
	Marion	99.79
	McDonald	64.84
	Mercer	62.17
	Miller	62.24
	Mississippi	116.36
	Moniteau	75.59
	Monroe	87.57
	Montgomery	96.75
	Morgan	74.15
	New Madrid	124.28
	Newton	72.23
	Nodaway	91.11
	Oregon	43.61
	Osage	57.38
	Ozark	45.50
	Pemiscot	101.37
	Perry	74.89
	Pettis	76.68
	Phelps	64.49
	Pike	96.99
	Platte	108.94
	Polk	57.90
	Pulaski	54.57
	Putnam	57.80
	Ralls	89.95
	Randolph	73.70
	Ray	76.50
	Reynolds	40.98
	Ripley	50.26
	Saline	112.72
	Schuyler	62.38
	Scotland	82.28
	Scott	114.26
	Shannon	46.80
	Shelby	99.55
	St. Louis	115.66
	St. Charles	118.81
	St. Clair	46.41
	St. Francois	70.41
	Ste. Genevieve	64.59
	Stoddard	123.09
	Stone	66.38
	Sullivan	52.05
	Taney	54.96
	Texas	45.99
	Vernon	60.42
	Warren	108.73
	Washington	53.77
	Wayne	42.80
	Webster	73.21
	Worth	63.16
	Wright	50.37
Montana	Beaverhead	25.00
	Big Horn	9.89
	Blaine	13.40
	Broadwater	25.64
	Carbon	26.40
	Carter	12.05
	Cascade	23.65
	Chouteau	17.99
	Custer	9.02
	Daniels	11.57
	Dawson	10.03
	Deer Lodge	36.15
	Fallon	9.84
	Fergus	19.39
	Flathead	111.95
	Gallatin	59.24

State	County	Fee/acre/yr.
	Garfield	11.07
	Glacier	15.30
	Golden Valley	12.64
	Granite	28.61
	Hill	14.52
	Jefferson	25.42
	Judith Basin	20.01
	Lake	35.81
	Lewis and Clark	33.96
	Liberty	13.62
	Lincoln	84.13
	Madison	28.08
	McCone	10.76
	Meagher	21.55
	Mineral	99.71
	Missoula	62.07
	Musselshell	11.07
	Park	57.22
	Petroleum	9.84
	Phillips	12.89
	Pondera	18.19
	Powder River	12.36
	Powell	21.21
	Prairie	12.64
	Ravalli	108.87
	Richland	13.40
	Roosevelt	14.18
	Rosebud	9.25
	Sanders	26.62
	Sheridan	13.28
	Silver Bow	35.17
	Stillwater	31.30
	Sweet Grass	24.10
	Teton	23.57
	Toole	16.09
	Treasure	11.27
	Valley	11.13
	Wheatland	11.49
	Wibaux	10.48
	Yellowstone	17.12
Nebraska	Adams	137.22
	Antelope	110.61
	Arthur	10.99
	Banner	20.02
	Blaine	13.33
	Boone	114.60
	Box Butte	27.76
	Boyd	35.75
	Brown	18.62
	Buffalo	97.18
	Burt	135.63
	Butler	128.64
	Cass	150.62
	Cedar	114.60
	Chase	51.13
	Cherry	13.81
	Cheyenne	23.21
	Clay	133.45
	Colfax	137.58
	Cuming	139.47
	Custer	49.34
	Dakota	124.78
	Dawes	19.34
	Dawson	80.77
	Deuel	25.97
	Dixon	107.84
	Dodge	145.90
	Douglas	161.67
	Dundy	35.33
	Fillmore	143.34
	Franklin	77.19
	Frontier	38.16
	Furnas	60.88
	Gage	90.78

State	County	Fee/acre/yr.
	Garden	15.89
	Garfield	25.77
	Gosper	82.30
	Grant	14.37
	Greeley	83.95
	Hall	116.23
	Hamilton	167.61
	Harlan	80.15
	Hayes	33.64
	Hitchcock	33.54
	Holt	54.41
	Hooker	11.51
	Howard	76.67
	Jefferson	102.12
	Johnson	66.17
	Kearney	137.35
	Keith	48.33
	Keya Paha	20.15
	Kimball	22.56
	Knox	72.12
	Lancaster	119.09
	Lincoln	37.35
	Logan	29.54
	Loup	19.27
	Madison	125.26
	McPherson	11.64
	Merrick	99.78
	Morrill	23.99
	Nance	88.86
	Nemaha	105.76
	Nuckolls	98.09
	Otoe	111.68
	Pawnee	67.28
	Perkins	59.06
	Phelps	117.11
	Pierce	112.43
	Platte	132.28
	Polk	154.52
	Red Willow	41.44
	Richardson	99.13
	Rock	28.02
	Saline	125.26
	Sarpy	154.94
	Saunders	136.96
	Scotts Bluff	48.56
	Seward	130.82
	Sheridan	18.01
	Sherman	61.59
	Sioux	14.89
	Stanton	113.76
	Thayer	107.19
	Thomas	13.07
	Thurston	131.28
	Valley	57.43
	Washington	156.63
	Wayne	113.69
	Webster	73.59
	Wheeler	31.85
	York	146.42
Nevada	Carson City	54.97
	Churchill	19.93
	Clark	45.99
	Douglas	23.63
	Elko	4.06
	Esmeralda	14.68
	Eureka	5.30
	Humboldt	8.12
	Lander	6.09
	Lincoln	23.82
	Lyon	17.98
	Mineral	3.51
	Nye	17.53
	Pershing	7.64
	Storey	314.53

State	County	Fee/acre/yr.
	Washoe	6.67
	White Pine	6.70
New Hampshire	Belknap	146.31
	Carroll	127.26
	Cheshire	78.41
	Coos	63.92
	Grafton	79.65
	Hillsborough	173.97
	Merrimack	106.44
	Rockingham	198.94
	Strafford	131.35
	Sullivan	105.47
New Jersey	Atlantic	313.95
	Bergen	1,074.04
	Burlington	246.83
	Camden	320.64
	Cape May	293.91
	Cumberland	204.76
	Essex	1,617.43
	Gloucester	303.47
	Hudson	325.99
	Hunterdon	417.95
	Mercer	517.56
	Middlesex	501.66
	Monmouth	549.95
	Morris	589.87
	Ocean	393.62
	Passaic	795.13
	Salem	201.19
	Somerset	522.34
	Sussex	271.97
	Union	3,213.07
	Warren	260.69
New Mexico	Bernalillo	22.54
	Catron	8.50
	Chaves	7.16
	Cibola	6.21
	Colfax	7.88
	Curry	11.51
	De Baca	4.92
	Dona Ana	35.59
	Eddy	8.90
	Grant	7.46
	Guadalupe	5.29
	Harding	5.62
	Hidalgo	4.92
	Lea	6.74
	Lincoln	7.03
	Los Alamos	303.55
	Luna	8.43
	McKinley	6.26
	Mora	11.03
	Otero	8.35
	Quay	6.66
	Rio Arriba	14.39
	Roosevelt	9.69
	San Juan	6.91
	San Miguel	7.51
	Sandoval	10.39
	Santa Fe	16.83
	Sierra	5.69
	Socorro	9.79
	Taos	23.31
	Torrance	7.23
	Union	7.31
	Valencia	18.74
New York	Albany	85.89
	Allegany	48.51
	Bronx	72.07
	Broome	72.69
	Cattaraugus	52.42
	Cayuga	89.11
	Chautauqua	57.24
	Chemung	66.73

State	County	Fee/acre/yr.
	Chenango	50.86
	Clinton	56.13
	Columbia	144.76
	Cortland	52.84
	Delaware	69.09
	Dutchess	143.79
	Erie	82.01
	Essex	58.49
	Franklin	46.57
	Fulton	59.53
	Genesee	72.97
	Greene	103.56
	Hamilton	50.52
	Herkimer	53.43
	Jefferson	45.46
	Kings	21,966.75
	Lewis	46.29
	Livingston	80.31
	Madison	56.61
	Monroe	98.43
	Montgomery	63.72
	Nassau	508.15
	New York	72.07
	Niagara	63.54
	Oneida	55.19
	Onondaga	87.45
	Ontario	89.32
	Orange	153.49
	Orleans	72.00
	Oswego	56.06
	Otsego	62.23
	Putnam	151.55
	Queens	142.13
	Rensselaer	95.25
	Richmond	4,887.05
	Rockland	2,400.85
	Saratoga	132.81
	Schenectady	95.73
	Schoharie	63.16
	Schuyler	79.21
	Seneca	81.63
	St. Lawrence	39.29
	Steuben	50.83
	Suffolk	324.23
	Sullivan	102.07
	Tioga	54.54
	Tompkins	76.43
	Ulster	139.77
	Warren	110.80
	Washington	67.25
	Wayne	68.71
	Westchester	446.33
	Wyoming	72.55
	Yates	109.66
North Carolina	Alamance	130.87
	Alexander	165.11
	Alleghany	133.29
	Anson	103.39
	Ashe	157.86
	Avery	193.38
	Beaufort	84.83
	Bertie	75.01
	Bladen	91.35
	Brunswick	119.42
	Buncombe	238.73
	Burke	147.59
	Cabarrus	203.31
	Caldwell	153.24
	Camden	78.86
	Carteret	91.25
	Caswell	79.87
	Catawba	149.88
	Chatham	137.70
	Cherokee	159.49

State	County	Fee/acre/yr.
	Chowan	87.95
	Clay	138.50
	Cleveland	114.25
	Columbus	84.17
	Craven	85.87
	Cumberland	86.63
	Currituck	113.45
	Dare	107.07
	Davidson	170.35
	Davie	171.46
	Duplin	113.14
	Durham	238.07
	Edgecombe	73.10
	Forsyth	230.61
	Franklin	118.55
	Gaston	168.27
	Gates	96.59
	Graham	167.26
	Granville	114.00
	Greene	108.25
	Guilford	171.67
	Halifax	65.81
	Harnett	148.46
	Haywood	175.79
	Henderson	216.70
	Hertford	66.40
	Hoke	88.92
	Hyde	68.28
	Iredell	166.91
	Jackson	268.01
	Johnston	135.51
	Jones	74.04
	Lee	116.02
	Lenoir	93.67
	Lincoln	154.63
	Macon	211.81
	Madison	150.26
	Martin	78.23
	McDowell	160.11
	Mecklenburg	571.51
	Mitchell	146.30
	Montgomery	113.76
	Moore	147.80
	Nash	105.82
	New Hanover	394.99
	Northampton	72.65
	Onslow	105.99
	Orange	185.75
	Pamlico	79.87
	Pasquotank	87.67
	Pender	117.37
	Perquimans	90.07
	Person	105.40
	Pitt	88.30
	Polk	203.51
	Randolph	133.02
	Richmond	114.32
	Robeson	81.53
	Rockingham	112.27
	Rowan	157.02
	Rutherford	111.99
	Sampson	110.33
	Scotland	99.92
	Stanly	142.70
	Stokes	106.79
	Surry	127.33
	Swain	174.61
	Transylvania	245.29
	Tyrrell	70.64
	Union	156.75
	Vance	96.03
	Wake	265.76
	Warren	71.12
	Washington	83.75

State	County	Fee/acre/yr.
	Watauga	207.43
	Wayne	114.46
	Wilkes	134.40
	Wilson	105.96
	Yadkin	146.20
	Yancey	179.92
North Dakota	Adams	22.96
	Barnes	63.65
	Benson	36.81
	Billings	22.43
	Bottineau	38.48
	Bowman	21.43
	Burke	23.88
	Burleigh	40.08
	Cass	81.59
	Cavalier	54.18
	Dickey	64.18
	Divide	18.40
	Dunn	25.99
	Eddy	38.09
	Emmons	33.53
	Foster	53.18
	Golden Valley	23.99
	Grand Forks	59.84
	Grant	26.27
	Griggs	51.93
	Hettinger	31.93
	Kidder	26.34
	LaMoure	61.58
	Logan	29.12
	McHenry	25.59
	McIntosh	33.50
	McKenzie	21.00
	McLean	37.38
	Mercer	27.12
	Morton	29.12
	Mountrail	25.91
	Nelson	33.46
	Oliver	29.08
	Pembina	73.40
	Pierce	29.26
	Ramsey	39.65
	Ransom	52.04
	Renville	46.06
	Richland	84.58
	Rolette	32.00
	Sargent	67.56
	Sheridan	26.63
	Sioux	25.45
	Slope	24.28
	Stark	38.66
	Steele	52.68
	Stutsman	49.73
	Towner	36.52
	Traill	82.62
	Walsh	67.70
	Ward	43.78
	Wells	46.06
	Williams	21.22
Ohio	Adams	81.37
	Allen	150.20
	Ashland	130.13
	Ashtabula	93.10
	Athens	79.06
	Auglaize	171.81
	Belmont	95.05
	Brown	102.41
	Butler	166.16
	Carroll	105.68
	Champaign	152.34
	Clark	146.05
	Clermont	145.16
	Clinton	141.07
	Columbiana	138.19

State	County	Fee/acre/yr.
	Coshocton	97.51
	Crawford	133.08
	Cuyahoga	486.47
	Darke	201.76
	Defiance	127.43
	Delaware	168.79
	Erie	133.82
	Fairfield	135.67
	Fayette	155.57
	Franklin	174.87
	Fulton	157.95
	Gallia	92.50
	Geauga	201.66
	Greene	170.92
	Guernsey	81.62
	Hamilton	207.02
	Hancock	134.50
	Hardin	138.94
	Harrison	85.50
	Henry	160.47
	Highland	102.87
	Hocking	101.91
	Holmes	165.52
	Huron	127.50
	Jackson	67.16
	Jefferson	78.32
	Knox	135.85
	Lake	214.63
	Lawrence	69.40
	Licking	139.12
	Logan	141.53
	Lorain	133.54
	Lucas	164.24
	Madison	144.77
	Mahoning	141.21
	Marion	135.67
	Medina	180.87
	Meigs	69.01
	Mercer	223.26
	Miami	162.11
	Monroe	65.60
	Montgomery	166.51
	Morgan	68.30
	Morrow	133.11
	Muskingum	92.75
	Noble	72.42
	Ottawa	135.10
	Paulding	137.80
	Perry	103.05
	Pickaway	136.24
	Pike	90.29
	Portage	147.68
	Preble	149.42
	Putnam	142.96
	Richland	141.07
	Ross	102.55
	Sandusky	133.86
	Scioto	79.95
	Seneca	138.51
	Shelby	169.22
	Stark	156.74
	Summit	240.25
	Trumbull	113.92
	Tuscarawas	108.91
	Union	146.01
	Van Wert	178.42
	Vinton	69.01
	Warren	203.26
	Washington	76.08
	Wayne	177.32
	Williams	108.81
	Wood	165.48
	Wyandot	142.96
Oklahoma	Adair	55.73

State	County	Fee/acre/yr.
	Alfalfa	40.03
	Atoka	39.32
	Beaver	18.80
	Beckham	31.12
	Blaine	33.51
	Bryan	49.88
	Caddo	37.67
	Canadian	54.25
	Carter	44.46
	Cherokee	66.75
	Choctaw	41.44
	Cimarron	14.22
	Cleveland	88.01
	Coal	35.49
	Comanche	38.90
	Cotton	31.72
	Craig	44.85
	Creek	50.34
	Custer	37.74
	Delaware	65.30
	Dewey	28.52
	Ellis	22.46
	Garfield	40.38
	Garvin	44.50
	Grady	45.34
	Grant	38.44
	Greer	24.12
	Harmon	26.83
	Harper	21.44
	Haskell	42.63
	Hughes	35.13
	Jackson	28.20
	Jefferson	28.48
	Johnston	37.84
	Kay	38.09
	Kingfisher	38.37
	Kiowa	27.07
	Latimer	37.53
	Le Flore	55.90
	Lincoln	48.55
	Logan	53.05
	Love	48.72
	Major	31.61
	Marshall	47.10
	Mayes	59.50
	McClain	57.52
	McCurtain	49.07
	McIntosh	43.41
	Murray	39.04
	Muskogee	49.71
	Noble	40.13
	Nowata	46.68
	Okfuskee	35.94
	Oklahoma	87.27
	Okmulgee	50.73
	Osage	29.71
	Ottawa	64.95
	Pawnee	37.49
	Payne	53.26
	Pittsburg	38.34
	Pontotoc	49.53
	Pottawatomie	49.46
	Pushmataha	32.04
	Roger Mills	29.04
	Rogers	69.39
	Seminole	39.75
	Sequoyah	56.40
	Stephens	35.70
	Texas	22.53
	Tillman	28.27
	Tulsa	102.37
	Wagoner	68.37
	Washington	47.10
	Washita	33.76

State	County	Fee/acre/yr.
	Woods	30.56
	Woodward	31.19
Oregon	Baker	20.33
	Benton	118.95
	Clackamas	270.41
	Clatsop	111.23
	Columbia	110.13
	Coos	64.66
	Crook	18.22
	Curry	68.32
	Deschutes	140.66
	Douglas	61.83
	Gilliam	9.98
	Grant	16.14
	Harney	10.98
	Hood River	380.97
	Jackson	93.89
	Jefferson	12.86
	Josephine	201.56
	Klamath	29.58
	Lake	20.40
	Lane	136.82
	Lincoln	96.14
	Linn	97.05
	Malheur	23.53
	Marion	159.26
	Morrow	19.07
	Multnomah	239.16
	Polk	123.14
	Sherman	11.96
	Tillamook	125.49
	Umatilla	32.73
	Union	31.03
	Wallowa	25.31
	Wasco	15.09
	Washington	187.90
	Wheeler	12.98
	Yamhill	183.72
Pennsylvania	Adams	174.71
	Allegheny	147.69
	Armstrong	80.59
	Beaver	134.80
	Bedford	103.51
	Berks	248.32
	Blair	127.96
	Bradford	103.82
	Bucks	344.23
	Butler	133.08
	Cambria	91.87
	Cameron	54.80
	Carbon	183.54
	Centre	151.83
	Chester	366.37
	Clarion	82.73
	Clearfield	74.25
	Clinton	151.76
	Columbia	131.54
	Crawford	79.12
	Cumberland	218.44
	Dauphin	127.30
	Delaware	386.76
	Elk	95.87
	Erie	96.36
	Fayette	93.10
	Forest	67.49
	Franklin	186.30
	Fulton	102.00
	Greene	84.30
	Huntingdon	107.43
	Indiana	78.45
	Jefferson	72.78
	Juniata	141.24
	Lackawanna	137.18
	Lancaster	351.20

State	County	Fee/acre/yr.
	Lawrence	115.07
	Lebanon	296.08
	Lehigh	233.47
	Luzerne	125.83
	Lycoming	119.55
	McKean	57.81
	Mercer	95.87
	Mifflin	137.56
	Monroe	220.33
	Montgomery	393.88
	Montour	153.68
	Northampton	230.35
	Northumberland	137.28
	Perry	141.59
	Philadelphia	1,270.88
	Pike	51.44
	Potter	77.05
	Schuylkill	180.42
	Snyder	163.14
	Somerset	73.76
	Sullivan	86.44
	Susquehanna	114.33
	Tioga	96.36
	Union	151.12
	Venango	86.69
	Warren	65.77
	Washington	127.75
	Wayne	104.56
	Westmoreland	133.36
	Wyoming	112.44
	York	211.57
Puerto Rico	All Areas	181.50
Rhode Island	Bristol	617.93
	Kent	208.49
	Newport	537.69
	Providence	350.93
	Washington	286.88
South Carolina	Abbeville	76.91
	Aiken	105.32
	Allendale	61.29
	Anderson	121.05
	Bamberg	61.39
	Barnwell	67.56
	Beaufort	93.75
	Berkeley	98.87
	Calhoun	77.43
	Charleston	172.77
	Cherokee	84.05
	Chester	78.16
	Chesterfield	75.91
	Clarendon	51.00
	Colleton	74.76
	Darlington	68.32
	Dillon	72.13
	Dorchester	95.34
	Edgefield	81.93
	Fairfield	77.36
	Florence	61.39
	Georgetown	65.23
	Greenville	180.08
	Greenwood	66.72
	Hampton	66.45
	Horry	83.60
	Jasper	75.32
	Kershaw	84.74
	Lancaster	109.09
	Laurens	93.92
	Lee	62.77
	Lexington	110.41
	Marion	64.51
	Marlboro	60.11
	McCormick	48.99
	Newberry	75.14
	Oconee	147.10

State	County	Fee/acre/yr.
	Orangeburg	70.05
	Pickens	154.51
	Richland	97.32
	Saluda	79.06
	Spartanburg	137.57
	Sumter	64.30
	Union	61.04
	Williamsburg	57.82
	York	139.44
South Dakota	Aurora	67.09
	Beadle	81.37
	Bennett	16.05
	Bon Homme	82.96
	Brookings	121.07
	Brown	82.89
	Brule	64.71
	Buffalo	33.60
	Butte	17.58
	Campbell	36.23
	Charles Mix	66.84
	Clark	71.99
	Clay	125.65
	Codington	76.25
	Corson	18.57
	Custer	32.57
	Davison	96.39
	Day	54.30
	Deuel	83.85
	Dewey	16.27
	Douglas	81.08
	Edmunds	62.29
	Fall River	14.63
	Faulk	55.26
	Grant	85.02
	Gregory	34.70
	Haakon	17.08
	Hamlin	101.50
	Hand	54.20
	Hanson	106.40
	Harding	11.93
	Hughes	55.76
	Hutchinson	93.41
	Hyde	39.49
	Jackson	22.59
	Jerauld	55.90
	Jones	20.67
	Kingsbury	94.29
	Lake	115.96
	Lawrence	40.31
	Lincoln	154.56
	Lyman	28.48
	Marshall	63.50
	McCook	120.68
	McPherson	43.47
	Meade	19.14
	Mellette	20.31
	Miner	91.27
	Minnehaha	146.22
	Moody	144.72
	Pennington	19.85
	Perkins	15.27
	Potter	56.79
	Roberts	71.92
	Sanborn	67.55
	Shannon	13.07
	Spink	84.56
	Stanley	26.07
	Sully	44.32
	Todd	14.53
	Tripp	31.75
	Turner	122.63
	Union	142.42
	Walworth	42.09
	Yankton	117.70

State	County	Fee/acre/yr.
	Ziebach	13.50
Tennessee	Anderson	166.17
	Bedford	108.43
	Benton	63.60
	Bledsoe	99.49
	Blount	193.27
	Bradley	154.33
	Campbell	106.02
	Cannon	87.89
	Carroll	69.52
	Carter	148.62
	Cheatham	121.16
	Chester	54.69
	Claiborne	87.01
	Clay	78.85
	Cocke	104.07
	Coffee	100.45
	Crockett	80.48
	Cumberland	108.04
	Davidson	176.53
	Decatur	61.01
	DeKalb	91.05
	Dickson	94.45
	Dyer	71.15
	Fayette	89.13
	Fentress	91.01
	Franklin	110.59
	Gibson	87.68
	Giles	83.35
	Grainger	107.90
	Greene	114.99
	Grundy	81.26
	Hamblen	132.87
	Hamilton	160.43
	Hancock	65.19
	Hardeman	72.46
	Hardin	71.83
	Hawkins	99.95
	Haywood	102.36
	Henderson	62.64
	Henry	78.85
	Hickman	67.92
	Houston	64.38
	Humphreys	80.69
	Jackson	82.11
	Jefferson	153.23
	Johnson	135.17
	Knox	217.64
	Lake	93.39
	Lauderdale	88.74
	Lawrence	75.16
	Lewis	73.85
	Lincoln	95.66
	Loudon	153.87
	Macon	97.15
	Madison	71.51
	Marion	83.49
	Marshall	85.62
	Maury	103.53
	McMinn	116.27
	McNairy	61.22
	Meigs	99.88
	Monroe	127.90
	Montgomery	122.30
	Moore	100.09
	Morgan	97.26
	Obion	90.41
	Overton	92.22
	Perry	56.22
	Pickett	82.43
	Polk	126.84
	Putnam	122.83
	Rhea	99.28
	Roane	144.29

State	County	Fee/acre/yr.
	Robertson	138.15
	Rutherford	138.40
	Scott	80.13
	Sequatchie	91.83
	Sevier	168.16
	Shelby	130.14
	Smith	75.41
	Stewart	74.59
	Sullivan	156.81
	Sumner	138.01
	Tipton	84.20
	Trousdale	109.35
	Unicoi	156.38
	Union	81.93
	Van Buren	105.59
	Warren	101.26
	Washington	182.10
	Wayne	57.14
	Weakley	84.45
	White	106.87
	Williamson	209.30
	Wilson	125.77
Texas	Anderson	66.16
	Andrews	8.86
	Angelina	85.40
	Aransas	46.08
	Archer	26.61
	Armstrong	28.43
	Atascosa	52.98
	Austin	110.52
	Bailey	21.77
	Bandera	72.85
	Bastrop	101.08
	Baylor	28.09
	Bee	50.47
	Bell	82.83
	Bexar	115.79
	Blanco	127.86
	Borden	15.82
	Bosque	65.45
	Bowie	61.36
	Brazoria	82.12
	Brazos	102.00
	Brewster	12.68
	Briscoe	22.55
	Brooks	28.74
	Brown	55.34
	Burleson	77.69
	Burnet	89.89
	Caldwell	89.42
	Calhoun	47.47
	Callahan	40.84
	Cameron	79.45
	Camp	70.39
	Carson	24.88
	Cass	55.71
	Castro	29.68
	Chambers	53.99
	Cherokee	66.80
	Childress	20.79
	Clay	42.66
	Cochran	18.19
	Coke	28.26
	Coleman	40.91
	Collin	143.41
	Collingsworth	22.52
	Colorado	89.49
	Comal	141.92
	Comanche	64.94
	Concho	42.80
	Cooke	88.37
	Coryell	65.79
	Cottle	16.73
	Crane	15.96

State	County	Fee/acre/yr.
	Crockett	17.04
	Crosby	23.12
	Culberson	9.26
	Dallam	25.49
	Dallas	124.72
	Dawson	21.33
	Deaf Smith	26.74
	Delta	49.39
	Denton	165.28
	DeWitt	70.66
	Dickens	19.81
	Dimmit	42.16
	Donley	29.14
	Duval	35.29
	Eastland	53.75
	Ector	13.08
	Edwards	33.98
	El Paso	52.40
	Ellis	86.04
	Erath	86.95
	Falls	52.67
	Fannin	69.27
	Fayette	114.54
	Fisher	29.28
	Floyd	30.97
	Foard	19.98
	Fort Bend	110.75
	Franklin	77.59
	Freestone	56.80
	Frio	55.24
	Gaines	26.23
	Galveston	97.47
	Garza	18.76
	Gillespie	115.22
	Glasscock	24.21
	Goliad	55.92
	Gonzales	87.39
	Gray	24.00
	Grayson	101.62
	Gregg	104.97
	Grimes	104.53
	Guadalupe	97.23
	Hale	32.05
	Hall	20.86
	Hamilton	67.14
	Hansford	25.02
	Hardeman	23.67
	Hardin	83.64
	Harris	144.49
	Harrison	76.95
	Hartley	27.18
	Haskell	20.01
	Hays	167.68
	Hemphill	20.01
	Henderson	80.56
	Hidalgo	82.15
	Hill	60.92
	Hockley	28.06
	Hood	110.48
	Hopkins	59.87
	Houston	60.68
	Howard	20.52
	Hudspeth	15.21
	Hunt	82.66
	Hutchinson	20.62
	Irion	25.39
	Jack	52.91
	Jackson	57.17
	Jasper	85.16
	Jeff Davis	12.98
	Jefferson	44.83
	Jim Hogg	36.11
	Jim Wells	49.43
	Johnson	110.28

State	County	Fee/acre/yr.
	Jones	30.09
	Karnes	70.25
	Kaufman	91.92
	Kendall	129.48
	Kenedy	17.78
	Kent	23.09
	Kerr	71.23
	Kimble	47.94
	King	16.43
	Kinney	32.52
	Kleberg	50.95
	Knox	20.89
	La Salle	52.81
	Lamar	58.49
	Lamb	31.31
	Lampasas	67.92
	Lavaca	79.28
	Lee	86.51
	Leon	67.78
	Liberty	67.75
	Limestone	51.15
	Lipscomb	21.84
	Live Oak	51.83
	Llano	73.16
	Loving	5.38
	Lubbock	50.10
	Lynn	24.34
	Madison	75.69
	Marion	60.14
	Martin	27.92
	Mason	64.03
	Matagorda	53.62
	Maverick	31.88
	McCulloch	50.10
	McLennan	70.08
	McMullen	38.00
	Medina	70.25
	Menard	39.45
	Midland	38.74
	Milam	96.86
	Mills	60.11
	Mitchell	21.33
	Montague	67.61
	Montgomery	159.71
	Moore	25.39
	Morris	56.80
	Motley	19.95
	Nacogdoches	68.19
	Navarro	55.51
	Newton	54.19
	Nolan	30.39
	Nueces	41.89
	Ochiltree	27.08
	Oldham	15.96
	Orange	89.86
	Palo Pinto	65.11
	Panola	56.83
	Parker	135.57
	Parmer	28.13
	Pecos	13.73
	Polk	73.90
	Potter	14.81
	Presidio	12.47
	Rains	68.22
	Randall	27.15
	Reagan	13.15
	Real	39.96
	Red River	44.96
	Reeves	7.27
	Refugio	24.68
	Roberts	17.78
	Robertson	64.74
	Rockwall	157.85
	Runnels	34.99

State	County	Fee/acre/yr.
	Rusk	59.13
	Sabine	73.50
	San Augustine	62.48
	San Jacinto	76.67
	San Patricio	43.21
	San Saba	65.92
	Schleicher	25.05
	Scurry	22.99
	Shackelford	29.55
	Shelby	79.18
	Sherman	29.14
	Smith	102.40
	Somervell	105.31
	Starr	47.87
	Stephens	37.83
	Sterling	14.27
	Stonewall	19.44
	Sutton	25.52
	Swisher	24.92
	Tarrant	171.44
	Taylor	30.63
	Terrell	10.51
	Terry	30.80
	Throckmorton	32.42
	Titus	69.64
	Tom Green	30.83
	Travis	103.79
	Trinity	62.68
	Tyler	79.08
	Upshur	77.42
	Upton	15.89
	Uvalde	54.06
	Val Verde	15.42
	Van Zandt	86.31
	Victoria	62.00
	Walker	90.03
	Waller	168.90
	Ward	10.01
	Washington	150.07
	Webb	29.28
	Wharton	68.73
	Wheeler	22.21
	Wichita	32.25
	Wilbarger	27.05
	Willacy	49.43
	Williamson	105.07
	Wilson	80.80
	Winkler	9.80
	Wise	103.18
	Wood	77.15
	Yoakum	21.87
	Young	37.42
	Zapata	31.61
	Zavala	41.52
Utah	Beaver	22.14
	Box Elder	13.33
	Cache	39.10
	Carbon	13.49
	Daggett	23.67
	Davis	71.85
	Duchesne	9.23
	Emery	18.84
	Garfield	25.20
	Grand	6.41
	Iron	20.90
	Juab	13.30
	Kane	15.63
	Millard	15.57
	Morgan	17.45
	Piute	32.48
	Rich	11.15
	Salt Lake	52.43
	San Juan	4.14
	Sanpete	23.85

State	County	Fee/acre/yr.
	Sevier	33.45
	Summit	25.28
	Tooele	13.23
	Uintah	7.01
	Utah	59.08
	Wasatch	42.30
	Washington	40.52
	Wayne	44.74
	Weber	64.52
Vermont	Addison	85.04
	Bennington	116.68
	Caledonia	88.92
	Chittenden	120.07
	Essex	52.04
	Franklin	78.27
	Grand Isle	106.34
	Lamoille	101.84
	Orange	86.54
	Orleans	67.96
	Rutland	75.93
	Washington	112.11
	Windham	111.69
	Windsor	106.03
Virginia	Accomack	103.29
	Albemarle	246.77
	Alleghany	87.58
	Amelia	86.38
	Amherst	102.76
	Appomattox	80.25
	Arlington	1,515.17
	Augusta	176.31
	Bath	117.41
	Bedford	124.85
	Bland	90.89
	Botetourt	123.16
	Brunswick	58.83
	Buchanan	74.47
	Buckingham	86.73
	Campbell	84.12
	Caroline	116.32
	Carroll	95.99
	Charles City	105.86
	Charlotte	64.01
	Chesapeake City	122.73
	Chesterfield	150.17
	Clarke	222.07
	Craig	89.34
	Culpeper	181.77
	Cumberland	101.10
	Dickenson	83.63
	Dinwiddie	84.62
	Essex	85.81
	Fairfax	427.13
	Fauquier	223.62
	Floyd	102.09
	Fluvanna	143.66
	Franklin	99.87
	Frederick	166.34
	Giles	74.47
	Gloucester	141.68
	Goochland	153.80
	Grayson	118.22
	Greene	193.89
	Greensville	57.17
	Halifax	64.75
	Hanover	156.87
	Henrico	185.37
	Henry	76.09
	Highland	95.26
	Isle of Wight	100.22
	James City	247.05
	King and Queen	87.05
	King George	141.83
	King William	105.22

State	County	Fee/acre/yr.
	Lancaster	129.04
	Lee	62.07
	Loudoun	337.55
	Louisa	161.27
	Lunenburg	67.07
	Madison	178.00
	Mathews	174.52
	Mecklenburg	72.57
	Middlesex	108.64
	Montgomery	137.46
	Nelson	129.11
	New Kent	155.71
	Northampton	121.71
	Northumberland	84.58
	Nottoway	87.93
	Orange	190.12
	Page	165.75
	Patrick	94.02
	Pittsylvania	68.48
	Powhatan	161.45
	Prince Edward	90.25
	Prince George	118.43
	Prince William	248.78
	Pulaski	86.62
	Rappahannock	237.93
	Richmond	81.23
	Roanoke	120.48
	Rockbridge	121.08
	Rockingham	198.82
	Russell	61.19
	Scott	58.51
	Shenandoah	157.26
	Smyth	78.59
	Southampton	75.18
	Spotsylvania	172.76
	Stafford	258.36
	Suffolk	127.42
	Surry	100.93
	Sussex	64.18
	Tazewell	62.42
	Virginia Beach City	149.86
	Warren	201.15
	Washington	110.93
	Westmoreland	100.79
	Wise	77.68
	Wythe	95.43
	York	140.66
Washington	Adams	21.30
	Asotin	14.73
	Benton	47.36
	Chelan	151.55
	Clallam	215.62
	Clark	218.89
	Columbia	18.62
	Cowlitz	150.38
	Douglas	17.62
	Ferry	7.35
	Franklin	50.65
	Garfield	16.39
	Grant	59.29
	Grays Harbor	36.37
	Island	246.28
	Jefferson	158.05
	King	370.78
	Kitsap	457.51
	Kittitas	76.49
	Klickitat	24.65
	Lewis	108.88
	Lincoln	19.25
	Mason	143.50
	Okanogan	22.94
	Pacific	59.79
	Pend Oreille	52.83
	Pierce	246.05

State	County	Fee/acre/yr.
	San Juan	228.83
	Skagit	131.22
	Skamania	175.87
	Snohomish	277.73
	Spokane	49.20
	Stevens	27.20
	Thurston	150.31
	Wahkiakum	81.18
	Walla Walla	36.09
	Whatcom	199.88
	Whitman	24.18
	Yakima	31.18
West Virginia	Barbour	55.49
	Berkeley	163.41
	Boone	49.28
	Braxton	46.40
	Brooke	55.27
	Cabell	85.07
	Calhoun	43.18
	Clay	53.14
	Doddridge	53.43
	Fayette	69.75
	Gilmer	41.79
	Grant	67.48
	Greenbrier	80.53
	Hampshire	102.21
	Hancock	83.23
	Hardy	80.53
	Harrison	60.13
	Jackson	62.65
	Jefferson	195.05
	Kanawha	61.45
	Lewis	55.88
	Lincoln	57.37
	Logan	55.31
	Marion	61.16
	Marshall	62.40
	Mason	59.99
	McDowell	68.08
	Mercer	63.08
	Mineral	85.32
	Mingo	40.23
	Monongalia	87.70
	Monroe	64.78
	Morgan	126.87
	Nicholas	72.44
	Ohio	65.63
	Pendleton	66.02
	Pleasants	54.85
	Pocahontas	62.47
	Preston	70.03
	Putnam	72.55
	Raleigh	70.60
	Randolph	51.51
	Ritchie	45.37
	Roane	48.71
	Summers	62.37
	Taylor	70.42
	Tucker	86.81
	Tyler	52.12
	Upshur	65.85
	Wayne	53.36
	Webster	62.26
	Wetzel	51.83
	Wirt	46.62
	Wood	66.20
	Wyoming	58.82
Wisconsin	Adams	108.11
	Ashland	51.32
	Barron	78.01
	Bayfield	56.61
	Brown	151.20
	Buffalo	93.79
	Burnett	68.53

State	County	Fee/acre/yr.
	Calumet	153.85
	Chippewa	76.02
	Clark	87.13
	Columbia	140.54
	Crawford	75.43
	Dane	168.83
	Dodge	149.25
	Door	113.44
	Douglas	48.43
	Dunn	92.43
	Eau Claire	83.69
	Florence	86.82
	Fond du Lac	139.39
	Forest	57.38
	Grant	116.02
	Green	121.94
	Green Lake	126.64
	Iowa	111.24
	Iron	64.31
	Jackson	86.19
	Jefferson	144.48
	Juneau	85.81
	Kenosha	140.40
	Kewaunee	121.28
	La Crosse	93.23
	Lafayette	136.43
	Langlade	77.17
	Lincoln	68.88
	Manitowoc	147.13
	Marathon	81.28
	Marinette	84.59
	Marquette	95.57
	Menominee	35.82
	Milwaukee	263.63
	Monroe	89.36
	Oconto	91.21
	Oneida	116.78
	Outagamie	146.92
	Ozaukee	156.29
	Pepin	91.59
	Pierce	110.30
	Polk	79.47
	Portage	91.77
	Price	52.99
	Racine	151.90
	Richland	83.93
	Rock	153.92
	Rusk	56.75
	Sauk	108.18
	Sawyer	63.90
	Shawano	100.13
	Sheboygan	146.12
	St. Croix	117.13
	Taylor	61.00
	Trempealeau	89.12
	Vernon	92.01
	Vilas	149.18
	Walworth	170.96
	Washburn	69.19
	Washington	162.56
	Waukesha	181.93
	Waupaca	107.06
	Waushara	96.40
	Winnebago	117.17
	Wood	87.73
Wyoming	Albany	10.02
	Big Horn	27.22
	Campbell	10.31
	Carbon	10.02
	Converse	6.73
	Crook	15.81
	Fremont	15.50
	Goshen	13.85
	Hot Springs	12.45

State	County	Fee/acre/yr.
	Johnson	10.82
	Laramie	12.81
	Lincoln	32.07
	Natrona	11.11
	Niobrara	9.56
	Park	24.97
	Platte	12.81
	Sheridan	14.68
	Sublette	23.97
	Sweetwater	3.61
	Teton	56.69
	Uinta	13.10
	Washakie	15.81
	Weston	8.33

[FR Doc. 2019–00700 Filed 2–1–19; 8:45 am]
BILLING CODE 6717–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2018–0988]

RIN 1625–AA09

Drawbridge Operation Regulations; Old Fort Bayou, MS

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations; request for comments.

SUMMARY: The Coast Guard is issuing a temporary deviation to the operating schedule that regulates the State Route 609 (SR 609) bascule bridge across the Old Fort Bayou, mile 1.6 at Ocean Springs, Harrison County, Mississippi. This deviation is needed to collect and analyze information on vehicle traffic congestion on SR 609 created when the drawbridge opens to vessel traffic. During this temporary deviation the drawbridge will not open to vessel traffic during specified times.

DATES: This deviation is effective from 6 a.m. February 4, 2019 through 6 p.m. June 4, 2019.

Comments and related material must be received by the Coast Guard on or before June 4, 2019.

ADDRESSES: You may submit comments identified by docket number USCG–2018–0988 using Federal eRulemaking Portal at *http://www.regulations.gov.* See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions about this rulemaking, call or email Mr. Doug Blakemore, Eighth Coast Guard District Bridge Administrator; telephone (504) 671–2128, email *Douglas.A.Blakemore@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
MDOT Mississippi Department of Transportation
NPRM Notice of proposed rulemaking
SR State Route
§ Section
U.S.C. United States Code

I. Background, Purpose, and Legal Basis

The Mississippi Department of Transportation (MDOT) has requested to change the operating requirements for the SR 609 bascule bridge across the Old Fort Bayou, mile 1.6, at Ocean Springs, Harrison County, Mississippi. This bridge currently operates according to 33 CFR 117.681. MDOT provided the Coast Guard with a vehicle traffic study that concluded that vehicle traffic becomes very congested on SR 609 during morning, noon and afternoon rush hours and that bridge openings for vessels adds to the congestion. This MDOT study and analysis is provided in the docket to this temporary rule.

The 120-day temporary deviation to the regulation will allow MDOT to collect additional vehicle traffic data to measure the impact of bridge closures on traffic congestion. It will also allow the Coast Guard to collect data on the impact of the regulation change on vessels.

This bridge has a vertical clearance of 26 feet above mean high water in the closed to vessel position and unlimited vertical clearance in the open to vessel traffic position. From January through December 2017 the bridge opened for vessel traffic 267 times. During this temporary deviation the bridge will operate as follows:

The draw of the SR 609 bascule bridge across the Old Fort Bayou, mile 1.6, Ocean Springs, Harrison County, Mississippi shall open on signal; except the draw need not open 6:30 a.m. to 8 a.m., 10:45 a.m. to 12:30 p.m., and 4 p.m. to 6 p.m. Monday through Friday except Federal holidays. From 9 p.m. to 5 a.m. the draw shall open on signal if at least eight-hours-notice is given. The bridge will open on signal for emergencies.

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.

II. Public Participation and Request for Comments

Public participation is essential to effective rulemaking. The Coast Guard will consider all comments and material received during the comment period. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

We encourage you to submit comments through the Federal eRulemaking Portal at *http://www.regulations.gov.* If your material cannot be submitted using *http://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

We accept anonymous comments. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided. For more about privacy and the docket, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

Documents mentioned in this temporary rule change as being available in this docket and all public comments, will be in our online docket at *http://www.regulations.gov* and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted or a final rule is published.

Dated: January 29, 2019.

Douglas Allen Blakemore, Sr.

Bridge Administrator, Eighth Coast Guard District.

[FR Doc. 2019–00871 Filed 2–1–19; 8:45 am]

BILLING CODE 9110–04–P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Endowment for the Arts

45 CFR Parts 1149 and 1158

RIN 3135–AA33

Civil Penalties Adjustment for 2019

AGENCY: National Endowment for the Arts, National Foundation on the Arts and the Humanities.

ACTION: Final rule.

SUMMARY: The National Endowment for the Arts (NEA) is adjusting the maximum civil monetary penalties (CMPs) that may be imposed for violations of the Program Fraud Civil Remedies Act (PFCRA) and the NEA's Restrictions on Lobbying to reflect the requirements of the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (the 2015 Act). The 2015 Act further amended the Federal Civil Penalties Inflation Adjustment Act of 1990 (the Inflation Adjustment Act) to improve the effectiveness of civil monetary penalties and to maintain their deterrent effect. This final rule provides the 2019 annual inflation adjustments to the initial ''catch-up'' adjustments made on June 15, 2017, and reflects all other inflation adjustments made in the interim.

DATES: *Effective date:* This rule is effective February 4, 2019. *Applicability date:* The adjusted civil monetary penalties established by this rule are applicable only to civil penalties assessed on or after January 15, 2019.

FOR FURTHER INFORMATION CONTACT: Aswathi Zachariah, Assistant General Counsel, National Endowment for the Arts, 400 7th St. SW, Washington, DC 20506, Telephone: 202–682–5418.

SUPPLEMENTARY INFORMATION:

1. Background

On December 12, 2017 the NEA issued a final rule entitled ''Federal Civil Penalties Adjustments'' which finalized the NEA's June 15, 2017 interim final rule entitled ''Implementing the Federal Civil Penalties Adjustment Act Improvements Act'', implementing the 2015 Act (section 701 of Pub. L. 114–74), which amended the Inflation Adjustment Act (28 U.S.C. 2461 note) requiring catch-up and annual adjustments to the NEA's CMPs. The 2015 Act requires agencies make annual adjustments to its CMPs for inflation.

A CMP is defined in the Inflation Adjustment Act as any penalty, fine, or other sanction that is (1) for a specific monetary amount as provided by Federal law, or has a maximum amount provided for by Federal law; (2) assessed or enforced by an agency pursuant to Federal law; and (3) assessed or enforced pursuant to an administrative proceeding or a civil action in the Federal courts.

These annual inflation adjustments are based on the percentage change in the Consumer Price Index for all Urban Consumers (CPI–U) for the month of October preceding the date of the adjustment, relative to the October CPI–U in the year of the previous adjustment. The formula for the amount of a CMP inflation adjustment is prescribed by law, as explained in OMB Memorandum M–16–06 (February 24, 2016), and therefore the amount of the adjustment is not subject to the exercise of discretion by the Chairman of the National Endowment for the Arts (Chairman).

The Office of Management and Budget has issued guidance on implementing and calculating the 2019 adjustment under the 2015 Act.[1] Per this guidance, the CPI–U adjustment multiplier for this annual adjustment is 1.02522. In its prior rules, the NEA identified two CMPs, which require adjustment: The penalty for false statements under the PFCRA and the penalty for violations of the NEA's Restrictions on Lobbying. With this rule, the NEA is adjusting the amount of those CMPs accordingly.

2. Matters Relating to the 2018–2019 Lapse in Appropriations

The 2015 Act requires adjustments to be made no later than January 15 of every year. Such adjustments are made by the agency after OMB issues its guidance delineating the applicable year's CPI–U adjustment multiplier. Beginning at midnight on December 22, 2018, the agency experienced a lapse in appropriations until January 25, 2019. The agency was unable to complete this rule during the period of a lapse in appropriations. Between January 15, 2019 and the date of publication, no CMPs have been assessed that would have been affected by this rule.

3. Dates of Applicability

The inflation adjustments contained in this rule shall apply to any violations assessed after January 15, 2019.

4. Adjustments

Two CMPs in NEA regulations require adjustment in accordance with the 2015 Act: (1) The penalty associated with the Program Fraud Civil Remedies Act (45 CFR 1149.9) and (2) the penalty associated with Restrictions on Lobbying (45 CFR 1158.400; 45 CFR part 1158, app. A).

A. Adjustments to Penalties Under the NEA's Program Fraud Civil Remedies Act Regulations

The current maximum penalty under the PFCRA for false claims and statements is currently set at $11,180. The post-adjustment penalty or range is obtained by multiplying the pre-adjustment penalty or range by the percent change in the CPI–U over the relevant time period and rounding to the nearest dollar. Between October 2017 and October 2018, the CPI–U increased by 102.522 percent. Therefore, the new post-adjustment maximum penalty under the PFCRA for false statements is $11,180 × 1.02522 = $11,461.96 which rounds to $11,462. Therefore, the maximum penalty under the PFCRA for false claims and statements will be $11,462.

B. Adjustments to Penalties Under the NEA's Restrictions on Lobbying Regulations

The penalty for violations of the Restrictions on Lobbying is currently set at a range of a minimum of $19,639 and a maximum of $196,387. The post-adjustment penalty or range is obtained by multiplying the pre-adjustment penalty or range by the percent change in the CPI–U over the relevant time

[1] OMB Memorandum M–19–04 (December 14, 2018).

period and rounding to the nearest dollar. Between October 2017 and October 2018, the CPI–U increased by 102.522 percent. Therefore, the new post-adjustment minimum penalty under the Restrictions on Lobbying is $19,639 × 1.02522 = $20,134.30, which rounds to $20,134, and the maximum penalty under the Restrictions on Lobbying is $196,387 × 1.02522 = $201,339.88, which rounds to $201,340. Therefore, the range of penalties under the law on the Restrictions on Lobbying shall be between $20,134 and $201,340.

Administrative Procedure Act

Section 553 of the Administrative Procedure Act requires agencies to provide an opportunity for notice and comment on rulemaking and also requires agencies to delay a rule's effective date for 30 days following the date of publication in the **Federal Register** unless an agency finds good cause to forgo these requirements. However, section 4(b)(2) of the 2015 Act requires agencies to adjust civil monetary penalties notwithstanding section 553 of the Administrative Procedure Act (APA) and publish annual inflation adjustments in the **Federal Register**. ''This means that the public procedure the APA generally requires . . . is not required for agencies to issue regulations implementing the annual adjustment.'' OMB Memorandum M–18–03.

Even if the 2015 Act did not except this final rule from section 553 of the APA, the NEA has good cause to dispense with notice and comment. Section 553(b)(B), authorizes agencies to dispense with notice and comment procedures for rulemaking if the agency finds good cause that notice and comment are impracticable, unnecessary, or contrary to public interest. The annual adjustments to civil penalties for inflation and the method of calculating those adjustments are established by section 5 of the 2015 Act, as amended, leaving no discretion for the NEA. Accordingly, public comment would be impracticable because the NEA would be unable to consider such comments in the rulemaking process.

Regulatory Planning and Review (Executive Order 12866)

Executive Order 12866 (E.O. 12866) established a process for review of rules by the Office of Information and Regulatory Affairs, which is within the Office of Management and Budget (OMB). Only ''significant'' proposed and final rules are subject to review under this Executive Order. ''Significant,'' as used in E.O. 12866, means ''economically significant.'' It refers to rules with (1) an impact on the economy of $100 million; or that (2) were inconsistent or interfered with an action taken or planned by another agency; (3) materially altered the budgetary impact of entitlements, grants, user fees, or loan programs; or (4) raised novel legal or policy issues.

This final rule would not be a significant policy change and OMB has not reviewed this final rule under E.O. 12866. The NEA has made the assessments required by E.O. 12866 and determined that this final rule: (1) Will not have an effect of $100 million or more on the economy; (2) will not adversely affect in a material way the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities; (3) will not create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (4) does not alter the budgetary effects of entitlements, grants, user fees, or loan programs or the rights or obligations of their recipients; and (5) does not raise novel legal or policy issues.

Reducing Regulation and Controlling Regulatory Costs (Executive Order 13771)

Executive Order 13771 (E.O. 13771) section 5 requires that agencies, in most circumstances, remove or rescind two regulations for every regulatory action (such as the promulgation of regulations) unless they request and are specifically exempted from that order's requirements by the Director of the Office of Management and Budget (the Director).

This final rule is not subject to the requirements of E.O. 13771 because this final rule is not significant under E.O. 12866. Per OMB guidance, annual inflation adjustments ''are not significant regulatory actions under E.O. 12866, they are not considered E.O. 13771 regulatory actions.'' [2] Furthermore, the NEA has requested and has received an exemption from the requirement that the agency rescind two regulations for every regulation it promulgates from the Director.

Federalism (Executive Order 13132)

This final rule does not have federalism implications, as set forth in E.O. 13132. As used in this order, federalism implications mean ''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.'' The NEA has determined that this final rule will not have federalism implications within the meaning of E.O. 13132.

Civil Justice Reform (Executive Order 12988)

This final rule meets the applicable standards set forth in section 3(a) and 3(b)(2) of E.O. 12988. Specifically, this final rule is written in clear language designed to help reduce litigation.

Indian Tribal Governments (Executive Order 13175)

Under the criteria in E.O. 13175, the NEA has evaluated this final rule and determined that it would have no potential effects on federally recognized Indian Tribes.

Takings (Executive Order 12630)

Under the criteria in E.O. 12630, this final rule does not have significant takings implications. Therefore, a takings implication assessment is not required.

Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b))

This final rule will not have a significant adverse impact on a substantial number of small entities, including small businesses, small governmental jurisdictions, or certain small not-for-profit organizations.

Paperwork Reduction Act of 1995 (44 U.S.C., Chapter 35)

This final rule will not impose any ''information collection'' requirements under the Paperwork Reduction Act. Under the act, information collection means the obtaining or disclosure of facts or opinions by or for an agency by 10 or more nonfederal persons.

Unfunded Mandates Act of 1995 (Section 202, Pub. L. 104–4)

This final rule does not contain a Federal mandate that will result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector of $100 million or more in any one year.

National Environmental Policy Act of 1969 (5 U.S.C. 804)

The final rule will not have a significant effect on the human environment.

Small Business Regulatory Enforcement Fairness Act of 1996 (Sec. 804, Pub. L. 104–121)

This final rule would not be a major rule as defined in section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This final rule will

[2] *Id.*

not result in an annual effect on the economy of $100 million or more, a major increase in costs or prices, significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign based companies in domestic and export markets.

E-Government Act of 2002 (44 U.S.C. 3504)

Section 206 of the E-Government Act requires agencies, to the extent practicable, to ensure that all information about that agency required to be published in the **Federal Register** is also published on a publicly accessible website. All information about the NEA required to be published in the **Federal Register** may be accessed at *www.arts.gov.* This Act also requires agencies to accept public comments on their rules ''by electronic means.'' See heading ''Public Participation'' for directions on electronic submission of public comments on this final rule.

Finally, the E-Government Act requires, to the extent practicable, that agencies ensure that a publicly accessible Federal Government website contains electronic dockets for rulemakings under the Administrative Procedure Act of 1946 (5 U.S.C. 551 *et seq.*). Under this Act, an electronic docket consists of all submissions under section 553(c) of title 5, United States Code; and all other materials that by agency rule or practice are included in the rulemaking docket under section 553(c) of title 5, United States Code, whether or not submitted electronically. The website *https://www.regulations.gov* contains electronic dockets for the NEA's rulemakings under the Administrative Procedure Act of 1946.

Plain Writing Act of 2010 (5 U.S.C. 301)

Under this Act, the term ''plain writing'' means writing that is clear, concise, well-organized, and follows other best practices appropriate to the subject or field and intended audience. To ensure that this final rule has been written in plain and clear language so that it can be used and understood by the public, the NEA has modeled the language of this final rule on the Federal Plain Language Guidelines.

Public Participation (Executive Order 13563)

The NEA encourages public participation by ensuring its documentation is understandable by the general public, and has written this final rule in compliance with Executive Order 13563 by ensuring its accessibility, consistency, simplicity of language, and overall comprehensibility.

List of Subjects in 45 CFR Parts 1149 and 1158

Administrative practice and procedure, Government contracts, Grant programs, Loan programs, Lobbying, Penalties.

For the reasons stated in the preamble, the NEA amends 45 CFR chapter XI, subchapter B, as follows:

PART 1149—PROGRAM FRAUD CIVIL REMEDIES ACT REGULATIONS

■ 1. The authority citation for part 1149 continues to read as follows:

Authority: 5 U.S.C. App. 8G(a)(2); 20 U.S.C. 959; 28 U.S.C. 2461 note; 31 U.S.C. 3801–3812.

■ 2. Revise § 1149.9(a)(1) to read as follows:

§ 1149.9 What civil penalties and assessments may I be subjected to?

(a) * * *

(1) A civil penalty of not more than $11,462 for each false, fictitious or fraudulent statement or claim; and

* * * * *

PART 1158—NEW RESTRICTIONS ON LOBBYING

■ 3. The authority citation for part 1158 continues to read as follows:

Authority: 20 U.S.C. 959; 28 U.S.C. 2461; 31 U.S.C. 1352.

§ 1158.400 [Amended]

■ 4. Amend § 1158.400(a), (b), and (e) by:

■ a. Removing ''$19,639'' and adding in its place ''$20,134'' each place it appears.

■ b. Removing ''$196,387'' and adding in its place ''$201,340'' each place it appears.

Appendix A to Part 1158 [Amended]

■ 5. Amend appendix A to part 1158 by:

■ a. Removing ''$19,639'' and adding in its place ''$20,134'' each place it appears.

■ b. Removing ''$196,387'' and adding in its place ''$201,340'' each place it appears.

Dated: January 30, 2019.

Gregory Gendron,

Director of Administrative Services.

[FR Doc. 2019–00843 Filed 2–1–19; 8:45 am]

BILLING CODE P

LEGAL SERVICES CORPORATION

45 CFR Part 1607

Governing Bodies

AGENCY: Legal Services Corporation.

ACTION: Final rule.

SUMMARY: The Legal Services Corporation (LSC) is adopting a final rule amending its regulation related to recipient governing bodies. This final rule changes two requirements and gives increased flexibility to recipient governing bodies in how they recruit, appoint, and retain client-eligible members. First, LSC is revising the definition of the term *eligible client* to remove the requirement that a client-eligible board member be financially eligible at the time of reappointment to a governing body. Second, LSC is eliminating the requirement that client-eligible members be appointed by outside groups. The final rule gives each recipient governing body the discretion to continue applying these provisions if it wishes but eliminates the requirement to do so.

DATES: This final rule is effective on February 4, 2019.

FOR FURTHER INFORMATION CONTACT: Stefanie K. Davis, Assistant General Counsel, Legal Services Corporation, 3333 K Street NW, Washington, DC 20007; (202) 295–1563 (phone), (202) 337–6519 (fax), or *sdavis@lsc.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In December 1977, Congress amended Section 1007(c) of the LSC Act. Public Law 95–222, 91 Stat. 1619. Through the amendment, Congress directed LSC to fund only those organizations whose governing bodies consisted of ''one-third . . . persons who are, when selected, eligible clients who may also be representatives of associations or organizations of eligible clients.'' 91 Stat. at 1622. LSC published a notice of proposed rulemaking (NPRM) to implement the new requirement in May 1978. In that NPRM, LSC proposed to define ''eligible client'' as an ''individual eligible to receive legal assistance under the LSC Act.'' 43 FR 21902, May 22, 1978. The proposed definition narrowed the LSC Act's definition of the term ''[e]ligible client,'' which the Act defines as ''any person financially unable to afford legal assistance.'' Sec. 1002(3), Public Law 88–452, title X; 42 U.S.C. 2996a(3). LSC also proposed to adopt a requirement that eligible client members ''be selected from, or designated by, a variety of appropriate groups including, but not

limited to, client and neighborhood associations and organizations.'' *Id.* This language reflected LSC's ''attempt to insure that programs will be accountable to the communities that they serve.'' On July 28, 1978, LSC adopted the proposed rule without change. 43 FR 32772, July 28, 1978.

The provisions governing the appointment of client-eligible members to recipient governing bodies remained unchanged for 16 years. In 1994, LSC proposed to revise Part 1607 in two relevant ways. First, LSC proposed to amend the regulation to reflect its interpretation of the statutory language requiring one-third of a recipient governing body's members to be ''persons who are, when selected, eligible clients'':

> [T]he language has been revised to make it clear that client board members must be eligible at the time of their appointment to each term of office. Thus, a client member who is financially eligible for services when first appointed to a recipient's board may not be reappointed to a second or subsequent term if, at the time of reappointment, the client board member is no longer financially eligible for LSC-funded services.

59 FR 30885, 30886, June 16, 1994. The second proposed revision ''would codify the current LSC interpretation of the language to require that client board members be selected by client groups that have been designated by the recipient.'' *Id.* at 30886–87.

In a final rule published on December 19, 1994, LSC adopted both proposed changes. LSC revised the proposed definition of ''eligible client'' to clarify that the member had to be financially eligible ''to receive legal assistance under the Act and part 1611'' of LSC's regulations. 59 FR 65249–50, Dec. 19, 1994. In so doing, LSC rejected comments recommending that LSC expand the definition to include individuals whose income exceeds LSC's financial eligibility limit, but who are eligible to receive non-LSC-funded legal assistance from a recipient. LSC limited the definition to individuals who were financially eligible for LSC-funded legal assistance because it ''wished to insure that the focus of the legal services program remains on the indigent population.'' *Id.* at 65250. As it did in 1978, LSC adopted a narrower definition of the term ''eligible client'' than the one provided in Section 1002 of the LSC Act.

With respect to LSC's proposal to require that client-eligible members be appointed by organizations or associations, LSC received comments both in support of and opposing the requirement. In the preamble to the final rule, LSC explained that favorable comments ''supported the clarification and the policy choice that it represented.'' *Id.* at 65251. LSC provided more detailed explanations of the comments in opposition. One basis for opposition was the difficulty or inability for some recipients to comply with the requirement because ''often there are no organized client groups within the service area and, even when there are, it is not necessarily true that client groups speak for the client community.'' *Id.* at 65251. The other was that ''recipients often come into contact with program clients or other financially eligible individuals who would make good client board members but who, for one reason or another, are not involved with any client group.'' *Id.* LSC adopted the language from the NPRM without change.

In 2015, LSC Board Member Julie Reiskin provided Management with a memorandum detailing concerns clients had expressed to her. The primary concerns were that some client governing body members were not truly representative of the population eligible for LSC-funded legal services and that the rule required more than Section 1007(c) of the LSC Act, which states that client-eligible members (1) must be eligible when selected, and (2) may be representatives of associations or organizations of eligible clients. 42 U.S.C. 2996f(c). Following up on this memorandum, in 2017, the Office of Legal Affairs (OLA) participated in Board Member Reiskin's and President Sandman's client-listening session at the National Legal Aid and Defender Association's (NLADA) annual conference. Recipients and their clients communicated that the two provisions discussed above present obstacles to recruiting and retaining qualified client-eligible members.

LSC added rulemaking on part 1607 to its annual rulemaking agenda in April 2017. On April 8, 2018, the Operations and Regulations Committee (''Committee'') of the Board voted to recommend that the Board authorize rulemaking on part 1607. The Board voted to authorize rulemaking on April 10, 2018. On July 25, 2018, the Committee voted to recommend that the Board approve publication of an NPRM in the **Federal Register** for public comment. On July 26, 2018, the Board accepted the Committee's recommendation and voted to approve publication of the NPRM. LSC published the NPRM in the **Federal Register** on August 6, 2018. 83 FR 38270, Aug. 6, 2018. The comment period remained open for sixty days and closed on October 5, 2018.

On January 17, 2019, the Committee voted to recommend that the Board adopt this final rule and approve its publication in the **Federal Register**. On January 18, 2019, the Board voted to adopt and publish this final rule.

Materials regarding this rulemaking are available in the open rulemaking section of LSC's website at *http://www.lsc.gov/about-lsc/laws-regulations-guidance/rulemaking.* After the effective date of the rule, those materials will appear in the closed rulemaking section at *http://www.lsc.gov/about-lsc/laws-regulations-guidance/rulemaking/closed-rulemaking.*

II. Section-by-Section Discussion of Proposed Changes and Comments

LSC received 91 timely comments during the public comment period—74 from individual client-eligible board members of recipients; 5 from other individual recipient non-client board members; 4 from LSC recipients' executive directors; 2 from entire recipient boards of directors; and 6 from others, including NLADA. An overwhelming majority of the comments favored the proposed changes.

§ 1607.1 Purpose

LSC proposed no changes to this section. LSC received no comments on this section.

§ 1607.2 Definitions

LSC proposed to remove the requirement that a board member be financially eligible ''at the time of appointment to each term of office to the recipient's governing body.'' This change will allow, but not require, recipient governing bodies to permit client-eligible members who improve their financial position to serve consecutive terms on a recipient's governing body.

LSC received 91 comments on the proposed change to this section. Seventy-six commenters agreed with the change, 10 commenters disagreed with the change, and 5 commenters discussed the change but did not express overall support or disagreement.

Comments: Executive directors, client-eligible board members, other individual board members of recipients, and entire recipient boards of directors who favored the change described how difficult the eligibility requirement makes it for recipient boards to recruit and retain quality board members. One executive director stressed that this is particularly true for recipients located in rural areas. Of recruiting, a client-eligible board member commented that recipient boards struggle to find client-eligible community members to serve

because it costs money to get to meetings and events, when ''this money could be spent on bread and milk.'' In discussing the difficulties of retention, an executive director described losing an impressive client-eligible board member who had represented a large rural area and was an active committee member because ''[h]er job promotion at a nonprofit serving homeless individuals disqualified her for continued service on the board.'' A second executive director wrote:

> [G]iven the complexity of LSC restrictions and the responsibilities of a Board for nonprofit management, new income eligible clients and lawyers alike, face a steep learning curve. Allowing for continued participation on the Board by formerly income eligible clients will allow them to learn and provide increasingly important support to their programs.

A client-eligible board member explained that good client-eligible representatives ''share information with and connect people to Legal Aid for help who otherwise would not have known what to do'' and argued that good representatives should ''get to stay on the board, regardless of income, as long as the person has lived in poverty.''

NLADA summarized the sentiments expressed in many client-eligible board member comments about the enduring experience of poverty: ''Many client-eligible board members feel that an improvement in their financial situation does not erase their understanding of what it means to live in poverty or their connections to the communities in which they have always lived.'' Client-eligible board members and many other stakeholders expressed the perversity of ''forcing out'' a client-eligible board member for improving their financial circumstance. One client-board member wrote that graduation from eligible to non-eligible financial status should be celebrated rather than punished. Another commented that the requirement makes clients feel as though making financial gain is wrong. A third stated that client members ''should not be penalized for trying to improve their life'' or better their ''financial health.''

Moreover, commenters emphasized that client-eligible board members' financial improvements are often modest. An administrative assistant employed by a recipient explained that

> [i]f a single client board member's monthly income rises to $1,400, they are technically no longer client-eligible, but that extra $135 is not going to change much of anything. They still would not be able to afford a private attorney. They are still going to be in the same situation[.]

Just one client-eligible board member expressed the contrary sentiment that only a person currently living in poverty ''can understand, explain, and propose ways to overcome issues'' facing low-income individuals.

Client-eligible board members, executive directors, and entire recipient boards of directors alike approved of increasing the flexibility for recipient governing boards to decide whether to appoint a client-eligible board member to an additional term without reassessing the member's financial eligibility. A recipient commented that ''such a decision should be made with no bias as to income.'' Another wrote, ''we would be troubled to lose such a member for a second term solely based on improved financial circumstances.'' In describing the importance of increased flexibility, an executive director wrote about his current board chairperson—a client-eligible board member—stating that management and other board members encouraged and supported the board chairperson in earning a higher education degree, which will likely lead to increased income. The executive director commented how unfortunate it would be if this member's success resulted in ineligibility to continue serving on the board.

Of the ten commenters opposed to the change, all were client-eligible board members. Three thought the proposed change limited the number of opportunities for other client-eligible members of the community to serve on boards. One stressed that LSC's focus should be to ensure clients are ''represented well'' on grantee boards and argued that the proposed change supported a recent phenomenon of client voices being pushed out of board discussions. A second wrote that ''people of privilege in positions of relative power without oversight would be emboldened to exclude client board members'' and that ''the LSC program and community program should'' jointly decide whether to retain ''members who improve their financial situation[s].'' A third expressed concern that ''[i]f a board member does not qualify for services, the board member cannot give first-hand input'' on ''whether their Legal Aid programs' system is working or needs to be changed.''

NLADA and a few client-eligible board members expressed concern about how many consecutive terms a client-eligible board member may serve once they are no longer financially eligible. Those who expressed this concern still supported the rule as written—to give discretion to grantees to decide when reappointment is appropriate.

Response: LSC adopts the proposed rule as final without changes. More than 83 percent of commenters favored applying the financial eligibility requirement for client-eligible board members to the initial appointment only, and not to subsequent, consecutive terms. LSC carefully considered the concerns submitted by the commenters who opposed the change. But the totality of the comments support LSC's conclusion that providing recipients with increased flexibility to retain high-quality client-eligible members—regardless of income—for additional consecutive terms is more likely to result in good representation of and for the client community than the current version of the rule. The rule is also consistent with the statutory language of Section 1007(c) of the LSC Act that ''at least one-third of [the recipient's governing body] consists of persons who are, when selected, eligible clients . . . .'' Where the current requirement of demonstrating financial eligibility at the time of appointment to each term of office has worked well for a recipient, the final rule allows the recipient to continue applying that requirement. On the other hand, the rule permits the recipient to reappoint a client-eligible board member to a successive term even if their income exceeds the financial eligibility income limit.

§ 1607.3 Composition

LSC proposed to eliminate the § 1607.3(c) requirement that client-eligible members be appointed by groups. The final rule will require recipients to ''solicit recommendations from groups in a manner that reflects, to the extent possible, the variety of interests within the client community . . . .''

LSC received 91 comments on the proposed change to this section. Eighty-one commenters agreed with the change, 5 commenters disagreed with the change, and 5 commenters wrote about the change but did not express overall support or disagreement.

Comments: Many commenters who favored the change approved giving recipient governing bodies the flexibility to ''recruit and keep the absolute best and most qualified client-eligible board members'' in the way that each body sees fit. An administrative assistant working for a recipient described the current procedure:

> From an administrative perspective, it has been extremely difficult getting organizations to refer clients for our board. The last three referrals we received were willing and

otherwise suitable, but over-income. And many organizations put-off or have ignored our requests altogether because it is time-consuming. Our client board member turnover rate has been high and participation low because many organization referrals have been forced, and/or not well-considered.

A board described a conflict it routinely experiences—that ''[t]he appointing organizations themselves are often in search of well qualified members of their own constituencies to serve on their boards.'' Moreover, a client-eligible board member, other board member, executive director, and NLADA each wrote that for rural programs, meeting this requirement is particularly difficult— ''nearly impossible.''

All types of stakeholders commented that many client-eligible community members are interested in serving on boards. One executive director described meeting clients and client-eligible community members who expressed their interest in board service but explained that the current appointment procedure stands in the way: ''[W]e must then work to identify a potential sponsoring organization in their own community, with mixed success[. W]e have lost strong contributors to the Board because of our inability to achieve a match, given the limited staff time and resources that can be devoted to this requirement.'' NLADA thinks the proposed rule will solve this problem:

Grantees may still use the procedure required by the existing 1607.3(c). They would, however, also be free to adopt their own unique appointment procedures to best help them find, recruit, and appoint client-eligible board members. [T]he goal of these procedures would still be to appoint client-eligible board members that reasonably reflect the diversity of the client population in their service area.

NLADA favors the change.

Of the five commenters opposed to the change, all were client-eligible board members. In discussing board member and client-board member dynamics, a commenter explained that client-eligible board members rely on appointing organizations to ensure their concerns are heard by the attorney board members. For recipients who do not have a community program to appoint board members, the commenter proposed that ''client members from adjacent communities be nominated and allowed to attend.'' A second stressed that the change would result in tribal organizations going unrepresented on boards: ''[B]oard members selected by regional agencies to serve on the legal services board represent multiple chapter houses. These . . . chapter houses are communities that are heard and present solutions to [tribal leadership]. There is no cultural sensitivity in this matter from Anglo board members.'' A third wrote that if the change was implemented, ''community organizations should have the first opportunity to fill the position'' before recipients.

Response: LSC adopts the proposed rule as final without changes. More than 89 percent of comments favored eliminating the requirement that client-eligible board members be appointed by groups. Based on the substance of the comments, LSC concludes that the benefits to recipients that are likely to flow from their governing boards' increased flexibility to recruit and appoint client eligible members—as described by executive director, client-eligible board members, and other board members—outweigh the potential harms described. Also, unlike the requirement that the majority of attorney members of recipient governing bodies be appointed by state, county, or local bar associations, LSC's governing statutes do not require client-eligible members to be appointed by groups.

Where the current procedure of having outside organizations appoint client-eligible board members works well for a recipient, the final rule allows the recipient to continue using the procedure. Where the current procedure does not work well, LSC intends that this change makes it easier for recipients to recruit and appoint client-eligible board members. This final rule gives the recipient governing body the authority and flexibility to implement an appointment procedure that takes its local circumstances into account.

§ 1607.4 Functions of a Governing Body

LSC proposed no changes to this section. LSC received no comments on this section.

§ 1607.5 Compensation

LSC proposed no changes to this section. LSC received no comments on this section.

§ 1607.6 Waiver

LSC proposed no changes to this section. LSC received no comments on this section.

List of Subjects in 45 CFR Part 1607

Grant program—law, Legal services.

For the reasons discussed in the preamble, the Legal Services Corporation amends 42 CFR part 1607 as follows:

PART 1607—GOVERNING BODIES

■ 1. The authority citation for part 1607 is revised to read as follows:

Authority: 42 U.S.C. 2996g(e).

■ 2. Amend § 1607.2 by revising paragraph (c) to read as follows.

§ 1607.2 Definitions.

* * * * *

(c) *Eligible client member* means a board member who is financially eligible to receive legal assistance under the Act and part 1611 of this chapter, without regard to whether the person actually has received or is receiving legal assistance at that time. Eligibility of client members must be determined by the recipient or, if the recipient so chooses, by the nominating organization(s) or group(s) in accordance with written policies adopted by the recipient

* * * * *

■ 3. Amend § 1607.3 by revising paragraph (c) to read as follows:

§ 1607.3 Composition.

* * * * *

(c) At least one-third of the members of a recipient's governing body must be eligible client members when initially appointed by the recipient. The recipient must solicit recommendations for eligible client members from a variety of appropriate groups designated by the recipient that may include, but are not limited to, client and neighborhood associations and community-based organizations that advocate for or deliver services or resources to the client community served by the recipient. Recipients should solicit recommendations from groups in a manner that reflects, to the extent possible, the variety of interests within the client community, and eligible client members should be selected so that they reasonably reflect the diversity of the eligible client population served by the recipient, including race, gender, ethnicity and other similar factors.

* * * * *

Dated: January 30, 2019.

Stefanie Davis,

Assistant General Counsel.

[FR Doc. 2019–00896 Filed 2–1–19; 8:45 am]

BILLING CODE 7050–01–P

LEGAL SERVICES CORPORATION

45 CFR Part 1611

Income Level for Individuals Eligible for Assistance

AGENCY: Legal Services Corporation.

ACTION: Final rule.

SUMMARY: The Legal Services Corporation (LSC) is required by law to establish maximum income levels for individuals eligible for legal assistance. This document updates the specified income levels to reflect the annual amendments to the Federal Poverty Guidelines issued by the U. S. Department of Health and Human Services (HHS).

DATES: Effective February 4, 2019.

FOR FURTHER INFORMATION CONTACT: Stefanie K. Davis, Assistant General Counsel, Legal Services Corporation, 3333 K St. NW, Washington, DC 20007; (202) 295–1563; *sdavis@lsc.gov.*

SUPPLEMENTARY INFORMATION: Section 1007(a)(2) of the Legal Services Corporation Act (Act), 42 U.S.C. 2996f(a)(2), requires LSC to establish maximum income levels for individuals eligible for legal assistance. Section 1611.3(c) of LSC's regulations establishes a maximum income level equivalent to 125% of the Federal Poverty Guidelines (Guidelines), which HHS is responsible for updating and issuing. 45 CFR 1611.3(c).

Each year, LSC updates appendix A to 45 CFR part 1611 to provide client income eligibility standards based on the most recent Guidelines. The figures for 2019, set out below, are equivalent to 125% of the Guidelines published by HHS on January 11, 2019.

In addition, LSC is publishing a chart listing income levels that are 200% of the Guidelines. This chart is for reference purposes only as an aid to recipients in assessing the financial eligibility of an applicant whose income is greater than 125% of the applicable Guidelines amount, but less than 200% of the applicable Guidelines amount (and who may be found to be financially eligible under duly adopted exceptions to the annual income ceiling in accordance with 45 CFR 1611.3, 1611.4, and 1611.5).

Except where there are minor variances due to rounding, the amount by which the guideline increases for each additional member of the household is a consistent amount.

List of Subjects in 45 CFR Part 1611

Grant programs—law, Legal services.

For reasons set forth in the preamble, the Legal Services Corporation amends 45 CFR part 1611 as follows:

PART 1611—FINANCIAL ELIGIBILITY

■ 1. The authority citation for part 1611 continues to read as follows:

Authority: 42 U.S.C. 2996g(e).

■ 2. Revise appendix A to part 1611 to read as follows:

Appendix A to Part 1611—Income Level for Individuals Eligible for Assistance

LEGAL SERVICES CORPORATION 2019 INCOME GUIDELINES *

Size of household	48 Contiguous States and the District of Columbia	Alaska	Hawaii
1	$15,613	$19,500	$17,975
2	21,138	26,413	24,325
3	26,663	33,325	30,675
4	32,188	40,238	37,025
5	37,713	47,150	43,375
6	43,238	54,063	49,725
7	48,763	60,975	56,075
8	54,288	67,888	62,425
For each additional member of the household in excess of 8, add:	5,525	6,913	6,350

* The figures in this table represent 125% of the Federal Poverty Guidelines by household size as determined by HHS.

REFERENCE CHART—200% OF FEDERAL POVERTY GUIDELINES *

Size of household	48 Contiguous States and the District of Columbia	Alaska	Hawaii
1	$24,980	$31,200	$28,760
2	33,820	42,260	38,920
3	42,660	53,320	49,080
4	51,500	64,380	59,240
5	60,340	75,440	69,400
6	69,180	86,500	79,560
7	78,020	97,560	89,720
8	86,860	108,620	99,880
For each additional member of the household in excess of 8, add:	8,840	11,060	10,160

* The figures in this table represent 200% of the Federal Poverty Guidelines by household size as determined by HHS.

Dated: January 30, 2019.

Stefanie Davis,

Assistant General Counsel.

[FR Doc. 2019–00889 Filed 2–1–19; 8:45 am]

BILLING CODE 7050–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 64

[CG Docket Nos. 13–24 and 03–123; FCC 18–79]

IP CTS Modernization and Reform

AGENCY: Federal Communications Commission.

ACTION: Final rule; announcement of effective date.

SUMMARY: In this document, the Commission announces that the Office of Management and Budget (OMB) has approved, for a period of three years, the information collection associated with rules adopted in the Commission's document *Misuse of internet Protocol (IP) Captioned Telephone Service et al.* Report and Order and Declaratory Ruling (*Order*). This document is consistent with the *Order,* which stated that the Commission would publish a document in the **Federal Register** announcing the effective date of those rules.

DATES: § 64.604(c)(5)(iii)(D)(*1*), (*6*) published at 83 FR 30082, June 27, 2018, is effective February 4, 2019.

FOR FURTHER INFORMATION CONTACT: Eliot Greenwald, Disability Rights Office, Consumer and Governmental Affairs Bureau, at (202) 418–2235, or email: *Eliot.Greenwald@fcc.gov.*

SUPPLEMENTARY INFORMATION: This document announces that, on December 19, 2018, OMB approved, for a period of three years, the information collection requirements contained in the Commission's *Order,* FCC 18–79, published at 83 FR 30082, June 27, 2018. The OMB Control Number is 3060–0463. The Commission publishes this notice as an announcement of the effective date of the rules. If you have any comments on the burden estimates listed below, or how the Commission can improve the collections and reduce any burdens caused thereby, please contact Cathy Williams, Federal Communications Commission, Room 1–C823, 445 12th Street SW, Washington, DC 20554. Please include the OMB Control Number, 3060–0463, in your correspondence. The Commission will also accept your comments via the internet if you send them to *PRA@fcc.gov.*

To request materials in accessible formats for people with disabilities (Braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice) or (202) 418–0432 (TTY).

SYNOPSIS

As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), the FCC is notifying the public that it received OMB approval on December 19, 2018, for the information collection requirements contained in the Commission's rules at § 64.604(c)(5)(iii)(D)(*1*), (*6*).

Under 5 CFR 1320, an agency may not conduct or sponsor a collection of information unless it displays a current, valid OMB Control Number.

No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act that does not display a current, valid OMB Control Number. The OMB Control Number is 3060–0463.

The foregoing notice is required by the Paperwork Reduction Act of 1995, Public Law 104–13, October 1, 1995, and 44 U.S.C. 3507.

The total annual reporting burdens and costs for the respondents are as follows:

OMB Control Number: 3060–0463.

OMB Approval Date: December 19, 2018.

OMB Expiration Date: December 31, 2021.

Title: Telecommunications Relay Services and Speech-to-Speech Services for Individuals with Hearing and Speech Disabilities, CG Docket No. 03–123.

Form Number: N/A.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit; Individuals or household; State, Local and Tribal Government.

Number of Respondents and Responses: 5,072 respondents; 7,314 responses.

Estimated Time per Response: 0.5 hours (30 minutes) to 80 hours.

Frequency of Response: Annually, monthly, on occasion, and one-time reporting requirements; Recordkeeping and Third-Party Disclosure requirements.

Obligation to Respond: Required to obtain or retain benefit. The statutory authority for the information collection requirements is found at section 225 of the Communications Act, 47 U.S.C. 225. The law was enacted on July 26, 1990, as Title IV of the ADA, Public Law 101–336, 104 Stat. 327, 366–69.

Total Annual Burden: 12,342 hours.

Total Annual Cost: $10,800.

Nature and Extent of Confidentiality: Confidentiality is an issue to the extent that individuals and households provide personally identifiable information, which is covered under the FCC's updated system of records notice (SORN), FCC/CGB–1, ''Informal Complaints, Inquiries, and Requests for Dispute Assistance.'' As required by the Privacy Act, 5 U.S.C. 552a, the Commission also published a SORN, FCC/CGB–1 ''Informal Complaints, Inquiries, and Requests for Dispute Assistance,'' in the **Federal Register** on August 15, 2014 (79 FR 48152) which became effective on September 24, 2014.

Privacy Impact Assessment: The FCC completed a Privacy Impact Assessment (PIA) on June 28, 2007. It may be reviewed at *https://www.fcc.gov/general/privacy-act-information#pia.* The Commission is in the process of updating the PIA to incorporate various revisions to it as a result of revisions to the SORN.

Needs and Uses: On December 21, 2001, the Commission released the 2001 TRS Cost Recovery Order, document FCC 01–371, published at 67 FR 4203, January 29, 2002, in which the Commission:

(1) Directed the Interstate Telecommunications Relay Services (TRS) Fund (TRS Fund) administrator to continue to use the average cost per minute compensation methodology for the traditional TRS compensation rate;

(2) required TRS providers to submit certain projected TRS-related cost and demand data to the TRS Fund administrator to be used to calculate the rate; and

(3) directed the TRS Fund administrator to expand its form for providers to itemize their actual and projected costs and demand data, and to include specific sections to capture speech-to-speech (STS) and video relay service (VRS) costs and minutes of use.

In 2003, the Commission released the 2003 Second Improved TRS Order, published at 68 FR 50973, August 25, 2003, which among other things required that TRS providers offer certain local exchange carrier (LEC)-based improved services and features where technologically feasible, including a speed dialing requirement which may entail voluntary recordkeeping for TRS providers to maintain a list of telephone numbers. See also 47 CFR 64.604(a)(3)(vi)(B).

In 2007, the Commission released the Section 225/255 VoIP Report and Order, published at 72 FR 43546, August 6, 2007, extending the disability access requirements that apply to

telecommunications service providers and equipment manufacturers under 47 U.S.C. 225, 255 to interconnected voice over internet protocol (VoIP) service providers and equipment manufacturers. As a result, under rules implementing section 225 of the Act, interconnected VoIP service providers are required to publicize information about telecommunications relay services (TRS) and 711 abbreviated dialing access to TRS. See also 47 CFR 64.604(c)(3).

In 2007, the Commission also released the 2007 Cost Recovery Report and Order and Declaratory Ruling, published at 73 FR 3197, January 17, 2008, in which the Commission:

(1) Adopted a new cost recovery methodology for interstate traditional TRS and interstate STS based on the Multi-state Average Rate Structure (MARS) plan, under which interstate TRS compensation rates are determined by weighted average of the states' intrastate compensation rates, and which includes for STS additional compensation approved by the Commission for STS outreach;

(2) requires STS providers to file a report annually with the TRS Fund administrator and the Commission on their specific outreach efforts directly attributable to the additional compensation approved by the Commission for STS outreach.

(3) adopted a new cost recovery methodology for interstate captioned telephone service (CTS), as well as internet Protocol captioned telephone service (IP CTS), based on the MARS plan;

(4) adopted a cost recovery methodology for internet Protocol (IP) Relay based on price caps;

(5) adopted a cost recovery methodology for VRS that adopted tiered rates based on call volume;

(6) clarified the nature and extent that certain categories of costs are compensable from the Fund; and

(7) addressed certain issues concerning the management and oversight of the Fund, including prohibiting financial incentives offered to consumers to make relay calls.

In 2018, the Commission released the IP CTS Modernization Order, published at 83 FR 30082, June 27, 2018, in which the Commission:

(1) Determined that it would transition the methodology for IP CTS cost recovery from the MARS plan to cost-based rates and adopted interim rates; and

(2) added two cost reporting requirements for IP CTS providers: (i) In annual cost data filings and supplementary information provided to the TRS Fund administrator, IP CTS providers that contract for the supply of services used in the provision of TRS, shall include information about payments under such contracts, classified according to the substantive cost categories specified by the TRS Fund administrator; and (ii) in the course of an audit or otherwise upon demand, IP CTS providers must make available any relevant documentation. 47 CFR 64.604(c)(5)(iii)(D)(*1*), (*6*).

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2019–00967 Filed 2–1–19; 8:45 am]

BILLING CODE 6712–01–P

GENERAL SERVICES ADMINISTRATION

48 CFR Parts 501, 519, and 552

[GSAR Change 97; GSAR Case 2017–G502; Docket No. GSA–GSAR–2018–0015; Sequence No. 1]

RIN 3090–AJ86

General Services Administration Acquisition Regulation (GSAR); Transition to SBA Mentor-Protégé Program

AGENCY: Office of Acquisition Policy, General Services Administration.

ACTION: Direct final rule.

SUMMARY: This direct final rule amends the General Services Administration Acquisition Regulation (GSAR) to remove the GSAR subpart GSA Mentor-Protégé Program and associated clauses that are duplicative of the Small Business Administration (SBA) governmentwide Mentor-Protégé program, and to remove several subcontracting provisions that are duplicative of the requirements in the Federal Acquisition Regulation (FAR) clause pertaining to the Small Business Subcontracting Plan.

DATES: This final rule is effective on April 3, 2019 without further notice unless adverse comments are received by March 3, 2019. If GSA receives adverse comments, we will publish a timely withdrawal in the **Federal Register** informing the public that the rule will not take effect.

ADDRESSES: Submit comments identified by GSAR Case 2017, G502, Transition to SBA Mentor-Protégé Program, by any one of the following methods:

- *Regulations.gov: http://www.regulations.gov.* Submit comments via the Federal eRulemaking portal by searching for ''GSAR Case 2017–G502''. Select the link ''Comment Now'' that corresponds with ''GSAR Case 2017–G502.'' Follow the instructions provided on the screen. Please include your name, company name (if any), and ''GSAR Case 2017–G502'' on your attached document.
- *Mail:* General Services Administration, Regulatory Secretariat Division (MVCB), ATTN: Lois Mandell, 1800 F Street NW, 2nd Floor, Washington, DC 20405.

Instructions: Please submit comments only and cite ''GSAR Case 2017–G502'' in all correspondence related to this case. All comments received will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check *https://www.regulations.gov,* approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Ms. Dana Bowman, Procurement Analyst, at 202–357–9652, for clarification of content. For information pertaining to status or publication schedules, contact the Regulatory Secretariat Division at 202–501–4755. Please cite GSAR Case 2017–G502, Transition to SBA Mentor-Protégé Program.

SUPPLEMENTARY INFORMATION:

I. Background

On August 24, 2016, the SBA published a final rule, Small Business Mentor-Protégé Programs, in the **Federal Register** at 81 FR 48557 to implement provisions of the Small Business Jobs Act of 2010, and the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2013. Based on authorities provided in these two statutes, the rule established a governmentwide mentor-protégé program for all small business concerns. Section 1641, of the NDAA FY 2013, provided that a Federal department or agency cannot carry out its own agency specific mentor-protégé program for small businesses unless the head of the department or agency submitted a plan for such a program to SBA and received the SBA Administrator's approval of the plan. Since the SBA final rule was published, GSA has focused on supporting existing mentor-protégé agreements but has not administered new mentor-protégé agreements. GSA is amending the GSAR to repeal the regulations implementing the GSA Mentor-Protégé Program and transition contractors to the governmentwide mentor-protégé

program to comply with the SBA final rule. GSA will reduce redundancy and gain efficiencies by using SBA's governmentwide mentor-protégé program.

Upon review of GSA's subcontracting requirements as part of regulatory reform efforts, it was determined that three subcontracting provisions were not necessary as they are duplicative of FAR requirements. GSAR provision 552.219–71, Notice to Offerors of Subcontracting Plan Requirements, requires any subcontracting plan submitted pursuant to FAR 52.219–9 to reflect a commitment to ensuring the maximum practicable opportunity to small business concerns. GSAR provision 552.219–72, Preparation, Submission, and Negotiation of Subcontracting Plans, requires an offeror that is submitting a subcontracting plan in accordance with FAR 52.219–9 to submit the subcontracting plan with the initial offer. This provision also provides guidance on the elements expected in a subcontracting plan. GSAR provision 552.219–73, Goals for Subcontracting Plans, provides guidance on the expected goals for any subcontracting plan submitted pursuant to FAR 52.219–9. GSA is repealing GSAR provisions 552.219–71, 552.219–72, and 552.219–73 as the requirements of these provisions duplicate the requirements in FAR clause 52.219–9, Small Business Subcontracting Plan. By repealing these provisions, GSA will gain administrative efficiencies by reducing duplication.

II. General Information

This direct final rule makes the following changes to the GSAR: (1) Removes subpart 519.70, GSA Mentor-Protégé Program and associated clauses: 552.219–75, *GSA Mentor-Protégé Program,* and 552.219–76, *Mentor Requirements and Evaluation,* and, (2) removes section 519.708, Contract Clauses and associated provisions: 552.219–71, *Notice to Offerors of Subcontracting Plan Requirements,* 552.219–72, *Preparation, Submission, and Negotiation of Subcontracting Plans,* and 552.219–73, *Goals for Subcontracting Plans.* This final rule also updates the table in part 501 to remove the outdated OMB control numbers. GSA is publishing this rule without a prior proposed rule because we view this as a noncontroversial action and anticipate no adverse comment. If GSA receives adverse comment, we will publish a timely withdrawal in the **Federal Register** informing the public that the rule will not take effect. Any parties interested in commenting must do so at this time.

III. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

IV. Executive Order 13771

This final rule is not subject to E.O. 13771, because this rule is not a significant regulatory action under E.O. 12866.

V. Regulatory Flexibility Act

GSA does not expect this direct final rule to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.,* because this rule removes certain GSAR provisions and clauses from the GSAM to comply with FAR 1.104 and statutory amendments in Section 1641 of NDAA FY 2013. GSA will use SBA's governmentwide mentor-protégé program instead of managing its own program. Additionally, this rule does not impose requirements involving capital investment, implementing procedures, or record keeping.

VI. Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C. chapter 35) does apply. These changes to the GSAR remove the GSA information collection requirements previously approved under the OMB Control Numbers 3090–0286 *GSA Mentor-Protégé Program* and 3090–0252 *Preparation, Submission and Negotiation of Subcontracting Plans.* GSA will submit to OMB a request to repeal the information collection requirements. For a copy of the information collection documents, contact the Regulatory Secretariat Division by mail at 1800 F Street NW, Washington, DC 20405, or by phone at 202–501–4755. Please cite the GSAR Case 2017–G502, Transition to SBA Mentor-Protégé Program.

List of Subjects in 48 CFR Parts 501, 519, and 552.

Government procurement.

Dated: January 30, 2019.

Jeffrey A. Koses,

Senior Procurement Executive, Office of Acquisition Policy, Office of Government-wide Policy, General Services Administration.

Therefore, GSA amends 48 CFR parts 501, 519, and 552 as set forth below:

■ 1. The authority citation for 48 CFR parts 501, 519 and 552 continues to read as follows:

Authority: 40 U.S.C. 121(c).

PART 501—GENERAL SERVICES ADMINISTRATION ACQUISITION REGULATION SYSTEM

501.106 [Amended]

■ 2. Amend section 501.106 in the table by removing GSAR references ''519.708(b)'', ''519.70'', ''552.219–72'', ''552.219–75'', and ''552.219–76'', and their corresponding OMB control numbers ''3090–0252'', ''3090–0286'', ''3090–0252'', ''3090–0286'', and ''3090–0286'', respectively.

PART 519—SMALL BUSINESS PROGRAMS

519.708 [Removed]

■ 3. Remove section 519.708.

Subpart 519.70 [Removed]

■ 4. Remove subpart 519.70.

PART 552—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

552.219–71 through 552.219–73 [Removed]

■ 5. Remove sections 552.219–71 through 552.219–73.

552.219–75 and 552.219–76 [Removed]

■ 6. Remove sections 552.219–75 and 552.219–76.

[FR Doc. 2019–00882 Filed 2–1–19; 8:45 am]

BILLING CODE 6820–61–P

Proposed Rules

Federal Register

Vol. 84, No. 23

Monday, February 4, 2019

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 Parts 141 and 385

[Docket No. RM19–12–000]

Revisions to the Filing Process for Commission Forms

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Commission is proposing to transition from the current use of the Visual FoxPro software, which is no longer supported by its developer, to a type of Extensible Markup Language (XML) called eXtensible Business Reporting Language (XBRL). The XBRL standard would be used to file the Commission's Form Nos. 1, 1–F, 2, 2–A, 3–Q electric, 3–Q natural gas, 6, 6–Q, 60, and 714. The use of XBRL should make the information in these forms easier for filers and data users to analyze and assist in automating regulatory filings and business information processing. In addition, the Commission believes that transitioning from the current Visual FoxPro system to XBRL will decrease the costs, over time, of preparing the necessary data for submission and complying with future changes to filing requirements set forth by the Commission. The Commission is also proposing to revise its regulations to require filers of Form No. 1–F to file their report in electronic media.

DATES: Comments are due March 6, 2019.

ADDRESSES: Comments, identified by docket number, may be filed electronically at *http://www.ferc.gov* in acceptable native applications and print-to-PDF, but not in scanned or picture format. For those unable to file electronically, comments may be filed by mail or hand-delivery to: Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE, Washington, DC 20426. The Comment Procedures Section of this document contains more detailed filing procedures.

FOR FURTHER INFORMATION CONTACT:

Robert Hudson (Technical Information), Office of Enforcement, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, (202) 502–6620, *Robert.Hudson@ferc.gov*.

Michael Chase (Legal Information), Office of General Counsel, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, (202) 502–6205, *Michael.Chase@ferc.gov*.

SUPPLEMENTARY INFORMATION:

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I. Background

1. Under the Commission's regulations, certain entities are required to report information to the Commission by filing one or more forms.[1] Currently, these entities use a Commission-distributed software application called Visual FoxPro. Each entity is required to gather its relevant financial and other data and enter the data into Visual FoxPro, which the entity maintains on its own computer system. The entity then uses the Visual FoxPro software to transmit the information to the Commission. However, Microsoft Corporation, the developer of Visual FoxPro, no longer supports this product.[2]

2. Recognizing that Microsoft Corporation no longer supports Visual FoxPro, on April 25, 2015, the Commission issued an order announcing its intention to replace the current Visual FoxPro filing format for Form Nos. 1, 1–F, 2, 2–A, 3–Q electric, 3–Q natural gas, 6, 6–Q, 60, and 714 (collectively, the VFP Forms) with an XML-based filing format.[3] The Commission stated that XML is the current industry standard for submission of electronic data, such as that captured in its forms, and that the XML data format has significant advantages over other approaches because it is non-proprietary, and would establish a single standard for nearly all Commission forms while also providing consistency with the Commission's current electronic tariff (eTariff) filings and the Electric Quarterly Report (EQR) systems.[4] The XML format facilitates the sharing of data across different information systems, particularly via the internet, by structuring the data using tags to identify particular data elements.

3. The Commission noted that the North American Energy Standards Board (NAESB)[5] had helped facilitate meetings to develop the Commission's eTariff system, and the Commission directed Commission staff to seek NAESB's assistance in the process of developing standards for the submission of the VFP Forms to the Commission in the new XML format.[6] NAESB facilitated 18 meetings during which the transition of the forms was discussed. Commission staff also discussed the filing of financial forms with other federal agencies.

[1] *See* 18 CFR 141.1 (requiring annual filing of FERC Form No. 1, Annual report of Major electric utilities, licensees and others); 18 CFR 141.2 (2018) (requiring annual filing of FERC Form No. 1–F, Annual report for Nonmajor public utilities and licensees); 18 CFR 260.1 (requiring annual filing of FERC Form No. 2, Annual report for Major natural gas companies); 18 CFR 260.2 (requiring annual filing of FERC Form No. 2–A, Annual report for Nonmajor natural gas companies); 18 CFR 141.400 and 18 CFR 260.300 (requiring quarterly filing of FERC Form No. 3–Q, Quarterly financial report of electric utilities, licensees, and natural gas companies); 18 CFR 357.2 (requiring annual filing of FERC Form No. 6, Annual Report of Oil Pipeline Companies); 18 CFR 357.4 (2018) (requiring quarterly filing of FERC Form No. 6–Q, Quarterly report of oil pipeline companies); 18 CFR 141.51 (requiring annual filing of FERC Form No. 714, Annual Electric Balancing Authority Area and Planning Area Report); and 18 CFR 366.23 and 18 CFR 369.1 (requiring annual filing of FERC Form No. 60, Annual reports of centralized service companies).

[2] The Commission has used Visual FoxPro, a Microsoft Windows-based programming language, since 1997.

[3] *Electronic Filing Protocols for Commission Forms,* 151 FERC ¶ 61,025 (2015) (April 2015 Order).

[4] *Id.* P 5.

[5] NAESB serves as a forum for the development and promotion of standards for wholesale and retail natural gas and electric industries. In response to the Commission's request on this matter, NAESB performed specific outreach to the oil pipeline industry to include participation from that sector.

[6] April 2015 Order, 151 FERC ¶ 61,025 at P 10.

II. Discussion

A. Proposed Adoption of XBRL

4. Based on these discussions, while we continue to find that XML is the most suitable format for filing Commission forms, we think a standard built on XML called eXtensible Business Reporting Language (XBRL) would be a superior method for both the Commission and filing entities to use. XBRL was developed specifically for reporting financial data and is used widely for reporting business and financial information.

5. The energy industry currently uses XML format to submit other filings and reports to the Commission, including eTariff and EQR.[7] In the April 2015 Order, the Commission noted that XML is commonly used to submit electronic data, and the Commission explained the features of XML that give it significant advantages over other approaches. In the April 2015 Order, the Commission also noted that other potential means of communicating electronic data, such as uploading a file formatted in comma-separated value (CSV) or using web-based forms either alone, or in combination, are less flexible and efficient than XML file uploads, and would be more expensive and time-consuming to develop and maintain.[8] Among other things, the Commission noted that CSV uploads are difficult to error check, would require conversion that has the potential to create data errors, and will not easily accommodate the large and complex footnotes that often accompany financial data.

6. In the April 2015 Order, the Commission determined that, rather than filers having to input their data into a proprietary database application, the XML format would permit filers to develop, or obtain from third-party vendors, a system for collecting form information that is best suited to their own internal systems.[9] This approach would enable filers to maintain their own information and data in the formats that they prefer and then repackage that material for submission to the Commission at the appropriate time. Using the XML format similarly would reduce costs for the Commission to process the information. Adopting the XML format also would eliminate the need for the Commission to provide software to filers. This approach allows for the independent design and implementation of future filing requirements rather than dependence on a vendor's continued development and support of their proprietary software.

7. There are two options available to an organization that chooses XML as the format for data submission. One option is to develop a customized XML system that meets the business reporting needs of an organization, the result of which is generally proprietary and unique to the organization and data collection. The Commission currently uses customized XML solutions for certain of its data collections, such as eTariff and EQR. The other option is to use a standard built upon the XML format, such as XBRL.[10] As explained in more detail below, the Commission believes that the use of the XBRL standard for certain forms offers significant advantages over the use of customized XML.

8. The XBRL standard provides features tailored to submission of business data and builds upon the advantages of the XML format set forth in the April 2015 Order.[11] The XBRL standard includes all the advantages of the XML format, such as its non-proprietary nature, its efficient sharing of data across different information systems, and its ability to include identified proprietary formats (*e.g.,* PDF, Microsoft Word, etc.). The XBRL standard has clearly defined mechanisms to handle important aspects of business data that add to these benefits by structuring the data with tags that utilize standard taxonomies in order to capture not only the value of the data, but also the inherent characteristics of the information.

9. As an international standard for digital reporting, XBRL enables the reporting of comprehensive, consistent, interoperable data that allows industry and other data users to automate submission, extraction, and analysis. XBRL is a language in which reporting terms can be authoritatively defined. Those terms can then be used to uniquely represent the contents of the Commission's data collections. XBRL is currently required for filing forms by a number of other federal agencies.[12]

10. XBRL provides an efficient way to exchange information inherent to the XML format and applies a standard way to capture the characteristics of that information. This is made possible through a number of interrelated technical specifications[13] developed and published by XBRL International, collectively referred to as the XBRL Specification. XBRL provides a way to define unambiguous, reusable definitions; report individual facts against those definitions; and, where necessary (and permitted), extend those definitions to take account of unique reporting ideas or aggregations. XBRL also allows filers to test the resulting report against the constraints set out in the definitions, file or publish the finished report, and process entire reports or individual data points in a platform-independent, vendor-neutral way. XBRL is supported by a large number of common off-the-shelf software packages and by a large number of service providers. All of these features, and the specific advantages discussed below, enhance interoperability with systems currently in use by many industries and governments. Furthermore, the open XBRL specifications are freely licensed to anyone seeking to use the standard.

11. Another advantage of using XBRL is that, in addition to collecting information (numbers and text), the XBRL International Units Registry (Registry) provides clear definitions and a standardized mechanism to record characteristics of information.[14] For example, XBRL requires that the time period be selected from the Registry and recorded in the same way by every reporting entity. In a customized XML collection, time period and other common characteristics are defined by the designer of the data collection system, and separate collection systems likely use different definitions. Moreover, when financial data collection systems are built on XML, CSV, or some other format, the method used to define units such as currencies, periods of time, the entity the data relates to, and disaggregation of data is recreated every time. This means data

[7] The Commission has required filers to submit in XML for eTariff and provides an XML option for filing EQRs.

[8] April 2015 Order, 151 FERC ¶ 61,025 at P 8.

[9] *Id.* P 6.

[10] XBRL International, Inc. (XBRL International), the global non-profit organization that develops and maintains the XBRL standard and related specifications, states that the standard is used by over 100 regulators, including the Department of Energy (DOE), Securities and Exchange Commission (SEC), and Federal Deposit Insurance Corporation, more than 10 million companies, is accepted in over 60 countries, and supported by more than 200 software packages.

[11] April 2015 Order, 151 FERC ¶ 61,025 at P 5.

[12] For example, the SEC requires the use of XBRL for filing 10–Q and 10–K forms, the DOE has launched an initiative through its Solar Energy Technologies Office to set data standards for the solar industry using XBRL, and members of the Federal Financial Institutions Examination Council require the forms collectively referred to as the Call Report to be filed in XBRL.

[13] A specification is a set of documented requirements to be satisfied by a material, design, product, or service.

[14] XBRL version 2.1 requires that all numeric facts be associated with a unit. The Registry provides a centralized list of units that promotes the consistent use of units across preparers and jurisdictions. The Registry is available at: *http://www.xbrl.org/utr/utr.xml.*

cannot be easily compared without manual reconciliation. The XBRL standard enables each number's context to be captured in a way that communicates definition, time period, units, and name of reporting entity consistently.

12. An additional advantage of the XBRL standard is that it defines relationships between elements separately from the element itself. This makes it possible to express multiple relationships and hierarchies among many elements. Unlike XBRL, XML specifies the relationship as part of the definition of an element. While it is possible to express multiple relationships in customized XML, developers must create custom code in order to do so. XBRL also allows the fields in a hierarchical relationship to share the same properties because the taxonomy allows relationships between concepts to be defined separately. For example, consider a balance sheet item such as Cash. The taxonomy would include the definition of Cash and would also demonstrate how Cash may relate to other balance sheet items (within the taxonomy) such as rolling up to Current Assets and eventually Total Assets. All three of these items (Cash, Current Assets, and Total Assets) are interrelated financial concepts that are defined and presented in the taxonomy as elements.

13. Furthermore, XBRL standardizes many unique characteristics of business reporting data, such as units, time period, entity identification, decimal places, and data labels, and allows the database designer to define its own custom characteristics for additional business reporting data. XBRL uses tags to apply these characteristics to the data, such as ''current'' for period, ''transmission'' for entity identification, ''dollars'' for units, and ''thousands'' for decimal places. This means that XBRL would define a simple term like ''Assets'' with a combination of defined tags for each characteristic, offering dimensionality. By contrast, customized XML, without custom code to address dimensionality, would likely have unique fields for every combination of characteristics, resulting in numerous fields with long descriptive names, such as ''Current_Assets_Transmission_Dollars_Thousands'' or ''PreviousYear_Assets_Transmission_Dollars_Thousands'' and no standardization across elements within the forms.

14. The XBRL standard also offers greater flexibility than a customized XML format as it results in the creation of a ''taxonomy,'' whereas customized XML solutions result in wholly custom, permanent documents, and code. Taxonomies are files containing relevant business terminology, their meanings, their data types, relationships among terms, and the rules or formulas they must follow. Taxonomies are not permanent documents, but rather are code that describes elements that can be used in other programs and software. Thus, unlike a customized XML solution, XBRL would operationalize with a taxonomy all information needed to create a form submission into publicly available code that can be used in many applications, and can be reused in other collections, saving time in developing those collections.

15. XBRL would also facilitate the implementation of changes to the reporting requirements. Any change to reporting requirements in a customized XML solution requires costly upgrades to the applications used by filers, organizations that extract and analyze data, and software providers that make the tools to create and use the data. Unlike customized XML solutions, XBRL-based solutions enable future changes, such as adding, amending, and deleting defined elements and relationships, without the need for costly development procedures. The Commission would also benefit from the advantages XBRL systems provide in terms of administering the various VFP Form data collections. Specifically, XBRL would allow more substantive changes to the taxonomy as a result of Commission directives, as well as enabling the Commission to make minor technical changes to maintain and revise the taxonomy, without costly development procedures.

16. Implementing an XBRL-based solution would lead to greater data quality through easier validation checks. XBRL taxonomies support simple formulas such as addition and subtraction and allow more complex formulas to be defined with a set of guidelines. In the Commission's current XML-based collection systems, such as the EQR system, filers may check their files prior to making their submission through a test submission feature on the Commission's website. This process requires a filer to submit their data into the test submission feature to receive an email detailing errors in their file. XBRL taxonomies contain validations that can be used to check a submission by filers on their own system without uploading anything to the Commission. This enables filers to confirm that their VFP Form submission is error-free prior to submission, thereby saving time and reducing burden on the filers. Furthermore, the taxonomy will contain instructions on how the Commission's system will convert the submission to a human-readable form. These instructions can be used to create the same human-readable form on the filer's computer prior to submission. Under the VFP system, filers have been able to view their submission in a human-readable format only after it has been filed.

17. Another advantage of a collection designed using the XBRL standard is that it simultaneously supports all previous taxonomies published for that form. Occasionally, a filer may be required to refile a form using a version of the form that is not current. With a customized XML approach, all filings must conform to the current version of the schema for the system to accept the submission. As a result, if the form changes substantively between the original submission and the subsequent refiling, the filer or the Commission must make certain technological adjustments to enable the submission of the refiling. By contrast, with the XBRL submission method, a refiling can be submitted using any prior version of the taxonomy at any time. This is possible because the structure of the XBRL submission file will be the same, and the validations are tied to each version of the taxonomy. Once the submission is accepted, it can then be compared with the prior filing for the same period to determine what has changed. Most XBRL software products allow filers to select a taxonomy version each time they create their submission to file.

18. Finally, the proposed XBRL-based FERC Form Nos. 1, 1–F, and 3–Q electric will incorporate energy storage-related data which the Commission required be submitted under Order No. 784.[15] Currently, utilities with energy storage assets and those that acquire the assets report using existing schedules and footnotes not intended for energy storage assets pending the availability of new and revised schedules.[16] The proposed XBRL-based forms will allow utilities to submit this data directly into the forms.

B. Proposed Process for Developing the XBRL Based Solution

19. Parties should submit comments on the proposed adoption of the XBRL standard in lieu of a customized XML solution. Should the Commission adopt XBRL in the Final Rule in this proceeding, the Commission plans to

[15] *See Third-Party Provision of Ancillary Services; Accounting and Financial Reporting for New Electric Storage Technologies,* Order No. 784, FERC Stats. & Regs. ¶ 31,349 (2013) (crossed-referenced at 144 FERC ¶ 61,056).

[16] *See Accounting and Reporting Guidance for New Electric Storage Technologies,* Docket No. AI14–I–000 (February 20, 2014).

convene staff-led technical conference(s), in consultation with NAESB. The technical conference(s) would enable interested industry members to discuss and propose revisions to the draft taxonomy that the Commission plans to release following the issuance of the Final Rule, along with other important components of the XBRL system.

20. The Commission also proposes that its initial launch of the XBRL system will include Commission incorporation of the prior three years of VFP Form data from the current VFP system. Providing access to the prior three years of form data in XBRL will allow form filers to correct previously filed data through refilings, when necessary, consistent with the Commission's informal policy concerning refilings of EQRs.[17] The Commission seeks comment on the time period of historical VFP Form data that should be converted by the Commission to the new XBRL system upon launch of the new XBRL system. After implementation of the XBRL system, the Commission anticipates ultimately transferring approximately 10 years of historical VFP Form data over to the XBRL system.

21. Although we do not envision that the Commission will need to make frequent changes to the taxonomy and related code, the Secretary of the Commission, under Order No. 703, has delegated authority to make such modifications when necessary.[18] Before the Commission implements any such changes, notice of the proposed change will be provided sufficiently in advance to notify companies and provide them time to comply with the changes to the taxonomy and related code.

C. Regulatory Text Revisions

22. With the exception of Form No. 1–F, current regulations already provide for the filing of Form Nos. 1, 2, 2–A, 3–Q electric, 3–Q natural gas, 6, 6–Q, 60, and 714 in electronic format according to the instructions for each form and filing. The Commission therefore sees no need for further regulatory text changes pertaining to these forms. Upon completion of the technical conference process, however, the Commission would issue an order revising the format instructions for the forms to accord with the results of the technical conferences. These instructions would cover only the format for making the electronic filings and will not include any revisions to the substance of the required filings, which the Commission will make when necessary in appropriate separate proceedings. The Commission is also proposing to require Form No. 1–F filers to submit Form No. 1–F in electronic format rather than filing an original and copies of the form on paper, as is currently required. The Commission therefore proposes to revise § 141.2(b)(1)(i) of the Commission's regulations[19] and Rule 2011 of its Rules of Practice and Procedure[20] to require Form No. 1–F filers to submit their reports using electronic media as prescribed in Rule 2011.

III. Information Collection Statement

23. The Paperwork Reduction Act (PRA)[21] requires each federal agency to seek and obtain Office of Management and Budget (OMB) approval before undertaking a collection of information directed to ten or more persons or contained in a rule of general applicability. OMB's regulations require approval of certain information collection requirements imposed by agency rules.[22] Upon approval of a collection of information, OMB will assign an OMB control number and an expiration date. Respondents subject to the filing requirements of an agency rule will not be penalized for failing to respond to these collections of information unless the of information display a valid OMB control number.

24. The revisions proposed in this NOPR would update the filing process for regulated entities required to file the VFP Forms. The information collected in the VFP Forms is required to be submitted annually or quarterly to the Commission under existing regulations and reporting requirements adopted under the Federal Power Act (FPA), the Natural Gas Act (NGA), the Interstate Commerce Act (ICA), and the Public Utility Holding Company Act of 2005 (PUHCA 2005). The VFP Forms would continue to be submitted to the Commission under existing regulations and reporting requirements. The proposed new and amended regulations and reporting requirements, if adopted, would require regulated entities to furnish the information collected in the VFP Forms using tags in XBRL-Related Documents.[23] The specified financial and operational information already is required to be collected and filed with the Commission pursuant to existing periodic and annual report requirements. Under this NOPR proposal, the information would need to be filed with the Commission using XBRL. The Commission anticipates that the revisions to the filing process for the VFP Forms, once effective, would reduce ongoing regulatory burdens.[24] The Commission will submit the proposed reporting requirements to OMB for its review and approval under section 3507(d) of the Paperwork Reduction Act.[25]

25. The Commission solicits public comments regarding the accuracy of the burden estimates and any suggested methods for minimizing respondents' burden. Specifically, the Commission asks that any revised burden or cost estimates submitted by commenters be supported by sufficient detail to understand how the estimates are generated.

26. The Commission's regulations currently require certain regulated entities to file information in VFP Forms on an annual and quarterly basis.[26] We propose no substantive changes to the information collected in the VFP Forms, but rather to transition from the VFP system currently used to collect the information to an XBRL system.[27] Compliance with the proposed new filing process would be mandatory.

27. FERC Form No. 1 (OMB Control No. 1902–0021), FERC Form No. 2 (OMB Control No. 1902–0028), and FERC Form No. 6 (OMB Control No. 1902–0022) prescribe the information that major electric utilities, licensees, and others; major natural gas companies; and oil pipeline companies, respectively, must disclose annually about their finances and operations. FERC Form No. 1–F (OMB Control No. 1902–0029) and FERC Form No. 2–A (OMB Control No. 1902–0030) prescribe the information that nonmajor electric

[17] The Commission's informal policy directs filers to correct the most recent 12 EQRs, or three years of data, with a note placed in the EQR stating that other reports may also contain the error. *See Plan for Retrospective Analysis of Existing Rules,* Docket No. AD12–6–000 (2011), *https://www.ferc.gov/legal/maj-ord-reg/retro-analysis/ferc-eo-13579.pdf.*

[18] 18 CFR 375.302(z).

[19] 18 CFR 141.2(b)(1)(i).

[20] 18 CFR 385.2011.

[21] 44 U.S.C. 3507(d).

[22] 5 CFR 1320.11.

[23] XBRL-Related Documents for purposes of this NOPR encompasses documents, code, and any other file related to presenting information in XBRL that are part of the filing submission.

[24] Burden is the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For further explanation of what is included in the information collection burden, refer to 5 CFR 1320.3.

[25] 44 U.S.C. 3507(d).

[26] *See supra* P 1 & n.1.

[27] While the NOPR does not change the information collected by any of the VFP Forms, the NOPR proposes to incorporate the energy storage-related data that the Commission required be reported under Order No. 784 into the new XBRL-based FERC Form Nos. 1, 1–F, and 3–Q electric. *See infra* P 18, n.15.

utilities and licensees; and nonmajor natural gas companies, respectively, must disclose annually about their finances and operations. FERC Form No. 3–Q (OMB Control No. 1902–0205) prescribes information that electric utilities, licensees, and natural gas companies must disclose quarterly about their finances and operations. FERC Form No. 6–Q (OMB Control No. 1902–0206) prescribes information that oil pipeline companies must disclose quarterly about their finances and operations. FERC Form No. 714 (OMB Control No. 1902–0140) prescribes information that certain electric transmitting utilities operating balancing authority areas or planning areas are required to file annually. FERC Form No. 60 (OMB Control No. 1902–0215) prescribes information that centralized service companies must disclose annually about their finances and operations.

28. The compliance burden estimates for the proposed revisions to the filing process for the VFP Forms are based on several assumptions and unique assessments for each form. However, all regulated entities required to submit the VFP Forms would have to map the reporting information to the Commission's standard XBRL taxonomy and create a final submission file(s). Based on discussions with other federal agencies, subject matter experts in XBRL data collection and the VFP Forms, and entities that have prepared their financial information in XBRL, we estimate that filers would incur the following average burden hours:

- XBRL Form Nos. 1, 1–F, 3–Q electric, 2, 2–A, 3–Q natural gas, 6, and 6–Q [28]
  - Burden hours to tag in XBRL:
    - 00 hours to prepare and submit the first filing using XBRL; and
    - 14 hours for each subsequent filing in XBRL.
- Form No. 60
  - Burden hours to tag in XBRL:
    - 20 hours to prepare and submit the first filing made in XBRL; and
    - 3 hours for each subsequent filing.
- Form No. 714
  - Burden hours to tag in XBRL:
    - 15 hours to prepare and submit the first filing made in XBRL; and
    - 2 hours for each subsequent filing.

29. *Public Reporting Burden:* The Commission's burden estimates for the proposal in this NOPR are for a one-time implementation of the transition to XBRL proposed in this NOPR, and an ongoing estimate for maintenance of the XBRL reporting system. The following estimates of reporting burden are related only to this NOPR and anticipate the costs to filers for compliance with the Commission's proposal in this NOPR.

RM19–12–000 NOPR

[One-time implementation burden]

Requirement	Number of respondents (1)	Annual number of responses per respondent (2)	Total number of responses (1) * (2) = (3)	Average burden & cost per response [29] (4)	Total annual burden hours & cost [30] (3) * (4) = (5)	Annual cost per respondent ($) (5) ÷ (1)
Form No. 1	207	1	207	100 hrs.; $6,931	20,700 hrs.; $1,434,717	$6,931.
Form No. 1–F	5	1	5	100 hrs.; $6,931	500 hrs.; $34,655	$6,931.
Form No. 3–Q electric	212	3	636	No Change [31]	No Change	No Change.
Form No. 2	92	1	92	100 hrs.; $6,931	9,200 hrs.; $637,652	$6,931.
Form No. 2–A	73	1	73	100 hrs.; $6,931	7,300 hrs.; $505,963	$6,931.
Form No. 3–Q natural gas.	165	3	495	No Change	No Change	No Change.
Form No. 6	244	1	244	100 hrs.; $6,931	24,400 hrs.; $1,691,164	$6,931.
Form No. 6–Q	244	3	732	No Change	No Change	No Change.
Form No. 60	39	1	39	20 hrs.; $1,386.20	780 hrs.; $54,062	$1,386.20.
Form No. 714	176	1	176	15 hrs.; $1,039.65	2,640 hrs.; $182,977	$1,039.65.
Total for Implementation. Burden			[32] 836		65,520 hrs.; $4,541,190	

RM19–12–000 NOPR

[Annual ongoing system maintenance burden]

Requirement	Number of respondents (1)	Annual number of responses per respondent (2)	Total number of responses (1) * (2) = (3)	Average burden & cost per response [33] (4)	Total annual burden hours & cost [34] (3) * (4) = (5)	Annual cost per respondent ($) (5) ÷ (1)
Form No. 1	207	1	207	14 hrs.; $970.34	2,898 hrs.; $200,860	$970.34.
Form No. 1–F	5	1	5	14 hrs.; $970.34	70 hrs.; $4,852	$970.34.
Form No. 3–Q electric.	212	3	636	No Change	No Change	No Change.
Form No. 2	92	1	92	14 hrs.; $970.34	1,288 hrs.; $89,271	$970.34.
Form No. 2–A	73	1	73	14 hrs.; $970.34	1,022 hrs.; $70,835	$970.34.

[28] The internal burden hours for tagging Form Nos. 1 and 3–Q electric are combined because the annual information reported in Form No. 1 is a compilation of the information reported in the prior three quarters in Form Nos. 3–Q electric in addition to the fourth quarter. Similarly, we have combined the number of internal burden hours for tagging the Form Nos. 2 and 3–Q natural gas and the Form Nos. 6 and 6–Q, respectively, because the annual Form Nos. 2 and 6 are based on a compilation of the information reported in the prior three quarters in Form Nos. 3–Q natural gas and 6–Q in addition to the fourth quarter.

RM19–12–000 NOPR—Continued

[Annual Ongoing System Maintenance Burden]

Requirement	Number of respondents (1)	Annual number of responses per respondent (2)	Total number of responses (1) * (2) = (3)	Average burden & cost per response [33] (4)	Total annual burden hours & cost [34] (3) * (4) = (5)	Annual cost per respondent ($) (5) ÷ (1)
Form No. 3–Q natural gas.	165	3	495	No Change	No Change	No Change.
Form No. 6	244	1	244	14 hrs.; $970.34	3,416 hrs.; $236,763	$970.34.
Form No. 6–Q	244	3	732	No Change	No Change	No Change.
Form No. 60	39	1	39	3 hrs.; $207.93	117 hrs.; $8,109	$207.93.
Form No. 714	176	1	176	2 hrs.; $138.62	352 hrs.; $24,397	$138.62.
Total for Ongoing Burden.			[35] 836		9,163 hrs.; $635,087.	

The Commission's estimates for the hourly wage figure (as related to the implementation and ongoing burden estimate) are based on the Bureau of Labor Statistics data (for the Utilities sector, at *http://www.bls.gov/oes/current/naics2_22.htm,* plus benefits information at *http://www.bls.gov/news.release/ecec.nr0.htm*). The salaries (plus benefits) for the eight occupational categories are:

- Management (Occupation Code: 11–0000): $94.28/hour
- Information Security Analysts (Occupation Code: 15–1122): $60.90/hour
- Legal (Occupation Code: 23–0000): $143.68/hour
- Office and Administrative Support: $41.34/hour
- Computer and Information Systems Manager (Occupation Code: 11–3021): $96.51
- Management Analyst (Occupation Code: 13–1111): $63.32/hour
- Computer and Information Systems Analyst (Occupation Code: 15–1120): $66.47/hour
- Accountants and Auditors (Occupation Code: 13–2011): $56.59/hour

The average hourly cost for all eight of these categories is calculated assuming the following weights in correspondence to effort applied by each respective occupation:

- Management (Occupation Code: 11–0000): 5%
- Information Security Analysts (Occupation Code: 15–1122): 5%
- Legal (Occupation Code: 23–0000): 5%
- Office and Administrative Support: 10%
- Computer and Information Systems Manager (Occupation Code: 11–3021): 10%
- Management Analyst (Occupation Code: 13–1111): 5%
- Computer and Information Systems Analyst (Occupation Code: 15–1120): 35%
- Accountants and Auditors (Occupation Code: 13–2011): 25%

Overall, the average hourly cost uses the following calculation with all seven occupations and their respective weights included:

[($94.28/hour * 0.05) + ($60.90/hour * 0.05) + ($143.68/hour * 0.05) + ($41.34/hour * 0.1) + ($96.51/hour * 0.1) + ($63.32/hour * 0.05) + ($66.47/hour * 0.35) + ($56.59/hour * 0.25)] ÷ 8 = $69.31.

The number of responses related to both the implementation and ongoing burden is 836 responses.[36]

The implementation burden will be 65,520 hours for Year 1.

The ongoing burden in Years 2 and 3 will be 9,163 hours per year.

The responses and burden for Years 1–3 for both the implementation and ongoing burden are as follows:

836 responses/year; [(65,520 hours for Year 1) + (9,163 hours for Year 2) + (9,163 hours for Year 3)] ÷ 3 years = 27,949 hours/year (annual average for Years 1–3).

30. *Out-of-pocket expenses:* We estimate that filers would incur the following out-of-pocket expenses for software, consulting, or filing agent services used in the Years 2 and 3 (following the first year of implementation):

- XBRL Form Nos. 1, 1–F, 3–Q electric, 2, 2–A, 3–Q natural gas, 6, and 6–Q:
  - Out-of-pocket cost for software and filing agent services: $4,912 for each filing.
  - Total out-of-pocket cost for software and filing agent services per year: (621 respondents) * ($4,912 for each filing) = $3,050,352.
- Form No. 60:
  - Out-of-pocket cost for software and filing agent services: $982 for each filing.
  - Total out-of-pocket cost for software and filing agent services per year: (39 respondents) * ($982 for each filing) = $38,298.
- Form No. 714:
  - Out-of-pocket cost for software and filing agent services: $737 for each filing.
  - Total out-of-pocket cost for software and filing agent services per year: (176 respondents) * ($737 for each filing) = $129,712.

[29] The average burden and cost per response is calculated using the hourly wage figures described in detail below.

[30] Every figure in this column is rounded to the nearest dollar.

[31] There is no change to the internal burden hours for filing Form Nos. 3–Q electric, 3–Q natural gas, and 6–Q because the burden hours associated with these quarterly forms are included in the burden hours calculated for filing Form Nos. 1, 2, and 6.

[32] This total number of responses does not include the responses for Form Nos. 3–Q electric, 3–Q natural gas, or 6–Q because the burden hours for tagging Form Nos. 1, 2, and 6 include the number of hours required to tag the quarterly responses. The quarterly filings are generally a subset of the annual filings.

[33] The average burden and cost per response is calculated using the hourly wage figures described in detail below.

[34] Every figure in this column is rounded to the nearest dollar.

[35] This total number of responses does not include the responses for Form Nos. 3–Q electric, 3–Q natural gas, or 6–Q because the burden hours for tagging Form Nos. 1, 2, and 6 include the number of hours required to tag the quarterly responses. The quarterly filings are generally a subset of the annual filings.

[36] This total number of responses does not include the responses for Form Nos. 3–Q electric, 3–Q natural gas, or 6–Q because the burden hours for tagging Form Nos. 1, 2, and 6 include the number of hours required to tag the quarterly responses. The quarterly filings are generally a subset of the annual filings.

31. Based on the number of filers we expect to be subject to the proposed requirements, the number of filings that we expect those filers to make and the burden hours and out-of-pocket cost estimates described, we estimate that the average yearly burden of the proposed requirements over the first three years would be 27,949 internal hours per year and $2,145,575 in out-of-pocket expenses per year. This would be incurred by an average of 836 filers for an average yearly burden per filer of 33.4 internal hours and $2,566 in out-of-pocket expenses over Years 1–3.

Titles: Form No. 1 (Annual Report of Major Electric Utilities, Licensees and Others); Form No. 1–F (Annual Report of Nonmajor Public Utilities and Licensees); Form No. 3–Q electric (Quarterly Financial Report of Electric Utilities, Licensees and Natural Gas Companies); Form No. 2 (Annual Report of Nonmajor Natural Gas Companies); Form No. 3–Q gas (Quarterly Financial Report of Electric Utilities, Licensees and Natural Gas Companies); Form No. 6 (Annual Report of Oil Pipeline Companies); Form No. 6–Q (Quarterly Financial Report of Oil Pipeline Companies); Form No. 60 (Annual Reports of Centralized Service Companies); Form No. 714 (Annual Electric Balancing Authority Area and Planning Area Report).

Action: Revision of Currently Approved Collections of Information.

OMB Control Nos.: 1902–0021 (Form No. 1), 1902–0029 (Form No. 1–F), 1902–0028 (Form No. 2), 1902–0205 (Form No. 3–Q), 1902–0022 (Form No. 6), 1902–0206 (Form No. 6–Q), 1902–0215 (Form No. 60), and 1902–0140 (Form No. 714).

Respondents: Public utilities, licensees, interstate natural gas companies, oil pipeline companies, centralized service companies, Balancing Authorities, or other for profit and/or not for profit institutions.

Frequency of Responses: Annual or quarterly.

Necessity of the Information: The Commission requires that the information collected in Form Nos. 1, 1–F, 3–Q electric, 2, 2–A, 3–Q natural gas, 6, 6–Q, 60, and 714 be submitted in an updated electronic format that is compatible with current technology and ensures access to the information required to be collected.

Internal Review: The Commission has reviewed the reporting requirements related to the VFP Forms and made a determination that revising the filing process for the VFP Forms will ensure the Commission has the necessary data to carry out its statutory mandates, while reducing unnecessary burden on industry. The Commission has assured itself, by means of its internal review, that there is specific, objective support for the burden estimate associated with the information requirements.

32. 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]. Please send comments concerning the collection of information and the associated burden estimates to the Commission, and to the Office of Management and Budget, Office of Information and Regulatory Affairs, 725 17th Street NW, 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 RM19–2–000 and any related information collection and its respective OMB Control Number [Form No. 1 (1902–0021), Form No. 1–F (1902–0029), Form No. 2 (1902–0028), Form No. 3–Q (1902–0205), Form No. 6 (1902–0022), Form No. 6–Q (1902–0206), Form No. 60 (1902–0215), and Form No. 714 (1902–0140)].

IV. Environmental Analysis

33. 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.[37] The Commission has categorically excluded certain actions from this requirement as not having a significant effect on the human environment.[38] The actions proposed here fall within the categorical exclusions in the Commission's regulations for rules that are clarifying, corrective, or procedural, or do not substantially change the effect of legislation or regulations being amended and for rules regarding information gathering, analysis, and dissemination.[39] In addition, the proposed rule is categorically excluded as an electric rate filing submitted by a public utility under sections 205 and 206 of the FPA[40] and as a rule regarding sales, exchange, and transportation of natural gas that require no construction of facilities.[41] Accordingly, no environmental assessment is necessary and none has been prepared in this NOPR.

V. Regulatory Flexibility Act

34. The Regulatory Flexibility Act of 1980 (RFA)[42] generally requires a description and analysis of proposed rules that will have significant economic impact on a substantial number of small entities. The Commission is not required to perform this sort of analysis if the proposed activities within the NOPR would not have such an effect.

35. Approximately 213 electric utility, licensees, and other companies are required to file the Form Nos. 1 and 3–Q electric, or Form No. 1–F, and therefore are subject to the requirements adopted by this rule. Of those filers, the Commission estimates approximately 40 will be small as defined by SBA regulations.[43] Approximately 244 oil pipeline companies are required to file the Form Nos. 6 and 6–Q, and therefore are subject to the requirements proposed in this NOPR. Of those oil pipeline filers, the Commission estimates approximately 23% will be small, as currently defined for ''All Other Pipeline Transportation'' companies (NAICS code 486990) as a company that, in combination with its affiliates, has total annual receipts of $37.5 million or less. Approximately 165 interstate natural gas pipelines are required to file the Form Nos. 2 and 3–Q natural gas, or Form No. 2–A, and therefore are subject to the requirements adopted by this rule. Most of the natural gas pipelines regulated by the Commission do not fall within the RFA's definition of a small entity, which is currently defined for natural gas pipelines (NAICS code 486210) as a company that, in combination with its affiliates, has total annual receipts of $27.5 million or less. For the year 2018, eleven companies not affiliated with larger companies had annual revenues in combination with its affiliates of $27.5 million or less and therefore could be considered a small entity under the RFA. This represents about seven percent of the total potential respondents that may have a significant burden imposed on them.

36. Approximately 39 holding companies currently file Form No. 60.

[37] *Regulations Implementing the National Environmental Policy Act of 1969,* Order No. 486, FERC Stats. & Regs, ¶ 30,783 (1987) (cross-referenced at 41 FERC ¶ 61,284).

[38] 18 CFR 380.4.

[39] 18 CFR 380.4(a)(2)(ii) and 380.4(a)(5).

[40] 18 CFR 380.4(a)(15).

[41] 18 CFR 380.4(a).

[42] 5 U.S.C. 601–612.

[43] The small business size standards are provided in 13 CFR 121.201. In 13 CFR 121.201, the SBA uses the North American Industry Classification System (NAICS) codes.

Commission staff estimates that these companies are not likely to fall within the RFA's definition of small[44] because holding companies of public utilities or natural gas pipelines are generally not small businesses. Finally, there are approximately 176 balancing authorities (NAICS code 221121) that are required to file Form No. 714. Of those balancing authorities, 33 percent (or approximately 58) are estimated to fall within the RFA's definition of small.

37. Accordingly, the Commission finds that the revised requirements set forth in this NOPR will not have a significant economic impact on a substantial number of small entities, and no regulatory flexibility analysis is required.

VI. Comment Procedures

38. The Commission invites interested persons to submit comments on the matters and issues proposed in this NOPR to be adopted, including any related matters or alternative proposals that commenters may wish to discuss. Comments are due March 6, 2019. Comments must refer to Docket No. RM19–12–000, and must include the commenter's name, the organization they represent, if applicable, and their address in their comments.

39. The Commission encourages comments to be filed electronically via the eFiling link on the Commission's website 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.

40. 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.

41. 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

42. 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.

43. 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 excluding the last three digits of this document in the docket number field.

44. User assistance is available for eLibrary and the Commission's website 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*.

List of Subjects

18 CFR Part 141

Electric power, Reporting and recordkeeping requirements.

18 CFR Part 385

Electric power, Reporting and recordkeeping requirements.

By direction of the Commission.

Issued: January 17, 2019.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

In consideration of the foregoing, the Commission proposes to amend parts 141 and 385 of chapter I, title 18 of the *Code of Federal Regulations,* as follows.

PART 141—STATEMENTS and REPORTS (SCHEDULES)

■ 1. The authority citation for part 141 continues to read as follows:

Authority: 15 U.S.C. 79; 15 U.S.C. 717–717z; 16 U.S.C. 791a–828c, 2601–2645; 31 U.S.C. 9701; 42 U.S.C. 7101–7352.2.

■ 2. Amend § 141.2 by revising paragraph (b)(1)(i) to read as follows:

§ 141.2 FERC Form No. 1–F, Annual report for Nonmajor public utilities and licensees.

* * * * *

(b) * * *

(1) * * *

(i) *Generally.* Each Nonmajor and each Nonoperating (formerly designated as Nonmajor) public utility and licensee as defined in Part 101 of this chapter, shall prepare and file with the Commission FERC Form No. 1–F as prescribed in § 385.2011 of this chapter and as indicated in the General Instructions set out in this form, and must be properly completed and verified. Filing on electronic media pursuant to § 385.2011 of this chapter is required.

* * * * *

PART 385—RULES OF PRACTICE AND PROCEDURE

■ 3. The authority citation for part 385 continues to read as follows:

Authority: 5 U.S.C. 551–557; 15 U.S.C. 717–717w, 3301–3432; 16 U.S.C. 791a–825v, 2601–2645; 28 U.S.C. 2461; 31 U.S.C. 3701, 9701; 42 U.S.C. 7101–7352, 16441, 16451–16463; 49 U.S.C. 60502; 49 App. U.S.C. 1–85 (1988); 28 U.S.C. 2461 note (1990); 28 U.S.C. 2461 note (2015).

■ 4. Amend § 385.2011 by revising paragraphs (a)(8) and (c)(3) to read as follows:

§ 385.2011 Procedures for filing on electronic media (Rule 2011).

* * * * *

(a) * * *

(8) FERC Form No. 1–F, Annual report for Nonmajor public utilities and licensees.

* * * * *

(c) * * *

(3) With the exception of the FERC Form Nos. 1, 1–F, 2, 2–A, 6, 60, and 714, the electronic media must be accompanied by the traditional prescribed number of paper copies.

* * * * *

[FR Doc. 2019–00460 Filed 2–1–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF STATE

22 CFR Part 171

[Public Notice: 9987]

RIN 1400–AE17

Privacy Act; STATE–01, Email Archive Management Records

AGENCY: Department of State.

ACTION: Proposed rule.

SUMMARY: In this proposed rulemaking, the Department of State proposes to

[44] 5 U.S.C. 601(3), citing to section 3 of the Small Business Act, 15 U.S.C. 632. Section 3 of the Small Business Act defines a ''small business concern'' as a business that is independently owned and operated and that is not dominant in its field of operation. 15 U.S.C. 632. The Small Business Size Standards component of the NAICS defines, for example, a small electric utility as one that, including its affiliates, is primarily engaged in the generation, transmission, and/or distribution of electric energy for sale and whose quantity of employees falls under a certain threshold dependent on the type of utility and its applicable NAICS code.

exempt portions of the Email Archive Management Records, STATE–01, from certain provisions of the Privacy Act of 1974.

DATES: Comments must be received on or before April 5, 2019.

ADDRESSES: You may view this proposed rule and submit your comments by visiting the *regulations.gov* website at *www.regulations.gov,* and searching for docket number DOS–2018–0010.

FOR FURTHER INFORMATION CONTACT: John C. Sullivan, Senior Agency Official for Privacy; Office of Global Information Services, A/GIS; Department of State, SA–2; 515 22nd Street NW; Washington, DC 20522–8001, or at *Privacy@state.gov* or on (202) 261–8407. Please include ''RIN 1400–AE17 State–01'' in subject line of your email.

SUPPLEMENTARY INFORMATION:

The Department of State maintains the Email Archive Management Records system of records. The primary purpose of this system of records is to capture emails and attachments that interact with a Department of State email account and to store them in a secure repository that allows for search, retrieval, and view when necessary.

The Department of State intends to amend 22 CFR 171.26 to exempt portions of the Email Archive Management Records system of records from the Privacy Act. The Email Archive Management Records can include all email messages and attachments in a specific employee's inbox. Any exemptions that the Department has claimed in connection with other systems of records could apply to records in the Email Archive Management Records, because similar records could be included in or attached to emails that were sent or received by a Department employee.

Records in the Email Archive Management Records are exempted from all subsections of the Privacy Act, except for subsections (b), (c)(1) and (2), (e)(4)(A) through (F), (e)(6), (7), (9), (10), and (11), and (i), to the extent that those records meet the criteria of subsection (j)(2).

Records also may be exempt from subsections (c)(3); (d); (e)(1); (e)(4)(G), (H), and (I); and (f) of the Privacy Act pursuant to 5 U.S.C. 552a(k)(1), (k)(2), (k)(3), (k)(4), (k)(5), (k)(6), and (k)(7). STATE–01 is exempted under subsection (k)(1) to the extent that records are subject to the provisions of 5 U.S.C. 552(b)(1). STATE–01 is exempted under subsection (k)(2) to the extent that records are comprised of investigatory material compiled for law enforcement purposes, subject to the limitations set forth in subsection (k)(2). STATE–01 is exempted under subsection (k)(3) to the extent that records are related to providing protective services pursuant to 18 U.S.C. 3056. STATE–01 is exempted under subsection (k)(4) to the extent that records are required by statute to be maintained and are used solely as statistical records. STATE–01 is exempted under subsection (k)(5) to the extent that records consist of investigatory material compiled solely for the purpose of determining suitability, eligibility, or qualifications for federal civilian employment, military service, federal contracts, or access to classified information, but only to the extent that disclosure of such material would reveal the identity of a confidential informant. STATE–01 is exempted under subsection (k)(6) to the extent that records consist of testing or examination material used solely to determine individual qualifications for appointment or promotion in the federal service, the disclosure of which would compromise the objectivity or fairness of the testing or examination process. STATE–01 is exempted under subsection (k)(7) to the extent that records consist of evaluation material used to determine potential for promotion in the armed services, but only to the extent that such disclosure would reveal the identity of a confidential informant.

List of Subjects in 22 CFR Part 171

Administrative practice and procedure; Freedom of information; Privacy.

For the reasons stated in the preamble, 22 CFR part 171 is proposed to be amended as follows:

PART 171—[AMENDED]

■ 1. The authority for part 171 continues to read as follows:

Authority: 22 U.S.C. 2651a; 5 U.S.C. 552, 552a; E.O. 12600 (52 FR 23781); Pub. L. 95–521, 92 Stat. 1824 (codified as amended at 5 U.S.C. app. 101–505); 5 CFR part 2634.

■ 2. Section 171.26 is amended by:

a. Adding an entry, in alphabetical order, for ''Email Archive Management Records, STATE–01'' to the list in paragraph (a)(2)(iii); and

b. Adding an entry, in alphabetical order, for ''Email Archive Management Records, STATE–01'' to the lists in paragraphs (b)(1) through (7).

Dated: December 21, 2018.

John C. Sullivan,

Senior Agency Official for Privacy, Deputy Assistant Secretary, Office of Global Information Services, Bureau of Administration, Department of State.

[FR Doc. 2019–00893 Filed 2–1–19; 8:45 am]

BILLING CODE 4710–24–P

FEDERAL MEDIATION AND CONCILIATION SERVICE

29 CFR Part 1404

RIN 3076–AA14

Arbitration Services

Correction

In proposed rule document 2018–27759 appearing on pages 614–619 in the issue of Thursday, January 31, 2019, make the following correction:

On page 614, in the first column, under the **DATES** heading, in the third line, ''January 19, 2019'' should read ''February 28, 2019''.

[FR Doc. C1–2018–27759 Filed 2–1–19; 8:45 am]

BILLING CODE 1301–00–D

POSTAL REGULATORY COMMISSION

39 CFR Part 3020

[Docket No. RM2019–3; Order No. 4987]

Competitive Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Commission seeks comments on whether to update its regulations to address proposed classification changes to product descriptions in the Mail Classification Schedule that may modify the market and/or competitive products lists. This document informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* April 5, 2019.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

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II. Background
III. Request for Comments
IV. Ordering Paragraphs

I. Introduction

The Commission initiates this advanced notice of proposed rulemaking (ANPR) to seek comments on whether to update its regulations to address proposed classification changes to product descriptions in the Mail Classification Schedule (MCS) that may modify the market dominant and/or competitive product lists. The Commission is specifically reviewing changes to regulations involving updates to the size and weight limitations applicable to market dominant mail matter. *See* 39 CFR 3020.111.

II. Background

Section 3682 provides that the Postal Service may establish size and weight limitations for mail matter in the market dominant category of mail consistent with regulations the Postal Regulatory Commission may prescribe under section 3622. 39 U.S.C. 3682. Commission rule 3020.111(a) requires the Postal Service to inform the Commission of updates to size and weight limitations for market dominant mail matter. 39 CFR 3020.111(a). The Commission is required to evaluate any proposed updates ''in accordance with the policies and the applicable criteria of chapter 36 of 39 U.S.C.'' 39 CFR 3020.111(c).

In Docket No. MC2019–3, the Postal Service filed a request pursuant to 39 CFR 3020.111 seeking to change the weight limit to 15.994 ounces (from 64 ounces) for Outbound Single-Piece First-Class Mail International (FCMI) Large Envelopes (Flats).[1] The Postal Service stated that FCMI Flats weighing 16 ounces or more would be charged the applicable First-Class Package International Service (FCPIS) price.[2] FCPIS is an existing product on the competitive product list.

In its Response to CIR No. 1, the Postal Service stated that the proposed classification change would have no effect on the market dominant product list because the FCMI product would still appear on the product list. Response to CIR No. 1, question 1. The Postal Service explained that only the portions of MCS section 1125 that concern the weight limitations for FCMI Flats would be revised, pursuant to 39 U.S.C. 3682. *Id.* The Postal Service also asserted that neither section 3682 nor the Commission rules on updates to size and weight limitations refer to 39 U.S.C. 3642 or 39 CFR part 3020 subpart B governing modifications to the product lists. *Id.*

Because the proposed update was in accordance with the policies and applicable criteria of chapter 36 of title 39, the Commission approved the update to the weight limitation in Order No. 4932.[3] However, in that order, the Commission stated ''that the practical impact of the proposed update is a transfer of FCMI Flats weighing over 15.994 ounces from the market dominant product list to the competitive product list.'' Order No. 4932 at 5. The Commission went on to express concerns ''that the Postal Service could use the size and weight limitation regulations to make extensive changes to product lists without proper Commission oversight.'' *Id.* For example, the Public Representative, in that docket, considered that the Postal Service could effectively eliminate products from a product list by drastically reducing the range of a product's weight limitations or could effectively add products to a product list by greatly expanding the limitations.[4]

III. Request for Comments

The Commission establishes Docket No. RM2019–3 to evaluate whether changes to MCS provisions that, in effect, add products to, remove products from, or transfer products between product lists, are changes that implicate the requirements of section 3642. In particular, the Commission requests comments from interested parties on whether it should update its regulations to require information pursuant to section 3642 when changes to the size and weight limitations appear to modify the product lists. Comments are due no later than 60 days after the date of publication of this document in the **Federal Register**. Commission rules require that comments be filed online according to the process outlined at 39 CFR 3001.9(a), unless a waiver is obtained. Additional information regarding how to submit comments online can be found at: *http://www.prc.gov/how-to-participate.* All comments accepted will be made available on the Commission's website at: *http://www.prc.gov.*

Pursuant to 39 U.S.C. 505, Kenneth E. Richardson is designated as an officer of the Commission (Public Representative) to represent the interests of the general public in this proceeding.

IV. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket No. RM2019–3 to evaluate whether changes to MCS provisions that add products to, remove products from, or transfer products between product lists, are changes that implicate the requirements of 39 U.S.C. 3642.

2. Interested persons may submit comments no later than 60 days from the date of publication of this document in the **Federal Register**.

3. Pursuant to 39 U.C.S. 505, the Commission appoints Kenneth E. Richardson to serve as an officer of the Commission (Public Representative) to represent the interests of the general public in this docket.

4. The Secretary shall arrange for publication of this Order in the **Federal Register**.

By the Commission.

Stacy L. Ruble,

Secretary.

[FR Doc. 2019–00665 Filed 2–1–19; 8:45 am]

BILLING CODE 7710–FW–P

[1] Docket No. MC2019–3, Notice of the United States Postal Service of Update to the Maximum Weight Limit for Outbound Single-Piece First-Class Mail International Large Envelopes (Flats) in the Mail Classification Schedule, October 10, 2018.

[2] International Mailing Services: Product and Price Changes-CPI, 83 FR 52351 (October 17, 2018). The Postal Services stated that, if mailed as FCPIS, these mailpieces would be charged from 17 percent to 157 percent more than the prices for FCMI Flats. *See* Docket No. MC2019–3, Response of the United States Postal Service to Commission Information Request No. 1, October 26, 2018, question 2 (Response to CIR No. 1).

[3] Docket No. MC2019–3, Order Approving Update to Weight Limitation, December 19, 2018, at 5 (Order No. 4932).

[4] Docket No. MC2019–3, Public Representative Comments, November 13, 2018, at 7.

Notices

Federal Register
Vol. 84, No. 23
Monday, February 4, 2019

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF COMMERCE

Economic Development Administration

Notice of Petitions by Firms for Determination of Eligibility To Apply for Trade Adjustment Assistance

AGENCY: Economic Development Administration, U.S. Department of Commerce.

ACTION: Notice and opportunity for public comment.

SUMMARY: The Economic Development Administration (EDA) has received petitions for certification of eligibility to apply for Trade Adjustment Assistance from the firms listed below. Accordingly, EDA has initiated investigations to determine whether increased imports into the United States of articles like or directly competitive with those produced by each of the firms contributed importantly to the total or partial separation of the firms' workers, or threat thereof, and to a decrease in sales or production of each petitioning firm.

SUPPLEMENTARY INFORMATION:

LIST OF PETITIONS RECEIVED BY EDA FOR CERTIFICATION OF ELIGIBILITY TO APPLY FOR TRADE ADJUSTMENT ASSISTANCE

[12/06/2018 through 01/28/2019]

Firm name	Firm address	Date accepted for investigation	Product(s)
Gainey's Concrete Products, LLC	28021 Coker Vail Road, Holden, LA 70744.	12/14/2018	The firm manufactures custom precast concrete products.
Armbrust International, Ltd	735 Allens Avenue, Providence, RI 02905.	12/14/2018	The firm manufactures chains made of gold, platinum, sterling silver, and other metals for bracelets, necklaces, and other jewelry.
Work Warm, LLC d/b/a Fortress Clothing and Aeris.	1175 South Blackhawk Boulevard, Mount Pleasant, UT 84647.	12/20/2018	The firm manufacturers cold weather clothing.

Any party having a substantial interest in these proceedings may request a public hearing on the matter. A written request for a hearing must be submitted to the Trade Adjustment Assistance Division, Room 71030, Economic Development Administration, U.S. Department of Commerce, Washington, DC 20230, no later than ten (10) calendar days following publication of this notice. These petitions are received pursuant to section 251 of the Trade Act of 1974, as amended.

Please follow the requirements set forth in EDA's regulations at 13 CFR 315.9 for procedures to request a public hearing. The Catalog of Federal Domestic Assistance official number and title for the program under which these petitions are submitted is 11.313, Trade Adjustment Assistance for Firms.

Irette Patterson,
Program Analyst.

[FR Doc. 2019–00801 Filed 2–1–19; 8:45 am]

BILLING CODE 3510–WH–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

Order Denying Export Privileges

In the Matter of: Eduard Roel Vazquez, Inmate Number: 32385–479, FCI Beaumont, P.O. Box 26020, Beaumont, TX 77720.

On March 22, 2018, in the U.S. District Court for the Southern District of Texas, Eduard Roel Vazquez (''Vazquez'') was convicted of violating Section 38 of the Arms Export Control Act (22 U.S.C. 2778 (2012)) (''AECA''). Vazquez was convicted of violating Section 38 of the AECA by knowingly and willfully aiding and abetting the export of, and attempting to export, two 7.62x39mm rifles and a 5.56mm rifle, items designated as defense articles on the United States Munitions List, from the United States to Mexico, without the required U.S. Department of State licenses. Vazquez was sentenced to 38 months in prison, three years of supervised release, and a $100 assessment.

The Export Administration Regulations (''EAR'' or ''Regulations'') are administered and enforced by the U.S. Department of Commerce's Bureau of Industry and Security (''BIS'').[1]

[1] The Regulations are currently codified in the Code of Federal Regulations at 15 CFR Parts 730–774 (2018). The Regulations originally issued under the Export Administration Act of 1979, as amended, 50 U.S.C. 4601–4623 (Supp. III 2015) (''EAA''), which lapsed on August 21, 2001. The President, through Executive Order 13,222 of August 17, 2001

Section 766.25 of the Regulations provides, in pertinent part, that the ''Director of [BIS's] Office of Exporter Services, in consultation with the Director of [BIS's] Office of Export Enforcement, may deny the export privileges of any person who has been convicted of a violation of . . . section 38 of the Arms Export Control Act (22 U.S.C. 2778).'' 15 CFR 766.25(a). The denial of export privileges under this provision may be for a period of up to 10 years from the date of the conviction. 15 CFR 766.25(d).[2] In addition, pursuant to Section 750.8 of the Regulations, BIS's Office of Exporter Services may revoke any BIS-issued licenses in which the person had an interest at the time of his/her conviction.[3]

BIS has received notice of Vazquez's conviction for violating Section 38 of the AECA, and has provided notice and an opportunity for Vazquez to make a written submission to BIS, as provided in Section 766.25 of the Regulations. BIS has not received a submission from Vazquez.

Based upon my review and consultations with BIS's Office of Export Enforcement, including its Director, and the facts available to BIS, I have decided to deny Vazquez's export privileges under the Regulations for a period of 10 years from the date of Vazquez's conviction. I have also decided to revoke all BIS-issued licenses in which Vazquez had an interest at the time of his conviction.

Accordingly, it is hereby *ordered*:

First, from the date of this Order until March 22, 2028, Eduard Roel Vazquez with a last known address of Inmate Number: 32385–479, FCI Beaumont, P.O. Box 26020, Beaumont, TX 77720, and when acting for or on his behalf, his successors, assigns, employees, agents or representatives (''the Denied Person''), may not, directly or indirectly, participate in any way in any transaction involving any commodity, software or technology (hereinafter collectively referred to as ''item'') exported or to be exported from the United States that is subject to the Regulations, including, but not limited to:

A. Applying for, obtaining, or using any license, license exception, or export control document;

B. Carrying on negotiations concerning, or ordering, buying, receiving, using, selling, delivering, storing, disposing of, forwarding, transporting, financing, or otherwise servicing in any way, any transaction involving any item exported or to be exported from the United States that is subject to the Regulations, or engaging in any other activity subject to the Regulations; or

C. Benefitting in any way from any transaction involving any item exported or to be exported from the United States that is subject to the Regulations, or from any other activity subject to the Regulations.

Second, no person may, directly or indirectly, do any of the following:

A. Export or reexport to or on behalf of the Denied Person any item subject to the Regulations;

B. Take any action that facilitates the acquisition or attempted acquisition by the Denied Person of the ownership, possession, or control of any item subject to the Regulations that has been or will be exported from the United States, including financing or other support activities related to a transaction whereby the Denied Person acquires or attempts to acquire such ownership, possession or control;

C. Take any action to acquire from or to facilitate the acquisition or attempted acquisition from the Denied Person of any item subject to the Regulations that has been exported from the United States;

D. Obtain from the Denied Person in the United States any item subject to the Regulations with knowledge or reason to know that the item will be, or is intended to be, exported from the United States; or

E. Engage in any transaction to service any item subject to the Regulations that has been or will be exported from the United States and which is owned, possessed or controlled by the Denied Person, or service any item, of whatever origin, that is owned, possessed or controlled by the Denied Person if such service involves the use of any item subject to the Regulations that has been or will be exported from the United States. For purposes of this paragraph, servicing means installation, maintenance, repair, modification or testing.

Third, after notice and opportunity for comment as provided in Section 766.23 of the Regulations, any other person, firm, corporation, or business organization related to Vazquez by ownership, control, position of responsibility, affiliation, or other connection in the conduct of trade or business may also be made subject to the provisions of this Order in order to prevent evasion of this Order.

Fourth, in accordance with Part 756 of the Regulations, Vazquez may file an appeal of this Order with the Under Secretary of Commerce for Industry and Security. The appeal must be filed within 45 days from the date of this Order and must comply with the provisions of Part 756 of the Regulations.

Fifth, a copy of this Order shall be delivered to Vazquez and shall be published in the **Federal Register**.

Sixth, this Order is effective immediately and shall remain in effect until March 22, 2028.

Issued this 31 day of December, 2018.

Karen H. Nies-Vogel,

Director, Office of Exporter Services.

[FR Doc. 2019–00862 Filed 2–1–19; 8:45 am]

BILLING CODE P

(3 CFR, 2001 Comp. 783 (2002)), which has been extended by successive Presidential Notices, the most recent being that of August 8, 2018 (83 FR 39,871 (Aug. 13, 2018)), continued the Regulations in full force and effect under the International Emergency Economic Powers Act, 50 U.S.C. 1701, *et seq.* (2012) (''IEEPA''). On August 13, 2018, the President signed into law the John S. McCain National Defense Authorization Act for Fiscal Year 2019, which includes the Export Control Reform Act of 2018, Title XVII, Subtitle B of Public Law 115–232, 132 Stat. 2208 (''ECRA''). While Section 1766 of ECRA repeals the provisions of the EAA (except for three sections which are inapplicable here), Section 1768 of ECRA provides, in pertinent part, that all rules and regulations that were made or issued under the EAA, including as continued in effect pursuant to IEEPA, and were in effect as of ECRA's date of enactment (August 13, 2018), shall continue in effect according to their terms until modified, superseded, set aside, or revoked through action undertaken pursuant to the authority provided under ECRA.

[2] *See also* Section 11(h) of the EAA, 50 U.S.C. 4610(h) (Supp. III 2015); Sections 1760(e) and 1768 of ECRA, Title XVII, Subtitle B of Public Law 115–232, 132 Stat. 2208, 2225 and 2233 (Aug. 13, 2018); and note 1, *supra.*

[3] *See* notes 1 and 2, *supra.*

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

In the Matter of: Veronica Trujillo, Inmate Number: 64909–408, FCI Phoenix, 37910 N 45th Avenue, Phoenix, AZ 85086; Order Denying Export Privileges

On August 11, 2017, in the U.S. District Court for the District of Arizona, Veronica Trujillo (''Trujillo'') was convicted of violating Section 38 of the Arms Export Control Act (22 U.S.C. 2778 (2012)) (''AECA''). Trujillo was convicted of violating Section 38 of the AECA by attempting to willfully and knowingly export and cause to be exported from the United States to Mexico 2000 rounds of Wolf 7.62x39 mm ammunition and 1,000 rounds of Wolf 9MM luger ammunition, items designated as defense articles on the United States Munitions List, without the required U.S. Department of State licenses. Trujillo was sentenced to 46 months in prison, with credit for time served, three years of supervised

release, and an assessment of $100. Trujillo also was placed on the U.S. Department of State Debarred List.

The Export Administration Regulations (''EAR'' or ''Regulations'') are administered and enforced by the U.S. Department of Commerce's Bureau of Industry and Security (''BIS'').[1] Section 766.25 of the Regulations provides, in pertinent part, that the ''Director of [BIS's] Office of Exporter Services, in consultation with the Director of [BIS's] Office of Export Enforcement, may deny the export privileges of any person who has been convicted of a violation of . . . section 38 of the Arms Export Control Act (22 U.S.C. 2778).'' 15 CFR 766.25(a). The denial of export privileges under this provision may be for a period of up to 10 years from the date of the conviction. 15 CFR 766.25(d).[2] In addition, pursuant to Section 750.8 of the Regulations, BIS's Office of Exporter Services may revoke any BIS-issued licenses in which the person had an interest at the time of his/her conviction.[3]

BIS has received notice of Trujillo's conviction for violating Section 38 of the AECA, and has provided notice and an opportunity for Trujillo to make a written submission to BIS, as provided in Section 766.25 of the Regulations. BIS has not received a submission from Trujillo.

Based upon my review and consultations with BIS's Office of Export Enforcement, including its Director, and the facts available to BIS, I have decided to deny Trujillo's export privileges under the Regulations for a period of seven years from the date of Trujillo's conviction. I have also decided to revoke all BIS-issued licenses in which Trujillo had an interest at the time of her conviction.

Accordingly, it is hereby *ordered:*

First, from the date of this Order until August 11, 2024, Veronica Trujillo, with a last known address of Inmate Number: 64909–408, FCI Phoenix, 37910 N 45th Avenue, Phoenix, AZ 85086, and when acting for or on her behalf, her successors, assigns, employees, agents or representatives (''the Denied Person''), may not, directly or indirectly, participate in any way in any transaction involving any commodity, software or technology (hereinafter collectively referred to as ''item'') exported or to be exported from the United States that is subject to the Regulations, including, but not limited to:

A. Applying for, obtaining, or using any license, license exception, or export control document;

B. Carrying on negotiations concerning, or ordering, buying, receiving, using, selling, delivering, storing, disposing of, forwarding, transporting, financing, or otherwise servicing in any way, any transaction involving any item exported or to be exported from the United States that is subject to the Regulations, or engaging in any other activity subject to the Regulations; or

C. Benefitting in any way from any transaction involving any item exported or to be exported from the United States that is subject to the Regulations, or from any other activity subject to the Regulations.

Second, no person may, directly or indirectly, do any of the following:

A. Export or reexport to or on behalf of the Denied Person any item subject to the Regulations;

B. Take any action that facilitates the acquisition or attempted acquisition by the Denied Person of the ownership, possession, or control of any item subject to the Regulations that has been or will be exported from the United States, including financing or other support activities related to a transaction whereby the Denied Person acquires or attempts to acquire such ownership, possession or control;

C. Take any action to acquire from or to facilitate the acquisition or attempted acquisition from the Denied Person of any item subject to the Regulations that has been exported from the United States;

D. Obtain from the Denied Person in the United States any item subject to the Regulations with knowledge or reason to know that the item will be, or is intended to be, exported from the United States; or

E. Engage in any transaction to service any item subject to the Regulations that has been or will be exported from the United States and which is owned, possessed or controlled by the Denied Person, or service any item, of whatever origin, that is owned, possessed or controlled by the Denied Person if such service involves the use of any item subject to the Regulations that has been or will be exported from the United States. For purposes of this paragraph, servicing means installation, maintenance, repair, modification or testing.

Third, after notice and opportunity for comment as provided in Section 766.23 of the Regulations, any other person, firm, corporation, or business organization related to Trujillo by ownership, control, position of responsibility, affiliation, or other connection in the conduct of trade or business may also be made subject to the provisions of this Order in order to prevent evasion of this Order.

Fourth, in accordance with Part 756 of the Regulations, Trujillo may file an appeal of this Order with the Under Secretary of Commerce for Industry and Security. The appeal must be filed within 45 days from the date of this Order and must comply with the provisions of Part 756 of the Regulations.

Fifth, a copy of this Order shall be delivered to Trujillo and shall be published in the **Federal Register**.

Sixth, this Order is effective immediately and shall remain in effect until August 11, 2024.

Issued this 31st day of December 2018.

Karen H. Nies-Vogel,

Director, Office of Exporter Services.

[FR Doc. 2019–00863 Filed 2–1–19; 8:45 am]

BILLING CODE P

[1] The Regulations are currently codified in the Code of Federal Regulations at 15 CFR Parts 730–774 (2018). The Regulations originally issued under the Export Administration Act of 1979, as amended, 50 U.S.C. 4601–4623 (Supp. III 2015) (''EAA''), which lapsed on August 21, 2001. The President, through Executive Order 13,222 of August 17, 2001 (3 CFR, 2001 Comp. 783 (2002)), which has been extended by successive Presidential Notices, the most recent being that of August 8, 2018 (83 FR 39,871 (Aug. 13, 2018)), continued the Regulations in full force and effect under the International Emergency Economic Powers Act, 50 U.S.C. 1701, *et seq.* (2012) (''IEEPA''). On August 13, 2018, the President signed into law the John S. McCain National Defense Authorization Act for Fiscal Year 2019, which includes the Export Control Reform Act of 2018, Title XVII, Subtitle B of Public Law 115–232, 132 Stat. 2208 (''ECRA''). While Section 1766 of ECRA repeals the provisions of the EAA (except for three sections which are inapplicable here), Section 1768 of ECRA provides, in pertinent part, that all rules and regulations that were made or issued under the EAA, including as continued in effect pursuant to IEEPA, and were in effect as of ECRA's date of enactment (August 13, 2018), shall continue in effect according to their terms until modified, superseded, set aside, or revoked through action undertaken pursuant to the authority provided under ECRA.

[2] *See also* Section 11(h) of the EAA, 50 U.S.C. 4610(h) (Supp. III 2015); Sections 1760(e) and 1768 of ECRA, Title XVII, Subtitle B of Public Law 115–232, 132 Stat. 2208, 2225 and 2233 (Aug. 13, 2018); and note 1, *supra.*

[3] *See* notes 1 and 2, *supra.*

DEPARTMENT OF COMMERCE

Bureau of Industry And Security

In the Matter of: Alexander Fishenko, Inmate Number: 73080–279, FCI Three Rivers, P.O. Box 4200, Three Rivers, TX 78071; Order Denying Export Privileges

On July 21, 2016, in the U.S. District Court for the Eastern District of New York, Alexander Fishenko (''Fishenko'') was convicted of violating the International Emergency Economic

Powers Act (50 U.S.C. § 1701, *et seq.* (2012)) (''IEEPA'') and Section 38 of the Arms Export Control Act (22 U.S.C. 2778 (2012)) (''AECA'').

Specifically, Fishenko was convicted of knowingly, intentionally and willfully exporting from the United States to Russia microelectronics without the required U.S. Department of Commerce licenses, in violation of IEEPA. Fishenko was also convicted of knowingly, intentionally and willfully exporting from the United States to Russia power amplifiers designated as defense articles on the United States Munitions List, namely five TriQuint parts TGA2517, without the required U.S. Department of State licenses, in violation of the AECA. Fishenko was sentenced to 120 months in prison, three years of supervised release, and a $1,900 assessment, and forfeited over $500,000 in criminal proceeds to the United States. Fishenko also was placed on the U.S. Department of State Debarred List.

The Export Administration Regulations (''EAR'' or ''Regulations'') are administered and enforced by the U.S. Department of Commerce's Bureau of Industry and Security (''BIS'').[1] Section 766.25 of the Regulations provides, in pertinent part, that the ''Director of [BIS's] Office of Exporter Services, in consultation with the Director of [BIS's] Office of Export Enforcement, may deny the export privileges of any person who has been convicted of a violation of . . . the International Emergency Economic Powers Act (50 U.S.C. § 1701–1706) . . . or section 38 of the Arms Export Control Act (22 U.S.C. 2778).'' 15 CFR 766.25(a). The denial of export privileges under this provision may be for a period of up to 10 years from the date of the conviction. 15 CFR 766.25(d).[2] In addition, pursuant to Section 750.8 of the Regulations, BIS's Office of Exporter Services may revoke any BIS-issued licenses in which the person had an interest at the time of his/her conviction.[3]

BIS has received notice of Fishenko's conviction for violating IEEPA and Section 38 of the AECA, and has provided notice and an opportunity for Fishenko to make a written submission to BIS, as provided in Section 766.25 of the Regulations. BIS has received a submission from Fishenko, via his counsel.

Based upon my review of the record, including Fishenko's submission and the facts available to BIS, and my consultations with BIS's Office of Export Enforcement, including its Director, I have decided to deny Fishenko's export privileges under the Regulations for a period of 10 years from the date of Fishenko's conviction. I have also decided to revoke all BIS-issued licenses in which Fishenko had an interest at the time of his conviction.

Accordingly, it is hereby *ordered*:

First, from the date of this Order until July 21, 2026, Alexander Fishenko with a last known address of Inmate Number: 73080–279, FCI Three Rivers, P.O. Box 4200, Three Rivers, TX 78071, and when acting for or on his behalf, his successors, assigns, employees, agents or representatives (''the Denied Person''), may not, directly or indirectly, participate in any way in any transaction involving any commodity, software or technology (hereinafter collectively referred to as ''item'') exported or to be exported from the United States that is subject to the Regulations, including, but not limited to:

A. Applying for, obtaining, or using any license, license exception, or export control document;

B. Carrying on negotiations concerning, or ordering, buying, receiving, using, selling, delivering, storing, disposing of, forwarding, transporting, financing, or otherwise servicing in any way, any transaction involving any item exported or to be exported from the United States that is subject to the Regulations, or engaging in any other activity subject to the Regulations; or

C. Benefitting in any way from any transaction involving any item exported or to be exported from the United States that is subject to the Regulations, or from any other activity subject to the Regulations.

Second, no person may, directly or indirectly, do any of the following:

A. Export or reexport to or on behalf of the Denied Person any item subject to the Regulations;

B. Take any action that facilitates the acquisition or attempted acquisition by the Denied Person of the ownership, possession, or control of any item subject to the Regulations that has been or will be exported from the United States, including financing or other support activities related to a transaction whereby the Denied Person acquires or attempts to acquire such ownership, possession or control;

C. Take any action to acquire from or to facilitate the acquisition or attempted acquisition from the Denied Person of any item subject to the Regulations that has been exported from the United States;

D. Obtain from the Denied Person in the United States any item subject to the Regulations with knowledge or reason to know that the item will be, or is intended to be, exported from the United States; or

E. Engage in any transaction to service any item subject to the Regulations that has been or will be exported from the United States and which is owned, possessed or controlled by the Denied Person, or service any item, of whatever origin, that is owned, possessed or controlled by the Denied Person if such service involves the use of any item subject to the Regulations that has been or will be exported from the United States. For purposes of this paragraph, servicing means installation, maintenance, repair, modification or testing.

Third, after notice and opportunity for comment as provided in Section 766.23 of the Regulations, any other person, firm, corporation, or business organization related to Fishenko by ownership, control, position of responsibility, affiliation, or other connection in the conduct of trade or business may also be made subject to the provisions of this Order in order to prevent evasion of this Order.

Fourth, in accordance with Part 756 of the Regulations, Fishenko may file an appeal of this Order with the Under Secretary of Commerce for Industry and Security. The appeal must be filed within 45 days from the date of this Order and must comply with the provisions of Part 756 of the Regulations.

[1] The Regulations are currently codified in the Code of Federal Regulations at 15 CFR Parts 730–774 (2018). The Regulations originally issued under the Export Administration Act of 1979, as amended, 50 U.S.C. 4601–4623 (Supp. III 2015) (''EAA''), which lapsed on August 21, 2001. The President, through Executive Order 13,222 of August 17, 2001 (3 CFR, 2001 Comp. 783 (2002)), which has been extended by successive Presidential Notices, the most recent being that of August 8, 2018 (83 FR 39,871 (Aug. 13, 2018)), continued the Regulations in full force and effect under the International Emergency Economic Powers Act, 50 U.S.C. 1701, *et seq.* (2012) (''IEEPA''). On August 13, 2018, the President signed into law the John S. McCain National Defense Authorization Act for Fiscal Year 2019, which includes the Export Control Reform Act of 2018, Title XVII, Subtitle B of Public Law 115–232, 132 Stat. 2208 (''ECRA''). While Section 1766 of ECRA repeals the provisions of the EAA (except for three sections which are inapplicable here), Section 1768 of ECRA provides, in pertinent part, that all rules and regulations that were made or issued under the EAA, including as continued in effect pursuant to IEEPA, and were in effect as of ECRA's date of enactment (August 13, 2018), shall continue in effect according to their terms until modified, superseded, set aside, or revoked through action undertaken pursuant to the authority provided under ECRA.

[2] *See also* Section 11(h) of the EAA, 50 U.S.C. 4610(h) (Supp. III 2015); Sections 1760(e) and 1768 of ECRA, Title XVII, Subtitle B of Public Law 115–232, 132 Stat. 2208, 2225 and 2233 (Aug. 13, 2018); and note 1, *supra.*

[3] *See* notes 1 and 2, *supra.*

Fifth, a copy of this Order shall be delivered to Fishenko and shall be published in the **Federal Register**.

Sixth, this Order is effective immediately and shall remain in effect until July 21, 2026.

Issued this 31st day of December, 2018.

Karen H. Nies-Vogel,

Director, Office of Exporter Services.

[FR Doc. 2019–00857 Filed 2–1–19; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

Order Denying Export Privileges

In the Matter of: Joel Prado, Jr., Inmate Number: 16443–479, USP Beaumont, U.S. Penitentiary, P.O. Box 26030, Beaumont, TX 77720

On February 23, 2017, in the U.S. District Court for the Southern District of Texas, Joel Prado, Jr. (''Prado'') was convicted of violating Section 38 of the Arms Export Control Act (22 U.S.C. 2778 (2012)) (''AECA''). Prado was convicted of violating Section 38 of the AECA by conspiring to knowingly and willfully export and cause to be exported from the United States to Mexico .223 caliber rifles, items designated as defense articles on the United States Munitions List, without the required U.S. Department of State licenses. Prado was sentenced to 96 months in prison, three years of supervised release, and an assessment of $200.

The Export Administration Regulations (''EAR'' or ''Regulations'') are administered and enforced by the U.S. Department of Commerce's Bureau of Industry and Security (''BIS'').[1] Section 766.25 of the Regulations provides, in pertinent part, that the ''Director of [BIS's] Office of Exporter Services, in consultation with the Director of [BIS's] Office of Export Enforcement, may deny the export privileges of any person who has been convicted of a violation of . . . section 38 of the Arms Export Control Act (22 U.S.C. 2778).'' 15 CFR 766.25(a). The denial of export privileges under this provision may be for a period of up to 10 years from the date of the conviction. 15 CFR 766.25(d).[2] In addition, pursuant to Section 750.8 of the Regulations, BIS's Office of Exporter Services may revoke any BIS-issued licenses in which the person had an interest at the time of his/her conviction.[3]

BIS has received notice of Prado's conviction for violating Section 38 of the AECA, and has provided notice and an opportunity for Prado to make a written submission to BIS, as provided in Section 766.25 of the Regulations. BIS has not received a submission from Prado.

Based upon my review and consultations with BIS's Office of Export Enforcement, including its Director, and the facts available to BIS, I have decided to deny Prado's export privileges under the Regulations for a period of 10 years from the date of Prado's conviction. I have also decided to revoke all BIS-issued licenses in which Prado had an interest at the time of his conviction.

Accordingly, it is hereby *ordered*:

First, from the date of this Order until February 23, 2027, Joel Prado, Jr., with a last known address of Inmate Number: 16443–479, USP Beaumont, U.S. Penitentiary, P.O. Box 26030, Beaumont, TX 77720, and when acting for or on his behalf, his successors, assigns, employees, agents or representatives (''the Denied Person''), may not, directly or indirectly, participate in any way in any transaction involving any commodity, software or technology (hereinafter collectively referred to as ''item'') exported or to be exported from the United States that is subject to the Regulations, including, but not limited to:

A. Applying for, obtaining, or using any license, license exception, or export control document;

B. Carrying on negotiations concerning, or ordering, buying, receiving, using, selling, delivering, storing, disposing of, forwarding, transporting, financing, or otherwise servicing in any way, any transaction involving any item exported or to be exported from the United States that is subject to the Regulations, or engaging in any other activity subject to the Regulations; or

C. Benefitting in any way from any transaction involving any item exported or to be exported from the United States that is subject to the Regulations, or from any other activity subject to the Regulations.

Second, no person may, directly or indirectly, do any of the following:

A. Export or reexport to or on behalf of the Denied Person any item subject to the Regulations;

B. Take any action that facilitates the acquisition or attempted acquisition by the Denied Person of the ownership, possession, or control of any item subject to the Regulations that has been or will be exported from the United States, including financing or other support activities related to a transaction whereby the Denied Person acquires or attempts to acquire such ownership, possession or control;

C. Take any action to acquire from or to facilitate the acquisition or attempted acquisition from the Denied Person of any item subject to the Regulations that has been exported from the United States;

D. Obtain from the Denied Person in the United States any item subject to the Regulations with knowledge or reason to know that the item will be, or is intended to be, exported from the United States; or

E. Engage in any transaction to service any item subject to the Regulations that has been or will be exported from the United States and which is owned, possessed or controlled by the Denied Person, or service any item, of whatever origin, that is owned, possessed or controlled by the Denied Person if such service involves the use of any item subject to the Regulations that has been or will be exported from the United States. For purposes of this paragraph, servicing means installation, maintenance, repair, modification or testing.

Third, after notice and opportunity for comment as provided in Section 766.23 of the Regulations, any other person, firm, corporation, or business organization related to Prado by ownership, control, position of responsibility, affiliation, or other connection in the conduct of trade or business may also be made subject to

[1] The Regulations are currently codified in the Code of Federal Regulations at 15 CFR parts 730–774 (2018). The Regulations originally issued under the Export Administration Act of 1979, as amended, 50 U.S.C. 4601–4623 (Supp. III 2015) (''EAA''), which lapsed on August 21, 2001. The President, through Executive Order 13222 of August 17, 2001 (3 CFR, 2001 Comp. 783 (2002)), which has been extended by successive Presidential Notices, the most recent being that of August 8, 2018 (83 FR 39871 (Aug. 13, 2018)), continued the Regulations in full force and effect under the International Emergency Economic Powers Act, 50 U.S.C. 1701, *et seq.* (2012) (''IEEPA''). On August 13, 2018, the President signed into law the John S. McCain National Defense Authorization Act for Fiscal Year 2019, which includes the Export Control Reform Act of 2018, Title XVII, Subtitle B of Public Law 115–232, 132 Stat. 2208 (''ECRA''). While Section 1766 of ECRA repeals the provisions of the EAA (except for three sections which are inapplicable here), Section 1768 of ECRA provides, in pertinent part, that all rules and regulations that were made or issued under the EAA, including as continued in effect pursuant to IEEPA, and were in effect as of ECRA's date of enactment (August 13, 2018), shall continue in effect according to their terms until modified, superseded, set aside, or revoked through action undertaken pursuant to the authority provided under ECRA.

[2] *See also* Section 11(h) of the EAA, 50 U.S.C. 4610(h) (Supp. III 2015); Sections 1760(e) and 1768 of ECRA, Title XVII, Subtitle B of Public Law 115–232, 132 Stat. 2208, 2225 and 2233 (Aug. 13, 2018); and note 1, *supra.*

[3] *See* notes 1 and 2, *supra.*

the provisions of this Order in order to prevent evasion of this Order.

Fourth, in accordance with Part 756 of the Regulations, Prado may file an appeal of this Order with the Under Secretary of Commerce for Industry and Security. The appeal must be filed within 45 days from the date of this Order and must comply with the provisions of Part 756 of the Regulations.

Fifth, a copy of this Order shall be delivered to Prado and shall be published in the **Federal Register**.

Sixth, this Order is effective immediately and shall remain in effect until February 23, 2027.

Issued this 31st day of December 2018.

Karen H. Nies-Vogel,

Director, Office of Exporter Services.

[FR Doc. 2019–00864 Filed 2–1–19; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

In the Matter of: Jose Jesus Campos-Flores, Inmate Number: 22762–479, FCI Bastrop, P.O. Box 1010, Bastrop, TX 78602; Order Denying Export Privileges

On November 16, 2017, in the U.S. District Court for the Southern District of Texas, Jose Jesus Campos-Flores (''Campos-Flores'') was convicted of violating Section 38 of the Arms Export Control Act (22 U.S.C. 2778 (2012)) (''AECA''). Campos-Flores was convicted of violating Section 38 of the AECA by knowingly exporting and attempting to export from the United States to Mexico firearms designated as defense articles on the United States Munitions List, without the required U.S. Department of State licenses. Campos-Flores was sentenced to 36 months in prison, three years of supervised release, and an assessment of $100.

The Export Administration Regulations (''EAR'' or ''Regulations'') are administered and enforced by the U.S. Department of Commerce's Bureau of Industry and Security (''BIS'').[1] Section 766.25 of the Regulations provides, in pertinent part, that the ''Director of [BIS's] Office of Exporter Services, in consultation with the Director of [BIS's] Office of Export Enforcement, may deny the export privileges of any person who has been convicted of a violation of . . . section 38 of the Arms Export Control Act (22 U.S.C. 2778).'' 15 CFR 766.25(a). The denial of export privileges under this provision may be for a period of up to 10 years from the date of the conviction. 15 CFR 766.25(d).[2] In addition, pursuant to Section 750.8 of the Regulations, BIS's Office of Exporter Services may revoke any BIS-issued licenses in which the person had an interest at the time of his/her conviction.[3]

BIS has received notice of Campos-Flores's conviction for violating Section 38 of the AECA, and has provided notice and an opportunity for Campos-Flores to make a written submission to BIS, as provided in Section 766.25 of the Regulations. BIS has not received a submission from Campos-Flores.

Based upon my review and consultations with BIS's Office of Export Enforcement, including its Director, and the facts available to BIS, I have decided to deny Campos-Flores's export privileges under the Regulations for a period of seven years from the date of Campos-Flores's conviction. I have also decided to revoke all BIS-issued licenses in which Campos-Flores had an interest at the time of his conviction.

Accordingly, it is hereby *ordered*:

First, from the date of this Order until November 16, 2024, Jose Jesus Campos-Flores, with a last known address of Inmate Number: 22762–479, FCI Bastrop, P.O. Box 1010, Bastrop, TX 78602, and when acting for or on his behalf, his successors, assigns, employees, agents or representatives (''the Denied Person''), may not, directly or indirectly, participate in any way in any transaction involving any commodity, software or technology (hereinafter collectively referred to as ''item'') exported or to be exported from the United States that is subject to the Regulations, including, but not limited to:

A. Applying for, obtaining, or using any license, license exception, or export control document;

B. Carrying on negotiations concerning, or ordering, buying, receiving, using, selling, delivering, storing, disposing of, forwarding, transporting, financing, or otherwise servicing in any way, any transaction involving any item exported or to be exported from the United States that is subject to the Regulations, or engaging in any other activity subject to the Regulations; or

C. Benefitting in any way from any transaction involving any item exported or to be exported from the United States that is subject to the Regulations, or from any other activity subject to the Regulations.

Second, no person may, directly or indirectly, do any of the following:

A. Export or reexport to or on behalf of the Denied Person any item subject to the Regulations;

B. Take any action that facilitates the acquisition or attempted acquisition by the Denied Person of the ownership, possession, or control of any item subject to the Regulations that has been or will be exported from the United States, including financing or other support activities related to a transaction whereby the Denied Person acquires or attempts to acquire such ownership, possession or control;

C. Take any action to acquire from or to facilitate the acquisition or attempted acquisition from the Denied Person of any item subject to the Regulations that has been exported from the United States;

D. Obtain from the Denied Person in the United States any item subject to the Regulations with knowledge or reason to know that the item will be, or is intended to be, exported from the United States; or

E. Engage in any transaction to service any item subject to the Regulations that has been or will be exported from the United States and which is owned, possessed or controlled by the Denied Person, or service any item, of whatever origin, that is owned, possessed or controlled by the Denied Person if such service involves the use of any item subject to the Regulations that has been or will be exported from the United States. For purposes of this paragraph, servicing means installation,

[1] The Regulations are currently codified in the Code of Federal Regulations at 15 CFR parts 730–774 (2018). The Regulations originally issued under the Export Administration Act of 1979, as amended, 50 U.S.C. 4601–4623 (Supp. III 2015) (''EAA''), which lapsed on August 21, 2001. The President, through Executive Order 13,222 of August 17, 2001 (3 CFR, 2001 Comp. 783 (2002)), which has been extended by successive Presidential Notices, the most recent being that of August 8, 2018 (83 FR 39,871 (Aug. 13, 2018)), continued the Regulations in full force and effect under the International Emergency Economic Powers Act, 50 U.S.C. 1701, *et seq.* (2012) (''IEEPA''). On August 13, 2018, the President signed into law the John S. McCain National Defense Authorization Act for Fiscal Year 2019, which includes the Export Control Reform Act of 2018, Title XVII, Subtitle B of Public Law 115–232, 132 Stat. 2208 (''ECRA''). While Section 1766 of ECRA repeals the provisions of the EAA (except for three sections which are inapplicable here), Section 1768 of ECRA provides, in pertinent part, that all rules and regulations that were made or issued under the EAA, including as continued in effect pursuant to IEEPA, and were in effect as of ECRA's date of enactment (August 13, 2018), shall continue in effect according to their terms until modified, superseded, set aside, or revoked through action undertaken pursuant to the authority provided under ECRA.

[2] *See also* Section 11(h) of the EAA, 50 U.S.C. 4610(h) (Supp. III 2015); Sections 1760(e) and 1768 of ECRA, Title XVII, Subtitle B of Public Law 115–232, 132 Stat. 2208, 2225 and 2233 (Aug. 13, 2018); and note 1, *supra.*

[3] *See* notes 1 and 2, *supra.*

maintenance, repair, modification or testing.

Third, after notice and opportunity for comment as provided in Section 766.23 of the Regulations, any other person, firm, corporation, or business organization related to Campos-Flores by ownership, control, position of responsibility, affiliation, or other connection in the conduct of trade or business may also be made subject to the provisions of this Order in order to prevent evasion of this Order.

Fourth, in accordance with Part 756 of the Regulations, Campos-Flores may file an appeal of this Order with the Under Secretary of Commerce for Industry and Security. The appeal must be filed within 45 days from the date of this Order and must comply with the provisions of Part 756 of the Regulations.

Fifth, a copy of this Order shall be delivered to Campos-Flores and shall be published in the **Federal Register**.

Sixth, this Order is effective immediately and shall remain in effect until November 16, 2024.

Issued this 31 day of December 2018.

Karen H. Nies-Vogel,

Director, Office of Exporter Services.

[FR Doc. 2019–00859 Filed 2–1–19; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XG516

Marine Mammals; File No. 22141

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; receipt of application.

SUMMARY: Notice is hereby given that Samuel Wasser, Ph.D., University of Washington, Department of Biology, P.O. Box 351800, Seattle, WA, 98195, has applied in due form for a permit to conduct research on marine mammals.

DATES: Written, telefaxed, or email comments must be received on or before March 6, 2019.

ADDRESSES: The application and related documents are available for review by selecting ''Records Open for Public Comment'' from the ''Features'' box on the Applications and Permits for Protected Species (APPS) home page, *https://apps.nmfs.noaa.gov,* and then selecting File No. 22141 from the list of available applications.

These documents are also available upon written request or by appointment in the Permits and Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301) 427–8401; fax (301) 713–0376.

Written comments on this application should be submitted to the Chief, Permits and Conservation Division, at the address listed above. Comments may also be submitted by facsimile to (301) 713–0376, or by email to *NMFS.Pr1Comments@noaa.gov.* Please include the File No. in the subject line of the email comment.

Those individuals requesting a public hearing should submit a written request to the Chief, Permits and Conservation Division at the address listed above. The request should set forth the specific reasons why a hearing on this application would be appropriate.

FOR FURTHER INFORMATION CONTACT: Courtney Smith or Jennifer Skidmore, (301) 427–8401.

SUPPLEMENTARY INFORMATION: The subject permit is requested under the authority of the Marine Mammal Protection Act of 1972, as amended (MMPA; 16 U.S.C. 1361 *et seq.*), the regulations governing the taking and importing of marine mammals (50 CFR part 216), the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), and the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR parts 222–226).

The applicant proposes to take cetaceans during vessel surveys within the inland waters of Washington to (1) improve the ability to temporally link the physiologic measures of killer whale nutritional stress with variation in prey abundance and toxicant levels, and (2) as a pilot study, gather fecal samples from baleen whales to establish a baseline for examining nutritional stress and toxin load as an indicator of ecosystem health. The primary target species are Southern Resident and transient killer whales (*Orcinus orca*), but additional cetaceans may include fin (*Balaenoptera physalus*), gray (*Eschrichtius robustus*), humpback (*Megaptera novaeangliae*), and minke (*B. acutorostrata*) whales. Research activities would include behavioral observations, photo-identification, fecal/scat collection, and incidental harassment. Please see the take table for complete list of take numbers by species. The permit would be valid for five years.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), an initial determination has been made that the activity proposed is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Concurrent with the publication of this notice in the **Federal Register**, NMFS is forwarding copies of the application to the Marine Mammal Commission and its Committee of Scientific Advisors.

Julia M. Harrison,

Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2019–00861 Filed 2–1–19; 8:45 am]

BILLING CODE 3510–22–P

BUREAU OF CONSUMER FINANCIAL PROTECTION

[Docket No. CFPB–2019–0004]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Notice and request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (PRA), the Bureau of Consumer Financial Protection (Bureau) is requesting Office of Management and Budget (OMB) approval of a generic Information Collection titled, ''Making Ends Meet Survey,'' under the Generic Information Collection Plan titled, ''Generic Information Collection Plan for Surveys Using the Consumer Credit Panel.''

DATES: Written comments are encouraged and must be received on or before March 6, 2019 to be assured of consideration.

ADDRESSES: Comments in response to this notice are to be directed towards OMB and to the attention of the OMB Desk Officer for the Bureau of Consumer Financial Protection. You may submit comments, identified by the title of the information collection, OMB Control Number (see below), and docket number (see above), by any of the following methods:

- *Electronic: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: OIRA_submission@omb.eop.gov.*
- *Fax:* (202) 395–5806.
- *Mail:* Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503.

In general, all comments received will become public records, including any personal information provided.

Sensitive personal information, such as account numbers or Social Security numbers, should not be included.

FOR FURTHER INFORMATION CONTACT: Documentation prepared in support of this information collection request is available at *www.reginfo.gov* (this link becomes active on the day following publication of this notice). Select ''Information Collection Review,'' under ''Currently under review, use the dropdown menu ''Select Agency'' and select ''Consumer Financial Protection Bureau'' (recent submissions to OMB will be at the top of the list). The same documentation is also available at *http://www.regulations.gov.* Requests for additional information should be directed to Darrin King, PRA Officer, at (202) 435–9575, or email: *CFPB_PRA@cfpb.gov.* If you require this document in an alternative electronic format, please contact *CFPB_Accessibility@cfpb.gov.* Please do not submit comments to these email boxes.

SUPPLEMENTARY INFORMATION:

Title of Collection: Making Ends Meet Survey.

OMB Control Number: 3170–0066.

Type of Review: Request for approval of a generic information collection under an existing generic information collection plan.

Affected Public: Individuals or households.

Estimated Number of Respondents: 2,000.

Estimated Total Annual Burden Hours: 1,600.

Abstract: Under the Dodd-Frank Wall Street Reform and Consumer Protection Act Public Law 111–203, the Bureau is charged with researching, analyzing, and reporting on topics relating to the Bureau's mission, including consumer behavior, consumer awareness, and developments in markets for consumer financial products and services. To improve its understanding of how consumers engage with financial markets, the Bureau has successfully used the Consumer Credit Panel (CCP), a proprietary sample dataset from one of the national credit reporting agencies, as a frame to survey people about their experiences in consumer credit markets. The Bureau seeks to obtain approval for a new survey named ''Making Ends Meet'' that will solicit information on the consumer's experience related to household financial shocks and how households respond to those shocks, including the use of credit products that do and do not appear in the CCP. This project will support the Bureau's ''household balance sheets'' research agenda, which seeks to monitor developments in consumers' financial situations, related changes in their use of financial products, and the effects that these decisions have on their balance sheets. All research under this collection will be related to the household balance sheet agenda, and, thus, will be for general, formative, and informational research on consumer financial markets and consumers' use of financial products and will not directly provide the basis for specific policymaking at the Bureau.

Request for Comments: The Bureau is publishing this notice and soliciting comments directed to the Office of management and Budget on: (a) Whether the collection of information is necessary for the proper performance of the functions of the Bureau, including whether the information will have practical utility; (b) The accuracy of the Bureau's estimate of the burden of the collection of information, including the validity of the methods and the assumptions used; (c) Ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Comments submitted in response to this notice will be reviewed by OMB as part of its review of this request. All comments will become a matter of public record.

Dated: January 29, 2019.

Darrin A. King,

Paperwork Reduction Act Officer, Bureau of Consumer Financial Protection.

[FR Doc. 2019–00906 Filed 2–1–19; 8:45 am]

BILLING CODE 4810–AM–P

BUREAU OF CONSUMER FINANCIAL PROTECTION

[Docket No. CFPB–2019–0001]

Agency Information Collection Activities: Comment Request

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Notice and request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (PRA), the Bureau of Consumer Financial Protection (Bureau) is requesting to renew the Office of Management and Budget (OMB) approval for an existing information collection titled, ''Joint Standards for Assessing the Diversity Policies and Practices.''

DATES: Written comments are encouraged and must be received on or before April 5, 2019 to be assured of consideration.

ADDRESSES: You may submit comments, identified by the title of the information collection, OMB Control Number (see below), and docket number (see above), by any of the following methods:

- *Electronic:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: FederalRegisterComments@cfpb.gov.* Include Docket No. CFPB–2019–0001 in the subject line of the message.
- *Mail:* Comment Intake, Bureau of Consumer Financial Protection (Attention: PRA Office), 1700 G Street NW, Washington, DC 20552.
- *Hand Delivery/Courier:* Comment Intake, Bureau of Consumer Financial Protection (Attention: PRA Office), 1700 G Street NW, Washington, DC 20552.

Please note that comments submitted after the comment period will not be accepted. In general, all comments received will become public records, including any personal information provided. Sensitive personal information, such as account numbers or Social Security numbers, should not be included.

FOR FURTHER INFORMATION CONTACT: Documentation prepared in support of this information collection request is available at *www.regulations.gov.* Requests for additional information should be directed to Darrin King, PRA Officer, at (202) 435–9575, or email: *CFPB_PRA@cfpb.gov.* If you require this document in an alternative electronic format, please contact *CFPB_Accessibility@cfpb.gov.* Please do not submit comments to these email boxes.

SUPPLEMENTARY INFORMATION:

Title of Collection: Joint Standards for Assessing the Diversity Policies and Practices.

OMB Control Number: 3170–0060.

Type of Review: Extension without change of an existing information collection.

Affected Public: Businesses and other for-profit entities.

Estimated Number of Respondents: 750.

Estimated Total Annual Burden Hours: 9,000.

Abstract: Section 342 of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 (Act) required the Office of the Comptroller of the Currency (OCC), Board of Governors of the Federal Reserve System (Board), Federal Deposit Insurance Corporation (FDIC), Bureau of Consumer Financial Protection (Bureau) and Securities and Exchange Commission (SEC) (together, Agencies and separately, Agency) each

to establish an Office of Minority and Women Inclusion (OMWI) to be responsible for all matters of the Agency relating to diversity in management, employment, and business activities. The Act also instructed each OMWI Director to develop standards for assessing the diversity policies and practices of entities regulated by the Agency. The Agencies worked together to develop joint standards (Joint Standards) and, on June 10, 2015, they jointly published in the **Federal Register** the ''Final Interagency Policy Statement Establishing Joint Standards for Assessing the Diversity Policies and Practices of Entities Regulated by the Agencies'' (Policy Statement). The Agencies will use the information provided to them to monitor progress and trends in the financial services industry with regard to diversity and inclusion in employment and contracting activities, as well as to identify and highlight those policies and practices that have been successful. The primary federal financial regulator will share information with other agencies, when appropriate, to support coordination of efforts and to avoid duplication. The Agencies may publish information disclosed to them, such as best practices, in any form that does not identify a particular entity or individual or disclose confidential business information. This is a routine request for OMB to renew its approval of the collections of information currently approved under this OMB control number.

Request for Comments: Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the Bureau, including whether the information will have practical utility; (b) The accuracy of the Bureau's estimate of the burden of the collection of information, including the validity of the methods and the assumptions used; (c) Ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record.

Dated: January 29, 2019.

Darrin A. King,

Paperwork Reduction Act Officer, Bureau of Consumer Financial Protection.

[FR Doc. 2019–00901 Filed 2–1–19; 8:45 am]

BILLING CODE 4810–AM–P

BUREAU OF CONSUMER FINANCIAL PROTECTION

[Docket No. CFPB–2019–0003]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Notice and request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (PRA), the Bureau of Consumer Financial Protection (Bureau) is proposing a new information collection, titled, ''Debt Collection Quantitative Disclosure Testing.''

DATES: Written comments are encouraged and must be received on or before March 6, 2019 to be assured of consideration.

ADDRESSES: You may submit comments, identified by the title of the information collection, OMB Control Number (see below), and docket number (see above), by any of the following methods:

- *Electronic: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *OMB:* Office of Management and Budget (OMB), New Executive Office Building, Room 10235, Washington, DC 20503 or fax to (202) 395–5806. Mailed or faxed comments to OMB should be to the attention of the OMB Desk Officer for the Bureau of Consumer Financial Protection.

Please note that comments submitted after the comment period will not be accepted. In general, all comments received will become public records, including any personal information provided. Sensitive personal information, such as account numbers or Social Security numbers, should not be included.

FOR FURTHER INFORMATION CONTACT: Documentation prepared in support of this information collection request is available at *www.reginfo.gov* (this link becomes active on the day following publication of this notice). Select ''Information Collection Review,'' under ''Currently under review, use the dropdown menu ''Select Agency'' and select ''Consumer Financial Protection Bureau'' (recent submissions to OMB will be at the top of the list). The same documentation is also available at *http://www.regulations.gov.* Requests for additional information should be directed to Darrin King, PRA Officer, at (202) 435–9575, or email: *CFPB_PRA@cfpb.gov. Please do not submit comments to this email box.*

SUPPLEMENTARY INFORMATION:

Title of Collection: Debt Collection Quantitative Disclosure Testing.

OMB Control Number: 3170–XXXX.

Type of Review: New Collection (Request for a New OMB Control Number).

Affected Public: Individuals.

Estimated Number of Respondents: 17,750 (includes screener and survey).

Estimated Total Annual Burden Hours: 3,555.

Abstract: The Dodd-Frank Wall Street Reform and Consumer Protection Act (Pub. L. 111–203) and other Federal consumer financial laws authorize the Bureau to engage in consumer protection rule writing. The Bureau relies on empirical evidence and rigorous research to improve its understanding of consumer financial markets for regulatory purposes. This PRA clearance seeks approval from OMB to conduct a web survey of 8,000 individuals as part of the Bureau's research on debt collection disclosures.

The survey will explore consumer comprehension and decision making in response to debt collection disclosure forms. The survey will oversample respondents who have had experience with debt collection in the past.

Request for Comments: The Bureau issued a 60-day **Federal Register** notice on June 5, 2017, 82 FR 25779, Docket Number: CFPB–2017–0013. Further, the Bureau published a 30-day **Federal Register** notice on 11/14/2017, 82 FR 52712, Docket No. CFPB–2017–0038. This request was then withdrawn by the Bureau after submission to OMB, therefore we are now re-publishing a thirty day notice for this collection and re-submitting it to OMB. Comments were solicited and continue to be invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the Bureau, including whether the information will have practical utility; (b) The accuracy of the Bureau's estimate of the burden of the collection of information, including the validity of the methods and the assumptions used; (c) Ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information

technology. Comments submitted in response to this notice will be reviewed by OMB as part of its review of this request. All comments will become a matter of public record.

Dated: January 29, 2019.

Darrin A. King,

Paperwork Reduction Act Officer, Bureau of Consumer Financial Protection.

[FR Doc. 2019–00905 Filed 2–1–19; 8:45 am]

BILLING CODE 4810–AM–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Defense Health Board; Notice of Federal Advisory Committee Meeting

AGENCY: Under Secretary of Defense for Personnel and Readiness, Defense Health Board, Department of Defense.

ACTION: Notice of federal advisory committee meeting.

SUMMARY: The Department of Defense (DoD) is publishing this notice to announce that the following Federal Advisory Committee meeting of the Defense Health Board (DHB) will take place.

DATES: Open to the public February 11, 2019 from 9:00 a.m. to 12:00 p.m.

ADDRESSES: The address of the open meeting is Gatehouse, 8111 Gatehouse Road, Room 345, Falls Church, Virginia 22042 (registration requested; see guidance in **SUPPLEMENTARY INFORMATION**, ''Meeting Accessibility'').

FOR FURTHER INFORMATION CONTACT: CAPT Juliann Althoff, Medical Corps, U.S. Navy, (703) 275–6060 (Voice), (703) 275–6064 (Facsimile), *juliann.m.althoff.mil@mail.mil* (Email). Mailing address is 7700 Arlington Boulevard, Suite 5101, Falls Church, Virginia 22042. Website: *http://www.health.mil/dhb*. The most up-to-date changes to the meeting agenda can be found on the website.

SUPPLEMENTARY INFORMATION: Due to circumstances beyond the control of the Department of Defense (DoD) and the Designated Federal Officer, the Defense Health Board was unable to provide public notification required 41 CFR 102–3.150(a) concerning the meeting on February 11, 2019 of the Defense Health Board. Accordingly, the Advisory Committee Management Officer for the Department of Defense, pursuant to 41 CFR 102–3.150(b), waives the 15-calendar day notification requirement. This meeting is being held under the provisions of the Federal Advisory Committee Act (FACA) (5 U.S.C., Appendix), the Government in the Sunshine Act (5 U.S.C. 552b), and 41 CFR 102–3.140 and 102–3.150.

Availability of Materials for the Meeting: Additional information, including the agenda, is available at the DHB website, *http://www.health.mil/dhb*. A copy of the agenda or any updates to the agenda for the February 11, 2019, meeting will be available on the DHB website. Any other materials presented in the meeting may be obtained at the meeting.

Purpose of the Meeting: The DHB provides independent advice and recommendations to maximize the safety and quality of, as well as access to, health care for DoD health care beneficiaries. The purpose of the meeting is to provide progress updates on specific taskings before the DHB. In addition, the DHB will receive information briefings on current issues related to military medicine.

Agenda: The DHB anticipates receiving a progress update from the Trauma and Injury Subcommittee on its Low-Volume High-Risk Surgical Procedures Review, a progress update on the Healthy Military Family Systems: Examining Child Abuse and Neglect Review, as well as updates related to previously submitted DHB reports. Any changes to the agenda can be found at the link provided in the **SUPPLEMENTARY INFORMATION** section.

Meeting Accessibility: Pursuant to 5 U.S.C. 552b and 41 CFR 102–3.140 through 102–3.165 and subject to availability of space, this meeting is open to the public from 9:00 a.m. to 12:00 p.m. on February 11, 2019. Seating is limited and is on a first-come basis. All members of the public who wish to attend the public meeting are requested to register by emailing their name, rank/title, and organization/company to *dha.ncr.dhb.mbx.defense-health-board@mail.mil* or by contacting Ms. Theresa Fassig Normil at (703) 275–6012. Registration will also be available at the door on the day of the meeting. Special Accommodations: Individuals requiring special accommodations to access the public meeting should contact Ms. Theresa Fassig Normil at least five (5) business days prior to the meeting so that appropriate arrangements can be made.

Written Statements: Any member of the public wishing to provide comments to the DHB related to its current taskings may do so in accordance with section 10(a)(3) of the Federal Advisory Committee Act, 41 CFR 102–3.105(j) and 102–3.140, and the procedures described in this notice. Written statements may be submitted to the DHB Designated Federal Officer (DFO), CAPT Juliann Althoff, at *juliann.m.althoff.mil@mail.mil* and should be no longer than two typewritten pages and include the issue, a short discussion, and a recommended course of action. Supporting documentation may also be included, to establish the appropriate historical context and to provide any necessary background information. If the written statement is not received at least five (5) business days prior to the meeting, the DFO may choose to postpone consideration of the statement until the next open meeting. The DFO will review all timely submissions with the DHB President and ensure they are provided to members of the DHB before the meeting that is subject to this notice. After reviewing the written comments, the President and the DFO may choose to invite the submitter to orally present their issue during an open portion of this meeting or at a future meeting. The DFO, in consultation with the DHB President, may allot time for members of the public to present their issues for review and discussion by the DHB.

Dated: January 28, 2019.

Shelly E. Finke,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2019–00838 Filed 2–1–19; 8:45 am]

BILLING CODE 5001–06–P

DELAWARE RIVER BASIN COMMISSION

Notice of Public Hearing and Business Meeting; February 13 and March 13, 2019

Notice is hereby given that the Delaware River Basin Commission will hold a public hearing on Wednesday, February 13, 2019. A business meeting will be held the following month on Wednesday, March 13, 2019. The hearing and meeting are open to the public and will take place at the Washington Crossing Historic Park Visitor Center, 1112 River Road, Washington Crossing, Pennsylvania.

Public Hearing. The public hearing on February 13, 2019 will begin at 1:30 p.m. Hearing items subject to the Commission's review will include draft dockets for withdrawals, discharges, and other projects that could have a substantial effect on the basin's water resources, as well as resolutions to: (a) Adopt the Water Resources Program for Fiscal Years 2019–2021; (b) continue the Monitoring Advisory and Coordination Committee (MACC); and (c) continue the Water Quality Advisory Committee (WQAC).

The list of projects scheduled for hearing, including project descriptions,

and the text of the proposed resolutions will be posted on the Commission's website, *www.drbc.gov,* in a long form of this notice at least ten days before the hearing date.

Written comments on matters scheduled for hearing on February 13 will be accepted through 5:00 p.m. on February 19.

The public is advised to check the Commission's website periodically prior to the hearing date, as items scheduled for hearing may be postponed if additional time is deemed necessary to complete the Commission's review, and items may be added up to ten days prior to the hearing date. In reviewing docket descriptions, the public is also asked to be aware that project details commonly change during the Commission's review, which is ongoing.

Public Meeting. The public business meeting on March 13, 2019 will begin at 10:30 a.m. and will include: Adoption of the Minutes of the Commission's December 12, 2018 Business Meeting, announcements of upcoming meetings and events, a report on hydrologic conditions, reports by the Executive Director and the Commission's General Counsel, and consideration of any items for which a hearing has been completed or is not required.

After all scheduled business has been completed and as time allows, the Business Meeting will be followed by up to one hour of Open Public Comment, an opportunity to address the Commission on any topic concerning management of the basin's water resources outside the context of a duly noticed, on-the-record public hearing.

There will be no opportunity for additional public comment for the record at the March 13 Business Meeting on items for which a hearing was completed on February 13 or a previous date. Commission consideration on March 13 of items for which the public hearing is closed may result in approval of the item (by docket or resolution) as proposed, approval with changes, denial, or deferral. When the Commissioners defer an action, they may announce an additional period for written comment on the item, with or without an additional hearing date, or they may take additional time to consider the input they have already received without requesting further public input. Any deferred items will be considered for action at a public meeting of the Commission on a future date.

Advance Sign-Up for Oral Comment. Individuals who wish to comment on the record during the public hearing on February 13 or to address the Commissioners informally during the Open Public Comment portion of the meeting on March 13 as time allows, are asked to sign-up in advance through EventBrite. Links to EventBrite for the Public Hearing and the Business Meeting are available at *www.drbc.gov.* For assistance, please contact Ms. Paula Schmitt of the Commission staff, at *paula.schmitt@drbc.gov.*

Addresses for Written Comment. Written comment on items scheduled for hearing may be made through the Commission's web-based comment system, a link to which is provided at *www.drbc.gov.* Use of the web-based system ensures that all submissions are captured in a single location and their receipt is acknowledged. Exceptions to the use of this system are available based on need, by writing to the attention of the Commission Secretary, DRBC, P.O. Box 7360, 25 Cosey Road, West Trenton, NJ 08628–0360. For assistance, please contact Paula Schmitt at *paula.schmitt@drbc.gov.*

Accommodations for Special Needs. Individuals in need of an accommodation as provided for in the Americans with Disabilities Act who wish to attend the meeting or hearing should contact the Commission Secretary directly at 609–883–9500 ext. 203 or through the Telecommunications Relay Services (TRS) at 711, to discuss how we can accommodate your needs.

Additional Information, Contacts. Additional public records relating to hearing items may be examined at the Commission's offices by appointment by contacting Denise McHugh, 609–883–9500, ext. 240. For other questions concerning hearing items, please contact David Kovach, Project Review Section Manager at 609–883–9500, ext. 264.

Dated: January 28, 2019.

Pamela M. Bush,

Commission Secretary and Assistant General Counsel.

[FR Doc. 2019–00851 Filed 2–1–19; 8:45 am]

BILLING CODE 6360–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2019–ICCD–0010]

Agency Information Collection Activities; Comment Request; Indian Education Professional Development Grants Program: GPRA and Service Payback Data Collection

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 April 5, 2019.

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–2019–ICCD–0010. 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. If the *regulations.gov* site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov.* Please include the docket ID number and the title of the information collection request when requesting documents or submitting comments. *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, 550 12th Street SW, PCP, Room 9086, Washington, DC 20202–0023.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Angela Hernandez-Marshall, 202–205–1909.

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: Indian Education Professional Development Grants Program: GPRA and Service Payback Data Collection.

OMB Control Number: 1810–0698.

Type of Review: An extension of an existing information collection.

Respondents/Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 1,740.

Total Estimated Number of Annual Burden Hours: 2,728.

Abstract: The Indian Education Professional Development program, authorized under title VII, part A of the Elementary and Secondary Education Act of 1965, as amended (ESEA), is designed to increase the number of, provide training to, and improve the skills of American Indian or Alaska Natives serving as teachers and school administrators in schools serving American Indian or Alaska Native students. Section 7122(h) of the ESEA (20 U.S.C. 7442(h)) requires that individuals who receive fmancial assistance through the Indian Education Professional Development program subsequently complete a service obligation equivalent to the amount of time for which the participant received financial assistance. Participants who do not satisfy the requirements of the regulations must repay all or a pro-rated part of the cost of assistance, in accordance with 20 U.S.C. 7442(h) and 34 CFR 263.8(a)(3). The regulations in part 263 implement requirements governing, among other things, the service obligation and reporting requirements of the participants in the Indian Education Professional Development program, and repayment of financial assistance by these participants. In order for the Federal Government to ensure that the goals of the program are achieved, certain data collection, recordkeeping, and documentation are necessary.

In addition, GPRA requires Federal agencies to establish performance measures for all programs, and the Department has established performance measures for the Indian Education Professional Development program. Data collection from participants who have received financial assistance under the Indian Education Professional Development program is a necessary element of the Department's effort to evaluate progress on these measures. The Department tracks participants who are receiving or have previously received support through the Indian Education Professional Development program. Participants must sign a payback agreement that includes contact information. Additionally, the Department receives information about participants from institutions of higher education (IHEs) and other eligible grantees when participants are no longer receiving assistance through the Indian Education Professional Development program. When the performance period is complete, the participant data are collected from the grantee and also from the participants.

Dated: January 30, 2019.

Kate Mullan,

Acting Director, Information Collection Clearance Program, Information Management Branch, Office of the Chief Information Officer.

[FR Doc. 2019–00876 Filed 2–1–19; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2019–ICCD–0011]

Agency Information Collection Activities; Comment Request; National Study of the Implementation of Adult Education Under the Workforce Innovation and Opportunity Act

AGENCY: Institute of Education Sciences (IES), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing a new information collection.

DATES: Interested persons are invited to submit comments on or before April 5, 2019.

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–2019–ICCD–0011. 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. If the regulations.gov site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov.* Please include the docket ID number and the title of the information collection request when requesting documents or submitting comments. *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, 550 12th Street SW, PCP, Room 9086, Washington, DC 20202–0023.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Melanie Ali, 202–245–8345.

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: National Study of the Implementation of Adult Education under the Workforce Innovation and Opportunity Act.

OMB Control Number: 1850–NEW.

Type of Review: A new information collection.

Respondents/Affected Public: Private Sector.

Total Estimated Number of Annual Responses: 631.

Total Estimated Number of Annual Burden Hours: 947.

Abstract: Title II of the Workforce Innovation and Opportunity Act (WIOA) of 2014 mandates a National Assessment of Adult Education. As part of the assessment, ED is conducting an implementation study of adult

education programs. The implementation study will include a survey of state directors of adult education, a survey of local providers of adult education, and analyses of extant data.

Dated: January 30, 2019.

Kate Mullan,

Acting Director, Information Collection Clearance Program, Information Management Branch, Office of the Chief Information Officer.

[FR Doc. 2019–00877 Filed 2–1–19; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Agency Information Collection Extension

AGENCY: Department of Energy.

ACTION: Submission for Office of Management and Budget (OMB) review; comment request.

SUMMARY: The Department of Energy (DOE) has submitted an information collection request to the OMB for extension under the provisions of the Paperwork Reduction Act of 1995. The information collection requests a three-year extension of its Human Reliability Program (HRP), OMB Control Number 1910–5122. The HRP is a security and safety reliability program for individuals who apply for or occupy certain positions that are critical to the national security. It requires an initial and annual supervisory review, medical assessment, management evaluation, and a DOE personnel security review of all applicants or incumbents. It is also used to ensure that employees assigned to nuclear explosive duties do not have emotional, mental, or physical conditions that could result in an accidental or unauthorized detonation of nuclear explosives.

DATES: Comments regarding this proposed information collection must be received on or before March 6, 2019. If you anticipate difficulty in submitting comments within that period of time allowed by this notice, please advise the OMB Desk Officer of your intention to make a submission as soon as possible. The Desk Officer may be telephoned at (202) 395–4718.

ADDRESSES: Written comments should be sent to the DOE Desk Officer, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10102, 735 17th Street NW, Washington, DC 20503, and to Mark Ott U.S. Department of Energy, Office of Corporate Security Strategy, Analysis and Special Operations (AU–1.2), 1000 Independence Ave. SW, Washington, DC 20585, telephone at (202) 586–6063, by fax at (202) 586–3333, or by email at *mark.ott@hq.doe.gov.* More information on the HRP can be found at *https://www.energy.gov/ehss/human-reliability-program-handbook.* Forms included in this collection can be found at *https://www.energy.gov/cio/management-administration-forms-0000-1999.*

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to the person listed above in **ADDRESSES**.

SUPPLEMENTARY INFORMATION: This information collection request contains: (1) OMB No. 1910–5122; (2) Information Collection Request Title: Human Reliability Program; (3) Type of Review: renewal; (4) Purpose: This collection provides for DOE management to ensure that individuals who occupy HRP positions meet program standards of reliability and physical and mental suitability. This information collection consists of forms that will certify to DOE that respondents were advised of the requirements for occupying or continuing to occupy an HRP position. The forms include: Human Reliability Program Certification (DOE F 470.3), Acknowledgement and Agreement to Participate in the Human Reliability Program (DOE F 470.4), Authorization and Consent to Release Human Reliability Program (HRP) Records in Connection with HRP (DOE F 470.5), Refusal of Consent (DOE F 470.6), and Human Reliability Program (HRP) Alcohol Testing Form (DOE F 470.7). (5) Annual Estimated Number of Respondents: 43,960 (6) Annual Estimated Number of Total Responses: 43,999 (7) Annual Estimated Number of Burden Hours: 3,819; (8) Annual Estimated Reporting and Recordkeeping Cost Burden: $342,888; and (9) Response Obligation: Mandatory.

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

Issued in Washington, DC, on December 20, 2018.

Matthew B. Moury,

Associate Under Secretary for Environment, Health, Safety and Security.

[FR Doc. 2019–00880 Filed 2–1–19; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

[Case Number 2018–011, EERE–2018–BT–WAV–0001]

Energy Conservation Program: Extension of Waiver to HH Technologies From the Department of Energy Walk-in Cooler and Walk-in Freezer Test Procedure

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Notice of extension of waiver.

SUMMARY: The U.S. Department of Energy (''DOE'') is granting a waiver extension (Case No. 2018–011) to HH Technologies to waive certain requirements of the DOE walk-in cooler and walk-in freezer test procedure for determining the energy consumption of thirty-five (35) RollSeal Automated Door System brand walk-in door basic models specified in their petition. HH Technologies is required to test and rate these basic models in accordance with the alternate test procedure specified.

DATES: The Extension of Waiver is effective on February 4, 2019. The Extension of Waiver will terminate upon the compliance date of any future amendment to the test procedure for walk-in doors located at 10 CFR part 431, subpart R, appendix A that addresses the issues presented in this waiver. At such time, HH Technologies must use the relevant test procedure for this equipment for any testing to demonstrate compliance with the applicable standards, and any other representations of energy use.

FOR FURTHER INFORMATION CONTACT: Ms. Lucy deButts, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, EE–5B, 1000 Independence Avenue SW, Washington, DC 20585–0121. Email: *AS_Waiver_Requests@ee.doe.gov*.

Mr. Michael Kido, U.S. Department of Energy, Office of the General Counsel, Mail Stop GC–33, Forrestal Building, 1000 Independence Avenue SW, Washington, DC 20585–0103. Telephone: (202) 586–8145. Email: *Michael.Kido@hq.doe.gov*.

SUPPLEMENTARY INFORMATION: In accordance with Title 10 of the Code of Federal Regulations (10 CFR 431.401(g)), DOE gives notice of the issuance of an Extension of Waiver as set forth below. The Extension of Waiver extends the Decision and Order granted to HH Technologies on October 23, 2018 (83 FR 53457, ''October 2018 Decision and Order'') to include thirty-five (35) additional RollSeal Automated

Door System brand basic models [1] of walk-in cooler doors, as requested by HH Technologies on November 5, 2018.[2] HH Technologies must test and rate the specifically identified walk-in door basic models in accordance with the alternate test procedure specified in the October 2018 Decision and Order. HH Technologies' representations concerning the energy efficiency of the specified basic models must be based on testing according to the provisions and restrictions in the alternate test procedure set forth in the October 2018 Decision and Order, and the representations must fairly disclose the results from that testing. Distributors, retailers, and private labelers are held to the same requirements when making representations regarding the energy efficiency of these products. (42 U.S.C. 6314(d))

DOE makes decisions on waiver extensions for only those basic models specifically set out in the request, not future models that may be manufactured by the petitioner. HH Technologies may submit a new or amended petition for waiver and request for grant of interim waiver, as appropriate, for additional basic models of walk-in doors. Alternatively, if appropriate, HH Technologies may request that DOE extend the scope of a waiver to include additional basic models employing the same technology as the basic model(s) set forth in the original petition consistent with 10 CFR 431.401(g).

Signed in Washington, DC, on January 18, 2019.

Steven Chalk,

Acting Deputy Assistant Secretary for Energy Efficiency, Energy Efficiency and Renewable Energy.

Case Number 2018–011

Extension of Waiver

I. Background and Authority

The Energy Policy and Conservation Act of 1975, as amended (''EPCA''),[3] among other things, authorizes DOE to regulate the energy efficiency of a number of consumer products and industrial equipment. (42 U.S.C. 6291–6317) Title III, Part C [4] of EPCA established the Energy Conservation Program for Certain Industrial Equipment, which sets forth a variety of provisions designed to improve energy efficiency for certain types of industrial equipment. This equipment includes walk-in coolers and walk-in freezers, the focus of this extension. (42 U.S.C. 6311(1)(G))

Under EPCA, DOE's energy conservation program consists essentially of four parts: (1) Testing, (2) labeling, (3) Federal energy conservation standards, and (4) certification and enforcement procedures. Relevant provisions of the Act include definitions (42 U.S.C. 6311), energy conservation standards (42 U.S.C. 6313), test procedures (42 U.S.C. 6314), labeling provisions (42 U.S.C. 6315), and the authority to require information and reports from manufacturers. (42 U.S.C. 6316)

The Federal testing requirements consist of test procedures that manufacturers of covered equipment must use as the basis for: (1) Certifying to DOE that their equipment complies with the applicable energy conservation standards adopted pursuant to EPCA (42 U.S.C. 6316(a); 42 U.S.C. 6295(s)), and (2) making representations about the efficiency of that equipment (42 U.S.C. 6314(d)). Similarly, DOE must use these test procedures to determine whether the equipment complies with relevant standards promulgated under EPCA. (42 U.S.C. 6316(a); 42 U.S.C. 6295(s))

Under 42 U.S.C. 6314, EPCA sets forth the criteria and procedures DOE must follow when prescribing or amending test procedures for covered equipment. EPCA requires that any test procedures prescribed or amended under this section must be reasonably designed to produce test results reflecting the energy efficiency, energy use, or estimated annual operating costs during a representative average use cycle, and requires that test procedures not be unduly burdensome to conduct. (42 U.S.C. 6314(a)(2)) The test procedure for walk-in doors is contained in 10 CFR part 431, subpart R, appendix A (''Appendix A'').

The regulations set forth in 10 CFR 431.401 provide that upon receipt of a petition, DOE will grant a waiver from the test procedure requirements if DOE determines either that the basic model for which the waiver was requested contains a design characteristic that prevents testing of the basic model according to the prescribed test procedure, or that the prescribed test procedure evaluates the basic model in a manner so unrepresentative of its true energy consumption characteristics as to provide materially inaccurate comparative data. 10 CFR 431.401(f)(2). DOE may grant the waiver subject to conditions, including adherence to alternate test procedures. *Id.*

A petitioner may request that DOE extend the scope of a waiver or an interim waiver to include additional basic models employing the same technology as the basic model(s) set forth in the original petition. 10 CFR 431.401(g). DOE will publish any such extension in the *Federal Register. Id.*

II. Request for an Extension of Waiver: Assertions and Determinations

On October 23, 2018, DOE issued a Decision and Order in Case Number 2018–001 granting HH Technologies a waiver to test the RollSeal Automated Door System brand basic models identified in its petition [5] using an alternate test procedure. 83 FR 53457 (''October 2018 Decision and Order''). HH Technologies stated that the test procedure applicable to walk-in doors set forth in 10 CFR part 431, subpart R, appendix A overstated the power consumption of the specified automated doors.

Appendix A accounts for the power consumption of all electrical components associated with each door and discounts the power consumption of electrical components based on their operating time by an assigned percent time off (''PTO'') value. 10 CFR part 431, subpart R, appendix A, section 4.5.2. Section 4.5.2 of appendix A specifies a PTO of 25% for ''other electricity-

[1] The additional basic models are as follows: RS–500 5K036x084, RS–500 5K042x084, RS–500 5K048x084, RS–500 5K054x084, RS–500 5K060x084, RS–500 5K066x084, RS–500 5K072x084, RS–500 5K036x090, RS–500 5K042x090, RS–500 5K048x090, RS–500 5K054x090, RS–500 5K060x090, RS–500 5K066x090, RS–500 5K072x090, RS–500 5K036x096, RS–500 5K042x096, RS–500 5K048x096, RS–500 5K054x096, RS–500 5K060x096, RS–500 5K066x096, RS–500 5K072x096, RS–500 5K036x102, RS–500 5K042x102, RS–500 5K048x102, RS–500 5K054x102, RS–500 5K060x102, RS–500 5K066x102, RS–500 5K072x102, RS–500 5K036x108, RS–500 5K042x108, RS–500 5K048x108, RS–500 5K054x108, RS–500 5K060x108, RS–500 5K066x108, RS–500 5K072x108.

[2] HH Technologies' request is available at *https://www.regulations.gov/document?D=EERE-2018-BT-WAV-0001-0015.*

[3] All references to EPCA in this document refer to the statute as amended through the EPS Improvement Act of 2017, Public Law 115–115 (January 12, 2018).

[4] For editorial reasons, upon codification in the U.S. Code, Part C was redesignated as Part A–1.

[5] The specific walk-in door basic models that are subject of the petition for waiver and application for interim waiver are included in HH Technologies' petition, which is available in the docket at *http://www.regulations.gov/docket?D=EERE-2018-BT-WAV-0001.*

consuming devices'' (*i.e.,* electrical devices other than lighting or anti-sweat heaters) that have demand-based controls, and a PTO of 0% for other electricity-consuming devices without a demand-based control. *Id.* In its petition for waiver, HH Technologies suggested applying a PTO value of 96% to the door motors and controls in the basic models specified in its petition. The walk-in door basic models specified by HH Technologies are automated and designed with microprocessor controls that use motion sensor inputs to trigger a door motor, which are considered by the DOE test procedure to be ''other electricity-consuming devices with demand-based control.'' HH Technologies asserted that the current PTO value overestimates the time that the motors and controls in the specified automated doors are in operation in high traffic applications. HH Technologies stated that as a result, the power consumption of the specified automated door motors and controls is overestimated.

Based on the information provided by HH Technologies, DOE determined that the basic models identified by HH Technologies in its petition cannot be tested and rated for energy consumption on a basis representative of their true energy consumption characteristics under the test procedure detailed under 10 CFR part 431, subpart R, appendix A. 83 FR 53457, 53458. The October 2018 Decision and Order specified that HH Technologies test and rate the subject basic models by using a PTO value of 96% for door motors. 83 FR 53457, 53459.

On November 5, 2018, HH Technologies submitted a request to extend the scope of the waiver it received in Case Number 2018–001 to thirty-five (35) additional RollSeal Automated Door System brand basic models.[6] HH Technologies stated that these basic models employ the same technology as the models covered by the existing waiver.

DOE has reviewed HH Technologies' waiver extension request and determined that the basic models identified in HH Technologies' request incorporate the same design characteristics as those basic models covered under the waiver in Case Number 2018–001 such that the test procedure would evaluate those basic models in a manner that is unrepresentative of their actual energy use. DOE has also determined that the alternate procedure specified in Case Number 2018–001 will allow for the accurate measurement of the energy use of the walk-in door basic models identified by HH Technologies in its waiver extension request.

III. Order

After careful consideration of HH Technologies' request that DOE extend the scope of the waiver granted under Case Number 2018–001 to include additional basic models, it is **ORDERED** that:

(1) HH Technologies must, as of the date of publication of this Extension of Waiver in the *Federal Register*, test and rate the following walk-in door basic models with the alternate test procedure as set forth in paragraph (2):

Brand name	Basic model
RollSeal Automated Door System	RS–500 5K036x084
RollSeal Automated Door System	RS–500 5K042x084
RollSeal Automated Door System	RS–500 5K048x084
RollSeal Automated Door System	RS–500 5K054x084
RollSeal Automated Door System	RS–500 5K060x084
RollSeal Automated Door System	RS–500 5K066x084
RollSeal Automated Door System	RS–500 5K072x084
RollSeal Automated Door System	RS–500 5K036x090
RollSeal Automated Door System	RS–500 5K042x090
RollSeal Automated Door System	RS–500 5K048x090
RollSeal Automated Door System	RS–500 5K054x090
RollSeal Automated Door System	RS–500 5K060x090
RollSeal Automated Door System	RS–500 5K066x090
RollSeal Automated Door System	RS–500 5K072x090
RollSeal Automated Door System	RS–500 5K036x096
RollSeal Automated Door System	RS–500 5K042x096
RollSeal Automated Door System	RS–500 5K048x096
RollSeal Automated Door System	RS–500 5K054x096
RollSeal Automated Door System	RS–500 5K060x096
RollSeal Automated Door System	RS–500 5K066x096
RollSeal Automated Door System	RS–500 5K072x096
RollSeal Automated Door System	RS–500 5K036x102
RollSeal Automated Door System	RS–500 5K042x102
RollSeal Automated Door System	RS–500 5K048x102
RollSeal Automated Door System	RS–500 5K054x102
RollSeal Automated Door System	RS–500 5K060x102
RollSeal Automated Door System	RS–500 5K066x102
RollSeal Automated Door System	RS–500 5K072x102
RollSeal Automated Door System	RS–500 5K036x108
RollSeal Automated Door System	RS–500 5K042x108
RollSeal Automated Door System	RS–500 5K048x108
RollSeal Automated Door System	RS–500 5K054x108
RollSeal Automated Door System	RS–500 5K060x108
RollSeal Automated Door System	RS–500 5K066x108

[6] The additional basic models are as follows: RS–500 5K036x084, RS–500 5K042x084, RS–500 5K048x084, RS–500 5K054x084, RS–500 5K060x084, RS–500 5K066x084, RS–500 5K072x084, RS–500 5K036x090, RS–500 5K042x090, RS–500 5K048x090, RS–500 5K054x090, RS–500 5K060x090, RS–500 5K066x090, RS–500 5K072x090, RS–500 5K036x096, RS–500 5K042x096, RS–500 5K048x096, RS–500 5K054x096, RS–500 5K060x096, RS–500 5K066x096, RS–500 5K072x096, RS–500 5K036x102, RS–500 5K042x102, RS–500 5K048x102, RS–500 5K054x102, RS–500 5K060x102, RS–500 5K066x102, RS–500 5K072x102, RS–500 5K036x108, RS–500 5K042x108, RS–500 5K048x108, RS–500 5K054x108, RS–500 5K060x108, RS–500 5K066x108, RS–500 5K072x108.

Brand name	Basic model
RollSeal Automated Door System	RS–500 5K072x108

(2) The alternate test procedure for the HH Technologies basic models referenced in paragraph (1) of this Order is the test procedure for walk-in doors prescribed by DOE at 10 CFR part 431, subpart R, appendix A, except that the percent time off (''PTO'') value specified in section 4.5.2 ''Direct Energy Consumption of Electrical Components of Non-Display Doors'' shall be 96% for door motors. All other requirements of 10 CFR part 431, subpart R, appendix A and DOE's regulations remain applicable.

(3) *Representations.* HH Technologies may not make representations about the energy use of the basic models identified in paragraph (1) of this Order for compliance, marketing, or other purposes unless the basic model has been tested in accordance with the provisions set forth above and such representations fairly disclose the results of such testing in accordance with 10 CFR part 431, subpart R, appendix A and 10 CFR part 429, subpart B, as specified in this Order.

(4) This Extension of Waiver shall remain in effect consistent with the provisions of 10 CFR 431.401.

(5) This Extension of Waiver is issued on the condition that the statements, representations, and documents provided by HH Technologies are valid. If HH Technologies makes any modifications to the controls or configurations of these basic models, the waiver will no longer be valid and HH Technologies will either be required to use the current Federal test method or submit a new application for a test procedure waiver. DOE may rescind or modify this Extension of Waiver at any time if it determines the factual basis underlying the petition for Extension of Waiver is incorrect, or the results from the alternate test procedure are unrepresentative of the basic model's true energy consumption characteristics. 10 CFR 431.401(k)(1). Likewise, HH Technologies may request that DOE rescind or modify the Extension of Waiver if HH Technologies discovers an error in the information provided to DOE as part of its petition, determines that the waiver is no longer needed, or for other appropriate reasons. 10 CFR 431.401(k)(2).

(6) Granting of this Extension of Waiver does not release HH Technologies from the certification requirements set forth at 10 CFR part 429.

Signed in Washington, DC, on January 18, 2019.

Steven Chalk,

Acting Deputy Assistant Secretary for Energy Efficiency Energy Efficiency and Renewable Energy.

[FR Doc. 2019–00886 Filed 2–1–19; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

[OE Docket No. EA–465]

Application To Export Electric Energy; Brookfield Renewable Trading and Marketing LP

AGENCY: Office of Electricity, DOE.

ACTION: Notice of application.

SUMMARY: Brookfield Renewable Trading and Marketing LP (BRTM or Applicant) has applied for authorization to transmit electric energy from the United States to Canada pursuant to the Federal Power Act.

DATES: Comments, protests, or motions to intervene must be submitted on or before March 6, 2019.

ADDRESSES: Comments, protests, motions to intervene, or requests for more information should be addressed to: Office of Electricity, Mail Code: OE–20, U.S. Department of Energy, 1000 Independence Avenue SW, Washington, DC 20585–0350. Because of delays in handling conventional mail, it is recommended that documents be transmitted by overnight mail, by electronic mail to *Electricity.Exports@hq.doe.gov,* or by facsimile to 202–586–8008.

SUPPLEMENTARY INFORMATION: Exports of electricity from the United States to a foreign country are regulated by the Department of Energy (DOE) pursuant to sections 301(b) and 402(f) of the Department of Energy Organization Act (42 U.S.C. 7151(b) and 7172(f)) and require authorization under section 202(e) of the Federal Power Act (16 U.S.C.§ 824a(e)).

On December 26, 2018, DOE received an application from BRTM for authorization to transmit electric energy from the United States to Canada as a power marketer for a five-year term using existing international transmission facilities.

In its application, BRTM states that it ''does not own generation or transmission assets and does not have a franchised electric service area.'' The electric energy that the Applicant proposes to export to Canada would be surplus energy purchased from third parties such as electric utilities and other suppliers within the United States pursuant to voluntary agreements. The existing international transmission facilities to be utilized by BETM have previously been authorized by Presidential Permits issued pursuant to Executive Order 10485, as amended, and are appropriate for open access transmission by third parties.

Procedural Matters: Any person desiring to be heard in this proceeding should file a comment or protest to the application at the address provided above. Protests should be filed in accordance with Rule 211 of the Federal Energy Regulatory Commission's Rules of Practice and Procedure (18 CFR 385.211). Any person desiring to become a party to these proceedings should file a motion to intervene at the above address in accordance with FERC Rule 214 (18 CFR 385.214). Five (5) copies of such comments, protests, or motions to intervene should be sent to the address provided above on or before the date listed above.

Comments and other filings concerning BRTM's application to export electric energy to Canada should be clearly marked with OE Docket No. EA–465. An additional copy is to be provided to Ruth Teetzel, Brookfield Renewable Trading and Marketing LP, 41 Victoria Street, Gatineau, Quebec J8X 2A1.

A final decision will be made on this application after the environmental impacts have been evaluated pursuant to DOE's National Environmental Policy Act Implementing Procedures (10 CFR part 1021) and after a determination is made by DOE that the proposed action will not have an adverse impact on the sufficiency of supply or reliability of the U.S. electric power supply system.

Copies of this application will be made available, upon request, for public inspection and copying at the address provided above, by accessing the program website at *http://energy.gov/node/11845,* or by emailing Angela Troy at *Angela.Troy@hq.doe.gov.*

Signed in Washington, DC, on January 4, 2019.

Christopher Lawrence,

Management and Program Analyst, Transmission Permitting and Technical Assistance, Office of Electricity.

[FR Doc. 2019–00883 Filed 2–1–19; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Western Area Power Administration

2021 Resource Pool, Pick-Sloan Missouri Basin Program—Eastern Division

AGENCY: Western Area Power Administration, Department of Energy.

ACTION: Notice to conclude the 2021 Resource Pool.

SUMMARY: Western Area Power Administration (WAPA) announces the conclusion of the 2021 Resource Pool provided for in a Notice of procedures and call for 2021 Resource Pool applications published in the **Federal Register** on May 29, 2018. WAPA determined there were no eligible new preference customers in the 2021 Resource Pool. Therefore, no allocations will be made as part of the 2021 Resource Pool.

DATES: The conclusion of the 2021 Resource Pool is effective March 6, 2019.

ADDRESSES: Information about the conclusion of the 2021 Resource Pool, including letters and other supporting documents made or kept by WAPA during the 2021 Resource Pool process, is available for public inspection and copying at the Upper Great Plains Region, Western Area Power Administration, 2900 4th Avenue North, Billings, MT 59101–1266.

FOR FURTHER INFORMATION CONTACT: Ms. Nancy Senitte, Public Utilities Specialist, Upper Great Plains Customer Service Region, Western Area Power Administration, 2900 4th Avenue North, Billings, MT 59101, telephone (406) 255–2933, email *senitte@wapa.gov*.

SUPPLEMENTARY INFORMATION: WAPA published the Notice of procedures and call for 2021 Resource Pool applications in the **Federal Register** (83 FR 24467, May 29, 2018) in accordance with the 2021 Power Marketing Initiative (2021 PMI) (76 FR 71015, Nov. 16, 2011). Applications for power were accepted until 4 p.m. Mountain Daylight Time on July 30, 2018. The procedures used to determine new preference customer eligibility were carried forward from the Post-2010 Resource Pool Procedures as published in the **Federal Register** (74 FR 20697, May 5, 2009). Specifically, these procedures included the General Eligibility Criteria, General Allocation Criteria, and General Contract Principles.

This **Federal Register** notice is to conclude the 2021 Resource Pool.

Conclusion of the 2021 Resource Pool

I. Review of Applicants Under 2021 Resource Pool

WAPA received and reviewed seven (7) applications from entities interested in an allocation of power from the 2021 Resource Pool. Review of the applications indicated that none of the applicants qualified under the procedures.

II. Conclusion of the 2021 Resource Pool

WAPA determined that there were no eligible new preference customers in the 2021 Resource Pool. Therefore, no allocations will be made under the 2021 Resource Pool. This **Federal Register** notice hereby concludes the 2021 Resource Pool.

III. Regulatory Procedure Requirements

Determination Under Executive Order 12866

WAPA has an exemption from centralized regulatory review under Executive Order 12866; accordingly, no clearance of this **Federal Register** notice by the Office of Management and Budget is required.

Dated: December 19, 2018.

Mark A. Gabriel,

Administrator.

[FR Doc. 2019–00884 Filed 2–1–19; 8:45 am]

BILLING CODE 6450–01–P

FEDERAL ELECTION COMMISSION

Sunshine Act Meeting

TIME AND DATE: Thursday, February 7, 2019 at 10:00 a.m.

PLACE: 1050 First Street NE, Washington, DC (12th Floor).

STATUS: This meeting will be open to the public.

MATTERS TO BE CONSIDERED:

Welcoming Remarks by Chair Ellen L. Weintraub

Draft Notice of Availability on REG 2018–05 (Size of Disclaimers in TV Ads)

Audit Division Recommendation Memorandum on Tony Cardenas for Congress (A17–01)

Proposed Final Audit Report on Friends of Erik Paulsen (A17–06)

Proposed Final Audit Report on Marsha Blackburn for Congress, Inc. (A17–02)

Management and Administrative Matters

CONTACT PERSON FOR MORE INFORMATION: Judith Ingram, Press Officer, Telephone: (202) 694–1220.

Individuals who plan to attend and require special assistance, such as sign language interpretation or other reasonable accommodations, should contact Dayna C. Brown, Secretary and Clerk, at (202) 694–1040, at least 72 hours prior to the meeting date.

Dayna C. Brown,

Secretary and Clerk of the Commission.

[FR Doc. 2019–01167 Filed 1–31–19; 4:15 pm]

BILLING CODE 6715–01–P

FEDERAL RESERVE SYSTEM

FEDERAL DEPOSIT INSURANCE CORPORATION

[FRB Docket No. OP–1644]

Final Guidance for the 2019

AGENCY: Board of Governors of the Federal Reserve System (Board) and Federal Deposit Insurance Corporation (FDIC).

ACTION: Final guidance.

SUMMARY: The Board and the FDIC (together, the ''Agencies'') are adopting this final guidance for the 2019 and subsequent resolution plan submissions by the eight largest, complex U.S. banking organizations (''Covered Companies'' or ''firms''). The final guidance is meant to assist these firms in developing their resolution plans, which are required to be submitted pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act (''Dodd-Frank Act''). The final guidance, which is largely based on prior guidance issued to these Covered Companies, describes the Agencies' expectations regarding a number of key vulnerabilities in plans for an orderly resolution under the U.S. Bankruptcy Code (*i.e.*, capital; liquidity; governance mechanisms; operational; legal entity rationalization and separability; and derivatives and trading activities). The final guidance also updates certain aspects of prior guidance based on the Agencies' review of these firms' most recent resolution plan submissions.

FOR FURTHER INFORMATION CONTACT:

Board: Michael Hsu, Associate Director, (202) 452–4330, Division of Supervision and Regulation, Jay Schwarz, Special Counsel, (202) 452–2970, or Steve Bowne, Counsel, (202) 452–3900, Legal Division. Users of Telecommunications Device for the Deaf (TDD) may call (202) 263–4869.

FDIC: Mike J. Morgan, Corporate Expert, *mimorgan@fdic.gov,* CFI Oversight Branch, Division of Risk Management Supervision; Alexandra Steinberg Barrage, Associate Director, Resolution Strategy and Policy, Office of Complex Financial Institutions, *abarrage@fdic.gov;* David N. Wall, Assistant General Counsel, *dwall@fdic.gov;* Pauline E. Calande, Senior Counsel, *pcalande@fdic.gov;* or Celia Van Gorder, Supervisory Counsel, *cvangorder@fdic.gov,* Legal Division, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.

SUPPLEMENTARY INFORMATION:

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I. Introduction

a. Background

Section 165(d) of the Dodd-Frank Wall Street Reform and Consumer Protection Act (12 U.S.C. 5365(d)) and the jointly issued implementing regulation, 12 CFR part 243 and 12 CFR part 381 (''the Rule''), requires certain financial companies to report periodically to the Board and the FDIC their plans for rapid and orderly resolution under the U.S. Bankruptcy Code [1] in the event of material financial distress or failure.

Among other requirements, the Rule requires each financial company's resolution plan to include a strategic analysis of the plan's components, a description of the range of specific actions the company proposes to take in resolution, and a description of the company's organizational structure, material entities, and interconnections and interdependencies. The Rule also requires that resolution plans include a confidential section that contains confidential supervisory and proprietary information submitted to the Agencies, and a section that the Agencies make available to the public. Public sections of resolution plans can be found on the Agencies' websites.[2]

Objectives of the Resolution Planning Process

The goal of the Dodd-Frank Act resolution planning process is to help ensure that a firm's failure would not have serious adverse effects on financial stability in the United States. Specifically, the resolution planning process requires firms to demonstrate that they have adequately assessed the challenges that their structure and business activities pose to resolution and that they have taken action to address those issues. Management should also consider resolvability as part of day-to-day decision making, particularly in connection with decisions related to structure, business activities, capital and liquidity allocation, and governance. In addition, firms are expected to maintain a meaningful set of options for selling operations and business lines to generate resources and to allow for restructuring under stress, including through the sale or wind down of discrete businesses that could further minimize the direct impact of distress or failure on the broader financial system. While these measures cannot guarantee that a firm's resolution would be simple or smoothly executed, these preparations can help ensure that the firm could be resolved under bankruptcy without government support or imperiling the broader financial system.

The guidance describes an iterative process aimed at strengthening the resolution planning capabilities of each financial institution. With respect to the eight largest, complex U.S. banking organizations (''Covered Companies'' or ''firms''),[3] the Agencies have previously provided guidance and other feedback.[4] In general, the feedback was intended to assist firms in their development of future resolution plan submissions and to provide additional clarity with respect to the expectations against which the Agencies will evaluate the resolution plan submissions. The Agencies reviewed the firms' 2017 resolution plans and issued a letter to each firm indicating that it had taken important steps to enhance its resolvability and facilitate its orderly resolution in bankruptcy.[5] As a result of those reviews and following the Agencies' joint decisions in December 2017, the Agencies identified four areas where more work may need to be done to improve the resolvability of the firms.[6] As described below, the Agencies have updated aspects of the prior guidance based on their review of the firms' 2017 resolution plans,[7] including two areas of the guidance regarding payment, clearing, and settlement services, and derivatives and trading activities.

While the capital and liquidity sections of the final guidance remain largely unchanged from the proposed guidance and the 2016 Guidance, the Agencies intend to provide additional information on resolution liquidity and internal loss absorbing capacity in the future. Accordingly, while certain concerns raised by commenters in connection with the proposed guidance have not resulted in changes to the capital and liquidity sections of the final guidance, the Agencies will consider these comments as they determine what future actions should be taken in these areas. The Agencies expect that any future actions in these areas, whether guidance or rules, would be adopted through notice and comment procedures, which would provide an additional opportunity for public input. The Agencies further expect to collaborate in taking such actions in a manner consistent with the Board's TLAC rule.[8] Until any such future actions are taken, the final guidance sets

[1] 11 U.S.C. 101 *et seq.*

[2] See the public sections of resolution plans submitted to the Agencies at *www.federalreserve.gov/bankinforeg/resolutionplans.htm* and *www.fdic.gov/regulations/reform/resplans/.*

[3] Bank of America Corporation, The Bank of New York Mellon Corporation, Citigroup Inc., The Goldman Sachs Group, Inc., JPMorgan Chase & Co., Morgan Stanley, State Street Corporation, and Wells Fargo & Company.

[4] This includes *Guidance for 2013 § 165(d) Annual Resolution Plan Submissions by Domestic Covered Companies that Submitted Initial Resolution Plans in 2012;* firm-specific feedback letters issued in August 2014 and April 2016; the February 2015 staff communication; and *Guidance for 2017 § 165(d) Annual Resolution Plan Submissions by Domestic Covered Companies that Submitted Resolution Plans in July 2015,* including the frequently asked questions that were published in response to the Guidance for the 2017 resolution plan submissions (taken together, ''prior guidance'').

[5] *See* Letters dated December 19, 2017, from the Board and FDIC to Bank of America Corporation, The Bank of New York Mellon Corporation, Citigroup Inc., The Goldman Sachs Group, Inc., JPMorgan Chase & Co., Morgan Stanley, State Street Corporation, and Wells Fargo & Company, *available at https://www.federalreserve.gov/supervisionreg/resolution-plans.htm.*

[6] *Id.*

[7] Currently, each firm's resolution strategy is designed to have the parent company recapitalize and provide liquidity resources to its material entity subsidiaries prior to entering bankruptcy proceedings. This single point of entry (''SPOE'') strategy calls for material entities to be provided with sufficient capital and liquidity resources to allow them to avoid multiple competing insolvencies and maintain continuity of operations throughout resolution.

[8] See 82 FR 8266.

forth the Agencies' supervisory expectations regarding development of the firms' resolution strategies. As noted below and in the final guidance, the final guidance is not a regulation but represents the Agencies' supervisory expectations for how the firms' resolution plans should address key vulnerabilities in resolution.

b. Proposed Guidance

In July 2018, the Agencies invited public comment on proposed resolution plan guidance for the eight largest, most complex U.S. banking organizations, to apply beginning with the firms' July 1, 2019 resolution plan submissions.[9] The proposed guidance described the Agencies' expectations in six substantive areas: Capital, liquidity, governance mechanisms, operational, legal entity rationalization and separability, and derivatives and trading activities. The proposed guidance was largely consistent with the guidance provided by the Agencies in April 2016 to assist in the development of their 2017 resolution plans, *Guidance for 2017 § 165(d) Annual Resolution Plan Submissions by Domestic Covered Companies that Submitted Resolution Plans in July 2015* (''2016 Guidance'').[10] Accordingly, the firms have already incorporated significant aspects of the proposed guidance into their resolution planning. The proposal updated the derivatives and trading activities, and payment, clearing, and settlement (''PCS'') activities areas of the 2016 Guidance based on the Agencies' review of the Covered Companies' 2017 resolution plans. It also made minor clarifications to certain areas of the 2016 Guidance. In general, the proposed revisions to the guidance were intended to streamline the firms' submissions and to provide additional clarity. The proposed guidance was not meant to limit a firm's consideration of additional vulnerabilities or obstacles that might arise based on the firm's particular structure, operations, or resolution strategy and that should be factored into the firm's submission.

The Agencies invited comments on all aspects of the proposed guidance. The Agencies also specifically requested comments on a number of issues, including whether the topics in the proposed guidance represent the key vulnerabilities of the Covered Companies in resolution, whether the proposed guidance was sufficiently clear, and whether the Agencies should consolidate all applicable guidance that covers expectations for resolution planning.

II. Overview of Comments

The Agencies received and reviewed six[11] comments on the proposed guidance. Commenters included various financial services trade associations, a financial market utility (''FMU''), a foreign banking organization (''FBO''), and several individuals. A number of commenters strongly supported efforts by the Agencies to consolidate existing resolution plan guidance. One commenter stated that consolidating prior guidance in one document would help streamline the resolution planning process while increasing clarity and transparency.

Various commenters urged the Agencies to acknowledge that an effective SPOE resolution strategy is a credible means of resolving a global systemically important bank (''GSIB'') in an orderly manner. These commenters also requested that elements of the guidance unrelated to an SPOE strategy be eliminated so firms can focus on issues tailored to address an SPOE resolution. Further, these commenters stated that acknowledging SPOE as a credible resolution strategy should lead to a reconsideration of the FDIC's resolution plan requirements for certain insured depository institutions (''IDIs'').[12] These commenters recommended that IDI plans be eliminated for firms adopting SPOE as a resolution strategy since SPOE focuses on the resolution of the parent holding company and not material subsidiaries. Commenters also suggested that the resolution planning process be further streamlined by adopting a two-year cycle for submission of resolution plans under Section 165(d) of the Dodd-Frank Act and for submission of IDI plans if IDI plan requirements were not eliminated for SPOE filers. Commenters also suggested that the Agencies engage more proactively with non-U.S. regulators to improve efficiency of resolution planning and enhance information sharing, including with respect to reducing ex ante ring-fencing.

The Agencies received specific responses to questions raised in the proposed guidance related to key vulnerabilities, PCS services, and derivatives and trading activities. Two commenters agreed that the proposed guidance generally addresses the vulnerabilities of Covered Companies in resolution (although one of the commenters suggested that the guidance should be refined to more explicitly encourage an analysis of certain concentration risks).

PCS. One commenter recommended that the PCS analysis should be limited to matters relevant to the successful execution of a filer's particular resolution strategy and offered general topical themes and specific recommendations for clarifying the PCS guidance and streamlining the resolution planning process. Another commenter suggested that the final guidance should highlight more clearly the importance of firms' continued engagement with key external stakeholders, including FMUs and agent banks. Two commenters provided specific recommendations with respect to: The scope of PCS services that would be analyzed in resolution plans; the extent to which the PCS guidance should be consistent with the Financial Stability Board's (''FSB's'') *Guidance on Continuity of Access to Financial Market Infrastructures (FMIs) for a Firm in Resolution,* published in July 2017; distinctions between different types of providers of PCS services; the content that would be presented in FMU, agent bank, and PCS service provider playbooks; the extent to which contingency analysis would be discussed in resolution plans; and expectations concerning communication of potential impacts of contingency or alternative arrangements on key clients.

Derivatives. One commenter supported the elimination in the proposed guidance of the expectation for a dealer firm to provide separate active and passive wind-down analyses. However, the commenter requested that the Agencies further eliminate other aspects of the guidance that may retain elements of a passive wind-down analysis. The commenter also recommended that the Agencies should allow firms to tailor capabilities and analysis to those supporting a firm's SPOE resolution strategy and incorporate reasonable alternative assumptions consistent with a firm's resolution strategy. In addition, this commenter stated that the Agencies should limit the development of derivatives capabilities and related analyses to material entities, eliminate modeling of operational costs at the level of specific derivatives activities, and clarify that ''linked'' non-derivatives trading positions should be defined by dealer firms in light of their overall business model and resolution strategies.

[9] 83 FR 32856.

[10] *Available at: https://www.federalreserve.gov/newsevents/pressreleases/files/bcreg20160413a1.pdf* and at *https://www.fdic.gov/news/news/press/2016/pr16031b.pdf.*

[11] The Board received two additional comments that were not directed to the FDIC.

[12] See FDIC, Resolution Plans Required for Insured Depository Institutions with $50 Billion or More in Total Assets, 77 FR 3075 (Jan. 23, 2012), codified at 12 CFR 360.10.

Capital and Liquidity. Commenters offered recommendations on resolution capital and liquidity that primarily covered four areas: (i) Secured support agreements; (ii) tailoring liquidity flow assumptions; (iii) avoiding false positive resolution triggers; and (iv) other requests.

Qualified Financial Contract (''QFC'') Stay Rules. One commenter criticized the proposed guidance requesting that additional resolution plan information be provided for firms who do not adhere to the International Swaps and Derivatives Association 2015 Universal Resolution Stay Protocol (or similar provisions of the U.S. protocol),[13] including explaining the firm's alternative method of complying with the QFC stay rules. The same commenter also recommended that the Agencies clarify the final guidance regarding the impact of bankruptcy claims status of guarantees of QFCs if a firm were to pursue the elevation alternative described in the guidance.

Foreign Banking Organizations. Two commenters provided recommendations with respect to enhancing the resolution planning process applicable to FBOs under Section 165(d) of the Dodd-Frank Act. The final guidance does not apply to FBOs, and the appropriate expectations for resolution plans of FBOs would be better considered in the context of guidance applicable to those firms. Accordingly, these comments are not addressed in this Supplementary Information section.

The comments received on the proposed guidance are further discussed below.

III. Final Guidance

After carefully considering the comments and conducting further analysis, the Agencies are issuing final guidance that includes certain modifications and clarifications to the proposed guidance. In particular, the PCS and the derivatives and trading activities sections of the final guidance contain several changes based on commenters' suggestions, while retaining the same key principles embodied in the proposed guidance. These principles include: (i) Streamlining the firms' submissions; (ii) facilitating continuity of PCS services in resolution; and (iii) helping ensure that a firm's derivatives and trading activities can be stabilized and de-risked during resolution without causing significant market disruption that could cause risks to the financial stability of the United States. In addition, the final guidance consolidates all prior resolution planning guidance for the firms in one document and clarifies that any prior guidance not included in the final guidance has been superseded. These changes are discussed in more detail below.

The final guidance is intended to assist firms in mitigating risks to the financial stability of the United States that could arise from their material financial distress or failure, consistent with Section 165 of the Dodd-Frank Act.

a. Consolidation of Prior Guidance

Commenters favored consolidating and making public the relevant aspects of all existing guidance into a single document. One commenter provided a list of examples of how prior guidance could be consolidated and recommended principles for the Agencies to follow. Accordingly, the final guidance includes a new section regarding the format, assumptions, and structure of resolution plans, which includes the aspects of previous guidance that remain applicable to resolution planning. In addition, because commenters found the Agencies' previously issued Frequently Asked Questions (''FAQs'') to the guidance to be helpful, those FAQs that remain relevant have been appended to the final guidance. To the extent not incorporated in or appended to the final guidance, prior guidance[14] is superseded.

Consistent with recommendations made by the commenters, the Agencies have updated the final guidance to maintain certain key concepts contained in prior firm-specific feedback letters. For example, the final guidance deletes the cross-reference to SR 14–1[15] as the Agencies believe the relevant elements and associated capabilities contained in SR 14–1 have been consolidated into the final guidance. In addition, the final guidance clarifies the content of a firm's external communications strategy contained in the firm's governance playbooks and the scope of actionable implementation plans to ensure continuity of shared services. The final guidance also provides that firms discuss compliance with the QFC stay rules (as defined below) and the potential impact of such compliance on a firm's resolution strategy. Additionally, as recommended by a commenter, certain FAQs that are no longer meaningful or relevant have not been consolidated and are excluded, such as FAQ LIQ 7.

A number of comments were directed at streamlining the resolution plan submission process. These comments included suggestions to formalize a two-year submission cycle and to allow firms to provide updates to quantitative analyses, while relying on references to previously submitted material where capabilities remain unchanged. Implementation of the changes proposed by these comments would require changes to the Rule. Accordingly, these comments would be better considered in connection with a future rulemaking proposal. The Agencies note, however, that the Rule provides that firms may incorporate by reference certain informational elements from previously submitted resolution plans to the extent such information remains accurate.

One commenter noted that, to the extent filers have adequately addressed deficiencies and shortcomings identified in prior firm-specific feedback, the Agencies should explicitly provide in the final guidance that the expectations set forth in that feedback do not continue to alter the expectations in the final guidance. This commenter noted that the final guidance should govern where it contains expectations similar to, or that directly supersede, expectations in prior feedback letters or similar communications. As stated above, prior guidance not incorporated in or appended to the final guidance is superseded. The Agencies note that in the future, firm-specific weaknesses and applicable remediation will continue to be addressed in firm-specific feedback communications in a manner that is consistent with applicable guidance.

The Agencies note that commenters described certain expectations that are set forth in the guidance as ''requirements.'' The Agencies are clarifying that the final guidance does not have the force and effect of law. Rather, the final guidance outlines the Agencies' supervisory expectations and priorities for the firms' resolution plans and articulates the Agencies' general views regarding appropriate practices for each subject area covered by the final guidance.[16]

b. Single Point of Entry (SPOE) Resolution Strategy

Some commenters suggested that the Agencies acknowledge the SPOE

[13] U.S. protocol has the same meaning as it does at 12 CFR 252.85(a). See also 12 CFR 382.5(a) (including a substantively identical definition).

[14] See footnote 5.

[15] SR Letter 14–1, ''Heightened Supervisory Expectations for Recovery and Resolution Preparedness for Certain Large Bank Holding Companies—Supplemental Guidance on Consolidated Supervision Framework for Large Financial Institutions'' (Jan. 24, 2014).

[16] *See generally,* Interagency Statement Clarifying the Role of Supervisory Guidance (Sept. 11, 2018) at *https://www.federalreserve.gov/supervisionreg/srletters/sr1805a1.pdf.*

strategy as a credible means of resolving a GSIB in an orderly manner. Commenters cited SPOE as a basis for eliminating various aspects of the Guidance they contend are relevant to non-SPOE resolution strategies.

The Agencies do not prescribe specific resolution strategies for any firm, nor do the Agencies identify a preferred strategy. Firms may submit resolution plans using the resolution strategies they believe would be most effective in achieving an orderly resolution of their firms, but must address the key vulnerabilities and support the underlying assumptions required to successfully execute their chosen resolution strategy. The final guidance is not intended to favor one strategy or another. It is flexible enough to allow firms to address the resolution obstacles that are relevant to their chosen strategy.

The Agencies have acknowledged the significant progress U.S. GSIBs have made in addressing key vulnerabilities and mitigants associated with SPOE. While significant progress has been made, like any resolution strategy for large bank holding companies, SPOE is untested and there remain inherent challenges and uncertainties associated with the resolution of a systemically important financial institution under any specific resolution strategy. In light of this uncertainty, the final guidance provides that the firms should develop and maintain capabilities to address situations where their selected strategy presents vulnerabilities.

Some commenters offered recommendations about IDI Plan requirements for filers that have adopted SPOE in their 165(d) Plans.[17] IDI Plans are outside of the scope of the guidance and have a unique objective from Title I ensuring least-cost resolution to the Deposit Insurance Fund in an IDI receivership. The FDIC plans to address proposed IDI Plan requirements through an advanced notice of public rulemaking in 2019.

c. Engagement With Non-U.S. Regulators

Certain commenters recommended the Agencies engage more proactively with non-U.S. regulators to improve the efficiency of resolution planning requirements. Additionally, certain commenters recommended the Agencies enhance information-sharing across jurisdictions in a manner that would expand and clarify the type of information that firms may share with cooperating regulatory authorities.

The Agencies acknowledge that engagement with non-U.S. regulators is critical. The Agencies already engage proactively with non-U.S. regulators related to resolution planning, and have established frameworks and information-sharing arrangements for effective cross-border resolution cooperation with counterparts in key foreign jurisdictions. This includes leading, as home authority Co-Chairs, the work of firm-specific cross-border Crisis Management Groups (''CMGs'') for U.S. GSIBs as well as entering into firm-specific cooperation agreements with CMG members. In furtherance of its resolution authority responsibilities, the FDIC also has concluded bilateral Resolution Memoranda of Understanding with foreign authorities that address cooperation and information sharing for cross-border resolution planning and crisis management preparedness.

In addition, the Agencies work on a bilateral and multilateral basis on cross-border resolution planning matters with authorities from other jurisdictions that regulate GSIBs, including by participating in joint working groups and interagency financial regulatory dialogues (such as the Joint U.S.-European Union Financial Regulatory Forum and the U.S.-UK Financial Regulatory Working Group) and by contributing to the development and ongoing implementation of standards for cross-border resolution by the FSB's Resolution Steering Group and its committees, including implementing the *Key Attributes of Effective Resolution Regimes for Financial Institutions.*[18] The Agencies will continue to coordinate with non-U.S. regulators regarding resolution matters.

d. Capital and Liquidity

Like the proposed guidance, the capital and liquidity sections (Sections II and Section III) of the final guidance remain materially unchanged from the 2016 Guidance, including the expectations to model resolution capital and liquidity needs for each material entity and to hold and pre-position sufficient resources to meet those needs. The only change to the capital section is to eliminate a superfluous reference to creditor challenge mitigation. The proposed guidance carried forward an unintentional reference to creditor challenge in the Resolution Capital Adequacy and Positioning (''RCAP'') discussion, which if left unedited suggests that pre-positioning of intercompany debt that is indirectly issued to a parent through one or more intermediate entities needs to be structured in a manner that ''mitigates uncertainty related to potential creditor challenge.'' The need to address creditor challenges is addressed in the Pre-Bankruptcy Parent Support section of the guidance. The relevant point regarding the firm's structuring of the internal debt is that it should ''ensure that the entity can be recapitalized.''

Although the Agencies received a number of written comments on resolution capital and liquidity, the commenters noted that the Agencies intend to issue information addressing issues relating to intra-group liquidity and internal loss absorbing capacity in resolution. These commenters therefore did not presume that the intra-group liquidity and internal loss-absorbing capacity recommendations would be addressed in this guidance. The Agencies have reviewed and considered the commenters' recommendations, and have responded to specific recommendations below, but have not adopted any modifications in the final guidance in response to those recommendations. The Agencies will continue to consider these comments as they assess the additional information they intend to provide in these areas.

Commenters offered recommendations on resolution capital and liquidity that primarily covered four areas: (i) Secured support agreements; (ii) tailoring liquidity flow assumptions; (iii) avoiding false positive resolution triggers; and (iv) other requests. Ultimately, the result of these recommendations would be to allow firms to, among other things, reduce the amount of resolution liquidity and capital resources (*e.g.,* Resolution Liquidity Adequacy and Positioning (''RLAP'') and RCAP) that would otherwise be positioned at a material entity.

Secured Support Agreements. Commenters recommended that as a result of the development (and adoption) of support agreements by filers, the Agencies should reconsider the pre-positioning expectations and legal entity friction assumptions (*e.g.,* ring fencing of surplus liquidity) articulated in the Agencies' prior guidance. Commenters noted the design objectives and intended benefits of secured support agreements for addressing the Agencies' expectation that firms balance the flexibility provided by holding contributable

[17] One commenter stated that the FDIC should finalize its public notice using SPOE as the strategy for resolution of GSIBs under Title II of the Dodd-Frank Act. Because Title II of the Dodd-Frank Act is outside the scope of this guidance, the FDIC does not address such comment at this time.

[18] ''Key Attributes of Effective Resolution Regimes for Financial Institutions'' (October 15, 2014), *http://www.fsb.org/wp-content/uploads/r_141015.pdf.*

resources at support providers with the certainty provided by pre-positioning resources at material subsidiaries. The legally binding features and enforceability of the secured support agreements, commenters asserted, maximize the firm's ability to direct capital and liquidity where and when it is needed, while maintaining a degree of certainty that contributable resources will be available to the material entities when needed. Similarly, commenters suggested that the Agencies should engage with non-U.S. regulators to establish support agreements as a key tool for meeting the capital and liquidity needs of material subsidiaries of a U.S. GSIB in a resolution scenario. Commenters believe that secured support agreements are complementary to the objectives of internal total loss-absorbing capacity (''TLAC'') and other gone-concern standards designed to provide host authorities comfort that non-locally positioned resources—or surplus resources moved out of a local material entity—will be available to the local material entity if and when needed in resolution.

The Agencies continue to consider the merits and limitations of secured support agreements. A successful SPOE resolution requires a balancing of the tradeoffs between the certainty provided by locally pre-positioned resources and the flexibility provided by a pool of globally available resources. A key objective of pre-positioning of resolution resources (*e.g.,* pre-positioned internal TLAC) is to delay the need for host authorities to take self-protective actions that disrupt the group SPOE resolution. However, over-calibration of pre-positioned internal TLAC can prove self-defeating, if excess resources are trapped in local jurisdictions when they are needed elsewhere within the group. The Agencies acknowledge that balancing these trade-offs successfully will require shared understandings between home and host authorities, and firms, about the expected allocation during a group resolution of resources held at the parent or other support entity.

However, secured support agreements remain an imperfect substitute for the certainty (and transparency) provided by pre-prepositioned resources. First, the Agencies note that secured support agreements are untested. While secured support agreements may offer a measure of assurance that available contributable resources within the firm will be allocated in a pre-determined manner, on their own, the agreements do not provide the same certainty as pre-positioned resources. More pre-positioned resources increase host comfort and cross-border cooperation during a group resolution because the host is in control of a known and quantifiable amount of emergency capital and liquidity, and not dependent on the potential delivery of contributable resources. Second, the availability and sufficiency of contributable resources for group resolution purposes may be unclear.

The Agencies' resolution resource estimation and positioning expectations, including many of the assumptions that restrict the flow of liquidity among affiliates for resolution planning purposes, support the broader goal of increasing host authority confidence through straightforward assumptions about the movement of liquidity within groups and transparency of resolution resource needs and resource locations. For example, enhancing clarity with respect to the size, location, and composition of pre-positioned resources, can provide authorities with the necessary comfort that resources are not being double-counted, and that they can be reasonably relied on to be available locally, when needed. The Agencies acknowledge that engagement with non-U.S. regulators is critical because the effectiveness of secured support agreements could be reduced if they do not provide key host regulators a sufficient level of comfort during stress. To that end, the Agencies will continue to coordinate with the non-U.S. regulators regarding resolution matters, including developments in the resolution capabilities of U.S. GSIBs and in existing secured support agreements.

Tailoring Liquidity Flow Assumptions. Commenters recommended that firms be permitted to make more idiosyncratic assumptions about flows of liquidity in their resolution planning liquidity estimates and methodologies for RLAP.[19] More specifically, commenters argued for the relaxation of various enumerated assumptions, which they assert reflect unrealistic assumptions about the generation of liquidity and the flows of liquidity between affiliates. Commenters further asserted that these restrictive assumptions are rendered less realistic and less necessary in light of the secured support agreements' framework for ensuring the timely allocation of resolution resources. The Agencies continue to evaluate the liquidity guidance for opportunities to enhance the efficiency of the resolution planning process.

Avoiding False Positive Resolution Triggers. One commenter requested that the Agencies clarify whether firms are permitted to tailor their resolution planning capital and liquidity estimates and methodologies based on specific factual circumstances concerning their material entities, as well as modify these assumptions during an actual stress scenario. According to the commenter, expressly providing firms with the ability to tailor and modify these estimates and methodologies would serve as a safeguard against premature bankruptcy filings.

The guidance provides firms with the flexibility to tailor their RLEN and Resolution Capital Execution Need (''RCEN'') methodologies. For the purposes of the resolution plan submissions, firms should assume conditions consistent with the DFAST Severely Adverse scenario.[20] In an actual stress environment, however, methodologies for estimating RLEN and RCEN should have the flexibility to incorporate actual stress conditions that may deviate from the DFAST Severely Adverse scenario. Firms' capabilities to calibrate and alter assumptions in their RLEN and RCEN methodologies to reflect actual stress conditions is a meaningful safeguard against false positive resolution triggers.

Other Requests. Commenters also sought modification of certain definitional issues. More specifically, commenters suggested that forthcoming guidance reconsider two additional aspects of the resolution planning capital and liquidity standards: (i) Whether firms can turn off restrictive market access assumptions post-recapitalization and (ii) whether investment grade status can substitute for the level of recapitalization necessary to achieve market confidence in stabilization for material entities not subject to ''well-capitalized'' standards or bank regulatory capital regimes. The two requests relate to definitional issues addressed in existing FAQs and would primarily impact a firm's assumptions regarding resolution capital and liquidity resource need estimates. Therefore, the Agencies will continue to consider these recommendations when they provide additional information in these areas in the future.

e. Operational: Payment, Clearing, and Settlement Activities

The Agencies received a number of comment letters regarding the proposed

[19] For Resolution Liquidity Execution Need (''RLEN''), the Agencies' guidance does not prescribe specific modeling assumptions for intra-affiliate flows.

[20] *See* final guidance, Section VIII, Guidance Assumption 4.

PCS guidance. Commenters generally recommended certain modifications and clarifications to the proposed guidance in order to streamline the resolution plan submissions and to provide further clarity. The Agencies have modified the final guidance to address certain matters raised by the commenters consistent with the Agencies' overall objective of facilitating continuity of PCS services in resolution.

i. PCS Terminology

The Agencies received several comments regarding the scope of the proposed guidance and requesting clarity and/or modification of certain terms and PCS-related concepts, such as ''PCS services providers,'' ''key clients,'' ''critical PCS services,'' and the scope of direct and indirect PCS activities. These clarifications in the final guidance also address several related comments, which are discussed in further detail below.

Providers of PCS Services: Under the final guidance, a firm is a provider of PCS services if it provides PCS services to clients as an agent bank or it provides clients with access to an FMU or agent bank through the firm's membership in or relationship with that service provider. A firm also is a provider if it provides clients with PCS services through the firm's own operations (*e.g.,* payment services or custody services). One commenter recommended that a firm's contingency plans should cover its relationships with the Society for Worldwide Interbank Financial Telecommunication (''SWIFT''), real-time gross settlement (''RTGS'') systems, and nostro-agents in the identification of key PCS providers. The Agencies note that the guidance is not prescriptive regarding the inclusion of specific providers and that a firm retains the discretion to identify SWIFT, RTGS, and/or certain nostro-agents as key PCS providers.

The Agencies note that, to the extent a firm addresses all items noted in the final PCS guidance section on Content Related to Users and/or Providers of PCS Services in other areas of the firm's submission (*e.g.,* the discussion of material entities and/or critical operations in its resolution plan), the firm may include a specific cross-reference to that PCS content accordingly, and a separate playbook need not be provided.

Key Client Identification: Some commenters requested that the guidance either adopt a more limited scope for the concept of key clients or clarify that a provider of PCS services may identify and describe its key clients by category or in a manner consistent with the services it provides. Commenters argued that consideration of a wider scope of key clients could be burdensome to administer and result in a list of key clients that may fluctuate over time. In response to these comments, the final guidance clarifies that firms should identify clients as key from the firm's perspective, rather than from the client's perspective. The final guidance further clarifies that a firm is expected to use both quantitative and qualitative criteria to identify key clients. Qualitative criteria may include categories of clients associated with PCS activities and business lines,[21] while quantitative criteria may include transaction volume/value, market value of exposures, market value of assets under custody, usage of PCS services, and availability/usage of intraday credit or liquidity. Commenters were also concerned that the list of key clients could fluctuate over time. The Agencies recognize that information provided in a firm's resolution plan, including a list of key clients, may change with each submission. Some commenters requested that the scope of key clients should be limited to GSIBs, arguing that such limitation would be more consistent with the limited scope of the FSB's July 2017 *Guidance on Continuity of Access To Financial Market Infrastructures (FMI) for a Firm in Resolution,* including the corresponding Annex, which provides a list of information requirements relevant to facilitating continuity of access (together, the ''FSB FMI Guidance''). The Agencies have not limited the scope of key clients to GSIBs, since key clients may include entities other than GSIBs, and continuity of access to services provided to all key clients supports a key objective of the guidance.

PCS Services: Commenters argued that a concept of critical PCS services that depended on the criticality of PCS services to a particular client would be impractical and difficult to administer. Commenters also argued that a concept of critical PCS services that hinged on the criticality of such services to a particular client would be an overly-broad standard. The final guidance replaces references to ''critical PCS services'' with ''PCS services,'' focuses on key clients, and clarifies that a firm should identify clients, FMUs, and agent banks as key from its perspective rather than its clients' perspective. Further, the final guidance modifies the definition of client by deleting the reference to ''reliance upon continued access'' such that a client is defined as ''*an individual or entity, including affiliates of the firm, to whom the firm provides PCS services.*'' As noted above, firms are expected to identify clients as key from the firm's perspective using both quantitative and qualitative criteria and have flexibility to tailor their identification methodologies and criteria. These clarifications are not expected to result in consideration of any additional PCS services provided by the firm.

Direct and Indirect Relationships: With respect to the scope of PCS providers, certain commenters sought to narrow the concept to those instances in which a firm that has a direct relationship with an FMU or agent bank provides indirect access to an FMU or agent bank through its membership or contractual relationship. The Agencies have not limited this concept, as continuity of PCS activities in resolution remains essential both with respect to the provision of PCS services to a firm's affiliates and where the firm is a provider of PCS services through its own operations.

In addition, one commenter stated that firms should be expected to understand which of an FMU's tools are most likely to be utilized in resolution, and to differentiate mitigating actions from adverse actions. The Agencies note that the guidance provides firms with discretion to identify such tools and contingency arrangements in their resolution plan submissions, including whether the arrangements are likely to be used by a PCS provider in resolution.

One commenter also focused on the need, to the extent possible, for firms to update contracts with agent banks to incorporate appropriate terms and conditions to prevent automatic termination and facilitate continued provision of critical outsourced services during resolution. The Agencies note that this comment is addressed under the Shared and Outsourced Services section of the final guidance. Notwithstanding the foregoing, the Agencies understand that in certain cases, PCS providers may not be permitted to provide continued access by an entity that has not met either its financial or contractual obligations. In addition, one commenter noted that firms should consider including continuity of access to key FMUs and key agent banks in their legal entity rationalization (''LER'') criteria. In order

[21] Commenters also suggested that a firm should consider the degree of interconnectedness among its clients and evaluate concentration risk from its perspective as a provider of PCS services (including where a firm is the sole provider or one of only a few providers for a particular service). The Agencies note that a firm may consider interconnectedness or concentration risk presented by a particular client as qualitative criteria when identifying key clients.

to enhance resolvability, firms have included continuity of critical operations in their LER criteria and certain firms also considered mitigation of continuity risk regarding FMU access in applying their LER criteria. The final guidance provides all firms with the flexibility, as appropriate, to consider continuity of access to key FMUs and key agent banks.

ii. Playbooks for Continued Access to PCS Services

The provision of PCS services by firms, FMUs, and agent banks is an essential component of the U.S. financial system, and maintaining the continuity of PCS services is important for the orderly resolution of firms. Prior guidance from the Agencies indicated that a firm's resolution plan submission should describe arrangements to facilitate continued access to PCS services through the firm's resolution. Firms have developed capabilities to identify and consider the risks associated with continuity of access to PCS services in resolution, including playbooks for key FMUs and key agent banks that describe potential adverse actions and possible contingency arrangements.

Some commenters suggested that filers could update certain discussions in the PCS playbooks for material changes only and not resubmit the complete discussion as part of the resolution plan submission. The Agencies acknowledge that the Rule generally allows for incorporation by reference of previously submitted information that remains accurate. However, certain PCS-related content may be more likely to change between submissions (such as provider rulebooks, key clients, volume and value of activity, exposure quantifications, and key PCS providers) and therefore would be expected to be provided in each submission. To the extent that certain updated information may be addressed in other sections of the firm's submission, the firm may include a specific cross-reference to that content in the appropriate playbook.

In addition, the Agencies have clarified the expectations for playbook content for both users and providers of PCS services. Firms are expected to provide a playbook for each key FMU and key agent bank that addresses financial and operational considerations that would assist the firm in maintaining continued access to PCS services for itself and its clients during stress and in resolution.

Form and Content: Some commenters suggested that playbooks for agent bank relationships might be different than those produced for FMUs, and as a result, analysis in playbooks for agent banks generally would be different from the analysis for FMUs in terms of content, organization, and level of detail. Another commenter suggested that firms should consider discussing whether contingency arrangements and/or analyses in playbooks would change depending on which entity enters into resolution. The final guidance sets out the expectations for PCS playbooks for FMUs and agent banks, and allows flexibility for a firm to tailor the contents of its PCS playbooks to the specific relationships of the firms with its key FMUs and key agent banks. Together with financial resources, a firm should consider operational resources (including critical services, MIS reporting, communications, and internal and external contacts) that would be needed to respond to adverse actions and execute any contingency arrangements.

Some commenters suggested that separate playbooks should not be expected for a firm's role as provider of PCS services. If the firm is both a user and provider of PCS services, content related to user and provider of PCS services may be provided in the same playbook, with appropriate and specific cross-references to other sections. Where a firm is a provider of PCS services through the firm's own operations, the firm is expected to produce a playbook for the material entities that provide those services, addressing each of the items described in the section on Content related to Provider of PCS Services.

Mapping: The final guidance specifies that each playbook should identify and map the PCS services provided by each material entity and critical operation to its key clients, and describe the scale and manner in which each provides PCS services and any related credit or liquidity offered in connection with such services.

Commenters focused on the issue of identification and mapping key clients to the firm's PCS activities. Comments concerning identification of key clients were discussed in connection with the definition of ''key client.'' The Agencies expect a firm to map each of its key clients to the firm's key FMUs and key agent banks. The Agencies note that a firm is expected to track PCS activities, map them to the relevant material entities and core business lines, and track customers and counterparties for PCS activities, including values and volumes of various transaction types, and used and unused capacity for all lines of credit. Firms are expected to report on the individual key clients to whom the firm provides PCS services. Some commenters argued that this mapping of key clients would require the development of new information and monitoring systems. However, based on the Agencies' engagement with firms, the Agencies have observed that firms already have the capability to identify and report these relationships on an individual basis.

Funding and Liquidity Analysis: Commenters recommended that PCS playbooks be consistent with the expectations in other parts of the final guidance, and that any PCS-related liquidity expectations should be factors incorporated into a filer's overall resolution liquidity models. Another commenter noted that firms should clarify further the extent to which they would rely on committed credit lines as liquidity resources in resolution. The final guidance clarifies that firms are expected to include a discussion of liquidity sources and uses of funds in business as usual (''BAU''), in stress, and in the resolution period. The final guidance is not prescriptive, and each firm is expected to determine the relevant PCS-related liquidity analysis that is specific to its PCS activities. There is no expectation for such liquidity analysis to include stress-testing or multiple scenario analysis. To the extent that specific FMU and agent bank information is provided, firms may include the information in the relevant FMU and agent bank playbooks or provide appropriate, specific cross-references to other sections of the resolution plan in the playbook.

Key Client Contingency Arrangements: Some commenters argued that if a filer's resolution strategy is designed to maintain client access to key FMUs and key agent banks, then contingency analysis regarding client loss of access to PCS services is not relevant to the successful execution of a firm's particular resolution strategy and should not be expected to be included in a firm's resolution plan submission. The Agencies consider the need to address contingencies (*e.g.,* the potential for loss of access to PCS services, FMUs, or agent banks) as supplemental to those in the firm's preferred resolution strategy, and maintain that the preparation of a loss of access contingency analysis is appropriate as the successful execution of a firm's preferred resolution strategy is not guaranteed. To minimize disruption to the provision of PCS services to clients, a filer should describe the potential range of contingency arrangements that the firm may take, including the viability of transferring client activity and related assets, as well as any

alternative arrangements that would allow the firm's key clients continued access to critical PCS services, in the event the firm could no longer provide such access.

Commenters also noted that filers should have flexibility to provide analysis that recognizes the different types and scope of PCS services offered by each PCS provider. The Agencies note that the guidance distinguishes between FMUs and agent banks and is not prescriptive, providing firms with discretion under the existing guidance to tailor analysis consistent with varied types of PCS services and PCS providers.

Commenters also indicated that a filer is not in the best position to understand the financial and operational impacts to its key clients, and suggested that any contingency arrangements for clients should be at a higher level and not be provided on a per-client basis. The Agencies are clarifying that the discussion of potential financial and operational impacts to key clients is from the perspective of the filer, and not from the clients' perspectives. The Agencies note that the final guidance is not prescriptive and that firms have the discretion to tailor the discussion to client impacts specific to the PCS services provided.[22]

Loss of Access: Several commenters requested additional clarity around loss of access to an FMU or agent bank, and the potential financial and operational impacts to a filer's material entities and key clients. The final guidance maintains that a firm is not expected to incorporate a scenario in which it loses FMU or agent bank access into its preferred resolution strategy or into its RLEN/RCEN analysis. In support of maintaining the continuity of PCS services, each playbook should provide analysis of the financial and operational impacts to the filer's material entities and key clients due to adverse actions that may be taken by an FMU or agent bank, and contingency actions that may be taken by the filer. Each playbook also should include considerations of any substitutes and/or any possible alternative arrangements, if available, that would allow the firm and its key clients to maintain continued access to PCS services in resolution.[23]

Client Communication: One commenter suggested that firms engage with users and clients and communicate the range of risk management actions and requirements that may be imposed on a user when a firm is in resolution, setting out a common set of expectations and processes across users to the extent possible. The Agencies recognize the importance of firms' engagement and communication with clients and the final guidance allows firms to determine the method, form, and timing of such engagement and communication with clients. Firms are best positioned to make decisions regarding common expectations and processes across users because the facts and circumstances of client relationships vary, which in turn informs the specific content in the playbooks.

The final guidance specifies that a firm should communicate to its key clients the potential impacts of implementation of any identified contingency arrangements or alternatives, and that playbooks should describe the firm's methodology for determining whether additional communication should be provided to some or all key clients (*e.g.,* due to the client's BAU usage of that access and/or related intraday credit or liquidity), and the expected timing and form of such communication. A firm is expected to consider the benefits of client communications in multiple forms (*e.g.,* verbal, written, and electronic), and at multiple times (*e.g.,* in BAU, stress events, and some point in advance of taking contingency actions) in order to provide adequate notice to key clients of the action and the potential impact on the client of that action. Firms should consider the benefits of tailoring client communications to different segments of clients in form, timing, or both, and providing sample client contracts or agreements containing provisions related to the firm's provision of intraday credit or liquidity in its resolution plan submission.[24]

iii. Other PCS Comments (FSB FMI Guidance, International Coordination, and Agency Communication)

Consistency with FSB FMI Guidance: Commenters recommended greater consistency with the FSB FMI Guidance. The final guidance remains consistent with the FSB FMI Guidance, focusing on the identification of providers, mapping of contractual relationships, continuity analysis (*e.g.,* adverse actions and contingency arrangements), communications, and discontinuity of access. Another commenter suggested that the Agencies should consider coordinating with firms' foreign resolution authorities with respect to content and the submission process for resolution-related reporting templates. The Agencies recognize that international coordination in resolution-related matters is important, and will continue to work with domestic and international counterparts through various forums, including CMGs. The final guidance is also consistent with FSB FMI Guidance in this respect, as it broadly addresses all information aspects contained in the FSB FMI Guidance, including those informational requirements specified in the FSB Annex. In addition, the final guidance provides a firm with the flexibility to provide playbooks that are tailored to the circumstances relevant to that firm and therefore does not adopt standardized resolution-related reporting templates.

Agency Communication: One commenter suggested that the Agencies engage ex ante with key market stakeholders, including PCS providers both in BAU and leading up to and during a firm's resolution. The Agencies proactively engage with firms and PCS providers through various forums including CMGs. As this comment is not applicable to the content contained in a firm's plan submissions, the Agencies did not make any modification to final guidance in response to this comment.

f. Legal Entity Rationalization and Separability

One commenter argued that the cost-benefit analysis does not justify requiring filers to maintain active virtual data rooms for each object of sale identified in their separability analysis. In order to reduce the burden on the firms, the Agencies have modified the Guidance to provide that firms should have the capability to populate a data room with information pertinent to a potential divestiture in a timely manner, rather than maintain an active data room. The Agencies expect to test this capability by asking firms to produce

[22] Examples of financial and operational impacts to key clients may include considerations such as intraday or uncommitted credit lines that a firm provides to key clients, settlement volumes/value, or market value of the activity that is processed for its key clients. To the extent certain key client relationships or PCS services to key clients are unique, firms are expected to address potential contingency arrangements for those instances on an individual client basis.

[23] Impact analysis in the final guidance is consistent with the FSB FMI Guidance regarding impact analysis of discontinuity of access that complements mitigation measures for dealing with a termination or suspension of access to FMI services. See FSB FMI Guidance, Section 2.5 (p. 17), and Annex, Items #17 and 18 (p. 27).

[24] In their most recent resolution plan submissions, all of the firms addressed the issue of client communications and provided descriptions of planned or existing client communications, with some firms submitting specific samples of such communication.

selected sale-related materials within a certain timeframe as part of future resolution plan reviews.

g. Derivatives and Trading Activities

The Agencies received a number of comments on Section VII (Derivatives and Trading Activities) of the proposed guidance. Commenters supported the proposed elimination of the active and passive wind-down scenario analyses and rating agency playbooks, but recommended certain modifications and clarifications to the proposed guidance in order to streamline the resolution plan submissions and provide further clarity.

After reviewing the comments on the proposed guidance, the Agencies have adopted final guidance that includes several adjustments and clarifications to address matters raised by the commenters. For example, commenters argued that having a dealer firm provide information on compression strategies that it would not expect to use in resolution would have limited regulatory purpose and distract resources away from developing other capabilities and analyses. The final guidance clarifies that this expectation only applies when a dealer firm expects to rely upon compression strategies for executing its preferred strategy. Commenters suggested a dealer firm should not have to model the operational costs necessary to execute its derivatives strategy by separating out and specifying costs at the level of specific derivatives activities, as a firm would have included those costs in the material entity cost analyses provided as part of its resolution plan. The final guidance clarifies that a dealer firm may choose not to model its operational costs for executing its derivatives strategy at the level of specific derivatives activities; however, a firm's cost analyses should provide operational cost estimates at a more granular level than the material entity level (*e.g.,* business line level within a material entity, subject to wind-down).

The Agencies also have made a number of changes to clarify the scope, intent, and terminology of the final guidance. For example, commenters recommended the Agencies confirm that the term ''material derivatives entities'' means a dealer firm's material entities that engage in derivatives activities. The final guidance confirms the definition of the term. Commenters suggested that a dealer firm should be expected only to incorporate capital and liquidity needs associated with derivatives activities into its RCEN and RLEN estimates with respect to its material entities. The final guidance includes this clarification. Commenters urged the Agencies to clarify that dealer firms may define linked non-derivatives trading positions based on their overall business and resolution strategy. The final guidance includes this clarification.

Some commenters recommended the Agencies adjust certain expectations that are not specified in the proposed guidance. The Agencies have determined not to modify the guidance in these instances. For example, commenters suggested the Agencies eliminate certain remnants of the passive wind-down analysis (*e.g.,* potential residual portfolio analysis under a scenario involving the sale of a line of business). The Agencies do not expect a dealer firm to include a separate wind-down or run-off analysis in its plan. Instead, a dealer firm is expected to assess the risk profile of any derivatives portfolios that would be included in the sale of a line of business and analyze the potential counterparty and market impacts of non-performance on these contracts upon the stability of U.S. financial markets. Commenters advocated for allowing a dealer firm to assume that inter-affiliate transactions may be unwound at lower costs than transactions with external counterparties. The Agencies confirm that the guidance would permit a dealer firm to make such an assumption as long as the firm provides adequate support for that assumption. Commenters recommended dealer firms should not be expected to replicate detailed information in their resolution plans to the extent that a firm is required to make the information available to regulators pursuant to other regulatory requirements or that information is provided elsewhere in the firm's resolution plan. The Agencies clarify that, consistent with the Rule, a dealer firm may cross-reference or incorporate by reference information that the firm has provided in its current plan submission in another section or has previously provided in a specific section of a past resolution plan submission. However, consistent with the Rule, the Agencies expect a dealer firm to submit all relevant information as part of a formal plan submission.

Commenters suggested tailoring certain capability expectations and resolution-specific assumptions in the guidance. The Agencies developed those expectations and resolution-specific assumptions in order to facilitate a dealer firm's planning and preparedness for an orderly resolution. A dealer firm's capabilities should demonstrate flexibility to account for alternative outcomes and permit sensitivity analysis, as it is difficult to predict precisely how a firm's untested resolution strategy may operate in an actual resolution scenario. As a result, the Agencies have not revised the guidance to include certain modifications recommended by commenters. For instance, commenters suggested the Agencies eliminate the expectation to provide timely transparency into management of risk transfers between material entities and non-material entities. The Agencies maintain expectations related to risk transfers between affiliates, as material exposures could exist outside material entities. In addition, commenters argued that a dealer firm that adopts an SPOE strategy should not be expected to demonstrate its capabilities with respect to the management of risk transfers between material entities that survive under its preferred resolution strategy. The Agencies maintain the expectations related to risk transfers between material entities, including surviving entities, because those capabilities would help facilitate a dealer firm's planning and preparedness for alternative outcomes that may arise in the context of an actual resolution.

Commenters advocated for allowing a dealer firm to present reasonable alternative assumptions on counterparty behavior in relation to early exits and break clauses if the assumed actions would benefit both parties. To establish a baseline, the Agencies expect a dealer firm to assume that counterparties will exercise any contractual termination rights, if exercising that right would economically benefit the counterparty. A dealer firm may perform additional sensitivity analysis around the baseline assumption by assessing the impact from alternative assumptions regarding counterparty actions that could deviate from the baseline assumption. Commenters argued that a dealer firm should be permitted to assume it could enter into or unwind bilateral inter-affiliate transactions in resolution, even if they are not strictly ''risk-reducing'' to both parties, as long as the firm provides a reasonable justification. The final guidance maintains this constraint related to market risk exposure, but clarifies that a firm may assume it could enter into or unwind inter-affiliate trades in resolution as long as those trades do not materially increase credit exposure to any participating entity. The Agencies believe that this provides firms with sufficient flexibility with respect to inter-affiliate trades in resolution. Commenters suggested a dealer firm should not be constrained to a 12–24 month timeline for its stabilization and resolution periods. The

Agencies continue to believe that the timeline to be reasonable for unwinding a dealer firm's derivatives portfolios, based on the firms' preferred wind-down strategy in their past submissions; therefore, that expectation remains unchanged.

The Agencies received comments related to the scope of derivatives portfolios defined in the guidance. After considering multiple relevant factors, the Agencies have not modified the guidance in these instances. For example, commenters recommended that the final guidance apply the capabilities specified in the Portfolio Segmentation and Forecasting section only to material entities of a dealer firm. While a dealer firm's capabilities may be commensurate with the size, scope, and complexity of its derivatives portfolio, the Agencies maintain that a dealer firm should have the capability to identify and report basic metrics on all of its derivatives positions, if only to confirm the portion of the firm's exposures exist outside its material entities. The final guidance further clarifies that a dealer firm's firm-wide derivatives portfolio should represent the vast majority (for example, 95 percent) of a dealer firm's derivatives transactions measured by the notional and gross market value of the firm's total derivatives transactions. Commenters also suggested that the potential residual portfolio analysis should consider only the derivatives transactions of a dealer firm's material entities. The Agencies expect a dealer firm to include the derivatives portfolios of both material and non-material entities in its potential residual portfolio analysis, as the composition of the firm's potential residual portfolio may be impacted by exposures in non-material entities.

h. Cross References to Supervisory Letters

Some commenters advocated eliminating the cross-references contained in the Board's SR letter 14–1 (which covers both recovery and resolution preparedness) and SR letter 14–8 (which is limited to recovery),[25] directly incorporating the relevant expectations in the guidance, and rescinding the SR letters. Commenters maintained that recovery planning guidance should remain separate from resolution planning guidance.

The Agencies have omitted the cross-references, which is consistent with the aim of consolidating expectations for resolution plan submissions. In the case of SR 14–8, the relevant resolution plan expectations have been incorporated into the Separability section of the guidance. In the case of SR 14–1, the resolution-related expectations and associated capabilities contained in SR 14–1 are also addressed by the final guidance. The Board will continue to rely on SR letters 14–1 and 14–8 for assessing firms' recovery planning.

i. Additional Comments

i. QFC Stay Rules

One commenter expressed that by requiring the production of additional plan content related to a firm's method of complying with the QFC stay rules only from those firms that do not adhere to the International Swaps and Derivatives Association 2015 Universal Resolution Stay Protocol (''ISDA Protocol''), the guidance may have the effect of discouraging such firms from complying with the QFC stay rules through any means other than ISDA Protocol adherence.

The QFC stay rules seek to improve the resolvability of U.S. GSIBs by mitigating the risk of potentially destabilizing closeouts of QFCs that could occur upon the entry of a GSIB or one or more of its affiliates into resolution. In connection with promulgating the QFC stay rules, the Agencies have recognized that the ability to comply with the QFC stay rules by adhering to the ISDA Protocol may be a desirable alternative to implementing the rules' restrictions on a counterparty-by-counterparty basis. Through their consideration of the ISDA Protocol in connection with promulgating the QFC stay rules, the Agencies have already assessed whether adherence to the ISDA Protocol addresses the risks that can arise from QFC closeouts. For firms that choose to adhere to the ISDA Protocol through other means, any additional plan content they provide can assist the Agencies in understanding how a firm's chosen alternative compliance method addresses these risks.

Notably, prior to the effective date of the QFC stay rules, all eight U.S. GSIBs elected to adhere to the ISDA Protocol and incur any fees associated with adhering to the ISDA Protocol. Therefore, as long as the U.S. GSIBs continue to adhere, the Agencies will not expect these firms to submit additional plan content related to compliance with the QFC stay rules through a method other than adherence to the ISDA Protocol.

ii. Bankruptcy Claims

The Agencies recognize that a firm's compliance with the ISDA Protocol may have an effect on various creditor constituencies, and that actions taken by these constituencies may have an effect on the prospect of the firm conducting an orderly resolution under the U.S. Bankruptcy Code. One commenter suggested that the Agencies provide additional guidance on the material impact on their resolution plans and communications plans with respect to all unsecured claimants, as well as depositors of an insured depository institution, that could arise from a firm choosing to satisfy the ISDA Protocol's stay conditions for credit enhancements (i.e., a parent company acting as a guarantor of its subsidiary's QFCs) by pursuing the elevation alternative wherein the firm files a motion with the bankruptcy court asking that QFC counterparties' claims receive administrative priority status. The guidance expressly recommends that firms both address legal issues associated with the implementation of the ISDA Protocol,[26] and also develop external communications strategies.[27]

This commenter also stated that, specifically in relation to the elevation alternative and QFC counterparties' claims in bankruptcy, the proposed guidance failed to address two vulnerabilities associated with those claims receiving administrative priority under Section 507 of Bankruptcy Code. First, the commenter asserted that a firm that elects in its resolution plan to pursue the elevation alternative may be exposed to civil liability to bondholders both immediately as a consequence of incorporating such a strategy into its plan, and in the future if the strategy is actually implemented through a bankruptcy court granting the firm's motion. The commenter asserted that a firm pursuing the elevation alternative may be required to make disclosures under Section 10(b) if the Securities Act of 1933 [28] prior to resolution to indicate to bondholders that its resolution strategy contemplates a bankruptcy court providing QFC counterparties' claims higher payment priority than the unsecured claims of bondholders. A firm's disclosure obligations, if any, under the Securities Act or other regulations during BAU that relate to adherence to the ISDA Protocol are beyond the scope of the guidance.

Second, with regard to liability to bondholders, the commenter also asserted that implementation of the

[25] SR Letter 14–8, ''Consolidated Recovery Planning for Certain Large Domestic Bank Holding Companies'' (Sept. 25, 2014).

[26] 83 F.R. 32867 (July 16, 2018).

[27] 83 F.R. 32864 (July 16, 2018).

[28] 15 U.S.C. 77a *et seq.*

elevation alternative may result in a creditor of the firm violating its indenture obligations regarding fiduciary duties and conflicts of interest where the creditor is a GSIB that is both a QFC counterparty of the firm, and an indenture trustee for bonds issued by the firm. For a GSIB that is a creditor of a firm in bankruptcy, its obligations to uphold its fiduciary duties or avoid conflicts of interest may affect the actions it takes during the course of the bankruptcy of a firm. The guidance focuses on firms addressing potential risks to their resolvability, which does not include discrete legal liabilities of the type discussed by the commenter that a third party may encounter upon a firm's entry into resolution. The Agencies expect firms to consider and address the dynamics of relationships with creditors to the extent any creditor's potential course of action could present legal obstacles in the bankruptcy court's consideration of a motion to seeking to implement the elevation alternative.

The commenter also suggested that further clarification is needed in the final guidance with respect to the impact of the elevation alternative on firms' relationships with secured borrowers. Specifically, the commenter contended that a firm's proposal in its resolution plan to comply with the ISDA Protocol by adopting the elevation alternative may compel any firms that provide secured loans or residential mortgages to direct borrowers during business as usual to seek administrative priority for such prepetition obligations in the event the borrowers file for bankruptcy. Similarly, the commenter noted that the possibility of a firm implementing the elevation alternative could motivate secured creditors in the ordinary course of business with GSIBs to seek contractual provisions that would designate their claims as administrative expenses in any future bankruptcy case. However, the extent to which a firm's adherence to the ISDA Protocol might impact its relationships with external stakeholders during BAU, including its adoption of the elevation alternative for emergency motions, is beyond the scope of the guidance.

The commenter also asked that the Agencies clarify whether there is legal support for a creditor obtaining priority status for its claim. The guidance provides that firms' resolution plans should address legal issues associated with the implementation of the stay pursuant to the ISDA Protocol, including if a firm pursues the elevation strategy.

The commenter also asked the Agencies to address whether the recovery in bankruptcy for depositors holding funds in accounts that exceed the amount of deposit insurance provided by the FDIC would be negatively impacted by a firm pursuing the elevation alternative. The extent of depositors' recoveries is an issue that may arise in the resolution of an insured depository institution under the Federal Deposit Insurance Act and, therefore, is beyond the scope of the guidance.

IV. Paperwork Reduction Act

In accordance with the requirements of the Paperwork Reduction Act of 1995 (''PRA'') (44 U.S.C. 3501 through 3521), the Agencies may not conduct or sponsor, and a respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget control number. The proposed guidance stated that the Agencies believed that the proposed changes to the 2016 Guidance would not result in an increase in information collection burden to the Covered Companies, and the Agencies invited public comment on this assessment. The Agencies received no comments regarding this assessment or the PRA more generally.

GUIDANCE FOR § 165(D) RESOLUTION PLAN SUBMISSIONS BY DOMESTIC COVERED COMPANIES.

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I. INTRODUCTION

Resolution Plan Requirement: Section 165(d) of the Dodd-Frank Wall Street Reform and Consumer Protection Act (12 U.S.C. 5365(d)) requires certain financial companies (Covered Companies) to report periodically to the Board of Governors of the Federal Reserve System (the Federal Reserve or Board) and the Federal Deposit Insurance Corporation (the FDIC) (together the Agencies) the Companies' [1] Plans for Rapid and Orderly Resolution in the event of Material Financial Distress or failure. On November 1, 2011, the Agencies promulgated a joint rule (the Rule) implementing the provisions of Section 165(d), 12 CFR parts 243 and 381.[2] Certain Covered Companies meeting criteria set out in the Rule must file a resolution plan (Plan) annually or at a different time period specified by the Agencies.

Overview of Guidance Document: This document is intended to assist the eight current U.S. Global Systemically Important Banks (GSIBs or firms) [3] in further developing their preferred resolution strategies. The document does not have the force and effect of law. Rather, it describes the Agencies' supervisory expectations regarding these firms' resolution plans and the Agencies' general views regarding specific areas where additional detail should be provided and where certain capabilities or optionality should be developed and maintained to demonstrate that each firm has considered fully, and is able to mitigate, obstacles to the successful implementation of the preferred strategy.[4]

This document is organized around a number of key vulnerabilities in resolution (i.e., capital; liquidity; governance mechanisms; operational;

[1] Capitalized terms not defined herein have the meaning set forth in the Rule.

[2] 76 Fed. Reg. 67323 (November 1, 2011).

[3] Bank of America Corporation, The Bank of New York Mellon Corporation, Citigroup Inc., The Goldman Sachs Group, Inc., JPMorgan Chase & Co., Morgan Stanley, State Street Corporation, and Wells Fargo & Company.

[4] This guidance consolidates the *Guidance for 2013 § 165(d) Annual Resolution Plan Submissions by Domestic Covered Companies that Submitted Initial Resolution Plans in 2012;* firm-specific feedback letters issued in August 2014 and April 2016; the February 2015 staff communication; and *Guidance for 2017 § 165(d) Annual Resolution Plan Submissions by Domestic Covered Companies that Submitted Resolution Plans in July 2015,* including the frequently asked questions that were published in response to the Guidance for the 2017 Plan Submissions (taken together, prior guidance). To the extent not incorporated in or appended to this guidance, prior guidance is superseded.

legal entity rationalization and separability; and derivatives and trading activities) that apply across resolution plans. Additional vulnerabilities or obstacles may arise based on a firm's particular structure, operations, or resolution strategy. Each firm is expected to satisfactorily address these vulnerabilities in its Plan—e.g., by developing sensitivity analysis for certain underlying assumptions, enhancing capabilities, providing detailed analysis, or increasing optionality development, as indicated below.

The Agencies will review the Plan to determine if it satisfactorily addresses key potential vulnerabilities, including those detailed below. If the Agencies jointly decide that these matters are not satisfactorily addressed in the Plan, the Agencies may determine jointly that the Plan is not credible or would not facilitate an orderly resolution under the U.S. Bankruptcy Code.

II. CAPITAL

Resolution Capital Adequacy and Positioning (RCAP): To help ensure that a firm's material entities [5] could operate while the parent company is in bankruptcy, the firm should have an adequate amount of loss-absorbing capacity to recapitalize those material entities. Thus, a firm should have outstanding a minimum amount of total loss-absorbing capital, as well as a minimum amount of long-term debt, to help ensure that the firm has adequate capacity to meet that need at a consolidated level (external TLAC).[6]

A firm's external TLAC should be complemented by appropriate positioning of additional loss-absorbing capacity within the firm (internal TLAC). The positioning of a firm's internal TLAC should balance the certainty associated with pre-positioning internal TLAC directly at material entities with the flexibility provided by holding recapitalization resources at the parent (contributable resources) to meet unanticipated losses at material entities. That balance should take account of both pre-positioning at material entities and holding resources at the parent, and the obstacles associated with each. Accordingly, the firm should not rely exclusively on either full pre-positioning or parent contributable resources to recapitalize any material entity. The plan should describe the positioning of internal TLAC within the firm, along with analysis supporting such positioning.

Finally, to the extent that pre-positioned internal TLAC at a material entity is in the form of intercompany debt and there are one or more entities between that material entity and the parent, the firm should structure the instruments so as to ensure that the material entity can be recapitalized.

Resolution Capital Execution Need (RCEN): To support the execution of the firm's resolution strategy, material entities need to be recapitalized to a level that allows them to operate or be wound down in an orderly manner following the parent company's bankruptcy filing. The firm should have a methodology for periodically estimating the amount of capital that may be needed to support each material entity after the bankruptcy filing (RCEN). The firm's positioning of internal TLAC should be able to support the RCEN estimates. In addition, the RCEN estimates should be incorporated into the firm's governance framework to ensure that the parent company files for bankruptcy at a time that enables execution of the preferred strategy.

The firm's RCEN methodology should use conservative forecasts for losses and risk-weighted assets and incorporate estimates of potential additional capital needs through the resolution period,[7] consistent with the firm's resolution strategy. However, the methodology is not required to produce aggregate losses that are greater than the amount of external TLAC that would be required for the firm under the Board's rule.[8] The RCEN methodology should be calibrated such that recapitalized material entities have sufficient capital to maintain market confidence as required under the preferred resolution strategy. Capital levels should meet or exceed all applicable regulatory capital requirements for ''well-capitalized'' status and meet estimated additional capital needs throughout resolution. Material entities that are not subject to capital requirements may be considered sufficiently recapitalized when they have achieved capital levels typically required to obtain an investment-grade credit rating or, if the entity is not rated, an equivalent level of financial soundness. Finally, the methodology should be independently reviewed, consistent with the firm's corporate governance processes and controls for the use of models and methodologies.

III. LIQUIDITY

The firm should have the liquidity capabilities necessary to execute its preferred resolution strategy. For resolution purposes, these capabilities should include having an appropriate model and process for estimating and maintaining sufficient liquidity at or readily available to material entities and a methodology for estimating the liquidity needed to successfully execute the resolution strategy, as described below.

Resolution Liquidity Adequacy and Positioning (RLAP): With respect to RLAP, the firm should be able to measure the stand-alone liquidity position of each material entity (including material entities that are non-U.S. branches)—i.e., the high-quality liquid assets (HQLA) at the material entity less net outflows to third parties and affiliates—and ensure that liquidity is readily available to meet any deficits. The RLAP model should cover a period of at least 30 days and reflect the idiosyncratic liquidity profile and risk of the firm. The model should balance the reduction in frictions associated with holding liquidity directly at material entities with the flexibility provided by holding HQLA at the parent available to meet unanticipated outflows at material entities. Thus, the firm should not rely exclusively on either full pre-positioning or the parent. The model [9] should ensure that the parent holding company holds sufficient HQLA (inclusive of its deposits at the U.S. branch of the lead bank subsidiary) to cover the sum of all stand-alone material entity net liquidity deficits. The stand-alone net liquidity position of each material entity (HQLA less net outflows) should be measured using the firm's internal liquidity stress test assumptions and should treat inter-affiliate exposures in the same manner as third-party exposures. For example, an overnight unsecured exposure to an affiliate should be assumed to mature. Finally, the firm should not assume that a net liquidity surplus at one material entity could be moved to meet net liquidity deficits at other material entities or to augment parent resources.

Additionally, the RLAP methodology should take into account (A) the daily contractual mismatches between inflows and outflows; (B) the daily

[5] The terms ''material entities,'' ''critical operations,'' and ''core business lines'' have the same meaning as in the Agencies' Rule.

[6] 82 Fed. Reg. 8266 (January 24, 2017).

[7] The resolution period begins immediately after the parent company bankruptcy filing and extends through the completion of the preferred resolution strategy.

[8] *See* 12 CFR 252.60–.65; 82 Fed. Reg. 8266 (January 24, 2017).

[9] ''Model'' refers to the set of calculations estimating the net liquidity surplus/deficit at each legal entity and for the firm in aggregate based on assumptions regarding available liquidity, e.g., HQLA, and third-party and interaffiliate net outflows.

flows from movement of cash and collateral for all inter-affiliate transactions; and (C) the daily stressed liquidity flows and trapped liquidity as a result of actions taken by clients, counterparties, key FMUs, and foreign supervisors, among others.

Resolution Liquidity Execution Need (RLEN): The firm should have a methodology for estimating the liquidity needed after the parent's bankruptcy filing to stabilize the surviving material entities and to allow those entities to operate post-filing. The RLEN estimate should be incorporated into the firm's governance framework to ensure that the firm files for bankruptcy in a timely way, i.e., prior to the firm's HQLA falling below the RLEN estimate.

The firm's RLEN methodology should:

(A) Estimate the minimum operating liquidity (MOL) needed at each material entity to ensure those entities could continue to operate post-parent's bankruptcy filing and/or to support a wind-down strategy;

(B) Provide daily cash flow forecasts by material entity to support estimation of peak funding needs to stabilize each entity under resolution;

(C) Provide a comprehensive breakout of all inter-affiliate transactions and arrangements that could impact the MOL or peak funding needs estimates; and

(D) Estimate the minimum amount of liquidity required at each material entity to meet the MOL and peak needs noted above, which would inform the firm's board(s) of directors of when they need to take resolution-related actions.

The MOL estimates should capture material entities' intraday liquidity requirements, operating expenses, working capital needs, and inter-affiliate funding frictions to ensure that material entities could operate without disruption during the resolution.

The peak funding needs estimates should be projected for each material entity and cover the length of time the firm expects it would take to stabilize that material entity. Inter-affiliate funding frictions should be taken into account in the estimation process.

The firm's forecasts of MOL and peak funding needs should ensure that material entities could operate post-filing consistent with regulatory requirements, market expectations, and the firm's post-failure strategy. These forecasts should inform the RLEN estimate, i.e., the minimum amount of HQLA required to facilitate the execution of the firm's strategy. The RLEN estimate should be tied to the firm's governance mechanisms and be incorporated into the playbooks as discussed below to assist the board of directors in taking timely resolution-related actions.

IV. GOVERNANCE MECHANISMS

Playbooks and Triggers: A firm should identify the governance mechanisms that would ensure execution of required board actions at the appropriate time (as anticipated under the firm's preferred strategy) and include pre-action triggers and existing agreements for such actions. Governance playbooks should detail the board and senior management actions necessary to facilitate the firm's preferred strategy and to mitigate vulnerabilities, and should incorporate the triggers identified below. The governance playbooks should also include a discussion of (A) the firm's proposed communications strategy, both internal and external; [10] (B) the boards of directors' fiduciary responsibilities and how planned actions would be consistent with such responsibilities applicable at the time actions are expected to be taken; (C) potential conflicts of interest, including interlocking boards of directors; and (D) any employee retention policy. All responsible parties and timeframes for action should be identified. Governance playbooks should be updated periodically for all entities whose boards of directors would need to act in advance of the commencement of resolution proceedings under the firm's preferred strategy.

The firm should demonstrate that key actions will be taken at the appropriate time in order to mitigate financial, operational, legal, and regulatory vulnerabilities. To ensure that these actions will occur, the firm should establish clearly identified triggers linked to specific actions for:

(A) The escalation of information to senior management and the board(s) to potentially take the corresponding actions at each stage of distress post-recovery leading eventually to the decision to file for bankruptcy;

(B) Successful recapitalization of subsidiaries prior to the parent's filing for bankruptcy and funding of such entities during the parent company's bankruptcy to the extent the preferred strategy relies on such actions or support; and

(C) The timely execution of a bankruptcy filing and related pre-filing actions.[11]

These triggers should be based, at a minimum, on capital, liquidity, and market metrics, and should incorporate the firm's methodologies for forecasting the liquidity and capital needed to operate as required by the preferred strategy following a parent company's bankruptcy filing. Additionally, the triggers and related actions should be specific.

Triggers linked to firm actions as contemplated by the firm's preferred strategy should identify when and under what conditions the firm, including the parent company and its material entities, would transition from business-as-usual conditions to a stress period and from a stress period to the runway and recapitalization/resolution periods. Corresponding escalation procedures, actions, and timeframes should be constructed so that breach of the triggers will allow prerequisite actions to be completed. For example, breach of the triggers needs to occur early enough to ensure that resources are available and can be downstreamed, if anticipated by the firm's strategy, and with adequate time for the preparation of the bankruptcy petition and first-day motions, necessary stakeholder communications, and requisite board actions. Triggers identifying the onset of the runway and recapitalization/resolution periods, and the associated escalation procedures and actions, should be discussed directly in the governance playbooks.

Pre-Bankruptcy Parent Support: The resolution plan should include a detailed legal analysis of the potential state law and bankruptcy law challenges and mitigants to planned provision of capital and liquidity to the subsidiaries prior to the parent's bankruptcy filing (Support). Specifically, the analysis should identify potential legal obstacles and explain how the firm would seek to ensure that Support would be provided as planned. Legal obstacles include claims of fraudulent transfer, preference, breach of fiduciary duty, and any other applicable legal theory identified by the firm. The analysis also should include related claims that may prevent or delay an effective recapitalization, such as equitable claims to enjoin the transfer (e.g., imposition of a constructive trust by the court). The analysis should apply the actions contemplated in the plan regarding each element of the claim, the anticipated timing for commencement and resolution of the claims, and the extent to which adjudication of such

[10] External communications include those with U.S. and foreign authorities and other external stakeholders.

[11] Key pre-filing actions include the preparation of any emergency motion required to be decided on the first day of the firm's bankruptcy. *See* ''*OPERATIONAL—Legal Obstacles Associated with Emergency Motions,*'' below.

claim could affect execution of the firm's preferred resolution strategy.

As noted, the analysis should include mitigants to the potential challenges to the planned Support. The plan should include the mitigant(s) to such challenges that the firm considers most effective. In identifying appropriate mitigants, the firm should consider the effectiveness of a contractually binding mechanism (CBM), pre-positioning of financial resources in material entities, and the creation of an intermediate holding company. Moreover, if the plan includes a CBM, the firm should consider whether it is appropriate that the CBM should have the following: (A) clearly defined triggers; (B) triggers that are synchronized to the firm's liquidity and capital methodologies; (C) perfected security interests in specified collateral sufficient to fully secure all Support obligations on a continuous basis (including mechanisms for adjusting the amount of collateral as the value of obligations under the agreement or collateral assets fluctuates); and (D) liquidated damages provisions or other features designed to make the CBM more enforceable. The firm also should consider related actions or agreements that may enhance the effectiveness of a CBM. A copy of any agreement and documents referenced therein (e.g., evidence of security interest perfection) should be included in the resolution plan.

The governance playbooks included in the resolution plan should incorporate any developments from the firm's analysis of potential legal challenges regarding the Support, including any Support approach(es) the firm has implemented. If the firm analyzed and addressed an issue noted in this section in a prior plan submission, the plan may reproduce that analysis and arguments and should build upon it to at least the extent described above. In preparing the analysis of these issues, firms may consult with law firms and other experts on these matters. The Agencies do not object to appropriate collaboration between firms, including through trade organizations and with the academic community, to develop analysis of common legal challenges and available mitigants.

V. OPERATIONAL

Payment, Clearing, and Settlement Activities

Framework. Maintaining continuity of payment, clearing, and settlement (PCS) services is critical for the orderly resolution of firms that are either users or providers,[12] or both, of PCS services. A firm should demonstrate capabilities for continued access to PCS services essential to an orderly resolution through a framework to support such access by:

- Identifying clients,[13] FMUs, and agent banks as key from the firm's perspective, using both quantitative (volume and value)[14] and qualitative criteria;
- Mapping material entities, critical operations, core business lines, and key clients to both key FMUs and key agent banks; and
- Developing a playbook for each key FMU and key agent bank reflecting the firm's role(s) as a user and/or provider of PCS services.

The framework should address both direct relationships (e.g., a firm's direct membership in an FMU, a firm's provision of clients with PCS services through its own operations, or a firm's contractual relationship with an agent bank) and indirect relationships (e.g., a firm's provision of clients with access to the relevant FMU or agent bank through the firm's membership in or relationship with that FMU or agent bank).

Playbooks for Continued Access to PCS Services. The firm is expected to provide a playbook for each key FMU and key agent bank that addresses considerations that would assist the firm and its key clients in maintaining continued access to PCS services in the period leading up to and including the firm's resolution. Each playbook should provide analysis of the financial and operational impact to the firm's material entities and key clients due to adverse actions that may be taken by a key FMU or a key agent bank and contingency actions that may be taken by the firm. Each playbook also should discuss any possible alternative arrangements that would allow the firm and its key clients continued access to PCS services in resolution. The firm is not expected to incorporate a scenario in which it loses key FMU or key agent bank access into its preferred resolution strategy or its RLEN/RCEN estimates. The firm should continue to engage with key FMUs, key agent banks, and key clients, and playbooks should reflect any feedback received during such ongoing outreach.

Content Related to Users of PCS Services. Individual key FMU and key agent bank playbooks should include:

- Description of the firm's relationship as a user with the key FMU or key agent bank and the identification and mapping of PCS services to material entities, critical operations, and core business lines that use those PCS services;
- Discussion of the potential range of adverse actions that may be taken by that key FMU or key agent bank when the firm is in resolution,[15] the operational and financial impact of such actions on each material entity, and contingency arrangements that may be initiated by the firm in response to potential adverse actions by the key FMU or key agent bank; and
- Discussion of PCS-related liquidity sources and uses in business-as-usual (BAU), in stress, and in the resolution period, presented by currency type (with U.S. dollar equivalent) and by material entity.
  - ○ PCS Liquidity Sources: These may include the amounts of intraday extensions of credit, liquidity buffer, inflows from FMU participants, and key client prefunded amounts in BAU, in stress, and in the resolution period. The playbook also should describe intraday credit arrangements (e.g., facilities of the key FMU, key agent bank, or a central bank) and any similar custodial arrangements that allow ready access to a firm's funds for PCS-related key FMU and key agent bank obligations (including margin requirements) in various currencies, including placements of firm liquidity at central banks, key FMUs, and key agent banks.
  - ○ PCS Liquidity Uses: These may include firm and key client margin and prefunding and intraday extensions of credit, including incremental amounts required during resolution.
  - ○ Intraday Liquidity Inflows and Outflows: The playbook should describe the firm's ability to control intraday liquidity inflows and outflows and to

[12] A firm is a user of PCS services if it accesses PCS services through an agent bank or it uses the services of a financial market utility (FMU) through its membership in that FMU or through an agent bank. A firm is a provider of PCS services if it provides PCS services to clients as an agent bank or it provides clients with access to an FMU or agent bank through the firm's membership in or relationship with that service provider. A firm is also a provider if it provides clients with PCS services through the firm's own operations (e.g., payment services or custody services).

[13] For purposes of this section V, a client is an individual or entity, including affiliates of the firm, to whom the firm provides PCS services and any related credit or liquidity offered in connection with those services.

[14] In identifying entities as key, examples of quantitative criteria may include: for a client, transaction volume/value, market value of exposures, assets under custody, usage of PCS services, and any extension of related intraday credit or liquidity; for an FMU, the aggregate volumes and values of all transactions processed through such FMU; and for an agent bank, assets under custody, the value of cash and securities settled, and extensions of intraday credit.

[15] Examples of potential adverse actions may include increased collateral and margin requirements and enhanced reporting and monitoring.

identify and prioritize time-specific payments. The playbook also should describe any account features that might restrict the firm's ready access to its liquidity sources.

Content Related to Providers of PCS Services.[16] Individual key FMU and key agent bank playbooks should include:

- Identification and mapping of PCS services to the material entities, critical operations, and core business lines that provide those PCS services, and a description of the scale and the way in which each provides PCS services;
- Identification and mapping of PCS services to key clients to whom the firm provides such PCS services and any related credit or liquidity offered in connection with such services;
- Discussion of the potential range of firm contingency arrangements available to minimize disruption to the provision of PCS services to its key clients, including the viability of transferring key client activity and any related assets, as well as any alternative arrangements that would allow the firm's key clients continued access to PCS services if the firm could no longer provide such access (e.g., due to the firm's loss of key FMU or key agent bank access), and the financial and operational impacts of such arrangements from the firm's perspective;
- Description of the range of contingency actions that the firm may take concerning its provision of intraday credit to key clients, including analysis quantifying the potential liquidity the firm could generate by taking such actions in stress and in the resolution period, such as (i) requiring key clients to designate or appropriately pre-position liquidity, including through prefunding of settlement activity, for PCS-related key FMU and key agent bank obligations at specific material entities of the firm (e.g., direct members of key FMUs) or any similar custodial arrangements that allow ready access to key clients' funds for such obligations in various currencies; (ii) delaying or restricting key client PCS activity; and (iii) restricting, imposing conditions upon (e.g., requiring collateral), or eliminating the provision of intraday credit or liquidity to key clients; and
- Description of how the firm will communicate to its key clients the potential impacts of implementation of any identified contingency arrangements or alternatives, including a description of the firm's methodology for determining whether any additional communication should be provided to some or all key clients (e.g., due to the key client's BAU usage of that access and/or related intraday credit or liquidity), and the expected timing and form of such communication.

Managing, Identifying, and Valuing Collateral: The firm should have capabilities related to managing, identifying, and valuing the collateral that it receives from and posts to external parties and its affiliates. Specifically, the firm should:

- Be able to query and provide aggregate statistics for all qualified financial contracts concerning cross-default clauses, downgrade triggers, and other key collateral-related contract terms—not just those terms that may be impacted in an adverse economic environment—across contract types, business lines, legal entities, and jurisdictions;
- Be able to track both firm collateral sources (i.e., counterparties that have pledged collateral) and uses (i.e., counterparties to whom collateral has been pledged) at the CUSIP level on at least a t+1 basis;
- Have robust risk measurements for cross-entity and cross-contract netting, including consideration of where collateral is held and pledged;
- Be able to identify CUSIP and asset class level information on collateral pledged to specific central counterparties by legal entity on at least a t+1 basis;
- Be able to track and report on inter-branch collateral pledged and received on at least a t+1 basis and have clear policies explaining the rationale for such inter-branch pledges, including any regulatory considerations; and
- Have a comprehensive collateral management policy that outlines how the firm as a whole approaches collateral and serves as a single source for governance.[17]

Management Information Systems: The firm should have the management information systems (MIS) capabilities to readily produce data on a legal entity basis and have controls to ensure data integrity and reliability. The firm also should perform a detailed analysis of the specific types of financial and risk data that would be required to execute the preferred resolution strategy and how frequently the firm would need to produce the information, with the appropriate level of granularity.

Shared and Outsourced Services: The firm should maintain a fully actionable implementation plan to ensure the continuity of shared services that support critical operations and robust arrangements to support the continuity of shared and outsourced services, including without limitation appropriate plans to retain key personnel relevant to the execution of the firm's strategy. The firm should (A) maintain an identification of all shared services that support critical operations (critical services);[18] (B) maintain a mapping of how/where these services support its core business lines and critical operations; (C) incorporate such mapping into legal entity rationalization criteria and implementation efforts; and (D) mitigate identified continuity risks through establishment of service-level agreements (SLAs) for all critical shared services. These SLAs should fully describe the services provided, reflect pricing considerations on an arm's-length basis where appropriate, and incorporate appropriate terms and conditions to (A) prevent automatic termination upon certain resolution-related events and (B) achieve continued provision of such services during resolution. The firm should also store SLAs in a central repository or repositories in a searchable format, develop and document contingency strategies and arrangements for replacement of critical shared services, and complete re-alignment or restructuring of activities within its corporate structure. In addition, the firm should ensure the financial resilience of internal shared service providers by maintaining working capital for six months (or through the period of stabilization as required in the firm's preferred strategy) in such entities sufficient to cover contract costs, consistent with the preferred resolution strategy.

The firm should identify all critical outsourced services that support critical operations and could not be promptly substituted. The firm should (A) evaluate the agreements governing these services to determine whether there are any that could be terminated despite continued performance upon the parent's bankruptcy filing, and (B) update contracts to incorporate appropriate terms and conditions to prevent automatic termination and facilitate continued provision of such services during resolution. Relying on entities projected to survive during

[16] Where a firm is a provider of PCS services through the firm's own operations, the firm is expected to produce a playbook for the material entities that provide those services, addressing each of the items described under ''Content Related to Providers of PCS Services,'' which include contingency arrangements to permit the firm's key clients to maintain continued access to PCS services.

[17] The policy may reference subsidiary or related policies already in place, as implementation may differ based on business line or other factors.

[18] This should be interpreted to include data access and intellectual property rights.

resolution to avoid contract termination is insufficient to ensure continuity. In the plan, the firm should document the amendment of any such agreements governing these services.

Legal Obstacles Associated with Emergency Motions: The Plan should address legal issues associated with the implementation of the stay on cross-default rights described in Section 2 of the International Swaps and Derivatives Association 2015 Universal Resolution Stay Protocol (Protocol), similar provisions of any U.S. protocol,[19] or other contractual provisions that comply with the Agencies' rules regarding stays from the exercise of cross-default rights in qualified financial contracts, to the extent relevant.[20] Generally, the Protocol provides two primary methods of satisfying the stay conditions for covered agreements for which the affiliate in Chapter 11 proceedings has provided a credit enhancement (A) transferring all such credit enhancements to a Bankruptcy Bridge Company (as defined in the Protocol) (bridge transfer); or (B) having such affiliate remain obligated with respect to such credit enhancements in the Chapter 11 proceeding (elevation).[21] A firm must file a motion for emergency relief (emergency motion) seeking approval of an order to effect either of these alternatives on the first day of its bankruptcy case.

First-day Issues—For each alternative the firm selects, the resolution plan should present the firm's analysis of issues that are likely to be raised at the hearing on the emergency motion and its best arguments in support of the emergency motion. A firm should include supporting legal precedent and describe the evidentiary support that the firm would anticipate presenting to the bankruptcy court—e.g., declarations or other expert testimony evidencing the solvency of transferred subsidiaries and that recapitalized entities have sufficient liquidity to perform their ongoing obligations.

For either alternative, the firm should address all potential significant legal obstacles identified by the firm. For example, the firm should address due process arguments likely to be made by creditors asserting that they have not had sufficient opportunity to respond to the emergency motion given the likelihood that a creditors' committee will not yet have been appointed. The firm also should consider, and discuss in its plan, whether it would enhance the successful implementation of its preferred strategy to conduct outreach to interested parties, such as potential creditors of the holding company and the bankruptcy bar, regarding the strategy.

If the firm chooses the bridge transfer alternative, its analysis and arguments should address at a minimum the following potential issues: (A) the legal basis for transferring the parent holding company's equity interests in certain subsidiaries (transferred subsidiaries) to a Bankruptcy Bridge Company, including the basis upon which the Bankruptcy Bridge Company would remain obligated for credit enhancements; (B) the ability of the bankruptcy court to retain jurisdiction, issue injunctions, or take other actions to prevent third parties from interfering with, or making collateral attacks on (i) a Bankruptcy Bridge Company, (ii) its transferred subsidiaries, or (iii) a trust or other legal entity designed to hold all ownership interests in a Bankruptcy Bridge Company (new ownership entity); and (C) the role of the bankruptcy court in granting the emergency motion due to public policy concerns—e.g., to preserve financial stability. The firm should also provide a draft agreement (e.g., trust agreement) detailing the preferred post-transfer governance relationships between the bankruptcy estate, the new ownership entity, and the Bankruptcy Bridge Company, including the proposed role and powers of the bankruptcy court and creditors' committee. Alternative approaches to these proposed post-transfer governance relationships should also be described, particularly given the strong interest that parties will have in the ongoing operations of the Bankruptcy Bridge Company and the likely absence of an appointed creditors' committee at the time of the hearing.

If the firm chooses the elevation alternative, the analysis and arguments should address at a minimum the following potential issues: (A) the legal basis upon which the parent company would seek to remain obligated for credit enhancements; (B) the ability of the bankruptcy court to retain jurisdiction, issue injunctions, or take other actions to prevent third parties from interfering with, or making collateral attacks on, the parent in bankruptcy or its subsidiaries; and (C) the role of the bankruptcy court in granting the emergency motion due to public policy concerns—e.g., to preserve financial stability.

Regulatory Implications—The plan should include a detailed explanation of the steps the firm would take to ensure that key domestic and foreign authorities would support, or not object to, the emergency motion (including specifying the expected approvals or forbearances and the requisite format—i.e., formal, affirmative statements of support or, alternatively, ''non-objections''). The potential impact on the firm's preferred resolution strategy if a specific approval or forbearance cannot be timely obtained should also be detailed.

Contingencies if Preferred Structure Fails—The plan should consider contingency arrangements in the event the bankruptcy court does not grant the emergency motion—e.g., whether alternative relief could satisfy the Transfer Conditions and/or U.S. Parent debtor-in-possession (DIP) Conditions of the Protocol;[22] the extent to which action upon certain aspects of the emergency motion may be deferred by the bankruptcy court without interfering with the resolution; and whether, if the credit-enhancement-related protections are not satisfied, there are alternative strategies to prevent the closeout of qualified financial contracts with credit enhancements (or reduce such counterparties' incentives to closeout) and the feasibility of the alternative(s).

Format—If the firm analyzed and addressed an issue noted in this section in a prior plan submission, the plan may incorporate this analysis and arguments and should build upon it to at least the extent required above. A bankruptcy playbook, which includes a sample emergency motion and draft documents setting forth the post-transfer governance terms substantially in the form they would be presented to the bankruptcy court, is an appropriate vehicle for detailing the issues outlined in this section. In preparing analysis of

[19] U.S. protocol has the same meaning as it does at 12 CFR 252.85(a). *See also* 12 CFR 382.5(a) (including a substantively identical definition).

[20] *See* 12 CFR part 47, 252.81–.88, and part 382 (together, the QFC stay rules). Plans submitted prior to the final initial applicability date of the QFC stay rules should reflect how the early termination of qualified financial contracts could impact the firm's resolution in light of the current state of its qualified financial contracts' compliance with the requirements of the QFC stay rules. The firm may also separately discuss the firm's resolution assuming that the final initial applicability date has been reached and all covered qualified financial contracts have been conformed to comply with the QFC stay rules. If the firm complies with the QFC stay rules other than through adherence to the Protocol, the plan also should explain how the alternative compliance method differs from Protocol, how those differences affect the analysis and other expectations of this ''Legal Obstacles Associated with Emergency Motions'' section, and how the firm plans to satisfy any different conditions or requirements of the alternative compliance method.

[21] Under its terms, the Protocol also provides for the transfer of credit enhancements to transferees other than a Bankruptcy Bridge Company.

[22] *See* Protocol sections 2(b)(ii) and (iii) and related definitions.

these issues, the firm may consult with law firms and other experts on these matters. The Agencies do not object to appropriate collaboration among firms, including through trade organizations and with the academic community and bankruptcy bar, to develop analysis of common legal challenges and available mitigants.

VI. LEGAL ENTITY RATIONALIZATION AND SEPARABILITY

Legal Entity Rationalization Criteria (LER Criteria): A firm should develop and implement legal entity rationalization criteria that support the firm's preferred resolution strategy and minimize risk to U.S. financial stability in the event of the firm's failure. LER Criteria should consider the best alignment of legal entities and business lines to improve the firm's resolvability under different market conditions. LER Criteria should govern the firm's corporate structure and arrangements between legal entities in a way that facilitates the firm's resolvability as its activities, technology, business models, or geographic footprint change over time.

Specifically, application of the criteria should:

(A) Facilitate the recapitalization and liquidity support of material entities, as required by the firm's resolution strategy. Such criteria should include clean lines of ownership, minimal use of multiple intermediate holding companies, and clean funding pathways between the parent and material operating entities;

(B) Facilitate the sale, transfer, or wind-down of certain discrete operations within a timeframe that would meaningfully increase the likelihood of an orderly resolution of the firm, including provisions for the continuity of associated services and mitigation of financial, operational, and legal challenges to separation and disposition;

(C) Adequately protect the subsidiary insured depository institutions from risks arising from the activities of any nonbank subsidiaries of the firm (other than those that are subsidiaries of an insured depository institution); and

(D) Minimize complexity that could impede an orderly resolution and minimize redundant and dormant entities.

These criteria should be built into the firm's ongoing process for creating, maintaining, and optimizing its structure and operations on a continuous basis.

Separability: The firm should identify discrete operations that could be sold or transferred in resolution, which individually or in the aggregate would provide meaningful optionality in resolution under different market conditions.

A firm's separability options should be actionable, and impediments to their execution and projected mitigation strategies should be identified in advance. Relevant impediments could include, for example, legal and regulatory preconditions, interconnectivity among the firm's operations, tax consequences, market conditions, and other considerations. To be actionable, divestiture options should be executable within a reasonable period of time.

In developing their options, firms should also consider potential consequences for U.S. financial stability of executing each option, taking into consideration impacts on counterparties, creditors, clients, depositors, and markets for specific assets.

Firms should have a comprehensive understanding of the entire organization and certain baseline capabilities. That understanding should include the operational and financial linkages among a firm's business lines, material entities, and critical operations. Additionally, information systems should be robust enough to produce the required data and information needed to execute separability options.

The level of detail and analysis should vary based on the firm's risk profile and scope of operations. A separability analysis should address the following elements:

- *Divestiture Options:* the options in the plan should be actionable and comprehensive, and should include:
  - ○ Options contemplating the sale, transfer, or disposal of significant assets, portfolios, legal entities or business lines.
  - ○ Options that may permanently change the firm's structure or business strategy.
- *Execution Plan:* for each divestiture option listed, the separability analysis should describe the steps necessary to execute the option. Among other considerations, the description should include:
  - ○ The identity and position of the senior management officials of the company who are primarily responsible for overseeing execution of the separability option.
  - ○ An estimated time frame for implementation.
  - ○ A description of any impediments to execution of the option and mitigation strategies to address those impediments.
  - ○ A description of the assumptions underpinning the option.
  - ○ A plan describing the methods and forms of communication with internal, external, and regulatory stakeholders.
- *Impact Assessment:* the separability analysis should holistically consider and describe the expected impact of individual divestiture options. This should include the following for each divestiture option:
  - ○ A financial impact assessment that describes the impact of executing the option on the firm's capital, liquidity, and balance sheet.
  - ○ A business impact assessment that describes the effect of executing the option on business lines and material entities, including reputational impact.
  - ○ A critical operation impact assessment that describes how execution of the option may affect the provision of any critical operation.
  - ○ An operational impact assessment and contingency plan that explains how operations can be maintained if the option is implemented; such an analysis should address internal operations (for example, shared services, IT requirements, and human resources) and access to market infrastructure (for example, clearing and settlement facilities and payment systems).

Further, the firm should have, and be able to demonstrate, the capability to populate in a timely manner a data room with information pertinent to a potential divestiture of the business (including, but not limited to, carve-out financial statements, valuation analysis, and a legal risk assessment).

Within the plan, the firm should demonstrate how the firm's LER Criteria and implementation efforts meet the guidance above. The plan should also provide the separability analysis noted above. Finally, the plan should include a description of the firm's legal entity rationalization governance process.

VII. DERIVATIVES AND TRADING ACTIVITIES

Applicability.

This section of the proposed guidance applies to Bank of America Corporation, Citigroup Inc., Goldman Sachs Group, Inc., JP Morgan Chase & Co., Morgan Stanley, and Wells Fargo & Company (each, a dealer firm).

Booking Practices.

A dealer firm should have booking practices commensurate with the size, scope, and complexity of a firm's derivatives portfolios,[23] including

[23] A firm's derivatives portfolios include its derivatives positions and linked non-derivatives

Continued

systems capabilities to track and monitor market, credit, and liquidity risk transfers between entities. The following booking practices-related capabilities should be addressed in a dealer firm's resolution plan:

Derivatives booking framework. A dealer firm should have a comprehensive booking model framework that articulates the principles, rationales, and approach to implementing its booking practices. The framework and its underlying components should be documented and adequately supported by internal controls (e.g., procedures, systems, and processes). Taken together, the derivatives booking framework and its components should provide transparency with respect to (i) what is being booked (e.g., product/counterparty), (ii) where it is being booked (e.g., legal entity/geography), (iii) by whom it is booked (e.g., business/trading desk); (iv) why it is booked that way (e.g., drivers/rationales); and (v) what controls are in place to monitor and manage those practices (e.g., governance/information systems).[24] The dealer firm's resolution plan should include detailed descriptions of the framework and each of its material components. In particular, a dealer firm's resolution plan should include descriptions of the documented booking models covering its firm-wide derivatives portfolio.[25] The descriptions should provide clarity with respect to the underlying trade flows (e.g., the mapping of trade flows based on multiple trade characteristics as decision points that determine on which entity a trade is booked, if risk is transferred, and at which entity that risk is subsequently managed). For example, a firm may choose to incorporate decision trees that depict the multiple trade flows within each documented booking model.[26] Furthermore, a dealer firm's resolution plan should describe its end-to-end trade booking and reporting processes, including a description of the current scope of automation (e.g., automated trade flows and detective monitoring) for the systems controls applied to its documented booking models. The plan should also discuss why the firm believes its current (or planned) scope of automation is sufficient for managing its derivatives activities and executing its preferred resolution strategy.[27]

Derivatives entity analysis and reporting. A dealer firm should have the ability to identify, assess, and report on each of its entities (material and non-material) with derivatives portfolios (a derivatives entity). First, the firm's resolution plan should describe its method (that may include both qualitative and quantitative criteria) for evaluating the significance of each derivatives entity both with respect to the firm's current activities and to its preferred resolution strategy.[28] Second, a dealer firm's resolution plan should demonstrate (including through illustrative samples) its ability to readily generate current derivatives entity profiles that (i) cover all derivatives entities, (ii) are reportable in a consistent manner, and (iii) include information regarding current legal ownership structure, business activities/volume, and risk profile (including applicable risk limits).

Inter-Affiliate Risk Monitoring and Controls.

A dealer firm should be able to assess how the management of inter-affiliate risks can be affected in resolution, including the potential disruption in the risk transfers of trades between affiliate entities. Therefore, a dealer firm should have capabilities to provide timely transparency into the management of risk transfers between affiliates by maintaining an inter-affiliate market risk framework, consisting of at least the following two components[29]:

1. A method for measuring, monitoring, and reporting the market risk exposures for a given material derivatives entity[30] resulting from the termination of a specific counterparty or a set of counterparties (e.g., all trades with a specific affiliate or with all affiliates in a specific jurisdiction)[31] and

2. A method for identifying, estimating associated costs of, and evaluating the effectiveness of, a re-hedge strategy in resolution put on by the same material derivatives entity.[32]

In determining the re-hedge strategy, the firm should consider whether the instruments used (and the risk factors and risk sensitives controlled for) are sufficiently tied to the material derivatives entity's trading and risk-management practices to demonstrate its ability to execute the strategy in resolution using existing resources (e.g., existing traders and systems).

A dealer firm's resolution plan should describe and demonstrate its inter-affiliate market risk framework (discussed above). In addition, the firm's plan should provide detailed descriptions of its compression strategies used for executing its preferred strategy and how those strategies would differ from those used currently to manage its inter-affiliate derivatives activities. To the extent a dealer firm relies on compression strategies for executing its preferred strategy, the plan should include detailed descriptions of its compression capabilities, the associated risks, and obstacles in resolution.

Portfolio Segmentation and Forecasting.

A dealer firm should have the capabilities to produce analysis that

trading positions. The firm may define linked non-derivatives trading positions based on its overall business and resolution strategy.

[24] The description of controls should include any components of the firm-wide market, credit, and liquidity risk management framework that are material to the management of its derivatives practices.

[25] ''Firm-wide derivatives portfolio'' should represent the vast majority (for example, 95%) of a dealer firm's derivatives transactions measured by firm-wide derivatives notional and by firm-wide gross market value of derivatives. Presumably, each asset class/product would have a booking model that is a function of the firm's regulatory and risk management requirements, client's preference, and regulatory requirements specifically for the underlying asset class, and other transaction related considerations.

[26] Some firms use trader mandates or similar controls to constrain the potential trading strategies that can be pursued by a business and to monitor the permissibility of booking activity. However, the mapping of trader mandates alone, especially those mandates that grant broad permissibility, may not provide sufficient distinction between booking model trade flows.

[27] Effective preventative (up-front) and detective (post-booking) controls embedded in a dealer firm's derivatives booking processes can help avoid and/or timely remediate trades that do not align with a documented booking model or related risk limits. Firms typically use a combination of manual and automated control functions. Although automation may not be best suited for all control functions, as compared to manual methods it can improve consistency and traceability with respect to derivatives booking practices. Nonetheless, non-automated methods can also be effective when supported by other internal controls (e.g., robust detective monitoring and escalation protocols).

[28] The firm should leverage any existing methods and criteria it uses for other entity assessments (e.g., legal entity rationalization and/or the pre-positioning of internal loss-absorbing resources). The firm's method for determining the significance of derivatives entities is allowed to diverge from the parameters for material entity designation under the Resolution Plan Rule (i.e., entities significant to the activities of a critical operation or core business line) but should be adequately supported and any differences should be explained.

[29] The inter-affiliate market risk framework is a supplement to the firm's systems capabilities to track and monitor market, credit, and liquidity risk transfers between entities.

[30] A ''material derivatives entity'' is a material entity with a derivatives portfolio.

[31] Firms may use industry market risk measures such as statistical risk measures (e.g., VaR or SVaR) or other risk measures (e.g., worst case scenario or stress test).

[32] A dealer firm's method may include an approach to identifying the risk factors and risk sensitivities, hedging instruments, and risk limits a derivatives entity would employ in its re-hedge strategy, and the quantification of any estimated basis risk that would result from hedging with only exchange-traded and centrally-cleared instruments in a severely adverse stress environment.

reflects derivatives portfolio segmentation and differentiation of assumptions taking into account trade-level characteristics. More specifically, a dealer firm should have the systems capabilities that would allow it to produce a spectrum of derivatives portfolio segmentation analysis using multiple segmentation dimensions, including (1) legal entity (and material entities that are branches), (2) trading desk and/or product, (3) cleared vs. clearable vs. non-clearable trades, (4) counterparty type, (5) currency, (6) maturity, (7) level of collateralization, and (8) netting set.[33] A dealer firm should also have the capabilities to segment and analyze the full contractual maturity (run-off) profile of its external and inter-affiliate derivatives portfolios. The dealer firm's resolution plan should describe and demonstrate the firm's ability to segment and analyze its firm-wide derivatives portfolio using the relevant segmentation dimensions and to report the results of such segmentation and analysis. In addition, the dealer firm's resolution plan should address the following segmentation and forecasting related capabilities:

''*Ease of exit*'' *position analysis.* A dealer firm should have, and its resolution plan should describe and demonstrate, a method and supporting systems capabilities for categorizing and ranking the ease of exit for its derivatives positions based on a set of well-defined and consistently applied segmentation criteria. These capabilities should cover the firm-wide derivatives portfolio and the resulting categories should represent a range in degree of difficulty (e.g., from easiest to most difficult to exit). The segmentation criteria should, at a minimum, reflect characteristics[34] that the firm believes could affect the level of financial incentive and operational effort required to facilitate the exit of derivatives portfolios (e.g., to motivate a potential step-in party to agree to the novation or an existing counterparty to bilaterally agree to a termination). Dealer firms should consider this methodology when separately identifying and analyzing the population of derivatives positions that it will include in the potential residual portfolio under the firm's preferred resolution strategy (discussed below).

Application of exit cost methodology. Each dealer firm should have a methodology for forecasting the cost and liquidity needed to exit positions (e.g., terminate/tear-up, sell, novate, and compress), and the operational resources related to those exits, under the specific scenario adopted in the firm's preferred resolution strategy. To help preserve sufficient optionality with respect to managing and de-risking its derivatives portfolios in a resolution, a dealer firm should have the systems capabilities to apply its exit cost methodology to its firm-wide derivatives portfolio, at the segmentation levels the firm would likely apply to exit the particular positions (e.g., valuation segment level). The dealer firm's plan should provide detailed descriptions of the forecasting methodology (inclusive of any challenge and validation processes) and data systems and reporting capabilities. The firm should also describe and demonstrate the application of the exit cost method and systems capabilities to the firm-wide derivatives portfolio.

Analysis of operational capacity. In resolution, a dealer firm should have the capabilities to forecast the incremental operational needs and expenses related to executing specific aspects of its preferred resolution strategy (e.g., executing timely derivatives portfolio novations). Therefore, a dealer firm should have, and its resolution plan should describe and demonstrate, the capabilities to assess the operational resources and forecast the costs (e.g., monthly expense rate) related to its current derivatives activities at an appropriately granular level and the incremental impact from executing its preferred resolution strategy.[35] In addition, a dealer firm should have the ability to manage the logistical and operational challenges related to novating (selling) derivatives portfolios during a resolution, including the design and adjustment of novation packages. A dealer firm's resolution plan should describe its methodology and demonstrate its supporting systems capabilities for timely segmenting, packaging, and novating derivatives positions. In developing its methodology, a dealer firm should consider the systems capabilities that may be needed to reliably generate preliminary novation packages tailored to the risk appetites of potential step-in counterparties (buyers), as well as the novation portfolio profile information that may be most relevant to such counterparties.

Sensitivity analysis. A dealer firm should have a method to apply sensitivity analyses to the key drivers of the derivatives-related costs and liquidity flows under its preferred resolution strategy. A dealer firm's resolution plan should describe its method for (i) evaluating the materiality of assumptions and (ii) identifying those assumptions (or combinations of assumptions) that constitute the key drivers for its forecasts of operational and financial resource needs under the preferred resolution strategy. In addition, using its preferred resolution strategy as a baseline, the dealer firm's resolution plan should describe and demonstrate its approach to testing the sensitivities of the identified key drivers and the potential impact on its forecasts of resource needs.[36]

Prime Brokerage Customer Account Transfers.

A dealer firm should have the operational capacity to facilitate the orderly transfer of prime brokerage accounts to peer prime brokers in periods of material financial distress and in resolution. The firm's plan should include an assessment of how it would transfer such accounts. This assessment should be informed by clients' relationships with other prime brokers, the use of automated and manual transaction processes, clients' overall long and short positions facilitated by the firm, and the liquidity of clients' portfolios. The assessment should also analyze the risks of and mitigants to the loss of customer-to-customer internalization (e.g., the inability to fund customer longs with customer shorts), operational challenges, and insufficient staffing to effectuate the scale and speed of prime brokerage account transfers envisioned under the firm's preferred resolution strategy.

In addition, a dealer firm should describe and demonstrate its ability to segment and analyze the quality and composition of prime brokerage customer account balances based on a set of well-defined and consistently applied segmentation criteria (e.g., size,

[33] The enumerated segmentation dimensions are not intended as an exhaustive list of relevant dimensions. With respect to any product/asset class, a firm may have reasons for not capturing data on (or not using) one or more of the enumerated segmentation dimensions, but those reasons should be explained.

[34] Examples of characteristics that may affect the level of financial incentive and operational effort could include: product, size, clearability, currency, maturity, level of collateralization, and other risk characteristics.

[35] A dealer firm should have separate categories for fixed and variable expenses. For example, more granular operational expenses could roll-up into categories for (i) fixed-compensation, (ii) fixed non-compensation, and (iii) variable cost.

[36] For example, key drivers of derivatives-related costs and liquidity flows might include the timing of derivatives unwind, cost of capital-related assumptions (target ROE, discount rate, WAL, capital constraints, tax rate), operational cost reduction rate, and operational capacity for novations. Other examples of key drivers likely also include CCP margin flow assumptions and risk-weighted assets forecast assumptions.

single-prime, platform, use of leverage, non-rehypothecatable securities, and liquidity of underlying assets). The capabilities should cover the firm's prime brokerage customer account balances, and the resulting segments should represent a range in potential transfer speed (e.g., from fastest to longest to transfer, from most liquid to least liquid). The selected segmentation criteria should reflect characteristics [37] that the firm believes could affect the speed at which the client account balance would be transferred to an alternate prime broker.

Derivatives Stabilization and De-risking Strategy.

A dealer firm's plan should provide a detailed analysis of the strategy to stabilize and de-risk its derivatives portfolios (derivatives strategy) that has been incorporated into its preferred resolution strategy.[38] In developing its derivatives strategy, a dealer firm should apply the following assumption constraints:

• *OTC derivatives market access:* At or before the start of the resolution period, each derivatives entity should be assumed to lack an investment-grade credit rating (e.g., unrated or downgraded below investment grade). The derivatives entity should also be assumed to have failed to establish or reestablish investment-grade status for the duration of the resolution period, unless the plan provides well-supported analysis to the contrary. As a result of the lack of investment grade status, it should be further assumed that the derivatives entity has no access to the bilateral OTC derivatives markets and must use exchange-traded and/or centrally-cleared instruments where any new hedging needs arise during the resolution period. Nevertheless, a dealer firm may assume the ability to engage in certain risk-reducing derivatives trades with bilateral OTC derivatives counterparties during the resolution period to facilitate novations with third parties and to close out inter-affiliate trades.[39]

• *Early exits (break clauses).* A dealer firm should assume that counterparties (external or affiliates) will exercise any contractual termination right, consistent with any rights stayed by the ISDA 2015 Universal Resolution Stay protocol or other applicable protocols or amendments,[40] (i) that is available to the counterparty at or following the start of the resolution period; and (ii) if exercising such right would economically benefit the counterparty (counterparty-initiated termination).

• *Time horizon:* The duration of the resolution period should be between 12 and 24 months. The resolution period begins immediately after the parent company bankruptcy filing and extends through the completion of the preferred resolution strategy.

A dealer firm's analysis of its derivatives strategy should take into account (i) the starting profile of its derivatives portfolios (e.g., nature, concentration, maturity, clearability, and liquidity of positions); (ii) the profile and function of the derivatives entities during the resolution period; (iii) the means, challenges, and capacity for managing and de-risking its derivatives portfolios (e.g., method for timely segmenting, packaging, and selling the derivatives positions; challenges with novating less liquid positions; re-hedging strategy); (iv) the financial and operational resources required to effect the derivatives strategy; and (v) any potential residual portfolio (further discussed below). In addition, the firm's resolution plan should address the following areas in the analysis of its derivatives strategy:

Forecasts of resource needs. The forecasts of capital and liquidity resource needs of material entities required to adequately support the firm's derivatives strategy should be incorporated into the firm's RCEN and RLEN estimates for its overall preferred resolution strategy. These include, for example, the costs and/or liquidity flows resulting from (i) the close-out of OTC derivatives, (ii) the hedging of derivatives portfolios, (iii) the quantified losses that could be incurred due to basis and other risks that would result from hedging with only exchange-traded and centrally cleared instruments in a severely adverse stress environment, and (iv) the operational costs.[41]

Potential residual derivatives portfolio. A dealer firm's resolution plan should include a method for estimating the composition of any potential residual derivatives portfolio transactions remaining at the end of the resolution period under its preferred resolution strategy. The method may be a combination of approaches (e.g., probabilistic and deterministic) but should demonstrate the dealer firm's capabilities related to portfolio segmentation (discussed above). The dealer firm's plan should also provide detailed descriptions of the trade characteristics used to identify the potential residual portfolio and of the resulting trades (or categories of trades).[42] A dealer firm should assess the risk profile of the potential residual portfolio (including its anticipated size, composition, complexity, counterparties) and the potential counterparty and market impacts of non-performance on the stability of U.S. financial markets (e.g., on funding markets and the underlying asset markets and on clients and counterparties).

Non-surviving entity analysis. To the extent the preferred resolution strategy assumes a material derivatives entity enters its own resolution proceeding after the entry of the parent company into a bankruptcy proceeding (a non-surviving material derivatives entity), the dealer firm should provide a detailed analysis of how the non-surviving material derivatives entity's resolution can be accomplished within a reasonable period of time and in a manner that substantially mitigates the risk of serious adverse effects on U.S. financial stability and to the orderly

[37] For example, relevant characteristics might include: product, size, clearability, currency, maturity, level of collateralization, and other risk characteristics.

[38] Subject to the relevant constraints, a firm's derivatives strategy may take the form of a going-concern strategy, an accelerated de-risking strategy (e.g., active wind-down) or an alternative, third strategy so long as the firm's resolution plan adequately supports the execution of the chosen strategy. For example, a firm may choose a going-concern scenario (e.g., derivatives entities reestablish investment grade status and do not enter a wind-down) as its derivatives strategy. Likewise, a firm may choose to adopt a combination of going-concern and accelerated de-risking scenarios as its derivatives strategy. For example, the derivatives strategy could be a stabilization scenario for the lead bank entity and an accelerated de-risking scenario for the broker-dealer entities.

[39] A firm may engage in bilateral OTC derivatives trades with, for example, (i) external counterparties, to effect the novation of the firm's side of a derivatives contract to a new counterparty, bilateral OTC trades with the acquiring counterparty; and, (ii) inter-affiliate counterparties, where the trades with inter-affiliate counterparties do not materially increase (a) the credit exposure of any participating counterparty and (b) the market risk of any such counterparty on a standalone basis, after taking into account hedging with exchange-traded and centrally-cleared instruments. The firm should provide analysis to support the risk nature of the trade on the basis of information that would be known to the firm at the time of the transaction.

[40] For each of the derivatives entities that have adhered to the Protocol, the dealer firm may assume that the protocol is in effect for all counterparties of that derivatives entity (except for any affiliated counterparty of the derivatives entity that has not yet adhered to the Protocol).

[41] A dealer firm may choose not to isolate and separately model the operational costs solely related to executing its derivatives strategy. However, the firm should provide transparency around operational cost estimation at a more granular level than material entity (e.g., business line level within a material entity, subject to wind-down).

[42] If under the firm's preferred resolution strategy, any derivatives portfolios are transferred during the resolution period by way of a line of business sale (or similar transaction), then those portfolios should nonetheless be included within the firm's potential residual portfolio analysis.

execution of the firm's preferred resolution strategy. In particular, the firm should provide an analysis of the potential impacts on funding markets and the underlying asset markets, on clients and counterparties (including affiliates), and on the preferred resolution strategy. If the non-surviving material derivatives entity is located in, or provides more than *de minimis* services to clients or counterparties located in, a non-U.S. jurisdiction, then the analysis should also specifically consider potential local market impacts.

VIII. FORMAT AND STRUCTURE OF PLANS

Format of Plan

Executive Summary. The Plan should contain an executive summary consistent with the Rule, which must include, among other things, a concise description of the key elements of the firm's strategy for an orderly resolution. In addition, the executive summary should include a discussion of the firm's assessment of any impediments to the firm's resolution strategy and its execution, as well as the steps it has taken to address any identified impediments.

Narrative. The Plan should include a strategic analysis consistent with the Rule. This analysis should take the form of a concise narrative that enhances the readability and understanding of the firm's discussion of its strategy for rapid and orderly resolution in bankruptcy or other applicable insolvency regimes (Narrative). The Narrative also should include a high level discussion of how the firm is addressing key vulnerabilities jointly identified by the Agencies. This is not an exhaustive list and does not preclude identification of further vulnerabilities or impediments.

Appendices. The Plan should contain a sufficient level of detail and analysis to substantiate and support the strategy described in the Narrative. Such detail and analysis should be included in appendices that are distinct from and clearly referenced in the related parts of the Narrative (Appendices).

Public Section. The Plan must be divided into a public section and a confidential section consistent with the requirements of the Rule.

Other Informational Requirements. The Plan must comply with all other informational requirements of the Rule. The firm may incorporate by reference previously submitted information as provided in the Rule.

Guidance Regarding Assumptions

1. The Plan should be based on the current state of the applicable legal and policy frameworks. Pending legislation or regulatory actions may be discussed as additional considerations.

2. The firm must submit a plan that does not rely on the provision of extraordinary support by the United States or any other government to the firm or its subsidiaries to prevent the failure of the firm.[43]

3. The firm should not assume that it will be able to sell critical operations or core business lines, or that unsecured funding will be available immediately prior to filing for bankruptcy.

4. The Plan should assume the Dodd-Frank Act Stress Test (DFAST) severely adverse scenario for the first quarter of the calendar year in which the Plan is submitted is the domestic and international economic environment at the time of the firm's failure and throughout the resolution process. The Plan should also discuss any changes to the resolution strategy under the adverse and baseline scenarios to the extent that these scenarios reflect obstacles to a rapid and orderly resolution that are not captured under the severely adverse scenario.

5. The resolution strategy may be based on an idiosyncratic event or action. The firm should justify use of that assumption, consistent with the conditions of the economic scenario.

6. Within the context of the applicable idiosyncratic scenario, markets are functioning and competitors are in a position to take on business. If a firm's Plan assumes the sale of assets, the firm should take into account all issues surrounding its ability to sell in market conditions present in the applicable economic condition at the time of sale (i.e., the Firm should take into consideration the size and scale of its operations as well as issues of separation and transfer.)

7. The firm should not assume any waivers of section 23A or 23B of the Federal Reserve Act in connection with the actions proposed to be taken prior to or in resolution.

8. The firm may assume that its depository institutions will have access to the Discount Window only for a few days after the point of failure to facilitate orderly resolution. However, the firm should not assume its subsidiary depository institutions will have access to the Discount Window while critically undercapitalized, in FDIC receivership, or operating as a bridge bank, nor should it assume any lending from a Federal Reserve credit facility to a non-bank affiliate.

[43] 12 CFR 243.4(a)(4)(ii) and 381.4(a)(4)(ii)

Financial Statements and Projections

The Plan should include the actual balance sheet for each material entity and the consolidating balance sheet adjustments between material entities as well as pro forma balance sheets for each material entity at the point of failure and at key junctures in the execution of the resolution strategy. It should also include projected statements of sources and uses of funds for the interim periods. The pro forma financial statements and accompanying notes in the Plan must clearly evidence the failure trigger event; the Plan's assumptions; and any transactions that are critical to the execution of the Plan's preferred strategy, such as recapitalizations, the creation of new legal entities, transfers of assets, and asset sales and unwinds.

Material Entities

Material entities should encompass those entities, including foreign offices and branches, which are significant to the maintenance of a critical operation or core business line. If the abrupt disruption or cessation of a core business line might have systemic consequences to U.S. financial stability, the entities essential to the continuation of such core business line should be considered for material entity designation. Material entities should include the following types of entities:

a. Any U.S.-based or non U.S. affiliates, including any branches, that are significant to the activities of a critical operation conducted in whole or material part in the United States.

b. Subsidiaries or foreign offices whose provision or support of global treasury operations, funding, or liquidity activities (inclusive of intercompany transactions) is significant to the activities of a critical operation.

c. Subsidiaries or foreign offices that provide material operational support in resolution (key personnel, information technology, data centers, real estate or other shared services) to the activities of a critical operation.

d. Subsidiaries or foreign offices that are engaged in derivatives booking activity that is significant to the activities of a critical operation, including those that conduct either the internal hedge side or the client-facing side of a transaction.

e. Subsidiaries or foreign offices engaged in asset custody or asset management that are significant to the activities of a critical operation.

f. Subsidiaries or foreign offices holding licenses or memberships in clearinghouses, exchanges, or other

FMUs that are significant to the activities of a critical operation.

For each material entity (including a branch), the Plan should enumerate, on a jurisdiction-by-jurisdiction basis, the specific mandatory and discretionary actions or forbearances that regulatory and resolution authorities would take during resolution, including any regulatory filings and notifications that would be required as part of the preferred strategy, and explain how the Plan addresses the actions and forbearances. Describe the consequences for the covered company's resolution strategy if specific actions in a non-U.S. jurisdiction were not taken, delayed, or forgone, as relevant.

IX. PUBLIC SECTION

The purpose of the public section is to inform the public's understanding of the firm's resolution strategy and how it works.

The public section should discuss the steps that the firm is taking to improve resolvability under the U.S. Bankruptcy Code. The public section should provide background information on each material entity and should be enhanced by including the firm's rationale for designating material entities. The public section should also discuss, at a high level, the firm's intra-group financial and operational interconnectedness (including the types of guarantees or support obligations in place that could impact the execution of the firm's strategy). There should also be a high-level discussion of the liquidity resources and loss-absorbing capacity of the firm.

The discussion of strategy in the public section should broadly explain how the firm has addressed any deficiencies, shortcomings, and other key vulnerabilities that the Agencies have identified in prior Plan submissions. For each material entity, it should be clear how the strategy provides for continuity, transfer, or orderly wind-down of the entity and its operations. There should also be a description of the resulting organization upon completion of the resolution process.

The public section may note that the resolution plan is not binding on a bankruptcy court or other resolution authority and that the proposed failure scenario and associated assumptions are hypothetical and do not necessarily reflect an event or events to which the firm is or may become subject.

APPENDIX: Frequently Asked Questions

In April 2016, the Federal Reserve Board and the Federal Deposit Insurance Corporation issued guidance for use in developing the 2017 resolution plan submissions by eight large domestic bank holding companies (BHCs).[44]

In response to frequently asked questions regarding the guidance from the BHCs, Board and FDIC staff jointly developed answers and provided those answers to the firms in 2016 so that firms could take them into account in developing their next resolution plan submissions.[45]

The questions in this Appendix:

- Comprise common questions asked by different BHCs. Not every question is applicable to every BHC; not every aspect of the guidance applies to each BHC's preferred strategy/structure; and
- Reflect updated references to correspond to the Agencies' final resolution planning guidance for the BHCs (the Final Guidance).

As indicated below, those questions and answers that are deemed to be no longer meaningful or relevant have not been consolidated in this Appendix to the Final Guidance and are superseded.

Capital

CAP 1. Capital Pre-Positioning and Balance

Q. How should a firm determine the appropriate balance between resources pre-positioned at the material entities and held at the parent?

A. The Final Guidance addresses this issue in the Capital section. The Agencies are not prescribing a specific percentage allocation of resources pre-positioned at the material entities versus resources held at the parent. In considering the balance between certainty and flexibility, the Agencies note that the risk profile of each material entity should inform the ''unanticipated losses'' at the entity, which should be taken into account in determining the appropriate balance. For instance, the balance would likely be different for a large, complex, foreign trading subsidiary versus a small, domestic bank subsidiary.

CAP 2. Not consolidated.

CAP 3. Definition of ''Well-Capitalized'' Status

Q. How should firms apply the term ''well-capitalized'' to material entities outside the U.S. or to material entities not subject to Basel III requirements?

A. Material entities must comply with the local capital requirements and expectations of their primary regulator. Material entities should be recapitalized to meet jurisdictional requirements and to maintain market confidence as required under the preferred resolution strategy.

CAP 4. RCEN Relationship to DFAST Severely Adverse Scenario

Q. How should the firm's RCEN and RLEN estimates relate to the DFAST Severely Adverse scenario (as per the 2014 feedback letters)? Can those estimates be recalibrated in actual stress conditions?

A. For resolution plan submission purposes, the estimation of RLEN and RCEN should assume macroeconomic conditions consistent with the DFAST Severely Adverse scenario.

However, the RLEN and RCEN methodologies should have the flexibility to incorporate macroeconomic conditions that may deviate from the DFAST Severely Adverse scenario in order to facilitate execution of the preferred resolution strategy.

CAP 5. Not consolidated.

Liquidity

LIQ 1. Inter-Company ''Frictions'' and Inter-Affiliate Deposits

Q. Can the Agencies clarify what kinds of frictions might occur between affiliates beyond regulatory ring-fencing?

A. Frictions are any impediments to the free flow of funds, collateral and other transactions between material entities. Examples include regulatory, legal, financial (i.e., tax consequences), market, or operational constraints or requirements. Explicit frictions are described in the Final Guidance and include the requirement that firms should not assume that a net liquidity sur- plus at one material entity subsidiary (including material entities that are non-U.S. branches) can be moved to meet net liquidity deficits at other material entities or to augment parent resources.

Q2. How should firms treat deposits at affiliate banks, including parent deposits? Should firms assume they are, or are not, fungible in resolution?

A. As stated in the Final Guidance, the model estimating the net liquidity surplus/deficit for the firm may assume the parent holding company's deposits at the U.S. branch of the lead bank subsidiary are available as HQLA. Further, the stand-alone net liquidity position of each material entity (HQLA less net outflows) should treat inter-affiliate exposures in the same manner as third-party exposures. For example, an overnight unsecured exposure, including deposits, made with an

[44] Bank of America Corporation, Bank of New York Mellon, Citigroup, Goldman Sachs, JPMorgan Chase, Morgan Stanley, State Street Corporation, and Wells Fargo & Company.

[45] The FAQs represent the views of staff of the Board of Governors of the Federal Reserve System and the Federal Deposit Insurance Corporation and do not bind the Board or the FDIC.

affiliate should be assumed to mature. As noted in the Liquidity section of the Final Guidance, firms should not assume that a net liquidity surplus at one material entity could be moved to meet net liquidity deficits at other material entities or to augment parent resources.

LIQ 2. Distinction between Liquidity Forecasting Periods

Q. How long is the stabilization period?

A. The stabilization period begins immediately after the parent company bankruptcy filing and extends until each material entity reestablishes market confidence. The stabilization period may not be less than 30 days. The reestablishment of market confidence may be reflected by the maintaining, reestablishing, or establishing of investment grade ratings or the equivalent financial condition for each entity. The stabilization period may vary by material entity, given differences in regulatory, counterparty, and other stakeholder interests in each entity.

Q2. How should we distinguish between the runway, resolution, and stabilization periods on the one hand, and RLAP and RLEN on the other, in terms of their length, sequencing, and liquidity thresholds?

A. In the Final Guidance, the Agencies did not specify a direct mathematical relationship between the runway period, the RLAP model, and RLEN model. As noted in prior guidance, firms may assume a runway period of up to 30 days prior to entering bankruptcy provided the period is sufficient for management to contemplate the necessary actions preceding the filing of bankruptcy. The RLAP model should provide for the adequate sizing and positioning of HQLA at material entities for anticipated net liquidity outflows for a period of at least

30 days. The RLEN model estimates the liquidity needed after the parent's bankruptcy filing to stabilize the surviving material entities and to allow those entities to operate post-filing. As noted in the Final Guidance, the RLEN model should be integrated into the firm's governance framework to ensure that the firm files for bankruptcy prior to HQLA falling below the RLEN estimate. See ''LIQ 4. RLEN and Minimum Operating Liquidity (MOL),'' Question 1, for further detail on the required components of the RLEN model.

Q3. What is the resolution period?

A. The resolution period begins immediately after the parent company bankruptcy filing and extends through the completion of the preferred strategy. After the stabilization period (see ''LIQ 2. Distinction between Liquidity Forecasting Periods,'' Question 1, regarding ''stabilization period''), financial statements and projections may be provided at quarterly intervals through the remainder of the resolution period.

LIQ 3. Inter-Affiliate Transaction Assumptions

Q. Does inter-affiliate funding refer to all kinds of intercompany transactions, including both unsecured and secured?

A. Yes.

LIQ 4. RLEN and Minimum Operating Liquidity (MOL)

Q. How should firms distinguish between the minimum operating liquidity (MOL) and peak funding needs during the RLEN period?

A. The RLEN should ensure that the firm has sufficient liquidity in the form of HQLA to facilitate the execution of the firm's resolution strategy; therefore, RLEN should include both MOL and peak funding needs. The peak funding needs represent the peak cumulative net out- flows during the stabilization period. The components of peak funding needs, including the monetization of assets and other management actions, should be transparent in the RLEN projections. The peak funding needs should be supported by projections of daily sources and uses of cash for each material entity, incorporating inter-affiliate and third-party exposures. In mathematical terms, RLEN = MOL + peak funding needs during the stabilization period. For the firms subject to the Derivatives and Trading Activities section of the Final Guidance (dealer firms), RLEN should also incorporate liquidity execution needs of the preferred derivatives strategy (see ''DER 1. Preferred Resolution Strategy and Wind-Down Scenarios'' in the Derivatives and Trading Activities section).

Q2. Should the MOL per entity make explicit the allocation for intraday liquidity requirements, inter-affiliate and other funding frictions, operating expenses, and working capital needs?

A. Yes, the components of the MOL estimates for each material entity should be transparent and supported.

Q3. Can MOLs decrease as MLEs wind down?

A. MOL estimates can decline as long as they are sufficiently supported by the firm's method- ology and assumptions.

LIQ 5. Liquidity Pre-Positioning and Balance

Q. *How should a firm determine the appropriate balance between liquidity resources pre-positioned at the material entities and held at the parent? Do the Agencies have a specific ratio allocation in mind?*

A. The Final Guidance addresses this issue in the Liquidity section. The Agencies are not prescribing a specific percentage allocation of resources pre-positioned at the material entities versus resources held at the parent. In considering the balance between certainty and flexibility, the risk profile of each material entity should inform the ''unanticipated outflows'' at the entity, which should be taken into account in determining the appropriate balance. For instance, the balance would likely be different for a large, complex, foreign trading subsidiary versus a small, domestic bank subsidiary.

LIQ 6. RLAP Guidance Application

Q. The RLAP guidance elements can be applied in different ways that yield disparate outcomes for the same situation. For instance, a parent overnight loan to a material entity could be assumed to unwind (treated as a third-party exposure), or it could be assumed to be trapped (to not augment parent resources). In such situations, what should a firm do to ensure it is applying the guidance appropriately?

A. Firms should interpret and apply the Final Guidance in the context of the Resolution Plan Assessment Framework and Determinations paper (April 2016), which states on page 10: ''*[Firms] must be able to track and measure their liquidity sources and uses at all material entities under normal and stressed conditions. They must also conduct liquidity stress tests that* ***appropriately capture the effect of stresses and impediments to the movement of funds***'' *(emphasis added).*

For instance, the Final Guidance states:

- ''The [RLAP] model should ensure that the parent holding company holds sufficient HQLA (inclusive of its deposits at the U.S. branch of the lead bank subsidiary) to cover the sum of all stand-alone material entity net liquidity deficits.''
- An RLAP model that utilizes the U.S. LCR definition of HQLA for each material entity and expands that for the parent to include parent deposits at the U.S. branch of the lead bank subsidiary would be consistent with the Final Guidance. For an RLAP model that utilizes an internal stress testing definition of HQLA that is more expansive than the U.S. LCR definition, the Agencies expect the firm to support whether that assumption is consistent with a liquidity stress test that appropriately captures the effect of

stresses and impediments to the movement of funds.

The Final Guidance also states:

• ''[T]he firm should not assume that a net liquidity surplus at one material entity could be moved to meet net liquidity deficits at other material entities **or to augment parent resources**'' (emphasis added).

• An RLAP model that assumes zero liquidity flows from material entities back to the parent would be consistent with this statement. Note, parent HQLA (including overnight secured lending collateralized by Treasury securities), as well as deposits at the U.S. branch of the lead bank subsidiary, would also be consistent with this statement.

In addition, the Final Guidance states:

• ''The stand-alone net liquidity position of each material entity (HQLA less net outflows) should be measured using the firm's internal liquidity stress test assumptions and should treat inter-affiliate exposures in the same manner as third-party exposures.''

A firm's RLAP model should ''treat inter-affiliate exposures in the same manner as third-party exposures'' only where the results would appropriately capture impediments to the movement of funds. For instance, application of third-party assumptions to inter-affiliate deposits that would result in treatment of inter-affiliate deposits as HQLA, and thus not subject to any impediments to the movement of funds, even though such impediments could exist, would not be consistent with the Final Guidance.

More generally, for material entities where the net liquidity position is comprised of a significant third party net outflow offset by an inter-affiliate net inflow, the Agencies note the heightened importance of taking into account ''trapped liquidity as a result of actions taken by clients, counterparties, financial market utilities (FMUs), and foreign supervisors, among others,'' as described in the Liquidity section of the Final Guidance.

LIQ 7. Not consolidated.

LIQ 8. Inter-Affiliate Transactions with Optionality

Q. How should firms treat an inter-affiliate transaction with an embedded option that may affect the contractual maturity date?

A. For the purpose of calculating a firm's net liquidity position at a material entity, RLAP and RLEN models should assume that these transactions mature at the earliest possible exercise date; this adjusted maturity should be applied symmetrically to both material entities involved in the transaction. See also ''LIQ 6. RLAP Guidance Application.''

LIQ 9. Stabilization and Regulatory Liquidity Requirements

Q. As it relates to the RLEN model and actions necessary to re-establish market confidence, what assumptions should firms make regarding compliance with regulatory liquidity requirements?

A. Firms should consider the applicable regulatory expectations for each material entity to achieve the stabilization needed to execute the preferred strategy. Firms' assumptions in the RLEN model regarding the actions necessary to reestablish market confidence during the stabilization period may vary by material entity, for example, based on differences in regulatory, counterparty, other stakeholder interests, and based on the preferred strategy for each material entity. See also ''LIQ 2. Distinction between Liquidity Forecasting Periods.''

LIQ 10. HQLA and Assets Not Eligible as HQLA in RLAP and RLEN Models

Q. The Final Guidance states that HQLA should be used to meet estimated net liquidity deficits in the RLAP model and that the RLEN estimate should be based on the minimum amount of HQLA required to facilitate the execution of the firm's preferred resolution strategy. How should firms incorporate any expected liquidity value of assets that are not eligible as HQLA (non-HQLA) into RLAP and RLEN models?

A. A firm's RLAP model should assume that only HQLA are available to meet net liquidity deficits at material entities. For a firm's RLEN model, firms may incorporate conservative estimates of potential liquidity that may be generated through the monetization of non-HQLA. The estimated liquidity value of non-HQLA should be supported by thorough analysis of the potential market constraints and asset value haircuts that may be required. Assumptions for the monetization of non-HQLA should be consistent with the preferred resolution strategy for each material entity. See ''LIQ 6. RLAP Guidance Application'' for detail on assets eligible as HQLA.

LIQ 11. Components of Minimum Operating Liquidity

Q. Do the agencies have particular definitions of the ''intraday liquidity requirements,'' ''operating expenses,'' and ''working capital needs'' components of minimum operating liquidity (MOL) estimates?

A. No. A firm may use its internal definitions of the components of MOL estimates. The components of MOL estimates should be well-supported by a firm's internal methodologies and calibrated to the specifics of each material entity.

LIQ 12. RLEN Model and Net Revenue Recognition

Q. Can firms assume in the RLEN model that cash-based net revenue generated by material entities after the parent holding company's bankruptcy filing is available to offset estimated liquidity needs?

A. Yes. Firms may incorporate cash revenue generated by material entities in the RLEN model. Cash revenue projections should be conservatively estimated and consistent with the operating environment and the preferred strategy for each material entity.

LIQ 13. RLEN Model and Inter-Affiliate Frictions

Q. Can a firm modify its assumptions regarding one or more inter-affiliate frictions during the stabilization or post-stabilization period in the RLEN model?

A. Once a material entity has achieved market confidence necessary for stabilization consistent with the preferred strategy, a firm may modify one or more inter-affiliate frictions, provided the firm provides sufficient analysis to support this assumption.

LIQ 14. RLEN Relationship to DFAST Severely Adverse scenario

(See ''CAP 4. RCEN Relationship to DFAST Severely Adverse Scenario'' in the Capital section.)

LIQ 15. Application of Inter-Affiliate Frictions Guidance to Intermediate Holding Companies (IHC)

Q. With respect to an IHC that has been established to facilitate recapitalization or liquidity support to material entities, how should firms apply the RLAP and RLEN guidance for inter-affiliate frictions?

A. For IHCs that provide funds for recapitalization or liquidity support to material entities and do not have any operations or outstanding third-party exposures of their own, the Agencies recognize that fewer potential impediments to the movement of the funds may exist when compared to movements of funds between operating material entities. Still, for both the RLAP and RLEN model, firms are expected to provide an analysis of, and take into account, potential inter-affiliate frictions that may exist between an IHC and material entities.

Specific to the Final Guidance for the RLAP model and the Q&A in ''LIQ 6. RLAP Guidance Application,'' it would be inconsistent with the guidance for firms to assume that an IHC could be used as an intermediary to facilitate transfers of net liquidity surpluses at one material entity to another material entity. Instead, firms may only assume

a one-way flow of funds from the IHC to the material entity. For the RLEN model, firms should assess the potential for inter-affiliate frictions in transactions from the IHC to material entities as well as from material entities to the IHC. The prohibition on assuming that net liquidity surplus at one material entity could be moved to meet net liquidity deficits at other material entities under the Final Guidance does not prohibit the firm from assuming that an IHC may provide liquidity to material entities.

LIQ 16. Access to Reserve Bank Daylight Credit

Q. What assumptions can firms make regarding access to Federal Reserve daylight credit?

A. Access to daylight credit is governed by the Federal Reserve Board's Policy on Payment System Risk (PSR Policy) and generally is provided only to institutions that are in sound financial condition based on their capital ratios and supervisory ratings and subject to the discretion of the Reserve Bank. For the purpose of Section 165(d) resolution plans only, firms may assume that subsidiary depository institutions that are at least adequately capitalized will have access to fully collateralized daylight credit even in cases where the supervisory ratings of the parent assumed in the exercise fall below fair as a result of the condition of the parent firm or an affiliate. However, the plan should not assume depository institutions will have access to intraday credit while undercapitalized, in FDIC receivership, or operating as a bridge bank. This guidance applies only to the Section 165(d) resolution plans and does not modify the PSR Policy.

Governance Mechanisms

GOV 1. Triggers

Q. Do firms need to have all three types of triggers (i.e., capital, liquidity, and market) for each phase (i.e., BAU to stress, stress to runway, runway to recapitalization; and recapitalization to bankruptcy filing/PNV)?

A. No, a firm does not need all three types of triggers for each phase.

Q2. Are firms required to have triggers for each material entity or are firm-wide triggers sufficient?

A. Triggers at the level of the consolidated company may not be sufficient without additional triggers at the material entity level depending upon the firm structure and/or preferred strategy. All triggers may not be applicable to all material entities. For example, pre-funded service entities or foreign branches may not require particular capital or liquidity triggers if they will not need these resources prior to the parent company entering bankruptcy.

Q3. Should firms include a formal regulatory trigger by which the Agencies can directly trigger a contractually binding mechanism?

A. No.

Q4. Could the Agencies clarify what is meant by ''synchronized'' triggers within the Final Guidance?

A. ''Synchronized to the firm's liquidity and capital methodologies'' in this context means informed by the firm's RCEN and RLEN estimates.

Q5. What are examples of market metrics and market metric triggers?

A. The Agencies are not prescribing specific market metrics or triggers.

Operational: Shared Services

OPS SS 1. Not consolidated.

OPS SS 2. Working Capital

Q. Must working capital be maintained for third party and internal shared service costs?

A. Where a firm maintains shared service companies to provide services to affiliates, working capital should be maintained in those entities sufficient to permit those entities to continue to provide services for six months or through the period of stabilization as required in the firm's preferred strategy. Costs related to third-party vendors and inter-affiliate services should be captured through the working capital element of the MOL estimate (RLEN).

Q2. When does the six month working capital requirement period begin?

A. The measurement of the six month working capital expectation begins upon the bankruptcy filing of the parent company. The expectation for maintaining the working capital is effective upon the July 2017 submission.

OPS SS 3. Not consolidated.

OPS SS 4. Not consolidated.

Operational: Payments, Clearing, and Settlement

OPS PCS 1. Not consolidated.

OPS PCS 2. Access to Reserve Bank Daylight Credit

(See ''LIQ 16. Access to Reserve Bank Daylight Credit'' in the Liquidity section)

Legal Entity Rationalization and Separability

LER 1. Data Room

Q. What information should be in the data room?

A. The Final Guidance addresses the data room on page in the section regarding Legal Entity Rationalization and Separability. The data room should contain the necessary information on discrete sales options to facilitate buyer due diligence. Including only a table of contents of information that could be provided when needed would not be sufficient.

Q2. Are firms expected to include in a data room described in the Final Guidance lists of individual employee names and compensation levels?

A. The firm should include the necessary information to facilitate buyer due diligence. In the circumstance where employee information would be important to buyer due diligence the firm should demonstrate the capability to provide such information in a timely manner. For individual employee names and compensation, the data room may include a representative sample and may have personally identifiable information redacted.

LER 2. Not consolidated.

LER 3. Legal Entity Rationalization Criteria

Q. Is it acceptable to take into account business-related criteria, in addition to the resolution requirements, so that the LER Criteria can be used for both resolution planning and business operations purposes?

A. Yes, LER criteria may incorporate both business and resolution considerations. In determining the best alignment of legal entities and business lines to improve the firm's resolvability under different market conditions, business considerations should not be prioritized over resolution needs.

LER 4. Creation of Additional Legal Entities

Q. Is the addition of legal entities acceptable, so long as it is consistent with the LER criteria?

A. Yes.

LER 5. Clean Funding Pathway

Q. Can you provide additional context around what is meant by clean lines of ownership and clean funding pathways in the legal entity rationalization criteria? Additionally, what types of funding are covered by the requirements?

A. The funding pathways between the parent and material entities and the ownership chain should minimize uncertainty in the provision of funds and facilitate recapitalization. Also, the complexity of ownership should not impede the flow of funding to a material entity under the firm's preferred resolution strategy. Potential sources of additional complexity could include, for example, multiple intermediate holding companies, tenor mismatches, or complicated ownership structures (including those involving multiple jurisdictions or fractional ownerships). Ownership should be as clean and simple as practicable, supporting the preferred strategy and actionable sales,

transfers, or wind-downs under varying market conditions. The clean funding pathways expectation applies to all funding provided to a subsidiary material entity regardless of type and should not be viewed solely to apply to internal TLAC.

Q2. The Final Guidance regarding legal entity rationalization criteria discusses ''clean lines of ownership'' and ''clean funding pathways.'' Does this statement mean that firms' legal entity rationalization criteria should require funding pathways and recapitalization to always follow lines of ownership?

A. No. However, the firm should identify and address or mitigate any legal, regulatory, financial, operational, and other factors that could complicate the recapitalization and/or liquidity support of material entities.

LER 6. Separability Options Information

Q. How should a firm approach inclusion of legal risk assessments and other buyer due diligence information into separability options?

A. The legal assessment should consider both buyer and seller legal aspects that could impede the timely or successful execution of the divestiture option. Where impediments are identified, mitigation strategies should be developed.

LER 7. Market Conditions

Q. What is meant by the phrase ''under different market conditions'' in the Legal Entity Rationalization and Separability section of the Final Guidance?

A. The phrase ''under different market conditions'' is meant to ensure that a firm has a menu of divestiture options from which at least some could be executed under different market stresses.

LER 8. Not consolidated.

LER 9. Application of Legal Entity Rationalization Criteria

Q. Which legal entities should be covered under the LER framework?

A. All legal entities. The scope of a firm's LER criteria should apply to the entire enterprise.

Q2. To the extent a firm has a large number of similar non-material entities (such as single-purpose entities formed for Community Reinvestment Act purposes), may a firm apply its legal entity rationalization criteria to these entities as a group, rather than at the individual entity level?

A. Yes.

Derivatives and Trading Activities

To the extent relevant, the derivatives and trading FAQs have been consolidated into the updated section of the Final Guidance.

Legal

LEG 1. Emergency Motion

Q. The Final Guidance states that ''the plan should consider contingency arrangements in the event the bankruptcy court does not grant the emergency motion.'' What are the Agencies' expectations given the industry's focus on complying with the ISDA Resolution Stay Protocol?

A. Firms may present a preferred strategy that makes use of the Protocol. Nonetheless, the Agencies expect firms also to consider the possibility that a bankruptcy court may not timely enter an order that satisfies the Transfer Conditions and/or the U.S. Parent debtor-in-possession Conditions of the Protocol as contemplated in the firm's preferred strategy. See the Legal Obstacles Associated with Emergency Motions section of the Final Guidance.

Q2. Could the Agencies clarify what further legal analysis would be expected regarding the impact of potential state law and bankruptcy law challenges and mitigants to the planned provision of Support?

A. The firms should address developments from the firm's own analysis of potential legal challenges regarding the Support and should also address any additional potential legal challenges identified by the Agencies in the Pre-Bankruptcy Parent Support section of the Final Guidance. A legal analysis should include a detailed discussion of the relevant facts, legal challenges, and Federal or State law and precedent. The analysis also should evaluate in detail the legal challenges identified in the Final Guidance under the heading ''Pre-Bankruptcy Parent Support,'' any other legal challenges identified by the firm, and the efficacy of potential mitigants to those challenges. Firms should identify each factual assumption underlying their legal analyses and discuss how the analyses and mitigants would change if the assumption were not to hold. Moreover, the analysis is not required to take the form of a legal opinion.

Q3. Not consolidated.

LEG 2. Contractually Binding Mechanisms

Q. Do the Agencies have any preference as to whether capital is down-streamed to key subsidiaries (including an IDI subsidiary) in the form of capital contributions vs. forgiveness of debt?

A. No. The Agencies do not have a preference as to the form of capital contribution or liquidity support.

Q2. The letter makes reference to a contractually binding mechanism. Does such an agreement relate to the provision of capital or liquidity? What classes of assets would be deemed to provide capital vs. liquidity?

A. Contractually binding mechanism is a generic term and includes the down-streaming of capital and/or liquidity as contemplated by the preferred strategy. Furthermore, it is up to the firm, as informed by any relevant guidance of the Agencies, to identify what assets would satisfy a subsidiary's need for capital and/or liquidity.

Q3. Is there a minimum acceptable duration for a contractually binding mechanism? Would an ''evergreen'' arrangement, renewable on a periodic basis (and with notice to the Agencies), be acceptable?

A. To the extent a firm utilizes a contractually binding mechanism, such mechanism, including its duration, should be appropriate for the firm's preferred strategy, including adequately addressing relevant financial, operational, and legal requirements and challenges.

Q4. Not consolidated.

Q5. Not consolidated.

Q6. The firm may need to amend its contractually binding mechanism from time to time resulting potentially from changes in relevant law, new or different regulatory expectations, etc. Is a firm able to do this as long as there is no undue risk to the enforceability (e.g., no signs of financial stress sufficient to unduly threaten the agreement's enforceability as a result of fraudulent transfer)?

A. Yes, however the Agencies should be informed of the proposed duration of the agreement, as well as any terms and conditions on renewal and/or amendment. Any amendments should be identified and discussed as part of the firm's next plan submission.

General

None of the general FAQs were consolidated.

By order of the Board of Governors of the Federal Reserve System.

Ann E. Misback,

Secretary of the Board.

Dated at Washington, DC, on December 18, 2018.

Federal Deposit Insurance Corporation.

Valerie J. Best,

Assistant Executive Secretary.

[FR Doc. 2019–00800 Filed 2–1–19; 8:45 am]

BILLING CODE P

FEDERAL RESERVE SYSTEM

Agency Information Collection Activities: Announcement of Board Approval Under Delegated Authority and Submission to OMB

AGENCY: Board of Governors of the Federal Reserve System.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) is adopting a proposal to extend for three years, without revision, the Basel II Interagency Pillar 2 Supervisory Guidance (Pillar 2 Guidance) (FR 4199; OMB No. 7100–0320).

FOR FURTHER INFORMATION CONTACT: 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.

OMB Desk Officer—Shagufta Ahmed—Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–6974.

SUPPLEMENTARY INFORMATION: On June 15, 1984, the Office of Management and Budget (OMB) delegated to the Board authority under the Paperwork Reduction Act (PRA) to approve and assign OMB control numbers to collection of information requests and requirements conducted or sponsored by the Board. Board-approved collections of information are incorporated into the official OMB inventory of currently approved collections of information. Copies of the Paperwork Reduction Act Submission, supporting statements and approved collection of information instrument(s) are placed into OMB's public docket files. The Board may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Final approval under OMB delegated authority of the extension for three years, without revision, (or the implementation) of the following information collection:

Report title: Basel II Interagency Pillar 2 Supervisory Guidance (Pillar 2 Guidance).

Agency form number: FR 4199.

OMB control number: 7100–0320.

Frequency: As needed.

Respondents: Banking institutions.

Estimated number of respondents: 13.

Estimated average hours per response: 420.

Estimated annual burden hours: 5,460.

General description of report: The advanced approaches framework requires certain banks and bank holding companies (BHCs) to use an internal ratings-based approach to calculate regulatory credit risk capital requirements and advance measurement approaches to calculate regulatory operational risk capital requirements.

A bank is required to comply with the advanced approaches framework if it meets either of two independent threshold criteria: (1) Consolidated total assets of $250 billion or more, as reported on the most recent year-end regulatory reports; or (2) consolidated total on-balance sheet foreign exposure of $10 billion or more at the most recent year-end.

A BHC is required to comply with the advanced approaches framework if the BHC has (1) consolidated total assets (excluding assets held by an insurance underwriting subsidiary) of $250 billion or more, as reported on the most recent year-end regulatory reports; (2) consolidated total on-balance sheet foreign exposure of $10 billion or more at the most recent year-end; or (3) a subsidiary depository institution (DI) that meets the criteria to be subject to the advanced approaches rule or elects to adopt the advanced approaches framework. As of year-end 2017, 13 BHCs meet the above criteria and are therefore subject to the advanced approaches rule.[1]

Also, some banks or BHCs may voluntarily decide to adopt the advanced approaches framework. Both mandatory and voluntary respondents are required to meet certain qualification requirements before they can use the advanced approaches framework for risk-based capital purposes.

The Pillar 2 Guidance sets the expectation that respondents maintain certain documentation as described in paragraphs 37, 41, 43, and 46 of this portion of the guidance. Details of the expectations for each section are provided below.

[1] Regulation YY permits a bank holding company that is a subsidiary of a foreign banking institution to elect not to comply with the advanced approaches rule prior to formation of an intermediate holding companies (IHCs) with the prior approval of the Board. 12 CFR 252.153(e)(2)(C). Currently, no savings and loan holding companies are subject to the advanced approaches rule.

Setting and Assessing Capital Adequacy Goals That Relate to Risk

Paragraph 37. In analyzing capital adequacy, a banking organization should evaluate the capacity of its capital to absorb losses. Because various definitions of capital are used within the banking industry, each banking organization should state clearly the definition of capital used in any aspect of its internal capital adequacy assessment process (ICAAP).[2] Since components of capital are not necessarily alike and have varying capacities to absorb losses, a banking organization should be able to demonstrate the relationship between its internal capital definition and its assessment of capital adequacy. If a banking organization's definition of capital differs from the regulatory definition, the banking organization should reconcile such differences and provide an analysis to support the inclusion of any capital instruments that are not recognized under the regulatory definition. Although common equity is generally the predominant component of a banking organization's capital structure, a banking organization may be able to support the inclusion of other capital instruments in its internal definition of capital if it can demonstrate a similar capacity to absorb losses. The banking organization should document any changes in its internal definition of capital and the reason for those changes.

Ensuring Integrity of Internal Capital Adequacy Assessments

Paragraph 41. A banking organization should maintain thorough documentation of its ICAAP to ensure transparency. At a minimum, this should include a description of the banking organization's overall capital-management process, including the

[2] Under the Board's capital plan rule (12 CFR 225.8), a bank holding company with total consolidated assets of $50 billion or more is required to develop and maintain a capital plan; however, on July 6, 2018, the Board issued a public statement regarding the impact of the Economic Growth, Regulatory Relief, and Consumer Protection Act (EGRRCPA) (Pub. L. No. 115–174, 132 Stat. 1296 (2018). The Board stated, consistent with EGRRCPA, that it will not action to require bank holding companies with total consolidated assets greater than or equal to $50 billion but less than $100 billion to comply with the Board's capital plan rule (*https://www.federalreserve.gov/newsevents/pressreleases/files/bcreg20180706b1.pdf*). Bank holding companies subject to the capital plan rule must have a capital policy that sets forth a capital adequacy process. ICAAP would constitute an internal capital adequacy process for purposes of the capital plan rule, and bank holding companies that have a satisfactory ICAAP generally would be considered to have a satisfactory internal capital adequacy process for purposes of the capital plan rule.

committees and individuals responsible for the ICAAP; the frequency and distribution of ICAAP-related reporting; and the procedures for the periodic evaluation of the appropriateness and adequacy of the ICAAP. In addition, where applicable, ICAAP documentation should demonstrate the banking organization's sound use of quantitative methods (including model selection and limitations) and data-selection techniques, as well as appropriate maintenance, controls, and validation. A banking organization should document and explain the role of third-party and vendor products, services, and information—including methodologies, model inputs, systems, data, and ratings—and the extent to which they are used within the ICAAP. A banking organization should have a process to regularly evaluate the performance of third-party and vendor products, services, and information. As part of the ICAAP documentation, a banking organization should document the assumptions, methods, data, information, and judgment used in its quantitative and qualitative approaches.

Paragraph 43. The board of directors and senior management have certain responsibilities in developing, implementing, and overseeing the ICAAP. The board should approve the ICAAP and its components. The board or its appropriately delegated agent should review the ICAAP and its components on a regular basis and approve any revisions. That review should encompass the effectiveness of the ICAAP, the appropriateness of risk tolerance levels and capital planning, and the strength of control infrastructures. Senior management should continually ensure that the ICAAP is functioning effectively and as intended, under a formal review policy that is explicit and well documented. Additionally, a banking organization's internal audit function should play a key role in reviewing the controls and governance surrounding the ICAAP on an ongoing basis.

Paragraph 46. As part of the ICAAP, the board or its delegated agent, as well as appropriate senior management, should periodically review the resulting assessment of overall capital adequacy. This review, which should occur at least annually, should include an analysis of how measures of internal capital adequacy compare with other capital measures (such as regulatory, accounting-based or market-determined). Upon completion of this review, the board or its delegated agent should determine that, consistent with safety and soundness, the banking organization's capital takes into account all material risks and is appropriate for its risk profile. However, in the event a capital deficiency is uncovered (that is, if capital is not consistent with the banking organization's risk profile or risk tolerance) management should consult and adhere to formal procedures to correct the capital deficiency.

Legal authorization and confidentiality: The collection of information is authorized pursuant to the International Lending Supervision Act (12 U.S.C. 3907(a)(1) and (b)(3)), section 1831o of the Federal Deposit Insurance Act (12 U.S.C. 1831o), section 5 of the Bank Holding Company Act of 1956 (12 U.S.C. 1844), section 10(b)(2) of the Homeowners' Loan Act (12 U.S.C. 1467a(b)), and section 171 of the Dodd-Frank Act (12 U.S.C. 5371). The FR 4199 is voluntary.

Because the collections of information associated with the FR 4199 do not involve the submission of information to the Board, no issues of confidentiality would normally arise. To the extent that the Board collects information kept by a banking organization as a record during an examination of the banking organization, confidential treatment may be afforded to the records under exemption 8 of the Freedom of Information Act (FOIA) (5 U.S.C. 552(b)(8)), which protects information collected as part of the Board's supervisory process. Additionally, individual respondents may request that certain information be afforded confidential treatment pursuant to exemption 4 of FOIA (5 U.S.C. 552(b)(4)) if the information has not previously been publicly disclosed and the release of the data would likely cause substantial harm to the competitive position of the respondent.

Current actions: On October 22, 2018, the Board published a notice in the **Federal Register** (83 FR 53248) requesting public comment for 60 days on the extension, without revision, of the FR 4199. The comment period for this notice expired on December 21, 2018. The Board did not receive any comments.

Board of Governors of the Federal Reserve System, January 30, 2019.

Michele Taylor Fennell,

Assistant Secretary of the Board.

[FR Doc. 2019–00903 Filed 2–1–19; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL TRADE COMMISSION

Agency Information Collection Activities; Submission for OMB Review; Comment Request

AGENCY: Federal Trade Commission (''FTC'' or ''Commission'').

ACTION: Notice; request for comments.

SUMMARY: The FTC intends to ask the Office of Management and Budget (''OMB'') to extend for an additional three years the current Paperwork Reduction Act (''PRA'') clearance for the information collection requirements in the Children's Online Privacy Protection Act Rule (''COPPA Rule'' or ''Rule''), which will expire on January 31, 2019.

DATES: Comments must be submitted by March 6, 2019.

ADDRESSES: Interested parties may file a comment online or on paper by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write ''COPPA Rule: Paperwork Comment, FTC File No. P155408'' on your comment, and file your comment online at *https://ftcpublic.commentworks.com/ftc/coppapra2,* by following the instructions on the web-based form. If you prefer to file your comment on paper, mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex J), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex J), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be addressed to Peder Magee, Attorney (202–326–3538), Division of Privacy and Identity Protection, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580.

SUPPLEMENTARY INFORMATION:

Title: COPPA Rule, 16 CFR part 312.

OMB Control Number: 3084–0117.

Type of Review: Extension of currently approved collection.

Abstract: Pursuant to the OMB regulations, 5 CFR part 1320, that implement the PRA, 44 U.S.C. 3501 *et seq.,* the FTC is providing a second opportunity for public comment while seeking OMB approval to renew the pre-existing clearance for the Rule. The COPPA Rule, 16 CFR part 312, requires commercial websites to provide notice and obtain parents' consent before

collecting, using, and/or disclosing personal information from children under age 13, with limited exceptions. The COPPA Rule contains certain statutorily required notice requirements that apply to operators of any website or online service directed to children and operators of any website or online service with actual knowledge of collecting personal information from children. Covered operators must: Provide online notice and direct notice to parents of how they collect, use, and disclose children's personal information; obtain the prior consent of the child's parent in order to engage in such collection, use, and disclosure, with limited exceptions; provide reasonable means for the parent to obtain access to the information and to direct its deletion; and, establish procedures that protect the confidentiality, security, and integrity of personal information collected from children.

On October 2, 2018, the FTC sought its initial public comment on the information collection requirements associated with the Rule.[1] Two commenters provided suggestions regarding the Rule's substantive requirements for covered operators. The Commission periodically reviews the Rule to ensure that it effectively protects children's online privacy, as directed by Congress, as new online technologies evolve, and to clarify existing obligations for operators under the Rule. For example, the Commission substantively revised the Rule in 2013.[2] The Commission will take these two comments under advisement in evaluating the Rule's continued effectiveness. The other comments were non-germane.

The associated burden estimates in the statement below concern strictly recurring compliance obligations under the COPPA Rule.

Burden Statement [3]

1. Estimated annual hours burden: 17,700 hours.

(a) New entrant web operators' disclosure burden: 16,800 hours.

(b) Safe harbor applicant reporting requirements: 100 hours, rounded (for an estimated one additional safe harbor applicant).

(c) Annual audit and report for safe harbor programs: 800 hours.

(d) Safe harbor program recordkeeping requirements: 0 or minimal.

2. Estimated annual labor costs: $5,768,900.

(a) New entrant web operators' disclosure burden: $5,723,200.

(b) Safe harbor applicant reporting requirements: $18,500.

(c) Annual audit and report for safe harbor programs: $27,200.

(d) Safe harbor program recordkeeping requirements: $0 or marginal.

3. Estimated annual non-labor costs: $0.

Request for Comments

You can file a comment online or on paper. For the FTC to consider your comment, we must receive it on or before March 6, 2019. Write ''COPPA Rule: Paperwork Comment, FTC File No. 155408'' on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the public FTC website, at *http://www.ftc.gov/os/publiccomments.shtm.*

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online, or to send them to the Commission by courier or overnight service. To make sure that the Commission considers your online comment, you must file it at *https://ftcpublic.commentworks.com/ftc/coppapra2* by following the instructions on the web-based form. When this Notice appears at *http://www.regulations.gov/#!home,* you also may file a comment through that website.

If you file your comment on paper, write ''COPPA Rule: Paperwork Comment, FTC File No. 155408'' on your comment and on the envelope, and mail it to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex J), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex J), Washington, DC 20024. If possible, submit your paper comment to the Commission by courier or overnight service.

Because your comment will be placed on the publicly accessible FTC website at *https://www.ftc.gov/,* you are solely responsible for making sure that your comment does not include any sensitive or confidential information. In particular, your comment should not include any sensitive personal information, such as your or anyone else's Social Security number; date of birth; driver's license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any ''trade secret or any commercial or financial information which . . . is privileged or confidential''—as provided by Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2)—including in particular competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled ''Confidential,'' and must comply with FTC Rule 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted on the public FTC website—as legally required by FTC Rule 4.9(b)—we cannot redact or remove your comment from the FTC website, unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants that request.

The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before March 6, 2019. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see *https://www.ftc.gov/site-information/privacy-policy.* For supporting documentation and other information underlying the PRA discussion in this Notice, see *http://www.reginfo.gov/public/jsp/PRA/praDashboard.jsp.*

Comments on the information collection requirements subject to review under the PRA should additionally be submitted to OMB. If

[1] 83 FR 49557 (October 2, 2018).

[2] 78 FR 3972, 4005 (Jan. 17, 2013).

[3] Details underlying the estimates within this Burden Statement can be found in the October 2, 2018 **Federal Register** Notice.

sent by U.S. mail, they should be addressed to Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for the Federal Trade Commission, New Executive Office Building, Docket Library, Room 10102, 725 17th Street NW, Washington, DC 20503. Comments sent to OMB by U.S. postal mail, however, are subject to delays due to heightened security precautions. Thus, comments instead can also be sent by email to *wliberante@omb.eop.gov.*

Heather Hippsley,

Deputy General Counsel.

[FR Doc. 2019–00904 Filed 2–1–19; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[OMB No.: 0970–0215]

Submission for OMB Review; Comment Request

Title: Tribal TANF Data Report, TANF Annual Report, and Reasonable Cause/Corrective Action Documentation Process–Final

Description: 42 U.S.C. 612 (Section 412 of the Social Security Act as amended by Public Law 104–193, the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (PRWORA)), mandates that federally recognized Indian Tribes with an approved Tribal TANF program collect and submit to the Secretary of the Department of Health and Human Services data on the recipients served by the Tribes' programs. This information includes both aggregated and disaggregated data on case characteristics and individual characteristics. In addition, Tribes that are subject to a penalty are allowed to provide reasonable cause justifications as to why a penalty should not be imposed or may develop and implement corrective compliance procedures to eliminate the source of the penalty. Finally, there is an annual report, which requires the Tribes to describe program characteristics. All of the above requirements are currently approved by OMB and the Administration for Children and Families is simply proposing to extend them without any changes.

Respondents: Federally recognized Indian tribes

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
FINAL tribal TANF report	74	4	451	133,496
Tribal TANF Annual Report	74	1	40	2,960
Tribal TANF reasonable cause/corrective	74	1	60	4,440

Estimated Total Annual Burden Hours: 140,896.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW, Washington, DC 20201. Attention Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV*, Attn: Desk Officer for the Administration for Children and Families.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2019–00808 Filed 2–1–19; 8:45 am]

BILLING CODE 4184–36–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Title: Prevention Services Data Collection.

OMB No.: 0970–NEW.

Description: Section 471(e)(4)(E) of the Social Security Act (the Act) (42 U.S.C. 671) as amended by Public Law 115–123 requires state and tribal child welfare agencies to collect and report to the Administration for Children and Families (ACF) information on children receiving prevention and family services and programs. States and tribes must report:

- The specific services or programs provided,
- The total expenditures for each of the services or programs provided,
- The duration of the services or programs provided, and
- If the child was identified in a prevention plan as a candidate for foster care:
  - The child's placement status at the beginning, and at the end, of the 12 month period that begins on the date the child was identified as a candidate for foster care in a prevention plan; and
  - whether the child entered foster care during the initial 12 month period and during the subsequent 12 month period.

It is anticipated that half or less of the tribes and states will choose to provide these prevention services in the first years of the program availability, but that number will increase over time.

The data collected will inform federal policy decisions, program management, and responses to Congressional and Departmental inquiries. Specifically, the data will provide information about the use and availability of prevention services to children to prevent the need for foster care placement. The data will contain personally identifiable information (date of birth and race/ethnicity).

Respondents: State and tribal child welfare agencies.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Prevention Services Data Collection	20	1	31	620

Estimated Total Annual Burden Hours: 620.

In compliance with the requirements of the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chap 35), the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW, Washington, DC 20201. Attn: ACF Reports Clearance Officer. Email address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2019–00895 Filed 2–1–19; 8:45 am]

BILLING CODE 4184–25–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2018–P–1877 and FDA–2018–P–3730]

Determination That ESBRIET (Pirfenidone) Film Coated Tablets, 534 Milligrams, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that ESBRIET (pirfenidone), film coated tablets, 534 milligrams (mg), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for pirfenidone, film coated tablets, 534 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Daniel Gottlieb, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6208, Silver Spring, MD 20993–0002, 301–796–6650.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

ESBRIET (pirfenidone), film coated tablets, 534 mg, is the subject of NDA 208780, held by Genentech, Inc., and initially approved on January 11, 2017. ESBRIET is indicated for the treatment of idiopathic pulmonary fibrosis. ESBRIET (pirfenidone), film coated tablets, 534 mg, is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book. Laurus Labs Ltd. submitted a citizen petition dated May 14, 2018 (Docket No. FDA–2018–P–1877), and Aziant Drug Research Solutions Pvt. Ltd. Submitted a citizen petition dated October 1, 2018 (FDA–2018–P–3730), under 21 CFR 10.30, requesting that the Agency determine whether ESBRIET (pirfenidone), film coated tablets, 534 mg, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petitions and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that ESBRIET (pirfenidone), film coated tablets, 534 mg, was not withdrawn for reasons of safety or effectiveness. The petitioners have identified no data or other information suggesting that this drug product was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of ESBRIET (pirfenidone), film coated tablets, 534 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list ESBRIET (pirfenidone), film coated tablets, 534 mg, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug

products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to this drug product, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: January 17, 2019.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2019–00847 Filed 2–1–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0250]

Labeling for Human Prescription Drug and Biological Products Approved Under the Accelerated Approval Regulatory Pathway; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''Labeling for Human Prescription Drug and Biological Products Approved Under the Accelerated Approval Regulatory Pathway.'' This guidance discusses FDA's recommendations for developing the indication and usage statements in the prescribing information for drugs approved under the accelerated approval regulatory pathway (hereafter accelerated approval). The guidance also discusses labeling considerations for indications approved under accelerated approval when clinical benefit has been verified and FDA terminates the conditions of accelerated approval, or when FDA withdraws accelerated approval of an indication while other indications for the drug remain approved. This guidance finalizes the draft guidance of the same name issued March 25, 2014.

DATES: The announcement of the guidance is published in the **Federal Register** on February 4, 2019.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time 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–2014–D–0250 for ''Labeling for Human Prescription Drug and Biological Products Approved Under the Accelerated Approval Regulatory Pathway; Guidance for Industry; Availability.'' 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002, or Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: John Gallagher, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6473, Silver Spring, MD 20993–0002, 240–402–4768; or

Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance for industry entitled ''Labeling for Human Prescription Drug and Biological Products Approved Under the Accelerated Approval Regulatory Pathway.'' Labeling must conform to the content and format requirements delineated in §§ 201.57(d) and 201.57 (21 CFR 201.56(d) and 201.57). Labeling for drugs approved under the accelerated approval process is fundamentally the same as for drugs approved under the traditional pathway; however, for drugs approved under accelerated approval there are additional labeling requirements as described in § 201.57(c)(2)(i)(B) and recommended elements for consideration. This guidance discusses FDA's recommendations for developing the indication and usage statements in the prescribing information for drugs approved under accelerated approval as defined in 21 CFR part 314, subpart H (for new drug applications) and 21 CFR part 601, subpart E (for biologics license applications), specifically 21 CFR 314.510 and 21 CFR 601.41. The guidance also discusses labeling considerations for indications approved under accelerated approval when clinical benefit has been verified and FDA terminates the conditions of accelerated approval under 21 CFR 314.560 or 21 CFR 601.46, or when FDA withdraws accelerated approval of an indication while other indications for the drug remain approved.

This guidance finalizes the draft guidance of the same name issued March 25, 2014 (79 FR 16344). Changes from the draft guidance include the recommendations regarding how to fulfill the regulatory requirement that the labeling for drugs approved under accelerated approval include a succinct description of the limitations of usefulness of the drug and any uncertainty about clinical benefits. The draft guidance proposed recommending inclusion of a statement in the indication describing the specific clinical benefit that remains to be established; the final guidance states that simply reporting the endpoint used, without this additional statement, may be sufficient, except in certain circumstances when additional context about the approval should be included.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on labeling for human prescription drug and biological products approved under accelerated approval. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in §§ 201.56 and 201.57 have been approved under OMB control number 0910–0572.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm,* or *https://www.regulations.gov.*

Dated: January 16, 2019.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2019–00894 Filed 2–1–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the National Clinical Care Commission

AGENCY: Office of Disease Prevention and Health Promotion, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The National Clinical Care Commission (the Commission) will conduct a virtual meeting on February 20, 2019. The Commission is charged to evaluate and make recommendations to the U.S. Department of Health and Human Services (HHS) Secretary and Congress regarding improvements to the coordination and leveraging of federal programs related to awareness and clinical care for complex metabolic or autoimmune diseases that result from issues related to insulin that represent a significant disease burden in the United States, which may include complications due to such diseases.

DATES: The meeting will take place on February 20, 2019, from 1:00 p.m. to approximately 5:00 p.m. Eastern Time (ET).

ADDRESSES: The meeting will be held online via webinar. To register to attend the meeting, please visit the registration website at *https://events.kauffmaninc.com/events/nccc2/register/?t=24.*

FOR FURTHER INFORMATION CONTACT: Clydette Powell, Designated Federal Officer, National Clinical Care Commission, U.S. Department of Health and Human Services, Office of the Assistant Secretary for Health, Office of Disease Prevention and Health Promotion, 1101 Wootton Parkway, Suite LL–100, Rockville, MD 20852. Email: *OHQ@hhs.gov.* Phone: 240–453–8239. Additional information may be obtained at *https://health.gov/hcq/national-clinical-care-commission.asp.*

SUPPLEMENTARY INFORMATION: The National Clinical Care Commission Act (Pub. L. 115–80) requires the HHS Secretary to establish the National Clinical Care Commission. The Commission consists of representatives of specific federal agencies and non-federal individuals and entities who represent diverse disciplines and views. The Commission will evaluate and make recommendations to the HHS Secretary and Congress regarding improvements to the coordination and leveraging of federal programs related to awareness and clinical care for complex metabolic or autoimmune diseases that result from issues related to insulin that represent a significant disease burden in the United States, which may include complications due to such diseases.

The inaugural meeting of the Commission was held on October 31, 2018, during which non-federal Commission members were sworn-in, and various federal interagency efforts surrounding diabetes program were presented. This virtual meeting will consist of presentations by the remaining federal agencies on the Commission which were not covered in the inaugural meeting. The final meeting agenda will be available prior to the meeting at *https://health.gov/hcq/national-clinical-care-commission.asp.*

Public Participation at Meeting: The Commission invites public comment on issues related to the Commission's charge. There will be no opportunity for oral comments at this virtual meeting. Written comments are welcome

throughout the process of the Commission and may be emailed to *OHQ@hhs.gov, or by mail to the following address: Public Commentary, National Clinical Care Commission,* 1101 Wootton Parkway, Suite LL–100, Rockville, MD 20852. Written comments should not exceed three pages in length.

To virtually attend the Commission meeting, individuals must pre-register at the registration website at *https://events.kauffmaninc.com/events/nccc2/register/?t=24.* Individuals who need special assistance, such as sign language interpretation or other reasonable accommodations, should indicate the special accommodation when registering online or by notifying Jennifer Gillissen at *jennifer.gillissen@kauffmaninc.com* by February 11.

Authority: The National Clinical Care Commission is required under the National Clinical Care Commission Act (Pub. L. 115–80). The Commission is governed by provisions of the Federal Advisory Committee Act (FACA), Public Law 92–463, as amended (5 U.S.C., App.) which sets forth standards for the formation and use of federal advisory committees.

Dated: January 24, 2019.

Donald Wright,

Deputy Assistant Secretary for Health.

[FR Doc. 2019–00360 Filed 2–1–19; 8:45 am]

BILLING CODE 4150–32–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Initial Review Group; Obstetrics and Maternal-Fetal Biology Subcommittee.

Date: February 22, 2019.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Peter Zelazowski, Ph.D., Scientific Review Officer, National Institutes of Health, NICHD, SRB, 6710B Rockledge Drive, Bethesda, MD 20892, 301–435–6902, *PETER.ZELAZOWSKI@NIH.GOV.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: January 30, 2019.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–00892 Filed 2–1–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Microbiology, Infectious Diseases and AIDS Initial Review Group, Microbiology and Infectious Diseases Research Committee, Microbiology and Infectious Diseases Research Committee (MID).

Date: June 11–12, 2019.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Amir E. Zeituni, Ph.D., Scientific Review Program, Division of Extramural Activities, SRP, RM 3G51, National Institutes of Health, NIAID, 5601 Fishers Lane, MSC 9823, Rockville, MD 20852–9823, 301–496–2550, *amir.zeituni@nih.gov.*

Name of Committee: Microbiology, Infectious Diseases and AIDS Initial Review Group, Microbiology and Infectious Diseases Research Committee, Microbiology and Infectious Diseases Research Committee (MID).

Date: October 17–18, 2019.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Amir E. Zeituni, Ph.D., Scientific Review Program, Division of Extramural Activities, SRP, RM 3G51, National Institutes of Health, NIAID, 5601 Fishers Lane, MSC 9823, Rockville, MD 20852–9823, 301–496–2550, *amir.zeituni@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: January 29, 2019.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–00832 Filed 2–1–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Molecular and Cellular Causal Aspects of Alzheimer's Disease.

Date: February 28, 2019.

Time: 8:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn & Suites Alexandria—Old Town, 625 First Street, Alexandria, VA 22314.

Contact Person: Carole L. Jelsema, Ph.D., Chief and Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4176, MSC 7850, Bethesda, MD 20892, (301) 435–1248, *jelsemac@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: January 29, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–00828 Filed 2–1–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Healthcare Delivery and Methodologies Integrated Review Group; Health Disparities and Equity Promotion Study Section.

Date: February 21–22, 2019.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The Whitehall, 1700 Smith Street, Houston, TX 77002.

Contact Person: Jessica Bellinger, Ph.D., Scientific Review Administrator, Center for Scientific of Review, National Institutes of Health, 6701 Rockledge Drive, Room 3158, Bethesda, MD 20892, 301–827–4446, *bellingerjd@csr.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: January 30, 2019.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–00888 Filed 2–1–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Maximizing the Scientific Value of the NHLBI Biorepository: Scientific Opportunities for Exploratory Research.

Date: February 27, 2019.

Time: 8:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The William F. Bolger Center, 9600 Newbridge Drive, Potomac, MD 20854.

Contact Person: Melissa E. Nagelin, Ph.D., Scientific Review Officer, Office of Scientific Review, National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Drive, Room 7202, Bethesda, MD 20892, 301–594–8518, *melissa.nagelin2@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: January 29, 2019.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–00827 Filed 2–1–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflicts: Interventions and Mechanisms for Addiction.

Date: February 28, 2019.

Time: 12:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Marc Boulay, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3110, MSC 7808, Bethesda, MD 20892, (301) 300–6541, *boulaymg@csr.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: January 29, 2019.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–00815 Filed 2–1–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Evaluation and Implementation of Patient Care.

Date: February 28, 2019.

Time: 7:30 a.m. to 3:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Melrose Hotel, 2430 Pennsylvania Avenue NW, Washington, DC 20037.
Contact Person: Gabriel B. Fosu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3108, MSC 7808, Bethesda, MD 20892, (301) 435–3562, *fosug@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: January 29, 2019.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–00820 Filed 2–1–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Auditory, Visual and Multisensory Integration.
Date: February 21, 2019.
Time: 8:00 a.m. to 6:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).
Contact Person: John Bishop, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5182, MSC 7844, Bethesda, MD 20892, (301) 408–9664, *bishopj@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: January 29, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–00812 Filed 2–1–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Board of Scientific Counselors, NIA.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the NATIONAL INSTITUTE ON AGING, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, NIA.
Date: May 7, 2019.
Closed: 8:00 a.m. to 8:30 a.m.
Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.
Place: National Institute on Aging, Biomedical Research Center, 3rd Floor Conference Room 03C227, 251 Bayview Boulevard, Baltimore, MD.

Open: 8:30 a.m. to 12:00 p.m.
Agenda: Committee discussion, individual presentations, laboratory overview.
Place: National Institute on Aging, Biomedical Research Center, 3rd Floor Conference Room 03C227, 251 Bayview Boulevard, Baltimore, MD.

Closed: 12:00 p.m. to 12:20 p.m.
Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.
Place: National Institute on Aging, Biomedical Research Center, 3rd Floor Conference Room 03C227, 251 Bayview Boulevard, Baltimore, MD.

Open: 12:20 p.m. to 2:20 p.m.
Agenda: Committee discussion, individual presentations, laboratory overview.
Place: National Institute on Aging, Biomedical Research Center, 3rd Floor Conference Room 03C227, 251 Bayview Boulevard, Baltimore, MD.

Closed: 2:20 p.m. to 2:30 p.m.
Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.
Place: National Institute on Aging, Biomedical Research Center, 3rd Floor Conference Room 03C227, 251 Bayview Boulevard, Baltimore, MD.

Open: 2:30 p.m. to 5:30 p.m.
Agenda: Committee discussion, individual presentations, laboratory overview.
Place: National Institute on Aging, Biomedical Research Center, 3rd Floor Conference Room 03C227, 251 Bayview Boulevard, Baltimore, MD.

Closed: 5:30 p.m. to 6:30 p.m.
Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.
Place: National Institute on Aging, Biomedical Research Center, 3rd Floor Conference Room 03C227, 251 Bayview Boulevard, Baltimore, MD.

Contact Person: Luigi Ferrucci, Ph.D., MD, Scientific Director, National Institute on Aging, 251 Bayview Boulevard, Suite 100, Room 4C225, Baltimore, MD 21224, 410–558–8110, *LF27Z@NIH.GOV.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: January 29, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–00830 Filed 2–1–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Oncology 2—Translational Clinical Integrated Review Group; Cancer Prevention Study Section.
Date: February 21–22, 2019.
Time: 8:00 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Ritz-Carlton Hotel, 1700 Tysons Boulevard, McLean, VA 22102.
Contact Person: Svetlana Kotliarova, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6214, Bethesda, MD 20892, 301–594–7945, *kotliars@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: January 29, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–00824 Filed 2–1–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Digestive, Kidney and Urological Systems Integrated Review Group; Systemic Injury by Environmental Exposure.
Date: February 28–March 1, 2019.
Time: 8:00 a.m. to 6:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Lorien Hotel and Spa, 1600 King Street, Alexandria, VA 22314.
Contact Person: Meenakshisundar Ananthanarayanan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4200, Bethesda, MD 20817, 301–435–1234, *ananth.ananthanarayanan@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: January 29, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–00818 Filed 2–1–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Clinical Trial Pilot Studies (R34).
Date: February 28–March 1, 2019.
Open: February 28, 2019, 8:00 a.m. to 6:00 p.m.
Agenda: To review and evaluate grant applications.
Place: The William F. Bolger Center, 9600 Newbridge Drive, Potomac, MD 20854.
Closed: March 1, 2019, 8:00 a.m. to 8:30 a.m.
Agenda: To review and evaluate grant applications.
Place: The William F. Bolger Center, 9600 Newbridge Drive, Potomac, MD 20854.
Contact Person: YingYing Li-Smerin, MD, Ph.D., Scientific Review Officer, Office of Scientific Review, National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Drive, Room 7184, Bethesda, MD 20892, 301–827–7942, *lismerin@nhlbi.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: January 29, 2019.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–00826 Filed 2–1–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; GEMSSTAR19.
Date: February 25, 2019.
Time: 8:00 a.m. to 6:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Bethesda North Marriott Hotel, 5701 Marinelli Road, Rockville, MD 20852.
Contact Person: Isis S. Mikhail, MD, MPH, DRPH, National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892, 301–402–7704, *Mikhaili@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: January 30, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–01012 Filed 2–1–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Molecular Mechanisms of Neurodysfunction.
Date: February 25, 2019.
Time: 1:00 p.m. to 2:30 p.m.
Agenda: To review and evaluate grant applications.
Place: Hotel Zoe Fisherman's Wharf, 425 North Point St, San Francisco, CA 94133.
Contact Person: Carole L. Jelsema, Ph.D., Chief and Scientific Review Administrator, MDCN Scientific Review Group, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4146, MSC 7850, Bethesda, MD 20892, (301) 435–1248, *jelsemac@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: January 29, 2019.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–00817 Filed 2–1–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel, NIA Clinical and Non-Clinical Studies.
Date: February 22, 2019.
Time: 12:15 p.m. to 3:45 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institute on Aging, Gateway Building, Suite 2C–212, 7201 Wisconsin Avenue, Bethesda, MD 20892, (Telephone Conference Call).
Contact Person: Maurizio Grimaldi, MD, Ph.D., Scientific Review Officer, National Institute on Aging, National Institutes of Health, 7201 Wisconsin Avenue, Room 2C218, Bethesda, MD 20892, 301–496–9374, *grimaldim2@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: January 29, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–00831 Filed 2–1–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Learning, Memory, Language, Communication and Related Neurosciences.
Date: February 21–22, 2019.
Time: 8:00 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: The Westin St. Francis, 335 Powell Street, San Francisco, CA 94102.
Contact Person: Susan Gillmor, Ph.D., Scientific Review Officer, National Institutes of Health, Center for Scientific Review, 6701 Rockledge Drive, Bethesda, MD 20892, 240–762–3076, *susan.gillmor@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: January 29, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–00825 Filed 2–1–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Healthcare Delivery and Methodologies Integrated Review Group; Dissemination and Implementation Research in Health Study Section.
Date: February 27–28, 2019.
Time: 8:00 a.m. to 6:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Melrose Hotel, 2430 Pennsylvania Ave. NW, Washington, DC 20037.
Contact Person: Yvonne Owens Ferguson, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3139, Bethesda, MD 20892, 301–827–3689, *fergusonyo@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: January 29, 2019.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–00819 Filed 2–1–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Minority Health and Health Disparities; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable materials, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Minority Health and Health Disparities Special Emphasis Panel; Review of Research Conference (R13) Grants.

Date: February 22, 2019.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Gateway Plaza, 7201 Wisconsin Avenue, Suite 525, Rm 533, Bethesda, MD 20817.

Contact Person: Deborah Ismond, Ph.D., Scientific Review Officer, Division of Scientific Programs, National Institute on Minority Health and Health Disparities, Gateway Plaza, 7201 Wisconsin Avenue, Bethesda, MD 20817, (301) 594–2704, *ismonddr@mail.nih.gov*.

Dated: January 29, 2019.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–00833 Filed 2–1–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Initial Review Group; Health, Behavior, and Context Subcommittee.

Date: February 25, 2019.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Kimberly L. Houston, MD, Scientific Review Officer, Eunice Kennedy Shriver National Institute of Children Health and Human Development, 6701B Rockledge Drive, Room 2127B, Bethesda, MD 20892, 301–827–4902, *kimberly.houston@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: January 30, 2019.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–00891 Filed 2–1–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Heart, Lung, and Blood Initial Review Group, Clinical Trials Review Committee.

Date: February 21–22, 2019.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Keary A. Cope, Ph.D., Scientific Review Officer, Office of Scientific Review, The National Institutes of Health, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7190, Bethesda, MD 20892–7924, 301–827–7912, *copeka@mail.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: January 29, 2019.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–00829 Filed 2–1–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; AREA (R15) Cardiovascular Sciences.

Date: February 28, 2019.

Time: 8:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The Ritz-Carlton, Pentagon City, 1250 S Hayes St., Arlington, VA 22202.

Contact Person: Abdelouahab Aitouche, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4222, MSC 7814, Bethesda, MD 20892, 301–435–2365, *aitouchea@csr.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844,

93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: January 30, 2019.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–00887 Filed 2–1–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Neurodevelopment, Synaptic Plasticity and Neurodegeneration.

Date: February 28–March 1, 2019.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Washington Marriott Georgetown, 1221 22nd Street NW, Washington, DC 20037.

Contact Person: Mary Schueler, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5214, MSC 7846, Bethesda, MD 20892. 301–451–0996, *marygs@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: January 29, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–00821 Filed 2–1–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Biophysical, Physiological, Pharmacological and Bioengineering Neuroscience.

Date: February 28–March 1, 2019.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Melrose Georgetown Hotel, 2430 Pennsylvania Avenue NW, Washington, DC 20037.

Contact Person: Sussan Paydar, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, RM 5222, Bethesda, MD 20817, (301) 827–4994, *sussan.paydar@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: January 29, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–00822 Filed 2–1–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Neuroscience AREA Grant Applications.

Date: February 28–March 1, 2019.

Time: 8:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The Darcy, Washington, DC, Curio, 1515 Rhode Island Avenue NW, Washington, DC 20005.

Contact Person: Richard D. Crosland, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4190, MSC 7850, Bethesda, MD 20892, 301–694–7084, *crosland@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: January 29, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–00814 Filed 2–1–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Epidemiology.

Date: February 28, 2019.

Time: 10:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Denise Wiesch, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3138, MSC 7770, Bethesda, MD 20892, (301) 437–3478, *wieschd@csr.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: January 29, 2019.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–00816 Filed 2–1–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Initial Review Group; Reproduction, Andrology, and Gynecology Subcommittee.

Date: February 22, 2019.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda Downtown, 7355 Wisconsin Ave., Bethesda, MD 20814.

Contact Person: Helen Huang, Scientific Review Branch (SRB), DER, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, DHHS 6710B, Rockledge Drive, Rm 2125B, Bethesda, MD 20817, 301–435–8380, *helen.huang@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: January 30, 2019.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–00890 Filed 2–1–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Genes, Genomes and Genetics.

Date: February 26, 2019.

Time: 10:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Elena Smirnova, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5187, MSC 7840, Bethesda, MD 20892, 301–357–9112, *smirnove@csr.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: January 29, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–00823 Filed 2–1–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Genes, Genomes, and Genetics Integrated Review Group; Genetic Variation and Evolution Study Section.

Date: February 27–28, 2019.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Joseph Thomas Peterson, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4118, MSC 7814, Bethesda, MD 20892, 301–408–9694, *petersonjt@csr.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: January 29, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–00811 Filed 2–1–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C.,

as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Molecular, Cellular and Developmental Neuroscience Integrated Review Group; Drug Discovery for the Nervous System Study Section.

Date: February 21–22, 2019.

Time: 8:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Washington Marriott Georgetown, 1221 22nd Street NW, Washington, DC 20037.

Contact Person: Mary Custer, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4148, MSC 7850, Bethesda, MD 20892, (301) 435–1164, *custerm@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: January 29, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–00813 Filed 2–1–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2019–0035]

Towing Safety Advisory Committee

AGENCY: U.S. Coast Guard, Department of Homeland Security.

ACTION: Notice of Federal Advisory Committee meeting.

SUMMARY: The Towing Safety Advisory Committee and its subcommittees will meet in Miami, Florida, to review and discuss recommendations from its subcommittees and to receive briefs on items listed in the agenda. All meetings will be open to the public.

DATES: *Meetings.* The subcommittees of the Towing Safety Advisory Committee will meet on Wednesday, February 20, 2019, from 8 a.m. to 5 p.m. to conduct work-group sessions. The full Committee will meet on Thursday, February 21, 2019, from 8 a.m. to 5 p.m. These meetings may end early if the subcommittees or the Committee has completed its business, or the meetings may be extended based on the number of public comments.

Comments and supporting documentation. To ensure your comments are reviewed by Committee members before the meetings, submit your written comments no later than February 14, 2019.

ADDRESSES: All meetings will be held at the Hyatt Place Miami Airport West/Doral, 3655 NW 82nd Ave., Miami, Florida 33166; hotel website: *www.hyattplacemiamiairportwest.com.*

For information on facilities or services for individuals with disabilities, or to request special assistance at the meetings, contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section as soon as possible.

Written comments must be submitted using the Federal eRulemaking Portal at *http://www.regulations.gov.* If you encounter technical difficulties when trying to submit comments, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** of this document.

Instructions: You are free to submit comments at any time, including orally at the meetings, but if you want Committee members to review your comment before the meetings, please submit your comments no later than February 14, 2019. We are particularly interested in comments on the issues in the ''Agenda'' section below. You must include ''Department of Homeland Security'' and the docket number USCG–2019–0035. For more information about the privacy and the docket, review the Privacy and Security Notice for the Federal Docket Management System at *https://www.regulations.gov/privacyNotice.*

Docket Search: For access to the docket or to read documents or comments related to this notice, go to *http://www.regulations.gov,* insert USCG–2019–0035 in the Search box, press Enter, and then click on the item you wish to view.

FOR FURTHER INFORMATION CONTACT: Mr. Douglas Scheffler, Alternate Designated Federal Officer of the Towing Safety Advisory Committee, Commandant (CG–OES–2), U.S. Coast Guard, 2703 Martin Luther King Jr. Avenue SE, Stop 7509, Washington, DC 20593–7509; telephone 202–372–1087, fax 202–372–8382 or email *Douglas.W.Scheffler@uscg.mil.*

SUPPLEMENTARY INFORMATION: Notice of this meeting is in compliance with the *Federal Advisory Committee Act,* Title 5 United States Code Appendix.

The Towing Safety Advisory Committee provides advice and recommendations to the Department of Homeland Security on matters relating to shallow-draft inland and coastal waterway navigation and towing safety. On December 4, 2018, the source of this stated purpose of the Committee, 33 U.S.C. 1231a, was repealed by the Frank Lobiondo Coast Guard Authorization Act of 2018 (PL 115–282, 132 Stat 4192) but section 601(d) of this Authorization Act allows the Towing Safety Advisory Committee to remain in force or in effect for a period of up to 2 years. Section 601(a) of the Authorization Act has established the National Towing Safety Advisory Committee, which has the same stated purpose and that will eventually replace the Towing Safety Advisory Committee.

Agenda of Meetings

On February 20 and 21, 2019, from 8 a.m. to 5 p.m., the Towing Safety Advisory Committee and its subcommittees will meet to review, discuss, deliberate, and formulate recommendations, as appropriate, on the following tasks:

- 46 Code of Federal Regulations Subchapter M Implementation (Task 16–01).
- Towing Liquefied Natural Gas Barges (Task 16–03).
- Load Line Exemption Review for River Barges on Lakes Erie and Ontario (Task 17–02).

All current Towing Safety Advisory Committee tasks can be found at *https://homeport.uscg.mil/Lists/Content/DispForm.aspx?&ID=574&Source=https://homeport.uscg.mil/missions/ports-and-waterways/safety-advisory-committees/tsac/recommendations-reports.*

A copy of all meeting documentation, including any draft final reports, will be available at *https://homeport.uscg.mil/missions/ports-and-waterways/safety-advisory-committees/tsac/announcements* no later than February 13, 2019. Alternatively, you may contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section above.

Public comments or questions will be taken throughout the meeting as the Committee discusses the issues and prior to deliberations and voting. There will also be a public comment period at the end of the meeting. Speakers are requested to limit their comments to 3 minutes. Please note that the public comment period may end before the period allotted, following the last call for comments. Please contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section above to register as a speaker.

Notices of Future 2019 Towing Safety Advisory Committee Meetings

To receive automatic email notices of future Towing Safety Advisory Committee meetings in 2019, go to the online docket, USCG–2019–0035 (*http://www.regulations.gov/#!docket Detail;D=USCG-2019-0035*), and select the Sign-up-for-Email-Alerts option. We plan to use the same docket number for all Towing Safety Advisory Committee meeting notices in 2019, so when the next meeting notice is published you will receive an email alert from *http://www.regulations.gov* when the notice appears in this docket, in addition to notices of other items being added to the docket.

Dated: January 29, 2019.

Jeffrey G. Lantz,

Director of Commercial Regulations and Standards.

[FR Doc. 2019–00860 Filed 2–1–19; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation of AmSpec LLC (New Haven, CT), as a Commercial Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation of AmSpec LLC (New Haven, CT), as a commercial laboratory.

SUMMARY: Notice is hereby given, pursuant to CBP regulations, that AmSpec LLC (New Haven, CT), has been accredited to test petroleum and certain petroleum products for customs purposes as of November 8, 2018.

DATES: AmSpec LLC (New Haven, CT) was accredited, as a commercial laboratory as of November 8, 2018. The next triennial inspection date will be scheduled for August 2021.

FOR FURTHER INFORMATION CONTACT: Dr. Justin Shey, Laboratories and Scientific Services Directorate, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW, Suite 1500N, Washington, DC 20229, tel. 202–344–1060.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to 19 CFR 151.12, that AmSpec LLC, 100 Wheeler St., Unit G, New Haven, CT 06512 has been accredited to test petroleum and certain petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.12.

AmSpec LLC (New Haven, CT) is accredited for the following laboratory analysis procedures and methods for petroleum and certain petroleum products set forth by the U.S. Customs and Border Protection Laboratory Methods (CBPL) and American Society for Testing and Materials (ASTM):

CBPL No.	ASTM	Title
27–14	D2622	Standard Test Method for Sulfur in Petroleum Products by Wavelength Dispersive X-Ray Fluorescence Spectrometry.
27–57	D7039	Standard Test Method for Sulfur in Gasoline and Diesel Fuel by Monochromatic Wavelength Dispersive X-Ray Fluorescence Spectrometry.

Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *CBPGaugersLabs@cbp.dhs.gov*. Please reference the website listed below for a complete listing of CBP approved gaugers and accredited laboratories. *http://www.cbp.gov/about/labs-scientific/commercial-gaugers-and-laboratories.*

Dated: December 20, 2018.

Patricia Hawes Coleman,

Acting Executive Director, Laboratories and Scientific Services Directorate.

[FR Doc. 2019–00918 Filed 2–1–19; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of Inspectorate America Corporation (Corpus Christi, TX) as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of Inspectorate America Corporation (Corpus Christi, TX), as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given, pursuant to CBP regulations, that Inspectorate America Corporation (Corpus Christi, TX), has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes for the next three years as of February 14, 2017.

DATES: Inspectorate America Corporation (Corpus Christi, TX) was approved and accredited as a commercial gauger and laboratory as of February 14, 2017. The next triennial inspection date will be scheduled for February 2020.

FOR FURTHER INFORMATION CONTACT: Dr. Justin Shey, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW, Suite 1500N, Washington, DC 20229, tel. 202–344–1060.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to 19 CFR 151.12 and 19 CFR 151.13, that Inspectorate America Corporation, 4717 Santa Elena, Corpus Christi, TX 78405, has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13.

Inspectorate America Corporation (Corpus Christi, TX) is approved for the following gauging procedures for petroleum and certain petroleum products from the American Petroleum Institute (API):

API chapters	Title
3	Tank Gauging.
7	Temperature Determination.
8	Sampling.
12	Calculations.
17	Maritime Measurement.

Inspectorate America Corporation (Corpus Christi, TX) is accredited for the following laboratory analysis procedures and methods for petroleum and certain petroleum products set forth

by the U.S. Customs and Border Protection Laboratory Methods (CBPL) and American Society for Testing and Materials (ASTM):

CBPL No.	ASTM	Title
27–03	D4006	Standard Test Method for Water in Crude Oil by Distillation.
27–04	D95	Standard Test Method for Water in Petroleum Products and Bituminous Materials by Distillation.
27–05	D4928	Standard Test Method for Water in Crude Oils by Coulometric Karl Fischer Titration.
27–06	D473	Standard Test Method for Sediment in Crude Oils and Fuel Oils by the Extraction Method.
27–08	D86	Standard Test Method for Distillation of Petroleum Products at Atmospheric Pressure.
27–11	D445	Standard Test Method for Kinematic Viscosity of Transparent and Opaque Liquids (and Calculation of Dynamic Viscosity).
27–13	D4294	Standard Test Method for Sulfur in Petroleum and Petroleum Products by Energy-Dispersive X-ray Fluorescence Spectrometry.
27–14	D2622	Standard Test Method for Sulfur in Petroleum Products by Wavelength Dispersive X-Ray Fluorescence Spectrometry.
27–46	D5002	Standard Test Method for Density and Relative Density of Crude Oils by Digital Density Analyzer.
27–48	D4052	Standard Test Method for Density and Relative Density of Liquids by Digital Density Meter.
27–58	D5191	Standard Test Method for Vapor Pressure of Petroleum Products (Mini Method).

Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *CBPGaugersLabs@cbp.dhs.gov*. Please reference the website listed below for a complete listing of CBP approved gaugers and accredited laboratories. *http://www.cbp.gov/about/labs-scientific/commercial-gaugers-and-laboratories*.

Dated: December 20, 2018.

Patricia Hawes Coleman,

Acting Executive Director, Laboratories and Scientific Services.

[FR Doc. 2019–00916 Filed 2–1–19; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation of Dixie Services Inc. (Galena Park, TX) as a Commercial Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation of Dixie Services Inc. (Galena Park, TX), as a commercial laboratory.

SUMMARY: Notice is hereby given, pursuant to CBP regulations, that Dixie Services Inc. (Galena Park, TX), has been accredited to test petroleum and certain petroleum products for customs purposes for the next three years as of August 28, 2018.

DATES: Dixie Services Inc. (Galena Park, TX) was accredited as a commercial laboratory as of August 28, 2018. The next triennial inspection date will be scheduled for August 2021.

FOR FURTHER INFORMATION CONTACT: Dr. Justin Shey, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW, Suite 1500N, Washington, DC 20229, tel. 202–344–1060.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to 19 CFR 151.12, that Dixie Services Inc., 1706 First Street, Galena Park, TX 77547 has been accredited to test petroleum and certain petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.12.

Dixie Services Inc. (Galena Park, TX) is accredited for the following laboratory analysis procedures and methods for petroleum and certain petroleum products set forth by the U.S. Customs and Border Protection Laboratory Methods (CBPL) and American Society for Testing and Materials (ASTM):

CBPL No.	ASTM	Title
27–04	D95	Standard Test Method for Water in Petroleum Products and Bituminous Materials by Distillation.
27–05	D4928	Standard Test Method for Water in Crude Oils by Coulometric Karl Fischer Titration.
27–06	D473	Standard Test Method for Sediment in Crude Oils and Fuel Oils by the Extraction Method.
27–07	D4807	Standard Test Method for Sediment in Crude Oil by Membrane Filtration.
27–08	D86	Standard Test Method for Distillation of Petroleum Products at Atmospheric Pressure.
27–11	D445	Standard Test Method for Kinematic Viscosity of Transparent and Opaque Liquids (and Calculation of Dynamic Viscosity).
27–13	D4294	Standard Test Method for Sulfur in Petroleum and Petroleum Products by Energy-Dispersive X-ray Fluorescence Spectrometry.
27–14	D2622	Standard Test Method for Sulfur in Petroleum Products by Wavelength Dispersive X-Ray Fluorescence Spectrometry.
27–39	D721	Standard Test Method for Oil Content of Petroleum Waxes.
27–46	D5002	Standard Test Method for Density and Relative Density of Crude Oils by Digital Density Analyzer.
27–48	D4052	Standard Test Method for Density and Relative Density of Liquids by Digital Density Meter.
27–50	D93	Standard Test Methods for Flash-Point by Pensky-Martens Closed Cup Tester.
27–53	D2709	Standard Test Method for Water and Sediment in Middle Distillate Fuels by Centrifuge.
27–58	D5191	Standard Test Method for Vapor Pressure of Petroleum Products (Mini Method).

Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border

Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *CBPGaugersLabs@cbp.dhs.gov.* Please reference the website listed below for a complete listing of CBP approved gaugers and accredited laboratories. *http://www.cbp.gov/about/labs-scientific/commercial-gaugers-and-laboratories.*

Dated: December 20, 2018.

Patricia Hawes Coleman,

Acting Executive Director, Laboratories and Scientific Services.

[FR Doc. 2019–00917 Filed 2–1–19; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of Spectrum International LLC (Roselle, NJ) as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of Spectrum International LLC (Roselle, NJ), as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given, pursuant to CBP regulations, that Spectrum International LLC (Roselle, NJ), has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes for the next three years as of July 23, 2018.

DATES: Spectrum International LLC (Roselle, NJ) was approved and accredited as a commercial gauger and laboratory as of July 23, 2018. The next triennial inspection date will be scheduled for July 2021.

FOR FURTHER INFORMATION CONTACT: Dr. Justin Shey, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW, Suite 1500N, Washington, DC 20229, tel. 202–344–1060.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to 19 CFR 151.12 and 19 CFR 151.13, that Spectrum International LLC, 109 Aldene Road, Roselle, NJ 07203, has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13.

Spectrum International LLC (Roselle, NJ) is approved for the following gauging procedures for petroleum and certain petroleum products from the American Petroleum Institute (API):

API chapters	Title
1	Vocabulary.
3	Tank Gauging.
7	Temperature Determination.
8	Sampling.
11	Physical Properties Data.
12	Calculations.
17	Maritime Measurement.

Spectrum International LLC (Roselle, NJ) is accredited for the following laboratory analysis procedures and methods for petroleum and certain petroleum products set forth by the U.S. Customs and Border Protection Laboratory Methods (CBPL) and American Society for Testing and Materials (ASTM):

CBPL No.	ASTM	Title
27–01	D 287	Standard Test Method for API Gravity of Crude Petroleum and Petroleum Products (Hydrometer Method).
27–02	D1298	Standard Test Method for Density, Relative Density (Specific Gravity), or API Gravity of Crude Petroleum and Liquid Petroleum Products by Hydrometer Method.
27–03	D4006	Standard Test Method for Water in Crude Oil by Distillation.
27–04	D95	Standard Test Method for Water in Petroleum Products and Bituminous Materials by Distillation.
27–05	D4928	Standard Test Method for Water in Crude Oils by Coulometric Karl Fischer Titration.
27–06	D473	Standard Test Method for Sediment in Crude Oils and Fuel Oils by the Extraction Method.
27–07	D4807	Standard Test Method for Sediment in Crude Oil by Membrane Filtration.
27–08	D86	Standard Test Method for Distillation of Petroleum Products at Atmospheric Pressure.
27–11	D445	Standard Test Method for Kinematic Viscosity of Transparent and Opaque Liquids (and Calculation of Dynamic Viscosity).
27–13	D4294	Standard Test Method for Sulfur in Petroleum and Petroleum Products by Energy-Dispersive X-ray Fluorescence Spectrometry.
27–48	D4052	Standard Test Method for Density and Relative Density of Liquids by Digital Density Meter.
27–50	D93	Standard Test Methods for Flash-Point by Pensky-Martens Closed Cup Tester.
27–53	D2709	Standard Test Method for Water and Sediment in Middle Distillate Fuels by Centrifuge.
27–57	D7039	Standard Test Method for Sulfur in Gasoline and Diesel Fuel by Monochromatic Wavelength Dispersive X-Ray Fluorescence Spectrometry.
27–58	D5191	Standard Test Method for Vapor Pressure of Petroleum Products (Mini Method).

Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *CBPGaugersLabs@cbp.dhs.gov.* Please reference the website listed below for a complete listing of CBP approved gaugers and accredited laboratories. *http://www.cbp.gov/about/labs-scientific/commercial-gaugers-and-laboratories.*

Dated: December 20, 2018.

Patricia Hawes Coleman,

Acting Executive Director, Laboratories and Scientific Services.

[FR Doc. 2019–00913 Filed 2–1–19; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of Certispec Services USA, Inc. (Texas City, TX) as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of Certispec Services USA, Inc. (Texas City, TX), as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given, pursuant to CBP regulations, that Certispec Services USA, Inc. (Texas City, TX), has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes for the next three years as of April 3, 2017.

DATES: Certispec Services USA, Inc. (Texas City, TX) was approved and accredited as a commercial gauger and laboratory as of April 3, 2017. The next triennial inspection date will be scheduled for April 2020.

FOR FURTHER INFORMATION CONTACT: Dr. Justin Shey, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW, Suite 1500N, Washington, DC 20229, tel. 202–344–1060.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to 19 CFR 151.12 and 19 CFR 151.13, that Certispec Services USA, Inc., 1448 Texas Ave, Texas City, TX 77590, has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. Certispec Services USA, Inc. (Texas City, TX) is approved for the following gauging procedures for petroleum and certain petroleum products from the American Petroleum Institute (API):

API chapters	Title
3	Tank Gauging.
8	Sampling.

Certispec Services USA, Inc. (Texas City, TX) is accredited for the following laboratory analysis procedures and methods for petroleum and certain petroleum products set forth by the U.S. Customs and Border Protection Laboratory Methods (CBPL) and American Society for Testing and Materials (ASTM):

CBPL No.	ASTM	Title
27–01	D287	Standard Test Method for API Gravity of Crude Petroleum and Petroleum Products (Hydrometer Method).
27–03	D4006	Standard Test Method for Water in Crude Oil by Distillation.
27–04	D95	Standard Test Method for Water in Petroleum Products and Bituminous Materials by Distillation.
27–05	D4928	Standard Test Method for Water in Crude Oils by Coulometric Karl Fischer Titration.
27–06	D473	Standard Test Method for Sediment in Crude Oils and Fuel Oils by the Extraction Method.
27–08	D86	Standard Test Method for Distillation of Petroleum Products at Atmospheric Pressure.
27–11	D445	Standard Test Method for Kinematic Viscosity of Transparent and Opaque Liquids (and Calculation of Dynamic Viscosity).
27–13	D4294	Standard Test Method for Sulfur in Petroleum and Petroleum Products by Energy-Dispersive X-ray Fluorescence Spectrometry.
27–48	D4052	Standard Test Method for Density and Relative Density of Liquids by Digital Density Meter.
27–50	D93	Standard Test Methods for Flash-Point by Pensky-Martens Closed Cup Tester.
27–57	D7039	Standard Test Method for Sulfur in Gasoline and Diesel Fuel by Monochromatic Wavelength Dispersive X-Ray Fluorescence Spectrometry.

Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *CBPGaugersLabs@cbp.dhs.gov*. Please reference the website listed below for a complete listing of CBP approved gaugers and accredited laboratories. *http://www.cbp.gov/about/labs-scientific/commercial-gaugers-and-laboratories.*

Dated: December 20, 2018.

Patricia Hawes Coleman,

Acting Executive Director, Laboratories and Scientific Services.

[FR Doc. 2019–00914 Filed 2–1–19; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of Intertek USA, Inc. (Texas City, TX) as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of Intertek USA, Inc. (Texas City, TX), as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given, pursuant to CBP regulations, that Intertek USA, Inc. (Texas City, TX), has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes for the next three years as of February 28, 2018.

DATES: Intertek USA, Inc. (Texas City, TX) was approved and accredited as a commercial gauger and laboratory as of February 28, 2018. The next triennial inspection date will be scheduled for February 2021.

FOR FURTHER INFORMATION CONTACT: Melanie A. Glass, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW, Suite 1500N, Washington, DC 20229, tel. 202–344–1060.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to 19 CFR 151.12 and 19 CFR 151.13, that Intertek USA, Inc., 728 4th Avenue South, Texas City, TX 77590, has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum

products for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13.

Intertek USA, Inc. (Texas City, TX) is approved for the following gauging procedures for petroleum and certain petroleum products from the American Petroleum Institute (API):

API chapters	Title
3	Tank gauging.
7	Temperature determination.
8	Sampling.
12	Calculations.
17	Maritime measurement.

Intertek USA, Inc. (Texas City, TX) is accredited for the following laboratory analysis procedures and methods for petroleum and certain petroleum products set forth by the U.S. Customs and Border Protection Laboratory Methods (CBPL) and American Society for Testing and Materials (ASTM):

CBPL No.	ASTM	Title
27–01	D287	Standard Test Method for API Gravity of Crude Petroleum and Petroleum Products (Hydrometer Method).
27–02	D1298	Standard Test Method for Density, Relative Density (Specific Gravity), or API Gravity of Crude Petroleum and Liquid Petroleum Products by Hydrometer Method.
27–03	D4006	Standard Test Method for Water in Crude Oil by Distillation.
27–04	D95	Standard Test Method for Water in Petroleum Products and Bituminous Materials by Distillation.
27–05	D4928	Standard Test Method for Water in Crude Oils by Coulometric Karl Fischer Titration.
27–06	D473	Standard Test Method for Sediment in Crude Oils and Fuel Oils by the Extraction Method.
27–07	D4807	Standard Test Method for Sediment in Crude Oil by Membrane Filtration.
27–08	D86	Standard Test Method for Distillation of Petroleum Products.
27–11	D445	Standard Test Method for Kinematic Viscosity of Transparent and Opaque Liquids.
27–13	D4294	Standard Test Method for Sulfur in Petroleum and Petroleum Products by Energy-Dispersive X-ray Fluorescence Spectrometry.
27–46	D5002	Standard Test Method for Density and Relative Density of Crude Oils by Digital Density Analyzer.
27–48	D4052	Standard Test Method for Density and Relative Density of Liquids by Digital Density Meter.
27–50	D93	Standard Test Methods for Flash-Point by Pensky-Martens Closed Cup Tester.
27–53	D2709	Standard Test Method for Water and Sediment in Middle Distillate Fuels by Centrifuge.
27–54	D1796	Standard Test Method for Water and Sediment in Fuel Oils by the Centrifuge Method.
	D70	Density of Semi-solid Bituminous Materials (Pycnometer method).
	D97	Standard Test Method for Pour Point of Petroleum Products.
	D4007	Standard Test Method for Water and Sediment in Crude Oil by the Centrifuge Method (Laboratory Procedure).

Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *CBPGaugersLabs@cbp.dhs.gov*. Please reference the website listed below for a complete listing of CBP approved gaugers and accredited laboratories. *http://www.cbp.gov/about/labs-scientific/commercial-gaugers-and-laboratories*.

Dated: January 11, 2019.

Patricia Hawes Coleman,

Acting Executive Director, Laboratories and Scientific Services.

[FR Doc. 2019–00915 Filed 2–1–19; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[190A2100DD/AAKC001030/A0A501010.999900253G]

Notice of Intent To Prepare an Environmental Impact Statement for the Eagle Shadow Mountain Solar Project on the Moapa River Indian Reservation, Clark County, Nevada

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of intent.

SUMMARY: The Bureau of Indian Affairs (BIA), as lead agency in cooperation with the Moapa Band of Paiute Indians (Moapa Band), the Bureau of Land Management (BLM), and other agencies, intend to prepare an Environmental Impact Statement (EIS) that will evaluate a photovoltaic (PV) solar energy generation project on the Moapa River Indian Reservation and a transmission line located on Tribal lands, Federal lands administered and managed by BLM, and land owned by NV Energy in Clark County, Nevada. This notice announces the beginning of the scoping process to solicit public comments and identify potential issues related to the EIS. It also announces that two public scoping meetings will be held in Nevada to identify potential issues, alternatives, and mitigation to be considered in the EIS.

DATES: Written comments on the scope of the EIS or implementation of the proposal must arrive by March 6, 2019. The dates and locations of the public scoping meetings will be published in the *Las Vegas Sun, Las Vegas Review-Journal,* and *Moapa Valley Progress* 15 days before the scoping meetings.

ADDRESSES: You may mail, email, or hand carry written comments to Mr. Chip Lewis, BIA Western Regional Office, 2600 North Central Avenue, 4th Floor Mailroom, Phoenix, Arizona 85004; telephone: (602) 379–6750; email: *Chip.Lewis@bia.gov*.

SUPPLEMENTARY INFORMATION: The proposed Federal action, taken under 25 U.S.C. 415, is BIA's approval of a solar energy ground lease and associated agreements entered into by the Moapa Band with 325MK 8me LLC (Applicant), a subsidiary of 8minutenergy. The agreements provide for construction, operation and maintenance (O&M), and decommissioning of a 300-megawatt (MW) alternating current solar photovoltaic (PV) electricity generation facility located entirely on the Moapa River Indian Reservation and specifically on lands held in trust by BIA for the Moapa Band. A proposed 230 kilovolt (kV) generation-tie transmission line required for interconnection of the solar project would be located on Tribal lands, Federal lands administered and managed by BLM, and private lands.

The BIA and BLM would approve rights-of-way (ROWs) authorizing the construction and operation of the transmission line. Together, the proposed solar energy facility, transmission line, and other associated facilities will make up the proposed solar project (Project).

The Project would be constructed on up to 2,300 acres located within a 4,770-acre lease area in Township 16 South, Range 64 East that includes all or parts of Sections 9, 10, 11, 12, 14, 15, 16, 21, and 22 Mount Diablo Meridian, Nevada. Access to the Project would be provided by I–15, US–93, and North Las Vegas Boulevard. The overhead 230kV generation-tie transmission line would be approximately 10 miles long and would connect the solar project to NV Energy's Reid-Gardner 230kV substation.

Construction of the Project is expected to take approximately 16 to 18 months. The Applicant is expected to operate the energy facility for up to 50 years under the terms of the lease. The Project is expected to be built in one phase of 300 MW to meet an existing Power Purchase Agreement (PPA) for the output of the Project. Major onsite facilities include multiple blocks of solar PV panels mounted on fixed tilt or tracking systems, pad mounted inverters and transformers, collection lines, battery storage facilities, project substation, access roads, and O&M facilities. Water will be needed during construction for dust control and a minimal amount will be needed during operations for administrative and sanitary water use and possibly for panel washing. The water supply required for the Project would be leased from the Moapa Band.

The purposes of the proposed Project are, among other things, to: (1) Help to provide a long-term, diverse, and viable economic revenue base and job opportunities for the Moapa Band; (2) help Nevada and neighboring states to meet their State renewable energy needs; and (3) allow the Moapa Band, in partnership with the Applicant, to optimize the use of the lease site while maximizing the potential economic benefit to the Tribe.

BIA will prepare the EIS in cooperation with the Moapa Band, BLM, Environmental Protection Agency (EPA), US Air Force (USAF), and Nevada Department of Wildlife (NDOW) and possibly the U.S. Army Corps of Engineers. In addition, the U.S. Fish and Wildlife Service (USFWS) and National Park Service (NPS) will provide input on the analysis. The resulting EIS will aim to (1) provide agency decision makers, the Moapa Band, and the general public with a comprehensive understanding of the impacts of the proposed Project and alternatives on the Reservation; (2) describe the cumulative impacts of increased development on the Reservation; and (3) identify and propose mitigation measures that would minimize or prevent significant adverse impacts. Consistent with these objectives, the EIS will analyze the proposed Project and appurtenant features, viable alternatives including generation-tie routing options, modified footprint alternatives, alternate routing for other Project ROWs, and the No Action alternative. Other alternatives may be identified in response to issues raised during the scoping process.

The EIS will provide a framework for BIA and BLM to make determinations and to decide whether to take the aforementioned Federal actions. In addition, BIA will use and coordinate the NEPA commenting process to satisfy its obligations under Section 106 of the National Historic Preservation Act (NHPA) (16 U.S.C. 470f) as provided for in 36 CFR 800.2(d)(3). Native American Tribal consultations will be conducted in accordance with policy, and Tribal concerns will be given due consideration, including impacts on Indian trust assets. Other Federal agencies may rely on the EIS to make decisions under their authority and the Moapa Band may also use the EIS to make decisions under their Tribal Environmental Policy Ordinance. USFWS will review the EIS for consistency with the Endangered Species Act, as amended, and other implementing acts, and may rely on the EIS to support its decisions and opinions regarding the Project.

Issues to be addressed in the EIS analysis may include, but would not be limited to, Project impacts on water resources, biological resources, threatened and endangered species, cultural resources, Native American religious concerns, and aesthetics. In addition to those resource topics identified above, Federal, State, and local agencies, along with other stakeholders that may be interested or affected by the BIA's decision on the proposed Project, are invited to participate in the scoping process to identify additional issues to be addressed.

Submission of Public Comments

Please include your name, return address, and the caption ''EIS, Eagle Shadow Mountain Solar Project,'' on the first page of any written comments. You may also submit comments at the public scoping meetings.

The public scoping meetings will be held to further describe the Project and identify potential issues and alternatives to be considered in the EIS. The first public scoping meeting will be held on the Reservation and the other public scoping meeting will be held in Las Vegas, Nevada. The dates of the public scoping meetings will be included in notices to be posted in the *Las Vegas Sun, Las Vegas Review-Journal,* and *Moapa Valley Progress* 15 days before the meetings.

Public Comment Availability

Comments, including names and addresses of respondents, will be available for public review at the mailing address shown in the **ADDRESSES** section during regular business hours, 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. 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.

Authority

This notice is published in accordance with 40 CFR 1501.7 of the Council of Environmental Quality regulations and 43 CFR 46.235 of the Department of the Interior Regulations implementing the procedural requirements of the NEPA (42 U.S.C. 4321 *et seq.*), and in accordance with the exercise of authority delegated to the Principal Deputy Assistant Secretary—Indian Affairs by part 209 of the Department Manual.

Dated: December 21, 2018.

Tara Sweeney,

Assistant Secretary—Indian Affairs.

[FR Doc. 2019–00899 Filed 2–1–19; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLWY–957000–18–L13100000–PP0000]

Notice of Stay of Filing of Plat of Survey, Wyoming

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of stay of filing of plat of survey, Wyoming.

SUMMARY: The Bureau of Land Management (BLM) has placed a stay on the filing of a plat of survey of the following described land, pending consideration of the protest and/or appeal that was filed within 30 calendar

days of publication in this **Federal Register**. A plat will not be officially filed until after disposition of protest and/or appeal.

FOR FURTHER INFORMATION CONTACT: Sonja Sparks, BLM Wyoming Chief Cadastral Surveyor at 307–775–6225 or *s75spark@blm.gov.* Persons who use a telecommunications device for the deaf may call the Federal Relay Service at 1–800–877–8339 to contact this office during normal business hours. The Service is available 24 hours a day, 7 days a week, to leave a message or question with this office. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The lands surveyed are: The plat and field notes representing the dependent resurvey of a portion of the east and west boundaries, and portions of the subdivisional lines, designed to restore the corners in their true original locations according to the best available evidence, Township 33 North, Range 70 West, Sixth Principal Meridian, Wyoming, Group No. 979, was accepted November 8, 2018. This survey was executed to determine boundaries of Federal Interest Minerals.

Copies of the preceding described plats and field notes are available to the public at a cost of $4.20 per plat and $.13 per page of field notes.

Dated: January 29, 2019.

Sonja S. Sparks,

Chief Cadastral Surveyor, Division of Support Services.

[FR Doc. 2019–00868 Filed 2–1–19; 8:45 am]

BILLING CODE 4310–22–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0027117; PPWOCRADN0–PCU00RP14.R50000]

Notice of Intent To Repatriate Cultural Items: San Diego Museum of Man, San Diego, CA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The San Diego Museum of Man, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, has determined that the cultural items listed in this notice meet the definition of unassociated funerary objects and sacred objects. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request to the San Diego Museum of Man. If no additional claimants come forward, transfer of control of the cultural items to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request with information in support of the claim to the San Diego Museum of Man at the address in this notice by March 6, 2019.

ADDRESSES: Ben Garcia, San Diego Museum of Man, 1350 El Prado, Balboa Park, San Diego, CA 32101, telephone (619) 239 -2001 ext.17, email *bgarcia@muesumofman.org.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3005, of the intent to repatriate cultural items under the control of the San Diego Museum of Man that meet the definition of unassociated funerary objects and sacred objects under 25 U.S.C. 3001.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American cultural items. The National Park Service is not responsible for the determinations in this notice.

History and Description of the Cultural Items

At an unknown date, sometime between the years of the 1920's and 1950's, 1,506 cultural items were removed from site CA–SDI–5017, also referred to as W–150, in the area of Rose Canyon in Pacific Beach, San Diego County, CA. Malcolm Rogers excavated these items on behalf of the San Diego Museum of Man for the purpose of archeological reconnaissance. Artifacts were also collected by a property owner Mr. Carroll D. Scott and were later donated to the San Diego Museum of Man on March 15, 1956. Human remains were believed to be associated with this site. Per consultation with Kumeyaay Nation representatives, human remains were subsequently discovered on a date after the 1950's. The 1,504 unassociated funerary items are: 46 modified faunal bone, 78 unmodified faunal bone, nine ceramic—other, one mixed decorated ceramic sherd, one rim decorated ceramic sherd, 410 undecorated body ceramic sherds, 14 undecorated rim sherds, 34 stone bifaces, eight choppers, three chipped stone cores, six chipped stone core tools, two chipped stone other, 348 projectile points, 26 chipped stone scrapers, 138 unworked flakes, four utilized flakes, 21 manos, one metate, two mortars, 71 groundstone—other, one pestle, 29 shaft straighteners, two historic ceramic pieces, 17 ecofacts, 128 modified shell, 79 unmodified shell (including 10 lots), four soil midden samples, 17 battered stone, and four stone—other.

At an unknown date, sometime between the years of the 1920's and 1950's, three sacred objects were removed from site CA–SDI–5017, also referred to as W–150, in the area of Rose Canyon in Pacific Beach, San Diego County, CA. Malcolm Rogers excavated these sacred objects on behalf of the San Diego Museum of Man for the purpose of archeological reconnaissance. Per consultation with the Kumeyaay Nation representatives, it was determined that these sacred objects are specifically used for traditional Kumeyaay religious ceremonies. Based upon consultation, these items meet the definition and criteria of sacred objects. The three sacred objects are two groundstone pestles and one ecofact.

At an unknown date, sometime between the years of the 1920's and 1950's, 63 cultural items were removed from site CA–SDI–11,767, also referred to as W–175, in the area of Mission Valley, San Diego County CA. Malcolm Rogers excavated these items on behalf of the San Diego Museum of Man for the purpose of archeological reconnaissance. Human remains were believed to be associated with this site. An updated report dated 10/5/1995 indicated an excavation and reburial of human remains beneath a rock cairn. The 63 unassociated funerary items are: Five chipped stone choppers, 17 chipped stone scrappers, two groundstone mono, six battered stones, five ecofacts, three chipped stone cores, one groundsone-other, seven chipped stone-unworked flakes, one chipped stone biface, five undecorated body ceramic sherds, 10 shell-unmodified, and one shell-modified.

Sites CA–SDI–5017 and CA–SDI–11,767 are all located within territory traditionally occupied by the Kumeyaay Nation as represented by The Tribes. Based on cultural resources collection research, geographic location, ethnographic information, oral history evidence and consultation with the Tribes these items have been culturally affiliated as Kumeyaay.

Determinations Made by the San Diego Museum of Man

Officials of the San Diego Museum of Man have determined that:

• Pursuant to 25 U.S.C. 3001(3)(B), 1,567 cultural items described above are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony and are believed, by a preponderance of the evidence, to have been removed from a specific burial site of a Native American individual.

• Pursuant to 25 U.S.C. 3001(3)(C), three cultural items described above are specific ceremonial objects needed by traditional Native American religious leaders for the practice of traditional Native American religions by their present-day adherents.

• Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the unassociated funerary objects, sacred objects and The Kumeyaay Nation, as represented by the Campo Band of Diegueno Mission Indians of the Campo Indian Reservation, California; Capitan Grande Band of Mission Indians of California (Barona Group of Capitan Grande Band of Mission Indians of the Barona Reservation, California; Viejas (Baron Long) Group of Capitan Grande Band of Mission Indians of the Viejas Reservation, California); Ewiiaapaayp Band of Kumeyaay Indians, California; Iipay Nation of Santa Ysabel, California (previously listed as the Santa Ysabel Band of Diegueno Mission Indians of the Santa Ysabel Reservation); Inaja Band of Diegueno Indians of the Inaja and Cosmit Reservation, California; Jamul Indian Village of California; La Posta Band of Diegueno Mission Indians of the La Posta Indian Reservation, California; Manzanita Band of Diegueno Mission Indians of the Manzanita Reservation, California; Mesa Grande Band of Diegueno Mission Indians of the Mesa Grande Reservation, California; San Pasqual Band of Diegueno Mission Indians of California; and the Sycuan Band of the Kumeyaay Nation, hereafter referred to as ''The Tribes.''

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request with information in support of the claim to Ben Garcia, San Diego Museum of Man, 1350 El Prado, Balboa Park, San Diego, CA 32101, telephone (619) 239 -2001 ext.17, email *bgarcia@muesumofman.org,* by March 6, 2019. After that date, if no additional claimants have come forward, transfer of control of the unassociated funerary objects and sacred objects to The Kumeyaay Nation, as represented by The Tribes, may proceed.

The San Diego Museum of Man is responsible for notifying The Tribes that this notice has been published.

Dated: December 4, 2018.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2019–00835 Filed 2–1–19; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0027141; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: U.S. Fish and Wildlife Service, Anchorage, AK and the University of Alaska Museum of the North, Fairbanks, AK

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Alaska Region, U.S. Fish and Wildlife Service, and the University of Alaska Museum of the North have completed an inventory of human remains and associated funerary objects, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, and has determined that there is a cultural affiliation between the human remains and associated funerary objects and present-day Indian Tribes or Native Hawaiian organizations. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request to the Alaska Region, U.S. Fish and Wildlife Service and the University of Alaska Museum of the North. If no additional requestors come forward, transfer of control of the human remains and associated funerary objects to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to the Alaska Region, U.S. Fish and Wildlife Service and the University of Alaska Museum of the North at the address in this notice by March 6, 2019.

ADDRESSES: Edward J. DeCleva, Regional Historic Preservation Officer/Archaeologist, U.S. Fish and Wildlife Service, 1011 East Tudor Road, MS–235, Anchorage, AK 99503, telephone (907) 786–3399, email *edward_decleva@fws.gov* and Dr. Joshua Reuther, Curator of Archaeology, University of Alaska Museum of the North, 1962 Yukon Drive, Fairbanks, AK 99775, telephone (907) 474–6945, email *jreuther@alaska.edu.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains and associated funerary objects under the control of the U.S. Fish and Wildlife Service (USFWS) and housed at the University of Alaska Museum of the North. The human remains and associated funerary objects were removed from the Port Moller Hot Springs Village archeological site (XPM–00001), Aleutians East Borough, AK.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by the Alaska Region, USFWS, and the University of Alaska Museum of the North professional staff, in consultation with representatives of the Agdaagux Tribe of King Cove; Chignik Bay Tribal Council (previously listed as the Native Village of Chignik); Chignik Lake Village; Ivanoff Bay Tribe (previously listed as the Ivanoff Bay Tribe and the Ivanoff Bay Village); Native Village of Belkofski; Native Village of Chignik Lagoon; Native Village of False Pass; Native Village of Nelson Lagoon; Native Village of Perryville; Native Village of Port Heiden; Native Village of Unga; Pauloff Harbor Village; Qagan Tayagungin Tribe of Sand Point Village; and the Aleut Corporation (hereafter referred to as ''The Consulting Tribes'').

History and Description of the Remains

In 1960, 1972, 1974, 1982, and 1984, human remains representing, at

minimum, 35 individuals were removed from Port Moller Hot Springs Village archeological site (XPM–00001) near Port Moller on the Alaska Peninsula partially within the boundary of the Alaska Peninsula National Wildlife Refuge, AK. Professional archeological excavations were carried out at the site as early as 1928 and most recently in 2014. Excavations were carried out at the site in 1960 by Chester S. Chard of the University of Wisconsin and Sosuke Sugihara of Meiji University in Japan. Large-scale excavation occurred at the site multiple times throughout the 1970s and 1980s by Hiroaki Okada, an archeologist at Hokkaido University in Japan.

At an unknown time, human remains representing, at minimum, four individuals were removed from the Port Moller area by an unknown individual. These human remains are also housed with the 35 individuals from the Port Moller Hot Springs Village archeological excavations.

In the years since being collected, different portions of these human remains have been held at various institutions and locations. Between 2015 and 2017, the U.S. Fish and Wildlife Service consolidated all 39 sets of human remains from the Port Moller Hot Springs Village Site and Port Moller vicinity at the University of Alaska Museum of the North. These human remains, which consist of cranial and post-cranial elements, belong to fourteen juveniles of unknown sex (Burials PM–1, PM–3, PM–5, PM–6, 72–1, 72 Isolate Remains–2, 82–1, 82–4, 82–5, 82–6, 84–1, 84 Isolate Remains–3, Box 5a–2, Box 5a–3), three adult females (Burials PM–2, PM–7, 84–2), seven adult males (Burials PM–4, 72–2, 72–3, 72–4, 82–2, 82–3, 82–7), nine adults of unknown sex (Burial 72–4a, 72 Isolate Remains–1, 74–1, 82–2a, 82–2b, 84 Isolate Remains–1, 84 Isolate Remains–2, Box 5a–1, Individual 5), and six individuals of unknown sex and unknown age (Burials 74–2, 74–3, 74–4, 82–1a, 82–6a, Individual 4). No known individuals were identified. The 217 associated funerary objects are: one bead, six red ochre samples, 127 animal bones, one triangular shale point, seven chipped-stone artifacts, four hammerstones/abraders, three pieces of worked bone or ivory, two bone pins, one carved ornament, one decorated pin, one whale bone adze, one leister prong, two stone points, two slab stones, one sword-like bone stick, three ivory pendants, eight buttons, five metal objects, one lot of beads and buttons, one length of braided hair, one lot of cloth and leather fragments, 30 leather fragments, one soil sample, and seven pieces of pottery.

The occupation of the Port Moller Hot Springs Village site has been divided into three phases: (1) Around 600 years BP, (2) around 1500 years BP, and (3) around 3000–3500 years BP. The 24 individuals removed from the site in 1960, 1972, 1974, and 1984 have been associated with the later period of occupation, or from approximately 600–1500 years BP. The 11 individuals removed from the site in 1982 are associated with a radiocarbon date from the oldest occupation at the site. Of the four individuals removed from the Port Moller area, three are associated with artifacts indicating a protohistoric or historic age, and one cannot be associated with a date.

The Port Moller region is strategically located at the junction of four important cultural areas: the Aglemiut Eskimo to the northeast, Aleut to the west, the Koniaq Eskimo on Kodiak Island, and the Eskimo of the southwestern interior region of Alaska to the east. Cultural affiliation between the prehistoric populations in the area of the Hot Springs Village site can only be determined through analyses of archeological and human remains, as very little oral history information is known concerning the use of the Port Moller area prior to 1900. Based on the archeological evidence, it is believed that the site is well within the Aleut area of influence, but some archeologists believe that due to the site's strategic location, the culture represented here likely received ideas from several different directions. The burial contexts of the human remains are consistent with those observed for pre-contact Aleut populations; namely, the custom of burying the dead inside compartments of semi-subterranean houses. The physical traits of the human remains have been determined by some as exhibiting a close affinity to the Alaska Eskimo, while others conclude that they represent Paleo-Aleuts. A biological relationship between these human remains and the inhabitants of the Nelson Lagoon area is supported by an ancient DNA study published in 2010.

Determinations Made by the Alaska Region, U.S. Fish and Wildlife Service and the University of Alaska Museum of the North

Officials of the Alaska Region, USFWS, and the University of Alaska Museum of the North have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of 39 individuals of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(3)(A), the 217 objects described in this notice are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and associated funerary objects and the Native Village of Nelson Lagoon.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to Edward DeCleva, Regional Historic Preservation Officer/Archaeologist, U.S. Fish and Wildlife Service, Alaska Region, 1011 East Tudor Road, MS–235, Anchorage, AK 99013, telephone (907) 786–3399, email *edward_decleva@fws.gov,* and Dr. Joshua D. Reuther, Curator of Archaeology, University of Alaska Museum of the North, 907 Yukon Drive, Fairbanks, AK 99775, telephone (907) 474–6945, email *jreuther@alaska.edu,* by March 6, 2019. After that date, if no additional requestors have come forward, transfer of control of the human remains and associated funerary objects to the Native Village of Nelson Lagoon may proceed.

The Alaska Region, U.S. Fish and Wildlife Service and the University of Alaska Museum of the North is responsible for notifying The Consulting Tribes that this notice has been published.

Dated: December 11, 2018.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2019–00837 Filed 2–1–19; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0027112; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Tennessee Valley Authority, Knoxville, TN

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Tennessee Valley Authority (TVA) has completed an inventory of human remains and associated funerary objects in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, and has determined that there is no cultural affiliation between the human remains and associated funerary objects and any present-day Indian Tribes or Native Hawaiian organizations. Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request to TVA. If no additional requestors come forward, transfer of control of the human remains and associated funerary objects to the Indian Tribes or Native Hawaiian organizations stated in this notice may proceed.

DATES: Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to TVA at the address in this notice by March 6, 2019.

ADDRESSES: Dr. Thomas O. Maher, TVA, 400 West Summit Hill Drive, WT11C, Knoxville TN 37902–1401, telephone (865) 632–7458, email *tomaher@tva.gov*.

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains and associated funerary objects under the control of TVA. The human remains and associated funerary objects were removed from archeological sites 40HW44 and 40HW45, Hawkins County, Tennessee.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3) and 43 CFR 10.11(d). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains and associated funerary objects was made by TVA professional staff in consultation with representatives of the Absentee-Shawnee Tribe of Indians of Oklahoma; Alabama-Coushatta Tribe of Texas (previously listed as the Alabama-Coushatta Tribes of Texas); Cherokee Nation; Coushatta Tribe of Louisiana; Eastern Band of Cherokee Indians; Poarch Band of Creeks (previously listed as the Poarch Band of Creek Indians of Alabama); The Chickasaw Nation; The Choctaw Nation of Oklahoma; The Muscogee (Creek) Nation; The Seminole Nation of Oklahoma; and the United Keetoowah Band of Cherokee Indians in Oklahoma; hereafter referred to as ''The Consulted Tribes.''

History and Description of the Remains

From June 23 to August 19, 1976, human remains representing, at minimum, 13 individuals were removed from site 40HW44 in Hawkins County, Tennessee, by the Office of Archaeological Research at the University of Alabama (OAR). TVA acquired this site on April 25, 1975 for the Phipps Bend Nuclear Power Plant project. TVA canceled the planned construction in the 1980s, and subsequently transferred this land to the Industrial Development Board of Hawkins County. This village site was explored using controlled surface collection, trenches, and five randomly placed 1x1 meter excavation units. Sixty-three features (pits, post molds and burials) were excavated. Five radiocarbon dates place the primary occupation during the Early Woodland (1000–300 B.C.) period.

The human remains are primarily adult males. No known individuals were identified. The 132 associated funerary objects include two animal bone fragments; one animal tooth pendant; one antler handle; two beaver incisors; one bone bullroarer; one bone pin; 23 pieces of chert debitage; 69 drilled bear canines; one Ebenezer PP/K; one greenstone celt; 17 Greenville Cluster PP/K; one piece of ground limestone; one ground steatite object; one piece of ground sandstone; one hammerstone; one limestone celt; three Long Branch Fabric Marked sherds; two chert preforms; one piece of red ochre; and two soapstone pendants.

From September 20 to November 15, 1976, human remains representing, at minimum, five individuals were removed from site 40HW45 in Hawkins County, Tennessee, by OAR. TVA acquired this site on April 25, 1975 for the Phipps Bend Nuclear Power Plant project. TVA canceled the planned construction in the 1980s, and subsequently transferred this land to the Industrial Development Board of Hawkins County. The site was explored using controlled surface collection, an eight meter long stratigraphic trench, and five randomly placed 2x2 meter excavation units. One hundred-twenty-four features, primarily pits of varying sizes, were excavated. Human burial units 1, 2 and 6 are from the Long Branch phase (600–400 B.C.) and burial units 4 and 7 from the Phipps phase (700–600 B.C.) of the Early Woodland period.

The human remains are primarily adult females. No known individuals were identified. The eight associated funerary objects include five Ebenezer PP/K; two Greenville Cluster PP/K; and one Nolichucky PP/K.

Determinations Made by the Tennessee Valley Authority

Officials of Tennessee Valley Authority have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice are Native American based on their presence in prehistoric archeological sites and osteological analysis.
- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of 18 individuals of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(3)(A), the 140 objects described in this notice are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- Pursuant to 25 U.S.C. 3001(2), a relationship of shared group identity cannot be reasonably traced between the Native American human remains and associated funerary objects and any present-day Indian Tribe.
- According to final judgments of the Indian Claims Commission or the Court of Federal Claims, the land from which the Native American human remains and associated funerary objects were removed is the aboriginal land of the Cherokee Nation; Eastern Band of Cherokee Indians; and the United Keetoowah Band of Cherokee Indians in Oklahoma.
- Pursuant to 43 CFR 10.11(c)(1), the disposition of the culturally unidentifiable human remains and associated funerary objects may be to the Cherokee Nation; Eastern Band of Cherokee Indians; and the United Keetoowah Band of Cherokee Indians in Oklahoma.

Additional Requestors and Disposition

Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to Dr. Thomas O. Maher, TVA,

400 West Summit Hill Drive, WT11C, Knoxville, TN 37902–1401, telephone (865) 632–7458, email *tomaher@tva.gov,* by March 6, 2019]. After that date, if no additional requestors have come forward, transfer of control of the human remains and associated funerary objects to the Cherokee Nation; Eastern Band of Cherokee Indians; and the United Keetoowah Band of Cherokee Indians in Oklahoma may proceed.

The Tennessee Valley Authority is responsible for notifying The Consulted Tribes that this notice has been published.

Dated: December 4, 2018.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2019–00836 Filed 2–1–19; 8:45 am]

BILLING CODE 4312–52–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. TA–131–045 and TPA–105–006]

U.S.-UK Trade Agreement: Advice on the Probable Economic Effect of Providing Duty-free Treatment for Currently Dutiable Imports

AGENCY: United States International Trade Commission.

ACTION: Cancellation of hearing.

SUMMARY: The Commission has cancelled the hearing scheduled for January 31, 2019 due to the lapse of appropriation between December 22, 2018 and January 25, 2019 and the inability to receive or accept requests to appear or prehearing briefs.

DATES: January 29, 2019.

FOR FURTHER INFORMATION CONTACT: Project Leader David Guberman (202–708–1396 or *david.guberman@usitc.gov*) or Deputy Project Leader Amanda Lawrence (202–205–3185 or *amanda.lawrence@usitc.gov)* for information specific to these investigations. For information on the legal aspects of these investigations, contact William Gearhart of the Commission's Office of the General Counsel (202–205–3091 or *william.gearhart@usitc.gov*). The media should contact Margaret O'Laughlin, Office of External Relations (202–205–1819 or *margaret.olaughlin@usitc.gov*). 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 these investigations may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION: On December 7, 2018, the United States International Trade Commission (USITC) instituted the above referenced investigations (83 FR 64154, December 13, 2018) and scheduled a public hearing for January 31, 2019. However, due to the lapse in appropriation (December 22, 2018 to January 25, 2019), the USITC was unable to receive or accept requests to appear at the hearing or prehearing briefs from potential witnesses. As a result, the USITC has cancelled the January 31, 2019 hearing. The USITC anticipates rescheduling the hearing, which will be announced in a forthcoming **Federal Register** notice.

By order of the Commission.

Issued: January 30, 2019.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2019–00866 Filed 2–1–19; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms, and Explosives

[Docket No. ATF 2018R–04]

Granting of Relief; Federal Firearms Privileges

AGENCY: Bureau of Alcohol, Tobacco, Firearms, and Explosives (ATF), Department of Justice.

ACTION: Notice of granting restoration of Federal firearms privileges.

SUMMARY: Xisico USA, Inc. (Xisico), has been granted relief from the disabilities imposed by Federal laws by the Director of ATF with respect to the acquisition, receipt, transfer, shipment, transportation, or possession of firearms.

FOR FURTHER INFORMATION CONTACT: Denise Brown, Enforcement Programs and Services; Bureau of Alcohol, Tobacco, Firearms and Explosives, U.S. Department of Justice; 99 New York Avenue NE, Washington, DC 20226; telephone (202) 648–7070.

SUPPLEMENTARY INFORMATION: The Attorney General is responsible for enforcing the provisions of the Gun Control Act of 1968 (GCA), title 18, United States Code (U.S.C.), chapter 44. He has delegated that responsibility to the Director of ATF, subject to the direction of the Attorney General and the Deputy Attorney General. 28 CFR 0.130(a). ATF has promulgated regulations that implement the provisions of the GCA in 27 CFR part 478.

Section 922(g) of the GCA prohibits certain persons from shipping or transporting any firearm in interstate or foreign commerce, or receiving any firearm which has been shipped or transported in interstate or foreign commerce, or possessing any firearm in or affecting commerce. These prohibitions apply to any person who—

(1) Has been convicted in any court of a crime punishable by imprisonment for a term exceeding one year;

(2) Is a fugitive from justice;

(3) Is an unlawful user of or addicted to any controlled substance;

(4) Has been adjudicated as a mental defective or committed to a mental institution;

(5) Is an alien illegally or unlawfully in the United States; or with certain exceptions, aliens admitted to the United States under a nonimmigrant visa;

(6) Has been discharged from the Armed Forces under dishonorable conditions;

(7) Having been a citizen of the United States, has renounced U.S. citizenship;

(8) Is subject to a court order that restrains the person from harassing, stalking, or threatening an intimate partner or child of such intimate partner; or

(9) Has been convicted in any court of a misdemeanor crime of domestic violence.

The term ''person'' is defined in section 921(a)(1) as including ''any individual, corporation, company, association, firm, partnership, society, or joint stock company.'' Section 925(c) of the GCA provides that a person who is prohibited from possessing, shipping, transporting, or receiving firearms or ammunition may make application to the Attorney General to remove the firearms disability imposed under section 922(g) ''if it is established to his satisfaction that the circumstances regarding the disability, and the applicant's record and reputation, are such that the applicant will not be likely to act in a manner dangerous to public safety and that the granting of the relief would not be contrary to the public interest.'' The Attorney General has delegated the authority to grant relief from firearms disabilities to the Director of ATF.

Section 925(c) further provides that ''[w]henever the Attorney General grants relief to any person pursuant to this section he shall promptly publish in the **Federal Register** notice of such action, together with the reasons therefor.'' Regulations implementing the provisions of section 925(c) are set forth in 27 CFR 478.144.

Since 1992, Congress has prohibited ATF from expending appropriated funds to investigate or act upon applications for relief from federal firearms disabilities. However, since 1993 Congress has authorized ATF to expend appropriated funds to investigate and act upon applications filed by corporations for relief from Federal firearms disabilities.

An application to ATF for relief from Federal firearms disabilities under 18 U.S.C. 925(c) was submitted for Xisico. In the matter under review, Xisico was convicted in Federal court of crimes punishable by imprisonment for a term exceeding one year. Specifically, Xisico was convicted on October 6, 2011, in the United States District Court for the Southern District of Texas, for a violation of 18 U.S.C. 541.

Pursuant to 18 U.S.C. 925(c), on November 1, 2018, Xisico was granted relief by ATF from the disabilities imposed by Federal law, 18 U.S.C. 922(g)(1), with respect to the acquisition, receipt, transfer, shipment, transportation, or possession of firearms as a result of this conviction. It has been established to ATF's satisfaction that the circumstances regarding Xisico's disabilities and its record and reputation are such that Xisico will not be likely to act in a manner dangerous to public safety, and that the granting of the relief would not be contrary to the public interest.

Date Approved: January 3, 2019.

Thomas E. Brandon,

Deputy Director.

[FR Doc. 2019–00854 Filed 2–1–19; 8:45 am]

BILLING CODE 4410–FY–P

DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms and Explosives

[OMB Number 1140–0052]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Strategic Planning Environmental Assessment Outreach

AGENCY: Bureau of Alcohol, Tobacco, Firearms and Explosives, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Department of Justice (DOJ), Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), will submit the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: The proposed information collection was previously published in the **Federal Register**, on November 5, 2018, allowing for a 60-day comment period. Comments are encouraged and will be accepted for an additional 30 days until March 6, 2019.

FOR FURTHER INFORMATION CONTACT: If you have additional comments, particularly with respect to the estimated public burden or associated response time, have suggestions, need a copy of the proposed information collection instrument with instructions, or desire any other additional information, please contact Charlayne Armentrout, Office of Strategic Management either by mail at 99 New York Avenue NE, Washington, DC 20226, by email at *Charlayne.Armentrout@atf.gov,* or by telephone at 202–648–7099.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension, without change, of a currently approved collection.

(2) *The Title of the Form/Collection:* Strategic Planning Environmental Assessment Outreach.

(3) *The agency form number, if any, and the applicable component of the Department sponsoring the collection:*

Form number: None.

Component: Bureau of Alcohol, Tobacco, Firearms and Explosives, U.S. Department of Justice.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: Business or other for-profit.

Other: Not-for-profit Institution, Federal Government, State, Local or Tribal Government.

Abstract: The Office of Strategic Management at ATF will use the information to help identify and validate the agency's internal strengths and weaknesses.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimated 1,500 respondents will utilize the survey, and it will take each respondent approximately 18 minutes to respond once to this Information Collection.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The estimated annual public burden associated with this collection is 450 hours, which is equal to 1,500 (# of respondents) * (.318 minutes).

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E.405A, Washington, DC 20530.

Dated: January 30, 2019.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2019–00839 Filed 2–1–19; 8:45 am]

BILLING CODE 4410–14–P

DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms and Explosives

[OMB Number 1140–0074]

Agency Information Collection Activities; Proposed eCollection eComments Requested; List of Responsible Persons

AGENCY: Bureau of Alcohol, Tobacco, Firearms and Explosives, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Department of Justice (DOJ), Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), will submit the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: The proposed information collection was previously published in the **Federal Register**, on November 8, 2018, allowing for a 60-day comment period. Comments are encouraged and will be accepted for an additional 30 days until March 6, 2019.

FOR FURTHER INFORMATION CONTACT: If you have additional comments, particularly with respect to the estimated public burden or associated response time, have suggestions, need a copy of the proposed information collection instrument with instructions, or desire any other additional information, please contact Shawn Stevens, Federal Explosives Licensing Center, either by mail at 244 Needy Road, Martinsburg, WV 25405, by email at *Shawn.Stevens@atf.gov,* or by telephone at 304–616–4400. Written comments and/or suggestions can also be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20503 or sent to *OIRA_submissions@omb.eop.gov*.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension, without change, of a currently approved collection.

(2) *The Title of the Form/Collection:* List of Responsible Persons.

(3) *The agency form number, if any, and the applicable component of the Department sponsoring the collection:*

Form number: None.

Component: Bureau of Alcohol, Tobacco, Firearms and Explosives, U.S. Department of Justice.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: Business or other for-profit.

Other: None.

Abstract: 27 CFR Section 555.57, requires that all persons holding ATF explosives licenses or permits as of May 23, 2003, report descriptive information about their responsible persons and possessors of explosives to ATF. Subsequent changes to their list of responsible persons must also be reported to ATF.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimated 50,000 respondents will utilize this information collection, and it will take each respondent approximately 1 hour to provide their responses twice a year.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The estimated annual public burden associated with this collection is 100,000 hours, which is equal to 50,000 (# of respondents) * 2 (# responses per person) * 1 hour (total time taken to respond).

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E.405A, Washington, DC 20530.

Dated: January 30, 2019.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

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DEPARTMENT OF JUSTICE

Antitrust Division

United States v. Bayer AG et al.; Response to Public Comments

Pursuant to the Antitrust Procedures and Penalties Act, 15 U.S.C. § 16(b)-(h), the United States hereby publishes below the Response to Public Comments on the Proposed Final Judgment in *United States v. Bayer AG et al.,* Civil Action No. 1:18-cv-01241 (JEB), which was filed in the United States District Court for the District of Columbia on January 29, 2019, together with copies of the 14 comments received by the United States.

Pursuant to the Court's January 2, 2019 order, comments were published electronically and are available to be viewed and downloaded at the Antitrust Division's Web site, at: *https://www.justice.gov/atr/case/us-v-bayer-ag-and-monsanto-company.* A copy of the United States' response to the comments is also available at the same location. Copies of the comments and the United States' response are available for inspection at the Office of the Clerk of the United States District Court for the District of Columbia. Copies of these materials may also be obtained from the Antitrust Division upon request and payment of the copying fee set by Department of Justice regulations.

Patricia A. Brink,

Director of Civil Enforcement.

United States District Court for the District of Columbia

United States of America, Plaintiff, v. Bayer AG, Monsanto Company, and BASF SE, Defendants.

Civil Action No. 1:18-cv-01241 (JEB)

RESPONSE OF PLAINTIFF UNITED STATES TO PUBLIC COMMENTS ON THE PROPOSED FINAL JUDGMENT

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I. Introduction

Pursuant to the requirements of the Antitrust Procedures and Penalties Act (the ''APPA'' or ''Tunney Act''), 15 U.S.C. §§ 16(b)–(h), the United States hereby responds to the public comments received regarding the proposed Final Judgment in this case. For the reasons set forth below, the remedy the United States obtained from Defendants addresses the competitive harm alleged in this action and is in the public interest. Accordingly, the United States recommends no modifications to the proposed Final Judgment.

This remedy is a victory for American farmers and consumers. It fully addresses the competitive threat posed by the merger by vesting the divestiture buyer, BASF, with the full complement of assets, personnel, and rights needed to preserve competition in each of the 17 affected markets. It requires divestitures that go beyond what would be needed to address the current horizontal overlaps or vertical concerns in order to ensure that BASF can step into Bayer's shoes, thereby preserving the competition that otherwise would be lost through the merger. It provides for the transfer of over 4,000 Bayer employees so that BASF will have the necessary expertise to run these divested businesses, and it provides for time-limited interim support agreements to avoid business disruptions during the transition period. It also incorporates further safeguards that allow BASF to obtain additional assets and personnel, if necessary, during the first year of operating these businesses. In short, the United States has gone to extraordinary lengths to ensure that BASF will seamlessly and successfully replace Bayer as an independent and vigorous competitor in each of the affected markets.

The competitive significance of the remedy is underscored by the $9 billion divestiture purchase price, which exceeds the value of most *mergers* reviewed by the United States and far exceeds the value of most merger remedies. Indeed, it is among the largest and most comprehensive remedies obtained by the United States in a merger challenge. As one commenter observes, ''the $9 billion divestiture, by which BASF would acquire Bayer's position in genetically modified seeds and seed traits, foundational herbicides, other crop seeds, and related research and development efforts appears to be as robust a divestiture as might be imagined.'' [1]

The United States received fourteen comments reflecting a wide array of views. After careful consideration of these comments, the United States has determined that nothing in them casts doubt on its conclusion that the public interest is well-served by the proposed remedy. The United States is publishing the comments and this response on the Antitrust Division website and is submitting to the **Federal Register** this response and the website address at which the comments may be viewed and downloaded, as set forth in the Court's order dated January 2, 2019 (Docket No. 21). Following **Federal Register** publication, the United States will move the Court to enter the proposed Final Judgment pursuant to 15 U.S.C. § 16(d).

II. Procedural History

On September 14, 2016, Bayer AG entered into an agreement to acquire Monsanto Company in a merger valued at approximately $66 billion. On May 29, 2018, the United States filed a civil antitrust Complaint seeking to enjoin Bayer from acquiring Monsanto. The Complaint alleges that the proposed acquisition would substantially lessen competition for the sale of a range of agricultural products to farmers in the United States in violation of Section 7 of the Clayton Act, 15 U.S.C. § 18.

Simultaneously with the filing of the Complaint, the United States filed a proposed Final Judgment, a stipulation signed by the parties that consents to entry of the proposed Final Judgment after compliance with the requirements of the Tunney Act, and a Competitive Impact Statement describing the transaction and the proposed Final Judgment. The United States caused the Complaint, the proposed Final Judgment, and Competitive Impact Statement to be published in the **Federal Register** on June 13, 2018, *see* 83 Fed. Reg. 27652 (June 13, 2018), and caused notice regarding the same, together with directions for the submission of written comments relating to the proposed Final Judgment, to be published in *The Washington Post* on June 5–11, 2018 and in the *St. Louis Post-Dispatch* on June 3, 4, 6, and 8–11, 2018. The 60-day period for public comment ended on August 13, 2018. The United States received 14 comments (Exhibits 1 through 14).

III. Standard of Judicial Review

The Clayton Act, as amended by the APPA, requires that proposed consent judgments in antitrust cases brought by the United States be subject to a 60-day comment period, after which the court shall determine whether entry of the proposed Final Judgment ''is in the

[1] Ducore Comment (attached as Exhibit 6) at 1.

public interest.'' 15 U.S.C. § 16(e)(1). In making that determination, the court, in accordance with the statute as amended in 2004, is required to consider:

(A) the competitive impact of such judgment, including termination of alleged violations, provisions for enforcement and modification, duration of relief sought, anticipated effects of alternative remedies actually considered, whether its terms are ambiguous, and any other competitive considerations bearing upon the adequacy of such judgment that the court deems necessary to a determination of whether the consent judgment is in the public interest; and

(B) the impact of entry of such judgment upon competition in the relevant market or markets, upon the public generally and individuals alleging specific injury from the violations set forth in the complaint including consideration of the public benefit, if any, to be derived from a determination of the issues at trial.

15 U.S.C. § 16(e)(1)(A) & (B). In considering these statutory factors, the court's inquiry is necessarily a limited one as the government is entitled to ''broad discretion to settle with the defendant within the reaches of the public interest.'' *United States v. Microsoft Corp.,* 56 F.3d 1448, 1461 (D.C. Cir. 1995); *see generally United States v. SBC Commc'ns, Inc.,* 489 F. Supp. 2d 1 (D.D.C. 2007) (assessing public interest standard under the Tunney Act); *United States v. U.S. Airways Group, Inc.,* 38 F. Supp. 3d 69, 75 (D.D.C. 2014) (explaining that the ''court's inquiry is limited'' in Tunney Act settlements); *United States v. InBev N.V./S.A.,* No. 08–1965 (JR), 2009 U.S. Dist. LEXIS 84787, at *3 (D.D.C. Aug. 11, 2009) (noting that the court's review of a consent judgment is limited and only inquires ''into whether the government's determination that the proposed remedies will cure the antitrust violations alleged in the complaint was reasonable, and whether the mechanisms to enforce the final judgment are clear and manageable'').

As the United States Court of Appeals for the District of Columbia Circuit has held, under the APPA a court considers, among other things, the relationship between the remedy secured and the specific allegations in the government's complaint, whether the decree is sufficiently clear, whether its enforcement mechanisms are sufficient, and whether the decree may positively harm third parties. *See Microsoft,* 56 F.3d at 1458–62. With respect to the adequacy of the relief secured by the decree, a court may not ''engage in an unrestricted evaluation of what relief would best serve the public.'' *United States v. BNS, Inc.,* 858 F.2d 456, 462 (9th Cir. 1988) (quoting *United States v. Bechtel Corp.,* 648 F.2d 660, 666 (9th Cir. 1981)); *see also Microsoft,* 56 F.3d at 1460–62; *United States v. Alcoa, Inc.,* 152 F. Supp. 2d 37, 40 (D.D.C. 2001); *InBev,* 2009 U.S. Dist. LEXIS 84787, at *3. Instead:

> [t]he balancing of competing social and political interests affected by a proposed antitrust consent decree must be left, in the first instance, to the discretion of the Attorney General. The court's role in protecting the public interest is one of insuring that the government has not breached its duty to the public in consenting to the decree. The court is required to determine not whether a particular decree is the one that will best serve society, but whether the settlement is ''*within the reaches of the public interest.*'' More elaborate requirements might undermine the effectiveness of antitrust enforcement by consent decree.

Bechtel, 648 F.2d at 666 (emphasis added) (citations omitted).[2]

In determining whether a proposed settlement is in the public interest, a district court ''must accord deference to the government's predictions about the efficacy of its remedies, and may not require that the remedies perfectly match the alleged violations.'' *SBC Commc'ns,* 489 F. Supp. 2d at 17; *see also U.S. Airways,* 38 F. Supp. 3d at 74–75 (noting that a court should not reject the proposed remedies because it believes others are preferable and that room must be made for the government to grant concessions in the negotiation process for settlements); *Microsoft,* 56 F.3d at 1461 (noting the need for courts to be ''deferential to the government's predictions as to the effect of the proposed remedies''); *United States v. Archer-Daniels-Midland Co.,* 272 F. Supp. 2d 1, 6 (D.D.C. 2003) (noting that the court should grant ''due respect to the government's prediction as to the effect of proposed remedies, its perception of the market structure, and its views of the nature of the case''). The ultimate question is whether ''the remedies [obtained in the decree are] so inconsonant with the allegations charged as to fall outside of the 'reaches of the public interest.' '' *Microsoft,* 56 F.3d at 1461 (*quoting United States v. Western Elec. Co.,* 900 F.2d 283, 309 (D.C. Cir. 1990)). To meet this standard, the United States ''need only provide a factual basis for concluding that the settlements are reasonably adequate remedies for the alleged harms.'' *SBC Commc'ns,* 489 F. Supp. 2d at 17.

Moreover, the court's role under the APPA is limited to reviewing the remedy in relationship to the violations that the United States has alleged in its complaint, and does not authorize the court to ''construct [its] own hypothetical case and then evaluate the decree against that case.'' *Microsoft,* 56 F.3d at 1459; *see also U.S. Airways,* 38 F. Supp. 3d at 75 (noting that the court must simply determine whether there is a factual foundation for the government's decisions such that its conclusions regarding the proposed settlements are reasonable); *InBev,* 2009 U.S. Dist. LEXIS 84787, at *20 (''the 'public interest' is not to be measured by comparing the violations alleged in the complaint against those the court believes could have, or even should have, been alleged''). Because the ''court's authority to review the decree depends entirely on the government's exercising its prosecutorial discretion by bringing a case in the first place,'' it follows that ''the court is only authorized to review the decree itself,'' and not to ''effectively redraft the complaint'' to inquire into other matters that the United States did not pursue. *Microsoft,* 56 F.3d at 1459–60.

In its 2004 amendments to the APPA,[3] Congress made clear its intent to preserve the practical benefits of utilizing consent decrees in antitrust enforcement, adding the unambiguous instruction that ''[n]othing in this section shall be construed to require the court to conduct an evidentiary hearing or to require the court to permit anyone to intervene.'' 15 U.S.C. § 16(e)(2); *see also U.S. Airways,* 38 F. Supp. 3d at 76 (indicating that a court is not required to hold an evidentiary hearing or to permit intervenors as part of its review under the Tunney Act). This language explicitly wrote into the statute what Congress intended when it first enacted the Tunney Act in 1974. As Senator Tunney explained: ''[t]he court is nowhere compelled to go to trial or to

[2] *See also BNS,* 858 F.2d at 464 (holding that the court's ''ultimate authority under the [APPA] is limited to approving or disapproving the consent decree''); *United States v. Gillette Co.,* 406 F. Supp. 713, 716 (D. Mass. 1975) (noting that, in this way, the court is constrained to ''look at the overall picture not hypercritically, nor with a microscope, but with an artist's reducing glass'').

[3] The 2004 amendments substituted ''shall'' for ''may'' in directing relevant factors for a court to consider and amended the list of factors to focus on competitive considerations and to address potentially ambiguous judgment terms. *Compare* 15 U.S.C. § 16(e) (2004), *with* 15 U.S.C. § 16(e)(1) (2006); *see also SBC Commc'ns,* 489 F. Supp. 2d at 11 (concluding that the 2004 amendments ''effected minimal changes'' to Tunney Act review).

engage in extended proceedings which might have the effect of vitiating the benefits of prompt and less costly settlement through the consent decree process.'' 119 Cong. Rec. 24,598 (1973) (statement of Sen. Tunney). Rather, the procedure for the public interest determination is left to the discretion of the court, with the recognition that the court's ''scope of review remains sharply proscribed by precedent and the nature of Tunney Act proceedings.'' *SBC Commc'ns,* 489 F. Supp. 2d at 11. A court can make its public interest determination based on the competitive impact statement and response to public comments alone. *U.S. Airways,* 38 F. Supp. 3d at 76; *see also United States v. Enova Corp.,* 107 F. Supp. 2d 10, 17 (D.D.C. 2000) (noting that the ''Tunney Act expressly allows the court to make its public interest determination on the basis of the competitive impact statement and response to comments alone''); S. Rep. No. 93–298, 93d Cong., 1st Sess., at 6 (1973) (''Where the public interest can be meaningfully evaluated simply on the basis of briefs and oral arguments, that is the approach that should be utilized.'').

IV. The Investigation and the Proposed Final Judgment

The proposed Final Judgment is the culmination of a thorough, comprehensive investigation conducted by the Antitrust Division of the United States Department of Justice. Based on the evidence gathered during its investigation, the United States concluded that Bayer's proposed acquisition of Monsanto would likely substantially lessen competition in 17 product markets in the agricultural industry, resulting in higher prices, less innovation, fewer choices, and lower-quality products for American farmers and consumers. Accordingly, the United States filed a civil antitrust lawsuit to block the acquisition as a violation of Section 7 of the Clayton Act, 15 U.S.C. § 18.

The proposed Final Judgment provides an effective and appropriate remedy for the transaction's likely competitive harm by requiring Bayer to divest its business in each relevant market, along with various supporting assets, to BASF, a global chemical company with an existing crop protection business. The United States identified a divestiture package that remedies all dimensions of harm threatened by the proposed merger. First, the proposed Final Judgment requires Bayer to divest those businesses that vigorously compete head-to-head with Monsanto today. Second, the proposed Final Judgment requires Bayer to divest seed treatment businesses that, when combined with Monsanto's seed business, would have given the combined company the incentive and ability to harm competition by raising the prices it charges rival seed companies. Third, because Bayer and Monsanto compete to develop new products and services for farmers, the proposed Final Judgment requires the divestiture of associated intellectual property and research capabilities, including ''pipeline'' projects, to enable BASF to replace Bayer as a leading innovator in the relevant markets. Fourth, the proposed Final Judgment requires the divestiture of additional assets that will give BASF the scale and scope to compete effectively today and in the future.

Specifically, Bayer is required to divest its entire global row crop seeds and traits business (with insignificant exceptions not relevant to the United States), its entire global vegetable seeds business, and all related research and development (''R&D'') assets. Bayer also must divest significant crop protection assets, including its global glufosinate ammonium business and IP and other assets to allow BASF to continue Bayer's efforts in developing new foundational herbicide systems. Finally, Bayer is required to divest certain seed treatments for corn, soy, and cotton.

Because many of the divested assets will be separated from Bayer's existing business units and incorporated into BASF, the proposed Final Judgment includes provisions aimed at ensuring that the assets are handed off in a seamless and efficient manner. To that end, Bayer is required to transfer existing third-party agreements and customer information to BASF, as well as to enter transition services agreements that ensure that BASF can continue to serve customers immediately upon completion of the divestitures. The transition services and interim supply agreements are time-limited to ensure that BASF will become fully independent of Bayer as soon as practicable.

The proposed Final Judgment also contemplates heightened safeguards intended to ensure that BASF is receiving everything it needs to replace Bayer as a competitor. The proposed Final Judgment requires Bayer to warrant that the assets being divested are sufficient for BASF to maintain the viability and competitiveness of the divested businesses following BASF's acquisition of the assets. In addition, the proposed Final Judgment gives BASF a one-year window after closing to identify any additional assets that are reasonably necessary to ensure the continued competitiveness of the divested businesses. The United States will have sole discretion to determine if Bayer must divest these additional assets. Finally, the proposed Final Judgment gives BASF a one-year window to hire all of the personnel from Bayer needed to support these businesses. These novel provisions strengthen the remedy by allowing BASF to identify additional assets or employees it needs to compete effectively after it has operated the divested businesses for a certain period of time.

The divestitures will ensure that BASF can step into Bayer's shoes, thereby preserving the competition that the merger would otherwise destroy. The proposed Final Judgment provides for the appointment of a monitoring trustee to have close oversight over the divestitures and the transitional agreements between Bayer and BASF to ensure that they proceed appropriately. The proposed Final Judgment also includes robust mechanisms that will allow the United States and the Court to monitor the effectiveness of the relief and to enforce compliance. And because the United States has determined that BASF, as the divestiture buyer, is a necessary party to effectuate complete relief, BASF has agreed to be joined to this action for the purposes of the divestitures.

V. Summary of Public Comments and the United States' Response

The United States received public comments from a group of state Attorneys General; certain Members of Congress; the National Federation of Independent Businesses (''NFIB''); Syngenta, a seed and agrochemical company; Daniel Ducore, former Assistant Director of the FTC Bureau of Competition's Compliance Division; Daniel Bellemare, an attorney; the Sierra Club; the Natural Resources Defense Council (''NRDC''); the Consumer Federation of America; ActionAid USA; the National Family Farm Coalition; Friends of the Earth; the Sustainable Food Center; and the Pollinator Stewardship Council.

Certain commenters acknowledge the meaningful protections for competition that the United States achieved, even as they advocate for modifications to the proposed Final Judgment. Syngenta, one of the Defendants' primary competitors, states that it ''believes that the [proposed Final Judgment] remedies many of the most complex and difficult anticompetitive aspects of the transaction.'' [4] Similarly, Daniel Ducore,

[4] Syngenta Comment (Exhibit 12) at 1.

who served for more than 25 years as Assistant Director of the division that oversaw all of the FTC's merger and non-merger remedies, notes that the remedy ''appears to be as robust a divestiture as might be imagined,'' and further observes that while ''[e]very remedy raises risks about the scope of divested assets, the particular buyer, and the implementation of the remedy,'' here the United States ''appears to have done everything possible to reduce those risks.'' [5]

The comments can be grouped into six categories: (1) BASF's suitability as a divestiture buyer, including whether it will have sufficient assets, expertise, and incentives to preserve competition; (2) concerns that BASF could fail to execute the remedy in a way that effectively preserves competition; (3) concerns about whether the proposed Final Judgment properly addresses issues related to seed treatments; (4) concerns that the remedy will not prevent the combined Bayer/Monsanto from leveraging its strengths in certain areas—in particular, digital agriculture and traits—to foreclose competition in other markets; (5) procedural matters, including government oversight and enforcement of proposed Final Judgment compliance; and (6) other miscellaneous comments, including general concerns about consolidation in the agricultural industry; concerns relating to the environment, wildlife and human health; and concerns that the United States' review process may have been influenced by politics. The comments are summarized in more detail below:

- A number of commenters express concern about BASF's suitability as a divestiture buyer and its ability to compete effectively with the divested assets. NRDC and the Attorneys General of California, Iowa, Massachusetts, Mississippi, and Oregon (''State Attorneys General'') express concerns that BASF may not be able to replace Bayer as a competitor, asserting that BASF has no seeds experience, that Monsanto is dominant in the market for genetically modified seeds, and that the divestiture may leave BASF reliant on the merged firm and discourage BASF from competing vigorously.[6] The Consumer Federation of America argues that the United States should have required the merged firm to divest the stronger set of assets to address each competitive overlap.[7] In contrast, Daniel Ducore states that the divestiture package includes everything that BASF could need to operate the divested businesses successfully.[8] Daniel Bellemare raises a different concern, suggesting that if BASF is already well-positioned to enter the relevant markets without the aid of the divested assets, it may not be an appropriate divestiture buyer.[9]
- Daniel Ducore and the State Attorneys General express concerns that BASF will fail to execute its business plans successfully and will therefore fail to replace the competition lost from the merger. Mr. Ducore opines that the divestiture package includes everything that BASF could need to operate the divested businesses successfully but nevertheless expresses concern that ''BASF, even if it obtains everything that was considered necessary and relevant when the remedy was negotiated, will fail to step in for Bayer and compete with the new Bayer-Monsanto as strongly as Bayer had competed with Monsanto before the deal.'' [10] Mr. Ducore urges the United States to monitor BASF's performance over the next few years to evaluate the effectiveness of the settlement. The State Attorneys General recommend that the Court ''order a retrospective study of the effects of the merger on competition two years after transfer of the divestiture assets has begun.'' [11]
- Syngenta and the Sustainable Food Center express concerns about various aspects of the seed treatment divestiture and seek modifications to the proposed Final Judgment's provisions concerning seed treatments. Syngenta asserts that certain provisions of the proposed Final Judgment should be modified to avoid the ''risk [of] reducing competition and inhibiting innovation in the affected product markets'' or otherwise undermining the purpose of the remedy.[12] The Sustainable Food Center seeks a broader divestiture of a class of seed treatments.[13]
- Several commenters, including the National Family Farm Coalition, Friends of the Earth, and NRDC, argue that allowing Bayer to retain Monsanto's leading digital agriculture platform will enhance the merged firm's ability to influence farmer choice in other areas, such as seed and crop protection markets.[14] Friends of the Earth, the Sustainable Food Center, and the Consumer Federation of America offer various suggestions regarding digital agriculture divestitures, including proposing that Monsanto divest its digital agriculture platform or revise its data access policies.[15] NRDC, the Consumer Federation of America, and the Pollinator Stewardship Council also raise broad cross-product leveraging concerns that the merged firm will be in a position to exploit its significant position in certain markets to achieve dominance in other markets.
- Three commenters take issue with various procedural aspects of the settlement. NFIB raises four concerns regarding aspects of the proposed Final Judgment pertaining to the United States' authority to oversee and enforce compliance with the settlement—generally advocating for greater protections for the Defendants—and proposes modifications to address each issue.[16] The State Attorneys General suggest certain measures relating to the enforcement mechanisms in the proposed Final Judgment, such as removing the provision allowing for possible early termination and mandating the appointment of a monitoring trustee.[17] And Daniel Bellemare argues that a public interest determination in a transaction this complex merits more than the limited judicial inquiry that the Tunney Act contemplates.[18]
- Certain commenters express concerns with consolidation in the agricultural industry in general; some of these comments also suggest that the United States should have sued to block this transaction.[19]

[5] Ducore Comment (Exhibit 6) at 1.

[6] NRDC Comment (Exhibit 9) at 3–4; State Attorneys General Comment (Exhibit 2) at 5–7.

[7] Consumer Fed'n of Am. Comment (Exhibit 4) at 1.

[8] Ducore Comment (Exhibit 6) at 5.

[9] Bellemare Comment (Exhibit 5) at 10–12.

[10] Ducore Comment (Exhibit 6) at 1–2.

[11] State Attorneys General Comment (Exhibit 2) at 2–3.

[12] Syngenta Comment (Exhibit 12) at 1.

[13] Sustainable Food Ctr. Comment (Exhibit 11) at 1.

[14] NRDC Comment (Exhibit 9) at 4, 6, 9–10; Friends of the Earth Comment (Exhibit 7) at 2–3; Nat'l Family Farm Coal. Comment (Exhibit 8).

[15] Friends of the Earth Comment (Exhibit 7) at 3–4; Consumer Fed'n of Am. Comment (Exhibit 4) at 2; Sustainable Food Ctr. Comment (Exhibit 11).

[16] NFIB Comment (Exhibit 13).

[17] State Attorneys General Comment (Exhibit 2) at 2–3.

[18] Bellemare Comment (Exhibit 5) at 12–15.

[19] In addition to their own comments, certain advocacy groups submitted lists of names of individuals supporting the group's comments and, in some cases, separate messages from individual members of the general public. These individual messages were not sent directly to the Division by their authors. ActionAid USA's submission included a list of more than 1,200 individual supporters of its comments. The Sierra Club enclosed more than 18,000 signatures and roughly

Continued

- A number of commenters, including Sierra Club, NRDC, ActionAid USA, and the National Family Farm Coalition, argue that the merger will have a negative effect on the environment, wildlife and human health.[20]
- A group of 27 Members of Congress refer to media reports that raise the possibility that the White House may have unduly influenced the review of this and other transactions. They urge that antitrust enforcement ''continue to be treated as a law enforcement matter properly left to the independent judgment of DOJ.'' [21]

a. Comments Regarding BASF's Suitability as a Divestiture Buyer and Ability to Compete Effectively

Comments questioning BASF's ability to preserve competition fall into two general categories: (1) BASF's ability to succeed with the divested assets and (2) BASF's incentives to compete aggressively against the merged company. The United States carefully considered these issues in crafting the proposed remedy. The proposed Final Judgment requires Bayer to divest a broad range of assets—essentially its entire global seeds and traits business as well as its digital agriculture business and important crop protection products—and to provide an array of transitional services. While it is impossible to predict with certainty how well BASF will perform with the divested assets (just as Bayer's own performance with those assets absent the merger is not certain), the proposed remedy ensures that BASF will be as well-positioned as possible and have the necessary incentives to step into Bayer's shoes to replace the competition that otherwise would be lost through the merger.

i. The Proposed Divestitures Give BASF Everything Necessary to Preserve Competition

The State Attorneys General assert that the proposed Final Judgment ''trusts that BASF can immediately step into the shoes of Bayer in the market'' with the divestiture assets and express concern about the consequences if BASF is not able to do so.[22] They also observe that BASF ''does not currently make seeds and has never run a seeds business.'' [23] Other commenters likewise express doubt about BASF's ability to replace Bayer as a competitor.[24]

The United States crafted the remedy specifically taking into account BASF's existing assets and capabilities.[25] The fact that United States has not identified viable alternative buyers is not a weakness in the remedy as some commenters might suggest,[26] but rather a reflection of the importance of the buyer to the remedy here and the high standard that the United States applied in evaluating potential buyers for the divested assets. BASF is a large multinational firm with extensive experience operating in jurisdictions around the world. And while it is correct that BASF has not owned a seed business, BASF has extensive agricultural experience in crop protection and trait research—closely related businesses that it will integrate with the seed businesses it is acquiring from Bayer.

This remedy is the result of a careful and thorough investigation, during which the United States scrutinized the merging parties' and BASF's businesses and operations to identify a comprehensive package of assets to be divested. The United States has structured the proposed remedy to position BASF to be as strong of a competitor as Bayer in the affected markets. To that end, the required divestitures go beyond what would be needed to address the current horizontal overlaps or vertical concerns in order to ensure that BASF can step into Bayer's shoes, thereby preserving the competition that otherwise would be lost through the merger. They also provide BASF with comparable scale and scope to Bayer and give BASF the assets it needs going forward to be a strong innovator.

Bayer is required to divest its entire global row crop seeds and traits business (with insignificant exceptions not relevant to the United States), its entire global vegetable seeds business, and all related R&D assets. Even though neither Bayer nor Monsanto sells hybrid wheat in the United States, Bayer must divest its entire wheat R&D platform as well as its research facility in Ghent, Belgium that is used to support R&D for wheat and other crops. These broad divestitures assure that BASF will be able to take advantage of cross-crop R&D synergies to the same extent as Bayer today. Similarly, Bayer is divesting its entire vegetable seed business, which encompasses 24 different crops, even though the transaction raises competition concerns in only five vegetable seed markets in the United States.

On the crop protection side, Bayer is divesting not only its global glufosinate ammonium business, which competes with Monsanto's Roundup, but also intellectual property and other assets to allow BASF to continue Bayer's efforts in developing new foundational herbicide systems.[27] Bayer is also required to divest certain seed treatments for corn, soy, and cotton to address horizontal and vertical concerns.[28] BASF is now able to offer these market-leading seed treatment products alongside its cotton and soy seeds, just as Bayer was able to do prior to the merger.

Without the merger, it is anticipated that competition would intensify between Bayer and Monsanto to pursue what the industry calls ''integrated solutions''—combinations of seeds, traits, and crop protection products supported by digital farming technologies and other services.[29] Commenters such as NRDC note the potential importance of digital agriculture tools (which help farmers maximize yields and get the most out of their other agriculture products) to future competition in the industry. Even though integrated solutions are still evolving, the proposed remedy requires Bayer to divest all assets related to Bayer's digital agriculture business, including pipeline products, and to transfer employees supporting these assets and products to BASF. With these assets and employees, BASF will be able to step into Bayer's shoes in pursuing integrated solutions.

As an additional precaution, the proposed Final Judgment requires Bayer

2,500 individual messages. NRDC and Friends of the Earth both submitted, along with their own comments, tens of thousands of what appear to be identical or substantially similar messages from individuals opposed to the merger. In addition, a number of other individuals sent emails about concerns relating to the transaction to the United States using various channels outside of the designated procedures for submitting Tunney Act comments. The United States has reviewed these messages and emails, and none appear to address the substance of the proposed Final Judgment or raise any issue not otherwise addressed in this Response to Comments. Accordingly, the United States has not addressed these lists of names, individual messages, or emails as separate comments and does not intend to file or publish them.

[20] *See, e.g.,* NRDC Comment (Exhibit 9) at 7–10.

[21] Members of Cong. Comment (Exhibit 3) at 2–3.

[22] State Attorneys General Comment (Exhibit 2) at 5.

[23] *Id.*

[24] *See, e.g.,* Consumer Fed'n of Am. Comment (Exhibit 4) at 1; NRDC Comment (Exhibit 9).

[25] *See* Competitive Impact Statement at 31–32.

[26] *See* State Attorneys General Comment (Exhibit 2) at 5.

[27] *See* Proposed Final Judgment § II(U); Complaint ¶ 36.

[28] *See* Complaint ¶ ¶ 38–50.

[29] *See id.* ¶ 61.

to warrant that the divestiture assets are ''sufficient in all material respects for BASF, taking into account BASF's assets and business, to maintain the viability and competitiveness'' of the businesses BASF has acquired.[30] And if BASF determines that Bayer has not divested all of the assets ''reasonably necessary for the continued competitiveness'' of the divested businesses, BASF may notify Bayer and the Monitoring Trustee that it requires those assets, and, in that situation, the United States will determine whether the assets should be divested.[31] One commenter notes that this aspect of the remedy ''perhaps reflect[ed] the Division's efforts to reduce any 'asset package risk' to near zero.'' [32]

BASF will have the benefit of not only all of Bayer's seeds and traits assets, but also of the approximately 4,000 former Bayer employees slated to move to BASF with the divestitures. These employees, who operated the divested businesses day-in and day-out for Bayer, have extensive seeds experience. If BASF determines during the following year that it lacks employees with expertise it needs, it may seek to hire, without any interference from Bayer, any additional Bayer employees who supported the divested businesses in any way since 2015.[33]

Complementing the divested assets and transferring personnel, the proposed remedy requires Bayer to provide transitional support to BASF to ensure that BASF will be able to step into Bayer's competitive shoes. For example, because prior to the merger Bayer was able to sell a suite of its own seed treatments for use on its proprietary canola, cotton, and soy seeds, Bayer is required to provide BASF a supply of these seed treatments at Bayer's cost until BASF is able to develop alternative sources of supply.[34] In addition to the various transition services specifically discussed in the proposed Final Judgment, Bayer is required to provide ''any other transition services reasonably necessary'' to facilitate a seamless transition of the divested businesses from Bayer to BASF.[35] One of the responsibilities of the Monitoring Trustee is to ensure that Bayer lives up to its obligation to provide such transition services to BASF. As Daniel Ducore observes, ''it's hard to identify anything that BASF *might* need that it isn't getting.'' [36]

Voicing a different concern about the sufficiency of the divestiture assets, the Consumer Federation of America writes that ''[t]he chances that BASF will be able to acquire the weaker agricultural assets of the two firms and use them to compete effectively are doubtful.'' [37] Yet Bayer has been a strong competitor even with what the Consumer Federation calls Bayer's ''weaker agricultural assets.'' And the proposed Final Judgment ensures that BASF will receive all of the assets it needs (along with transitional support) to step into Bayer's shoes, thereby replacing any competition that would otherwise be lost as a result of the merger. To the extent commenters believe that Monsanto, by itself, held too much market power prior to the merger, that concern is not specific to the merger and not within the four corners of the United States' Complaint. *See U.S. Airways,* 38 F. Supp. 3d at 76 (''Moreover, the Court's role under the APPA is limited to reviewing the remedy in relationship to the violations that the United States has alleged in its Complaint. . . .'') (quoting *United States* v. *Graftech Int'l,* No. 10-cv-2039, 2011 WL 1566781, at *13 (D.D.C. Mar. 24, 2011)).

While the proposed Final Judgment requires the merging parties to divest Bayer's assets, and not Monsanto's, it also does not permit them to pick and choose among Bayer's and Monsanto's assets to divest only the weakest links in each company's portfolio. Bayer is not divesting Monsanto's canola business, even though Monsanto has a much smaller market share than Bayer in canola.[38] Bayer is divesting its entire global vegetable seeds business (Nunhems) even though Bayer's share for certain vegetable seeds is larger than Monsanto's.[39] Similarly, Bayer is required to divest its market-leading nematicidal seed treatment products, which enjoy over a 95% share for corn and 85% share for soy, rather than Monsanto's NemaStrike product, which has only recently become available for commercial sale.[40]

The required divestitures are also not wholly limited to Bayer assets. Bayer is a relatively new entrant to the soybean business in the United States. It has emerged as a serious threat to Monsanto in the southern United States, but it lacks germplasm and varieties suitable to the Midwest, an important soybean growing region. To help strengthen BASF as a competitor to the merged company (and other firms), the merged company is obligated to divest not only Bayer's global soybean business, but also certain groups of Monsanto soybeans used for research and breeding.[41] These Monsanto assets will help make BASF a stronger competitor in the Midwest than Bayer was before the merger.

In contrast to some commenters' concern that BASF may not be able to compete effectively with the seed assets it is acquiring from Bayer, Daniel Bellemare questions whether BASF would have entered the seeds markets and become a significant competitor on its own without the divestitures.[42] Even for a large company with substantial resources such as BASF, however, barriers to entry in these markets are high.[43] BASF needs Bayer's extensive libraries of seeds and other assets to compete as an integrated firm on a global scale in seeds and traits.

ii. BASF Has a Strong Incentive to Compete Aggressively Against Bayer

Certain commenters also express concern that BASF will lack sufficient incentive to compete against the merged company due to the number of post-divestiture agreements between BASF and Bayer as well as BASF's interest in dicamba production.[44] These concerns do not cast doubt on the strength of the proposed remedy. The proposed Final Judgment incentivizes BASF to compete aggressively against Bayer and other competitors, and encourages BASF to become independent from Bayer as soon as is reasonably possible.

Bayer is obligated under the proposed Final Judgment to provide various forms of transitional support to BASF. These arrangements lead the State Attorneys General to suggest that, ''[b]ecause BASF will have to rely on Bayer to make these assets work, the company will have a disincentive to anger Bayer.'' [45] The tolling, supply, and transition service agreements are designed to eliminate any potential gaps in BASF's ability to fully compete with the divested assets from the outset. The intention is not to establish an ''ongoing, close relationship'' between BASF and Bayer as the State Attorneys

[30] Proposed Final Judgment § IV(F)(1).

[31] *Id.* § IV(F)(2).

[32] Ducore Comment (Exhibit 6) at 4.

[33] *See* Proposed Final Judgment § IV(E).

[34] *See id.* § IV(G)(1).

[35] *See id.* § IV(H)(4).

[36] Ducore Comment (Exhibit 6) at 5.

[37] Consumer Fed'n of Am. Comment (Exhibit 4) at 1.

[38] *See* Complaint ¶ 28 (Bayer's share is 60%; Monsanto's share is 14%).

[39] *See, e.g., id.* ¶ 58 (Bayer's share of watermelon seeds is much larger than Monsanto's).

[40] *See* Complaint ¶¶ 41–42.

[41] Proposed Final Judgment §§ IV(N), II(S).

[42] Bellemare Comment (Exhibit 5) at 10–12.

[43] *See* Complaint ¶ 62.

[44] State Attorneys General Comment (Exhibit 2) at 6–7; NRDC Comment (Exhibit 9) at 2.

[45] State Attorneys General Comment (Exhibit 2) at 6.

General suggest.[46] To the contrary, the proposed Final Judgment sets relatively short initial time periods for these arrangements (generally two years or less), which may be extended only with the approval of the United States. The proposed Final Judgment encourages BASF to end these arrangements as soon as practicable, requiring BASF to use ''best efforts to develop or procure alternative sources of supply by the end of the initial periods'' for tolling and supply agreements, and ''to develop alternative solutions by the end of the initial periods'' for transition service agreements.[47] The Monitoring Trustee will closely track BASF's progress towards operating without reliance on Bayer.[48] In the meantime, BASF will not have to pull its competitive punches out of concern that Bayer will stop providing the tolling, supply, or other transitional services that it needs. Bayer's obligations are clearly stated in the proposed Final Judgment (and detailed in separate agreements between BASF and Bayer), and the Monitoring Trustee will assess whether Bayer is fulfilling its responsibilities.

NRDC suggests that BASF may not be an effective competitor to the merged company because of BASF's existing interest in the herbicide dicamba.[49] The United States carefully considered BASF's premerger role as a supplier of dicamba to Monsanto in evaluating BASF's suitability as a buyer of the divestiture assets. As the owner of Bayer's glufosinate ammonium business and the LibertyLink traits, BASF will earn returns from selling seed containing the LibertyLink traits, licensing those traits to third party seed companies, and selling the Liberty herbicides. These interests will greatly outweigh any benefit BASF would gain, as a supplier of dicamba, from Monsanto's sale of seed containing Monsanto's dicamba-tolerance traits.[50] Further, the proposed remedy is structured so that BASF will not only have an appropriate incentive to promote its already-commercialized LibertyLink traits, but also traits that potentially would compete with Monsanto's dicamba-tolerance traits in the future, such as isoxaflutole tolerance.[51]

b. Comments Regarding BASF's Ability to Execute the Remedy Successfully and Requests for Ongoing Study

Three commenters—the State Attorneys General, Daniel Ducore, and Consumer Federation of America—raise concerns that the size and complexity of the proposed remedy create uncertainty as to whether BASF will be able to execute its current plans successfully and preserve competition at premerger levels. As Mr. Ducore describes his concern, there remains a risk that BASF ''will fail to step in for Bayer and compete with the new Bayer-Monsanto as strongly as Bayer had competed with Monsanto before the deal,'' notwithstanding that the remedy package ''appears to be as robust a divestiture as might be imagined.'' [52] The commenters do not propose any specific measures that could be incorporated to reduce these risks. Nor do they urge the court to block the merger. Instead, Mr. Ducore and the State Attorneys General propose that the United States commit to conduct a retrospective study on the success of the settlement in preserving competition, with the State Attorneys General requesting that this Court order that the study be conducted two years after the divestitures have been completed.[53] The commenters argue that the uncertainty inherent in the large and complex transfer of businesses and assets justifies greater oversight of BASF's future operations than the government would typically undertake in conjunction with a merger settlement. Mr. Ducore proposes a particularly extensive ''ongoing assessment,'' including, for example, tracking BASF's ongoing performance, assessing BASF's evaluation of its R&D projects, and reviewing BASF's sales and pricing levels.[54]

An obligatory retrospective study of the effects of this merger and settlement on competition is not necessary to protect the public interest. As described more fully in Section V(a), the United States has incorporated a number of safeguards in the proposed Final Judgment to ensure that BASF will be fully capable of stepping into Bayer's shoes as an effective competitor. The United States intends to monitor the divestitures to ensure that all of the assets and businesses are transferred to BASF in accordance with the terms of the proposed Final Judgment, and it has even taken the unusual step of requesting the appointment of a monitoring trustee to supplement the government's oversight of this process. The Monitoring Trustee has authority to access the relevant company personnel, books, records, and other pertinent information to ensure that Defendants comply with their obligations, and the trustee will provide regular updates to the United States on Defendants' compliance.[55] The Trustee will continue to monitor compliance with the proposed Final Judgment for as long as the transitional agreements required by the proposed Final Judgment remain in place (unless this period shortened or extended by the United States).[56] Thus, the proposed Final Judgment contemplates several years of oversight by the Monitoring Trustee with regular reporting to the United States to address issues that may arise with respect to the remedy.

That said, the United States deliberately crafted the proposed Final Judgment as a complete and permanent structural resolution that remedies the antitrust violations alleged in the Complaint without the need for future government involvement in BASF's (or Bayer's) business operations. A retroactive assessment would not help shape the remedy in this matter. The commenters do not explain how they expect the United States to use the results of the assessment they would require, but they may be suggesting that the United States should require additional remedies in the future in the event the post-hoc review reveals deficiencies in the settlement. As a law enforcement agency, the United States is ill-equipped to continually oversee broader market operations as suggested by the commenters. The United States should not be second-guessing, for example, BASF's business plans or R&D investments several years from now, when many of the relevant circumstances may have changed from today. Indeed, as it would be impossible to predict with certainty how well Bayer would have performed with the divested assets absent the merger, it also would be impossible to assess with certainty BASF's performance in comparison. To the contrary, once the

[46] *Id.* at 7.

[47] Proposed Final Judgment §§ IV(G)(10); (H)(6).

[48] Nor will Bayer want the transitional agreements to continue longer than necessary, as Bayer is required during the initial terms to provide the tolling and other services at variable cost (or better). Proposed Final Judgment §§ IV(G), (H).

[49] NRDC Comment (Exhibit 9) at 2.

[50] It is also unclear for how long (or to what extent) BASF will continue to supply dicamba to Monsanto. In 2017, Monsanto broke ground on a $975 million expansion of a facility in Louisiana to produce dicamba. *See, e.g., https://monsanto.com/news-releases/monsanto-board-of-directors-approves-expansion-in-luling-louisiana/.*

[51] To ensure that BASF has a similar incentive to Bayer to commercialize and promote these traits, Bayer is required to provide BASF with a supply of isoxaflutole at Bayer's cost and to use best efforts to obtain regulatory approvals for the use of isoxaflutole over soybeans and cotton containing an isoxaflutole-tolerance trait. Proposed Final Judgment §§ IV(G)(2); (L)(3).

[52] Ducore Comment (Exhibit 6) at 1–2.

[53] State Attorneys General Comment (Exhibit 2) at 2–3.

[54] Ducore Comment (Exhibit 6) at 5–7.

[55] Proposed Final Judgment §§ VIII(G), (H).

[56] *Id.* § VIII(J).

United States has remedied the antitrust violations—as the proposed Final Judgment does here—competition, not the government, should determine how individual competitors and the market as a whole perform going forward.

c. Comments Regarding Seed Treatments

Two commenters raise questions relating to seed treatments. Syngenta generally supports the proposed Final Judgment, noting that it ''resolves many of the most complex and difficult anticompetitive aspects of the Transaction;'' [57] however, Syngenta seeks modifications to provisions that require Bayer to supply BASF with seed treatments and proposes restrictions on BASF's ability to sell divested seed treatments to Bayer. In addition, the Sustainable Food Center proposes that all of Bayer's neonicotinoid seed treatments be divested to BASF. We respond to each of these comments below.

i. The Proposed Final Judgment Appropriately Requires Bayer to Supply Seed Treatments to BASF at Variable Cost

The proposed Final Judgment requires Bayer to supply certain seed treatments products to BASF at ''variable cost'' for a limited period of time to ensure continuity of seed treatment supply for the divested businesses.[58] Syngenta expresses concern that the term ''variable cost'' is susceptible to different interpretations and could ''permit BASF the opportunity to buy the products at a fraction of their full production costs,'' which would give BASF ''a cost advantage above any competitor'' and ''distort normal competitive dynamics'' for these products.[59] In particular, Syngenta asserts that the agribusiness usage of the term ''variable cost'' would include only ''direct input costs'' (such as the cost of raw materials), and exclude other costs that would vary with production levels, resulting in BASF paying too little for these products.[60] Essentially, Syngenta appears to be concerned that BASF may get too good a deal from Bayer on seed treatment products, which could make it more challenging for Syngenta, the second largest seed treatment supplier, to compete with BASF. Syngenta asks that the proposed Final Judgment be ''clarified to note that 'variable cost' is defined more broadly than its typical industry definition to include an appropriate allocation of fixed costs.'' [61] To accomplish this, Syngenta proposes amending the proposed Final Judgment to require Bayer to supply BASF these seed treatment products at ''fully absorbed cost,'' an accounting measure that includes an allocation of certain fixed costs.[62]

Syngenta's concerns are misplaced, and the proposed Final Judgment changes that Syngenta requests are not necessary. The seed treatment supply provisions aim to place BASF in the same cost position as Bayer before the merger. By doing so, the remedy preserves competition during the transition period since BASF's pricing decisions will be based on the same underlying cost structure as Bayer prior to the merger. To accomplish this, the proposed Final Judgment uses the economic concept of ''variable cost,'' *i.e.,* ''that part of cost which varies with the level of output.'' [63] This measure of costs will capture costs that directly relate to Bayer's production of seed treatments for BASF—including, for example, a per-unit allocation for machine use, where appropriate—regardless of the accounting label that industry participants might place on any specific cost item. Thus, there is no basis for concern that Bayer will be selling seed treatments to BASF at a fraction of the production costs. To the contrary, BASF will fully reimburse Bayer for the costs directly related to producing these seed treatment products.

Syngenta's proposal to change the cost standard for seed treatments would also introduce needless complication. Bayer is required to provide several additional products and services at ''variable cost'' for the purpose of placing BASF in the same cost position as Bayer before the merger. Amending the proposed Final Judgment to introduce another cost standard specific to seed treatments would create confusion in addition to being unnecessary. It would also create a risk that Bayer would face conflicting obligations across jurisdictions, as the European Commission and other jurisdictions have imposed the same variable cost requirements as the United States in their respective settlement documents.[64]

ii. BASF Cannot Resell Bayer Seed Treatments Supplied under Section IV(G)(1) for Use on Non-BASF Seeds

Section IV(G)(1) of the proposed Final Judgment requires Bayer to supply BASF with the seed treatments that Bayer is not divesting to BASF but that Bayer has been using in the divested seed businesses. These provisions allow BASF to seamlessly continue marketing the same combinations of seeds and seed treatments that Bayer offered before the merger while BASF transitions to alternative sources of supply. Syngenta suggests, however, that this section could be read to permit BASF to resell these Bayer seed treatments for use on other companies' seeds in competition with Syngenta, Bayer, and other producers of seed treatments. Syngenta proposes amending the proposed Final Judgment to expressly prohibit this.[65]

Syngenta's proposed amendment is unnecessary, as it would merely repeat what is already clear from the text of the proposed Final Judgment. The title of Section IV(G)(1) makes plain that the provision relates to ''Seed Treatment Supply Agreements *for* Broad Acre Seeds and Traits Business,'' [66] that is, the agreements are intended to supply the Broad Acre Seeds and Traits business BASF is acquiring from Bayer. Moreover, the body of the provision limits its scope to Bayer seed treatments that have been ''used by Bayer in the Broad Acre Seeds and Traits Business.'' [67] The European Commission Commitments likewise prohibit resale because they require Bayer to supply these seed treatments to BASF for use on BASF seeds.[68] Given that Section IV(G)(1) is limited to the supply of seed treatments to BASF for use on its own

[57] Syngenta Comment (Exhibit 12) at 1.

[58] Proposed Final Judgment at § IV(G).

[59] Syngenta Comment (Exhibit 12) at 1, 3–4.

[60] *Id.* at 3.

[61] *Id.* at 4.

[62] *Id.*

[63] *See, e.g., Variable cost,* Oxford Dictionary of Economics (5th ed. 2017).

[64] *See, e.g.,* European Commission, Case M.8084—Bayer/Monsanto, Modification of Commitments, Schedule, at ¶ 21, p. 39 (divested seed treatments to be tolled at variable cost), at ¶ 68(c) (glufosinate formulations supplied at variable cost), and 9, 13, 28, 65 and 67 (transitional supplies or services will be supplied by Bayer at variable cost), dated April 11, 2018, available at *http://ec.europa.eu/competition/mergers/cases/decisions/m8084_12985_3.pdf;* Competition Commission of India, Order under Section 31(7) of the Competition Act, Combination Registration No. C–2017/08/523, at ¶ 180(c), p. 54 (glufosinate formulation to be supplied at variable cost) and ¶ 181, p. 54 (transitions supplies or services provided at variable cost), dated June 14, 2018, available at *https://www.cci.gov.in/sites/default/files/Notice_order_document/Order_14.06.2018.pdf.*

[65] Syngenta Comment (Exhibit 12) at 2.

[66] Proposed Final Judgment § IV(G)(1) (emphasis added).

[67] *Id.* § IV(G)(1).

[68] *See* European Commission, Case M.8084—Bayer/Monsanto, Modification of Commitments, Schedule, at ¶ 66(d) and 66(e), p. 52 (in connection with the divestiture of Broad Acre Seeds and Traits, requiring Bayer to supply seed treatment ''used on'' divested canola seeds and seed treatment ''for divested cotton and soy varieties''), dated April 11, 2018, available at *http://ec.europa.eu/competition/mergers/cases/decisions/m8084_12985_3.pdf.*

seeds, Syngenta's proposed amendment should be rejected.

iii. The Proposed Final Judgment Allows BASF to Sell Seed Treatments to Bayer

Syngenta is also concerned that nothing prevents BASF from entering into arm's-length commercial agreements to supply Bayer with the seed treatments products it is obtaining through the divestitures. Syngenta contends that allowing BASF to enter into such an agreement with Bayer would undermine the remedy because it would ''permit Bayer to recreate the sort of product bundles that were the source of significant concern in the Transaction.'' [69] Syngenta proposes to close the purported ''loophole'' by amending the proposed Final Judgment to prohibit BASF from selling divested seed treatments to Bayer except for use in Bayer's branded seed business.[70]

Syngenta's concerns are based on a fundamental misunderstanding of the United States' theory of harm relating to seed treatments and the basis for requiring divestiture of certain seed treatment products. The United States has alleged that the merger would substantially lessen competition through the vertical integration of Bayer and Monsanto in one respect: By combining Monsanto's strong position in corn and soybean seeds with Bayer's dominant position in certain seed treatments, the merger would give the combined company the incentive and ability to harm its seed rivals by raising the price of those seed treatments—a key input for genetically modified seeds. For example, before the merger, Bayer sold the only seed treatment that effectively controls a destructive pest called corn rootworm. Because Bayer did not sell corn seeds itself, it had a strong incentive to sell that seed treatment to all corn seed companies, including Monsanto's rivals. But the merger changes this calculus because Bayer now owns Monsanto, the largest supplier of corn seeds in the United States. If Bayer were permitted to retain its corn seed treatment, it would have a strong incentive to raise the price of that treatment to its seed rivals (or stop selling it altogether), knowing that its rivals rely on the product and would be less able to compete effectively without it.

In other words, the possibility that Bayer may continue to use the divested seed treatments on its seeds does not, in and of itself, give rise to competitive harm. Rather, the problem is one of incentives. By vesting control of both products in one firm, the merger would create an incentive for the combined firm to raise its rivals' costs to make it harder for them to compete to sell seeds. To ensure that the merger does not give rise to this incentive to foreclose other competitors, the United States has required Bayer to divest certain seed treatments to BASF. In doing so, the United States has preserved the competitive status quo: The seeds and seed treatments remain under the control of different firms, Bayer and BASF, respectively. Accordingly, the divestiture of these seed treatments to BASF fully resolves the vertical foreclosure allegations in the Complaint.

iv. Concerns Regarding All Neonicotinoid Seed Treatments Are Outside the Scope of the Complaint

Sustainable Food Center comments that the merger should not be permitted unless Bayer divests, among other things, all its ''neonicotinoid seed treatments.'' [71] ''Neonicotinoids'' refer to a particular chemical class of insecticides. Under the proposed Final Judgment, Bayer will divest seed treatments based on the chemical clothianidin, which is one type of neonicotinoid. Bayer also sells seed treatments based on the chemicals imidacloprid and thiacloprid, two other types of neonicotinoid. The Complaint does not include a claim relating to these types of seed treatments. Accordingly, there is no basis for requiring Bayer to divest these products as a condition of approving the merger.

d. Comments Related to Digital Agriculture and Cross-Product Leveraging

Several commenters argue that allowing Bayer to retain Monsanto's leading digital agriculture platform will enhance the merged firm's ability to influence farmer choice in other areas, such as seed and crop protection markets.[72] Digital agriculture, although still emerging, refers to tools and services that allow farmers to collect, store, process, or interpret data about their crops. Digital agriculture is expected to drive an industry trend toward ''integrated solutions''—combinations of seeds, traits, and crop protection products supported by digital farming technologies and other services. Certain commenters argue that the merged firm will be able to use its platform to recommend its own products, ''locking in'' farmers to the merged firm's portfolio of products.[73] Several commenters urge the United States to seek to block the merger altogether based on these concerns.[74] Other commenters propose modifications to the settlement on this basis. For example, Friends of the Earth and the Consumer Federation of America argue that Monsanto's digital agriculture platform should be divested instead of Bayer's.[75] Friends of the Earth also suggests that the merged firm should be required to update its privacy policy to allow farmers to more easily remove data from its digital agriculture platform.[76] Consumer Federation similarly urges the Court to impose ''rigorous open access conditions'' for its digital agriculture interfaces.[77]

The United States has not alleged anticompetitive effects arising from Bayer's acquisition of Monsanto's digital agriculture platform. Nonetheless, the United States recognizes that BASF's ability to compete in the future in the individual seed and crop protection markets that are subject of the Complaint may depend on the strength of BASF's digital agriculture platform. The leading global agricultural businesses (including Bayer and Monsanto) project that digital agriculture will be a key driver of seed and crop protection sales in the future. To ensure BASF has the digital agriculture capabilities it needs to replace Bayer as a competitor going forward, the proposed Final Judgment requires Bayer to divest all assets related to its digital agriculture portfolio and pipeline of products to BASF. Although Bayer's digital agriculture products are not as developed as Monsanto's, the divestiture provides BASF with similar

[69] Syngenta Comment (Exhibit 12) at 2.

[70] *Id.* at 2–3.

[71] Sustainable Food Ctr. Comment (Exhibit 11).

[72] NRDC Comment (Exhibit 9) at 4, 6, 9–10; Friends of the Earth Comment (Exhibit 7) at 2–3; Nat'l Family Farm Coal. Comment (Exhibit 8).

[73] NRDC Comment (Exhibit 9) at 4 (asserting that the bundled products would ''effectively turn farmers into captured users''); Friends of the Earth Comment (Exhibit 7) at 3 (alleging that the merged firm will be ''well-positioned to continue leveraging'' Monsanto's platform ''to sell more of its products''); Nat'l Family Farm Coal. Comment (Exhibit 8) at 1 (arguing that the merged firm will be able to ''leverage the sale of one product into another''); Pollinator Stewardship Council Comment (Exhibit 10) at 2 (observing that ''fewer technology 'platforms' will dominate the marketplace,'' making it hard for smaller companies to compete, and ''farmers will be locked into using these platforms as fewer choices will be available in the marketplace'').

[74] *See, e.g.,* NRDC Comment (Exhibit 9); Nat'l Family Farm Coal. Comment (Exhibit 8); Friends of the Earth Comment (Exhibit 7).

[75] Friends of the Earth Comment (Exhibit 7) at 3–4; Consumer Fed'n of Am. Comment (Exhibit 4) at 1.

[76] Friends of the Earth Comment (Exhibit 7) at 3–4.

[77] Consumer Fed'n of Am. Comment (Exhibit 4) at 2.

scale, scope, and innovation incentives as Bayer before the merger.

Comments advocating for open access to digital agriculture data or for particular privacy policy provisions should be rejected as requests for regulatory relief. The merger does not directly implicate these issues. Moreover, behavioral remedies that require firms to commit to particular business actions, such as requiring open access or particular privacy provisions, are disfavored mechanisms for addressing the effects of a merger, as they are inherently more difficult to craft and administer and they risk unintended consequences. For example, imposing a remedy that restricts the behavior of one competitor (the merged firm) but not others may interfere with the competitive marketplace. The structural divestiture of Bayer's digital agriculture assets raises none of these concerns.

Several commenters also express broad concerns that the merged firm, by virtue of its broader portfolio of products including Monsanto's digital agriculture platform, will be able to leverage its significant position in certain markets to foreclose competition in other markets.[78] Many of these cross-product leveraging concerns appear to be animated by Monsanto's significant presence in traits: Commenters fear that the merger will give the combined Bayer/Monsanto new opportunities to leverage its strength in trait markets to foreclose competition in other, unspecified, markets. For example, NRDC argues that Monsanto has leveraged its ''virtual monopoly power'' in seeds in anticompetitive ways in the past, and that a ''larger, more-powerful Bayer/Monsanto corporation would be in an equal if not better position to do so in the future by denying access to key traits, charging monopoly prices, or coercing its competitors into anti-competitive collaboration.'' [79]

To the extent the commenters have concerns about anticompetitive effects in markets beyond those alleged in the Complaint and remedied by the proposed Final Judgment, the commenters have not identified them. Nor do the commenters explain why the merger, as remedied, would result in such harm. It would be inappropriate to require a remedy for such broad, amorphous concerns, unsupported by the rigorous antitrust analysis the law requires. Furthermore, any such concerns go beyond the allegations in the complaint and are thus beyond the scope of Tunney Act review. *See U.S. Airways,* 38 F. Supp. 3d at 76 (''Moreover, the Court's role under the APPA is limited to reviewing the remedy in relationship to the violations that the United States has alleged in its Complaint. . . .'') (quoting *Graftech,* 2011 WL 1566781, at *13). Going forward, the antitrust laws will continue to apply to the merged firm, and the United States will challenge practices that run afoul of applicable statutes.

e. Comments Regarding Procedural Matters, Including Government Oversight and Enforcement of Proposed Final Judgment Compliance

Several commenters express concerns about procedural aspects of the proposed Final Judgment. One commenter argues that the judicial review procedures set forth in the APPA may be inapt in large transactions requiring complicated divestitures. Another commenter argues that the proposed Final Judgment should require, rather than permit, the appointment of a monitoring trustee. Two commenters are concerned that the proposed Final Judgment's jurisdictional provisions are inadequate. One commenter fears that the proposed Final Judgment's enforcement provisions improperly favor the United States. As explained below, these concerns lack merit and do not require any amendment of the proposed Final Judgment.

i. The Standard of Review Established by Congress Is Appropriate

One commenter, Daniel Bellemare, argues that a proposed decree remedying the anticompetitive effects of a complex transaction such as Bayer's acquisition of Monsanto may not be suited for a public interest review under the APPA.[80] Mr. Bellemare suggests instead that a trial or preliminary injunction hearing may be a better forum for the resolution of complicated antitrust issues.[81]

Irrespective of the size or nature of a transaction, the APPA requires a court to conduct a limited public interest determination when reviewing a proposed decree. Congress vested authority in the Department of Justice, rather than the courts, to investigate and prosecute violations of the Federal antitrust laws. *See* 28 C.F.R. §§ 0.40, 0.41; 15 U.S.C. §§ 4, 9, 15a. This prosecutorial authority includes the ability to craft remedies, such as the proposed Final Judgment. In light of the fact that a proposed decree is the product of the United States' exercise of prosecutorial discretion, courts have interpreted the APPA to permit only a limited inquiry into whether a settlement is ''within the reaches of the public interest.'' *Microsoft,* 56 F.3d at 1458–61 (citation omitted). The court's public interest determination focuses on whether the settlement appropriately addresses the allegations identified in the complaint. *Id.* at 1458–59; *see also SBC Commc'ns,* 489 F. Supp. 2d at 11 (the court's ''scope of review remains sharply proscribed by precedent and the nature of the Tunney Act proceedings''). The APPA does not require a court to expend judicial time and resources considering alternative remedies or probing the adequacy of the complaint itself. The limited judicial review required by the APPA is appropriate for this matter and is not unduly burdensome for this Court.

ii. Modifications Concerning the Monitoring Trustee Are Unnecessary

The State Attorneys General propose that the appointment of a monitoring trustee should be required, rather than left to the ''discretion'' of the United States.[82] This proposal is moot. This Court granted the United States' motion to appoint the Honorable Michael B. Mukasey as Monitoring Trustee on August 14, 2018.

iii. The Proposed Final Judgment's Jurisdictional Provisions Are Sufficient

The State Attorneys General contend that the Court should affirmatively retain jurisdiction throughout the ten-year term of the Final Judgment.[83] The commenters appear to misunderstand the terms of the proposed Final Judgment, which provides that the Court retains jurisdiction, without limitation, to enable any party to seek orders or directions necessary or appropriate to carry out the terms of the proposed Final Judgment.[84]

By its terms, the Final Judgment is to expire ten years from the date of its entry; however, the United States may terminate the Final Judgment after six years if it finds that the divestitures

[78] NRDC Comment (Exhibit 9) at 3; Pollinator Stewardship Council Comment (Exhibit 10) at 3–4; Consumer Fed'n of Am. Comment (Exhibit 4) at 1–2.

[79] NRDC Comment (Exhibit 9) at 3. *See also* Consumer Fed'n of Am. Comment (Exhibit 4) at 1–2 (asserting that the proposed remedy fails to prevent the merged firm from ''expanding its market power and vertical leverage''); Pollinator Stewardship Council Comment (Exhibit 10) at 3–4 (asserting that ''Monsanto can already exert considerable market power through its cross-licensing agreements'' and ''[the merger] would likely lessen competition even further'').

[80] Bellemare Comment (Exhibit 5) at 14–15.

[81] *Id.* at 15.

[82] State Attorneys General Comment (Exhibit 2) at 2.

[83] *Id.*

[84] Proposed Final Judgment § XIII.

have been completed and the continuation of the Final Judgment is no longer necessary or in the public interest.[85] The State Attorneys General ask that the Court require that the proposed Final Judgment, or at least certain of its provisions, remain in place for the full ten-year term, with no option to terminate after six years.[86] This request is unnecessary. The proposed Final Judgment is designed to address the very potential for uncertainty that troubles the State Attorneys General: it allows the decree to remain in place for ten years if competition so requires, but it also reasonably allows for the decree to be terminated earlier if it becomes unnecessary to protect competition.

This flexibility is important because, while equitable relief under the Clayton Act ''should unfetter a market from anticompetitive conduct,'' *Ford Motor Co.* v. *United States,* 405 U.S. 562, 577 (1972), at the same time relief ''must not be punitive,'' *United States* v. *E. I. du Pont de Nemours & Co.,* 366 U.S. 316, 326 (1961). District courts have regularly approved consent decrees providing for the sort of flexibility contemplated here. *See, e.g., United States* v. *Northrup Grumman Corp.,* No. 1:02 CIV 02432, 2003 U.S. Dist. LEXIS 10636, at *26 (D.D.C. June 10, 2003) (approving decree with seven-year term and option for government to seek three-year extension); *United States* v. *Alex Brown & Sons, Inc.,* No. 96 CIV 5313 (RWS), 1997 WL 314390, at *8 (S.D.N.Y. Apr. 24, 1997) (approving decree with a ten-year term except that certain portions of the decree would expire in five years and the Antitrust Division had the option to terminate those portions after only two years); *United States* v. *Lykes Bros. Steamship Co.,* No. CIV.A. 95 1839, 1995 WL 803552, at *4 (D.D.C. Oct. 5, 1995) (approving decree with five-year term and option for government to extend an additional five years).

If, after six years (but before the end of the full ten-year term) the divestitures have been completed and the United States determines that effective competition thereby has been preserved, then the public interest is not served by a continuation of the decree and the associated burdens placed upon the United States, the Defendants, and the Court. It should also be noted that the proposed Final Judgment also includes a provision allowing the United States to seek a one-time extension of the decree in any enforcement proceeding in which the Court finds that the Defendants have violated the decree. In any event, in applying its review function under the Tunney Act, the district court's role is not to make a *de novo* determination of what the public interest requires but rather to determine whether the settlement reflected in the proposed final judgment falls ''within the reaches of the public interest.'' *Massachusetts* v. *Microsoft Corp.,* 373 F.3d 1199, 1237 (D.C. Cir. 2004) (quoting *United States* v. *Microsoft Corp.,* 56 F.3d 1448, 1458 (D.C. Cir. 1995)). This provision falls within those reaches.

In its comment, NFIB complains that the proposed Final Judgment's jurisdictional provision does not explicitly say ''[t]he Court has determined that this matter constitutes a case or controversy.'' [87] This argument has no merit. Although ''a court must assure itself of the existence of subject-matter jurisdiction,'' *Kaplan* v. *Cent. Bank of the Islamic Republic of Iran,* 896 F.3d 501, 511 (D.C. Cir. 2018), a court's written decision need not ''explicitly discuss it,'' *Trans World Airlines* v. *Morales,* 949 F.2d 141, 144 (5th Cir. 1991), *aff'd in part, rev'd in part,* 504 U.S. 374 (1992). More importantly, the Supreme Court has already determined that a proposed antitrust consent decree filed simultaneously with the United States' complaint satisfied Article III's case or controversy requirement because, among other things, ''a suit for an injunction deals primarily, not with past violations, but with threatened future ones.'' *Swift & Co.* v. *United States,* 276 U.S. 311, 326 (1928). It is sufficient, therefore, for the proposed Final Judgment to state that the ''Court has jurisdiction over the subject matter of and each of the parties hereto with respect to this action.'' [88]

iv. The Proposed Final Judgment Appropriately Grants the United States Discretion over Certain Decisions

The NFIB claims the phrase ''sole discretion,'' as it applies to the United States throughout the proposed Final Judgment, ''encourages, if not authorizes, arbitrary action,'' and requests that a new paragraph be inserted in the proposed Final Judgment imposing an explicit duty on the United States ''to act reasonably in the circumstances.'' [89]

Certain aspects of the proposed Final Judgment contemplate flexibility to ensure that the assets are handed off smoothly and effectively. For example, Paragraph IV(F)(2) of the proposed Final Judgment provides that, within one year, if BASF determines that additional Bayer assets are reasonably necessary for the continued competitiveness of the divested businesses, BASF may request that the United States require Bayer to divest additional assets. This provision allows BASF to fill any gaps that could not reasonably be foreseen before it started operating those businesses. At the same time, an efficient and impartial arbiter is needed to ensure that any such requests are valid. With respect to this and all other provisions allowing the United States to exercise its discretion, the United States intends to strike a balance between ensuring that BASF has the resources to replace Bayer as an independent and vigorous competitor and guarding against BASF seeking more from Bayer than is necessary or BASF relying on Bayer for transition services for longer than necessary.

The term ''sole discretion'' appears regularly in consent decrees approved by this and other courts as in the public interest. *See, e.g., United States* v. *Heraeus Electro-Nite Co., LLC,* No. 1:14–CV–00005–JEB, 2014 U.S. Dist. LEXIS 62755, at *6 (D.D.C. Apr. 7, 2014) (approving antitrust consent decree ordering divestiture ''to an Acquirer acceptable to the United States, in its sole discretion''); *United States* v. *Anheuser-Busch InBev SA/NV,* No. CV 13–127(RWR), 2013 U.S. Dist. LEXIS 167309, at *14 (D.D.C. Oct. 21, 2013) (approving decree providing that ''United States, in its sole discretion, may agree to one or more extensions of [] time period [to complete divestiture]''). NFIB's suggestion ignores that ''a presumption of regularity attaches to the actions of Government agencies'' such as the Department of Justice. *U.S. Postal Serv.* v. *Gregory,* 534 U.S. 1, 10 (2001) (citing *United States* v. *Chem. Found., Inc.,* 272 U.S. 1, 14–15 (1926)). NFIB has offered no reason to believe the United States would exercise its discretion other than in ways that it reasonably determines would best advance its longstanding mission of protecting competition and consumers. The proposed modification should be rejected.[90]

v. The Proposed Final Judgment Is Not the Product of ''Economic Leverage''

NFIB misconstrues the proposed Final Judgment when it insists that ''[t]he

[85] *Id.* § XV.

[86] State Attorneys General Comment (Exhibit 2) at 3, 8.

[87] NFIB Comment (Exhibit 13) at 2.

[88] Proposed Final Judgment § I.

[89] NFIB Comment (Exhibit 13) at 2–3.

[90] *See Mission,* U.S. Dep't of Justice Antitrust Div., *https://www.justice.gov/atr/mission* (last updated July 20, 2015) (''The mission of the Antitrust Division is to promote economic competition,'' which ''benefits American consumers through lower prices, better quality and greater choice'').

Court should not permit the Justice Department to use the economic leverage it gained over the Defendants by filing an antitrust lawsuit to pressure the Defendants to give up the assistance of corporate counsel.'' [91] The proposed Final Judgment merely gives the United States the right ''to interview, either informally or on the record, Defendants' officers, employees, or agents,'' for compliance purposes, with ''their individual counsel present.'' [92] That provision does not, however, exclude corporate counsel. NFIB's comment also ignores that ''in the absence of clear evidence to the contrary, courts presume that [government officials] have properly discharged their official duties.'' *Chem. Found.,* 272 U.S. at 14–15.

NFIB similarly complains that the Defendants' agreement to a ''preponderance of the evidence'' standard in decree enforcement proceedings was a product of the United States' purported ''economic leverage.'' [93] The terms of the proposed Final Judgment were determined through negotiation, and both sides benefit in certain ways from the agreement to a preponderance standard. The United States and the public gain by making the investigation and enforcement of antitrust consent decrees more efficient; the clear and convincing evidence standard, which would otherwise apply, would subject the parties to more onerous and resource-intensive investigations. The preponderance standard lessens those burdens, while still ensuring that the United States carries the burden of proving a decree violation. The D.C. Circuit has already recognized that the standard of proof in decree enforcement proceedings can be waived. *See United States* v. *Volvo Powertrain Corp.,* 758 F.3d 330, 338–39 (D.C. Cir. 2014) (concluding that the defendant waived the ''clear and convincing'' standard by oral representation in the district court). NFIB has identified no valid reason why the Defendants' waiver of the clear and convincing standard here should not similarly be honored.

f. Additional Issues Raised By Commenters

i. Commenters Concerned About Industry Consolidation Fail to Acknowledge the Effect of the Remedy

Several commenters oppose the merger based on general concerns about consolidation in the agricultural industry. They view the merger as part of a pattern of consolidation and raise concerns regarding the impact of such consolidation on prices and innovation. For example, the comment by certain Members of Congress notes that this transaction ''comes in the midst of other agro-chemical company mergers . . . and is only the latest example in decades of consolidation in the industry.'' [94] NRDC states that ''today's agricultural inputs markets already resemble the tight, seemingly impenetrable oligopoly that the Clayton Act abhors as a result of considerable and unchecked consolidation over the past twenty years.'' [95] The Sustainable Food Center asserts that ''[f]armers in our network have expressed growing concern with consolidation in the market for agricultural inputs.'' [96] While these commenters cite consolidation as a reason to block the merger, they fail to acknowledge that the remedy ensures that the merger will not increase concentration in the affected markets.[97]

The United States agrees that the proposed merger, unremedied, poses a substantial threat to competition. At the same time, the United States is confident that the proposed divestitures to BASF will fully address those concerns. As detailed above in Section V(a), the proposed Final Judgment will ensure that BASF replaces Bayer as an independent and vigorous competitor in each of the markets in which the merger would otherwise lessen competition. The United States has gone to extraordinary lengths to ensure that this settlement will prevent increased concentration in the affected markets by vesting BASF with the full complement of assets, personnel, and rights needed to preserve competition in the affected markets.

It is well established that courts ''must accord deference to the government's predictions about the efficacy of its remedies.'' *SBC Commc'ns,* 489 F. Supp. 2d at 17. According appropriate deference to the United States here, the proposed settlement is well within ''the reaches of the public interest.'' *Microsoft,* 56 F.3d at 1461.

ii. Comments Regarding the Environmental Impact of Agricultural Chemicals Are Beyond the Scope of this Action

A number of commenters express concerns relating to the environment. Some commenters express broad concerns that the merger would result in environmental harm.[98] Others commenters express general concerns, not specific to the merger, about the effect of agricultural chemicals on wildlife, human health, and the environment.[99] NRDC expresses concern about the effect of the merger on pollinators, specifically that Bayer may seek to leverage Monsanto's seed position to expand the use of neonicotinoid seed treatments and other pesticides, resulting in harm to pollinators.[100]

These comments are beyond the purview of the Tunney Act. The United States did not allege that the merger would result in harm to the environment and, thus, environmental concerns are beyond the scope of this proceeding and do not provide a basis for rejecting the proposed Final Judgment. *See U.S. Airways,* 38 F. Supp. 3d at 76 (''Moreover, the Court's role under the APPA is limited to reviewing the remedy in relationship to the violations that the United States has alleged in its Complaint. . . .'') (quoting *Graftech,* 2011 WL 1566781, at *13).

Moreover, commenters generally concerned about the environmental impact of agricultural chemicals offer no reason why the merger would have an effect on such issues. Similarly, commenters who broadly allege that the merger will result in environmental harm offer no specific basis for their concerns. Regarding NRDC's concern that the merger will increase the use of neonicotinoid seed treatments, as described in Section V(d), the United States carefully considered whether the merger would allow the merged firm to leverage Monsanto's seed position to advance its position in certain seed treatments. Ultimately, the United States did not find a basis to compel the divestiture of all of the neonicotinoid seed treatments that are the subject of NRDC's complaint.

[91] NFIB Comment (Exhibit 13) at 3.

[92] Proposed Final Judgment § X.

[93] NFIB Comment (Exhibit 13) at 4.

[94] Members of Cong. Comment (Exhibit 3) at 1.

[95] NRDC Comment (Exhibit 9) at 4.

[96] Sustainable Food Ctr. Comment (Exhibit 11) at 1.

[97] To the extent that commenters raised substantive issues regarding the efficacy of the relief contained in the proposed Final Judgment to remedy the competitive harm at issue in this transaction we discuss and respond to them above. A number of comments, however, expressed opposition to the merger without addressing any specific aspects of the transaction or the settlement. *See, e.g.,* Pollinator Stewardship Council Comment (Exhibit 10) at 1 (asking the United States to ''block this biotechnology mega-merger''); ActionAid USA Comment (Exhibit 1) at 2 (''The only answer to this merger is NO.'').

[98] ActionAid USA Comment (Exhibit 1) at 1; Members of Cong. Comment (Exhibit 3) at 2.

[99] Sierra Club Comment (Exhibit 14) at 1; Nat'l Family Farm Coal. Comment (Exhibit 8) at 1.

[100] NRDC Comment (Exhibit 9) at 7–10.

iii. The United States Conducted an Impartial and Independent Merger Analysis

Members of Congress refer to news reports that raise the possibility that the White House may have ''exercised outsized influence'' in the review of this transaction and other deals.[101] The commenters do not make any specific claims regarding the investigation of this merger, but rather urge that antitrust enforcement ''continue to be treated as a law enforcement matter properly left to the independent judgment of DOJ.'' [102]

Any suggestion that the settlement at issue here is or could be the result of improper lobbying or political pressure is both unsubstantiated and meritless. The settlement followed a thorough and comprehensive investigation, and it is the result of extensive, good faith negotiations between the United States and Defendants. The proposed Final Judgment requires substantial relief that addresses the competitive harm alleged in the Complaint. In short, there is no basis to allege that the settlement results from anything other than the United States' independent investigation and analysis.

VI. Conclusion

After careful consideration of the public comments, the United States continues to believe that the proposed Final Judgment, as drafted, provides an effective and appropriate remedy for the antitrust violations alleged in the Complaint, and is therefore in the public interest. The United States will move this Court to enter the proposed Final Judgment after the comments and this response are published pursuant to 15 U.S.C. § 16(d).

Dated: January 29, 2019

Respectfully submitted,

J. Richard Doidge, Trial Attorney, U.S. Department of Justice, Antitrust Division, 450 5th Street NW, Suite 8000, Washington, DC 20530, Tel: (202) 514–8944.

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[101] Members of Cong. Comment (Exhibit 3) at 2–3.

[102] *Id.* at 2.

DEPARTMENT OF JUSTICE

[OMB Number 1121–0312]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Revision of a Currently Approved Collection: 2018–2020 Survey of State Criminal History Information Systems (SSCHIS)

AGENCY: Bureau of Justice Statistics, Department of Justice.

ACTION: 30-Day Notice.

SUMMARY: The Department of Justice (DOJ), Office of Justice Programs, Bureau of Justice Statistics, will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 30 days until March 6, 2019.

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 Devon Adams, Supervisory Program Manager, Bureau of Justice Statistics, 810 Seventh Street NW, Washington, DC 20531 (email: *devon.adams@ojp.usdoj.gov;* telephone: (202–305–0765).

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 Statistics, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of this information collection:

(1) *Type of Information Collection:* Revision of a currently collection approved collection.

(2) *The Title of the Form/Collection:* 2018–2020 Survey of State Criminal History Information Systems (SSCHIS).

(3) *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* The form number is N/A. The applicable component within the Department of Justice is the Bureau of Justice Statistics, in the Office of Justice Programs.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Respondents are state government agencies, primarily state criminal history record repositories. The SSCHIS report, the most comprehensive data available on the collection and maintenance of information by state criminal history record systems, describes the status of such systems and record repositories on a biennial basis. Data collected from state record repositories serves as the basis for estimating the percentage of total state records that are immediately available through the FBI's Interstate Identification Index (III), and the percentage of arrest records that include dispositions. Other data presented include the number of records maintained by each state, the percentage of automated records in the system, and the number of states participating in the National Fingerprint File and the National Crime Prevention and Privacy Compact which authorizes the interstate exchange of criminal history records for noncriminal justice purposes. The SSCHIS also contains information regarding the timeliness and completeness of data in state record systems and procedures employed to improve data quality.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The total number of respondents is 56. The average length of time per respondent is 6.75 hours. This estimate is based on the average amount of time reported by five states that reviewed the survey.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total burden associated with this collection is estimated to be 378 hours.

If additional information is required contact: Melody Braswell, Department

Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E.405A, Washington, DC 20530.

Dated: January 30, 2019.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2019–00844 Filed 2–1–19; 8:45 am]

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DEPARTMENT OF JUSTICE

[OMB Number 1121–0249]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension of a Currently Approved Collection: Mortality in Correctional Institutions (State Prisons)

AGENCY: Bureau of Justice Statistics, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Department of Justice (DOJ), Office of Justice Programs, Bureau of Justice Statistics, will be submitting an extension to an existing information collection to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 30 days until April 5, 2019.

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 E. Ann Carson, Statistician, 810 Seventh Street NW, Washington, DC 20531 (email: *elizabeth.carson@usdoj.gov;* telephone: 202–616–3496).

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 Statistics, 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 a currently approved collection.

2. *The Title of the Form/Collection:* Mortality in Correctional Institutions (State Prisons) (MCI-State Prisons).

3. The agency form number, if any, and the applicable component of the Department sponsoring the collection:

The MCI-State Prisons collection currently includes the following forms:

• NPS–4: *Annual Summary of Inmate Deaths in State Prisons.* Annually, this form is sent to the 50 state DOCs to collect the number of state prisoner deaths in a calendar year.

• NPS–4A: *State Prison Inmate Death Report Form.* Annually, this form is sent to the 50 state DOCs to collect details about each state prisoner death.

The applicable component within the Department of Justice is the Bureau of Justice Statistics (BJS), in the Office of Justice Programs.

BJS proposes to transfer the MCI-Jails information collection from the currently approved OMB collection under control number 1121–0094, where it was bundled with the Annual Survey of Jails and the Survey of Jails in Indian Country collections in 2015, to this collection (OMB Control Number 1121–0249, expiration 03/31/2019) to form a single mortality collection program.

The combined mortality collection would include the 50 state departments of corrections (DOCs) plus approximately 3,000 local jail jurisdictions and would collect data on the number and characteristics of inmate deaths in the custody of state and local correctional facilities.

Prior to 2015, BJS collected mortality data from both state prisons and local jails under the OMB Control Number 1121–0249. In 2015, the Mortality in Correctional Institutions (Jails) (MCI-Jails) portion of the collection was bundled with the Annual Survey of Jails (ASJ) and the Survey of Jails in Indian Country (SJIC) in an attempt to consolidate the response burden placed on jails. However, the overlap among these three collections is small, both in terms of jails covered in each and context collected.

• MCI-Jails requests annual data from about 3,000 jail jurisdictions on deaths, the confined population as of December 31, average daily population (ADP), number of holds for other jurisdictions, and number of admissions to the jail during the calendar year.

• The ASJ samples approximately 900 local jails, and provides data to estimate the number and characteristics of local jail inmates nationwide. The ASJ collects population information, including the number of confined inmates, number of individuals supervised in the community by local jails, average daily population, and the number of holds for other authorities as of June 30. The ASJ also obtains data on inmate movements, including the number of admissions and discharges; facility characteristics, including rated and peak capacities and staffing; and inmate characteristics, including race and ethnicity, sex, age group (adult or juvenile), primary offense, and conviction status.

• The SJIC collects data from Indian country jails that are not part of either the ASJ or the MCI-Jails collections. The SJIC collects information from confinement facilities, detention centers, jails, and other facilities operated by tribal authorities or the Bureau of Indian Affairs.

Although there is some duplication in data collected by the ASJ and MCI-Jails, the reference dates are different and the ASJ is a sample, whereas MCI-Jails is a full enumeration of jail jurisdictions. Due to seasonal fluctuations in jail populations, and fewer inmates held at year-end (December 31), the ASJ uses the last weekday in June as its reference date. MCI-Jails uses December 31 as its reference date, and more importantly, uses ADP from January 1 to December 31 as the denominator in calculating mortality rates, which is consistent with the time period represented by the numerator, the number of deaths in a calendar year.

The following forms are proposed to be transferred from OMB Control Number 1121–0094 to OMB Control Number 1121–0249:

• CJ–9: *Death Report on Inmates under Jail Jurisdiction.* This form goes to all jail jurisdictions that are operated by a county or city. Jail administrators are requested to complete the form if their facilities had one or more deaths in a calendar year.

• CJ–10: *Death Report on Inmates in Private and Multi-Jurisdictional Jails.* This form goes to all confinement facilities administered by two or more local governments (regional jails) and privately owned or operated confinement facilities. Jail administrators are requested to complete the form if their facilities had one or more deaths in a calendar year.

• CJ–9A: *Annual Summary on Inmates under Jail Jurisdiction.* This form goes to county and city jail jurisdictions. The form collects the number of male and female deaths in custody in a calendar year, the number of males and females confined as of December 31, the number of male and female admissions during the year, the average daily population by sex, and the number of persons confined on behalf of other agencies.

• CJ–10A: *Annual Summary on Inmates in Private and Multi-Jurisdictional Jails.* This form goes to confinement facilities administered by two or more local governments (regional jails) and to privately owned or operated facilities. The form collects the same information as Form CJ–9A.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

The combined MCI for prisons and jails would collect annual data from the 50 state departments of corrections and roughly 3,000 jail jurisdictions on the number and nature of deaths in their custody.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:*

Respondent	Type of contact	Number of total data respondents	Number of responses	Average reporting time (minutes)	Total burden (hours)
State prisons	Annual summary form (NPS–4) submission—online and mail.	50	50	5	4
	Death record form (NPS–4A) submission—online and mail.	50	3,750	*30	1,875
	Data quality follow-up—email and telephone.	50	46	15	12
	Initial verification call—telephone	50	50	8	7
Total for state prisons		50	3,800		1,898
Local jails	Annual summary form (CJ9A, CJ–10A) submission—online and mail.	3,000	3,000	15	750
	Death record form (CJ–9, CJ–10) submission—online and mail.	3,000	1,100	*30	550
	Data quality follow-up—email and telephone.	3,000	900	15	225
	Initial verification call—telephone	3,000	3,000	8	400
Total for local jails		3,000	4,100		1,925
Total hours for MCI (state prison and local jail).		3,050	7,900		3,823

*Minutes per death.

State Prison Respondent Burden. Reporting time estimates from state prison authorities are based on previous MCI data collection cycles. Based on 2016 data, 50 DOCs submitted data on 3,750 inmate deaths. The average response time for the death report form (NPS–4A) is 30 minutes per death. Given these assumptions, we expect that in any data collection year:

• 50 state prison respondents will submit 3,750 death reports, with an average response time of 30 minutes per death report form, for a total burden of 1,875 hours.

Each state prison respondent will need to fill out a one-item annual summary form (NPS–4) with an estimated reporting time of 5 minutes. We expect the response time to remain constant:

• 50 state prison respondents will each submit an annual summary form, with an average response time of 5 minutes per annual summary form, for a total burden of 4 hours.

The 50 state prison respondents will be called to participate in the verification call (with an estimated reporting time of 8 minutes) prior to the start of the data collection. We expect that in any data collection year:

• 50 state prison respondents will have an average response time of 8 minutes per verification call, for a total burden of 7 hours.

Data quality follow-up occurs between May and July of each collection year and involves confirming, clarifying or correcting data reported on the NPS–4 and NPS–4A forms submitted by the respondent. Not all DOC records submitted require data quality follow-up. An average of 46 respondents require some level of follow-up annually, which averages about 15 minutes per respondent, for a total burden of 12 hours.

Thus, the total burden of hours associated with the prison data collection is 1,898 hours, with an average burden of 38 hours per year across the 50 state prison respondents. This is an increase in burden from the 2016 MCI clearance package, due to an increase in the number of deaths reported.

Local Jail Respondent Burden. Reporting time estimates from local jail authorities are based on previous MCI data collection cycles. Based 2016 data, approximately 3,000 DOCs submitted data on 1,100 inmate deaths. The average response time for the death report form (CJ–9 or CJ–10) is 30 minutes per death. Given these assumptions, we expect that in any data collection year:

• 3,000 local jail respondents will submit 1,100 death reports, with an average response time of 30 minutes per death report form, for a total burden of 550 hours.

Each local jail respondent will need to fill out a five-item annual summary form (CJ–9A or CJ–10A) with an estimated reporting time of 15 minutes. We expect the response time to remain constant:

• 3,000 local jail respondents will each submit an annual summary form, with an average response time of 15 minutes per annual summary form, for a total burden of 750 hours.

The 3,000 local jail respondents will be called to participate in the verification call (with an estimated reporting time of 8 minutes) prior to the start of the data collection. We expect that in any data collection year:

• 3,000 local jail respondents will have an average response time of 8 minutes per verification call, for a total burden of 400 hours.

Data quality follow-up occurs between May and July of each collection year and involves confirming, clarifying, or correcting data reported on the CJ–9/CJ–9A or CJ–10/CJ–10A forms submitted by the respondent. Not all local jail records submitted require data quality follow-up. An average of 900 local jail respondents require some level of follow-up annually, which averages about 15 minutes per respondent, for a total burden of 225 hours.

The total burden of hours associated with the local jail data collection is 1,925 hours, with an average burden of 39 minutes per year across the 3,000 local jail respondents. This is an increase in burden from the 2016 MCI-Jails clearance package (OMB control number 1121–0094), due to an increase in the number of deaths reported and in the number of local jail respondents who will need to be contacted for data quality follow-up, based on recent years' data collections.

Combined State Prison/Local Jail Burden estimate. The total burden estimate for MCI across all 3,050 state prisons and local jails is 3,823 hours per year.

If additional information is required, contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E.405A, Washington, DC 20530.

Dated: January 30, 2019.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2019–00852 Filed 2–1–19; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF JUSTICE

[OMB Number 1110–0077]

Agency Information Collection Activities; Proposed eCollection eComments Requested New Collection (Previously Submitted as an Emergency Collection) FIX NICS Act State Implementation Plan Survey

AGENCY: Criminal Justice Information Services Division, Federal Bureau of Investigation, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Department of Justice (DOJ), Federal Bureau of Investigation (FBI), Criminal Justice Information Services (CJIS) Division will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection was previously published in the **Federal Register** Volume xx, Number xxx, page xx–xx, on Month xx, 2018, allowing for a 60 day comment period.

DATES: Comments are encourages and will be accepted for an additional 30 day until March 6, 2019.

FOR FURTHER INFORMATION CONTACT: If you have 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 Gerry Lynn Brovey, Supervisory Information Liaison Specialist, FBI, CJIS, Resources Management Section, Administrative Unit, Module C–2, 1000 Custer Hollow Road, Clarksburg, West Virginia 26306 (telephone: 304–625–4320) or email *glbrovey@fbi.gov.* Written comments and/or suggestions can also be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20503. Additionally, comments may be submitted via email to *OIRA_submission@omb.eop.gov.*

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agencies 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: New Collection.

(2) Title of the Form/Collection: FIX NICS Act State Implementation Plan Survey.

(3) Agency form number, if any, and the applicable component of the Department sponsoring the collection: Sponsoring component: Department of Justice, Federal Bureau of Investigation, Criminal Justice Information Services Division.

(4) Affected public who will be asked or required to respond, as well as a brief abstract: Primary: State, local, federal and tribal law enforcement agencies. This collection is needed for the reporting or making available of appropriate records to the National Instant Criminal Background Check System (NICS) established under section 103 of the Brady Handgun Violence Prevention Act. Acceptable data is stored as part of the NICS of the FBI.

(5) An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply: It is estimated 56 respondents will complete each form within approximately 2,400 minutes.

(6) An estimate of the total public burden (in hours) associated with the collection: There are an estimated 2,240 total annual burden hours associated with this collection.

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, Suite 3E.405B, Washington, DC 20530.

Dated: January 30, 2019.

Melody Braswell,

Department Clearance Officer, PRA, U.S. Department of Justice.

[FR Doc. 2019–00846 Filed 2–1–19; 8:45 am]

BILLING CODE 4410–02–P

DEPARTMENT OF JUSTICE

[OMB Number 1121–NEW]

Agency Information Collection Activities; Proposed Collection Comments Requested; New Collection: Annual Survey of Jails in Indian Country

AGENCY: Bureau of Justice Statistics, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Department of Justice (DOJ), Office of Justice Programs, Bureau of Justice Statistics, will be submitting a request for a new collection to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 60 days until April 5, 2019.

FOR FURTHER INFORMATION CONTACT: If you have 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 Todd D. Minton, Bureau of Justice Statistics, 810 Seventh Street NW, Washington, DC 20531 (email: *Todd.Minton@usdoj.gov;* telephone: 202–305–9630).

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 Statistics, 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:* New collection.

2. *Title of the Form/Collection:* Annual Survey of Jails in Indian Country (SJIC).

3. *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* The form number is CJ–5B: *Survey of Jails in Indian Country (SJIC).* This form is sent to approximately 84 confinement facilities, detention centers, and other correctional facilities operated by tribal authorities or the Bureau of Indian Affairs (BIA). The applicable component within the Department of Justice is the Bureau of Justice Statistics (BJS), in the Office of Justice Programs.

The Bureau of Justice Statistics (BJS) requests clearance to conduct the Survey of Jails in Indian Country (SJIC) for a three-year period and also requests a new unique clearance number for the SJIC data collection. The SJIC is currently approved through 1/31/2019 under OMB Control Number 1121–0094 along with the Annual Survey of Jails (ASJ), and until recently, the jail portion of the Mortality in Correctional Institutions (MCI-formerly the Deaths in Custody Reporting Program). Considering these data collections are unique in substance, collection period, and respondents, each collection has required enhancements at different periods of time. Consequently, BJS has revised the combined clearance multiple times over the past several years, and in some cases, BJS delayed enhancing a unique survey until all data collections could be addressed with a single revision. This process does not allow BJS to address the critical needs of a single collection in a timely manner. As a solution, BJS proposes to separate these collections and obtained a unique OMB clearance for each. The ASJ, when it is next fielded in 2020, will retain the OMB Control Number 1121–0094. The MCI-Jails collection will be combined with the MCI-Prison collection under OMB Control Number 1121–0249. The SJIC will obtain a new OMB Control Number through this application.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:* The affected public that will be asked to respond to CJ–5B includes jail administrators from approximately 84 confinement facilities, detention centers, and other correctional facilities operated by tribal authorities or the Bureau of Indian Affairs. The respondents will be asked to provide information for the following categories:

(a) At midyear (last weekday in the month of June), the number of inmates confined in jail facilities including: Male and female adult and juvenile inmates; persons under age 18 held as adults; convicted and unconvicted males and females; persons held for a felony and a misdemeanor; the inmates most serious offense (*i.e.,* domestic violence offense, aggravated or simple assault, rape, other violent, burglary, larceny-theft, drug law violation, DWI/DUI of alcohol or drugs, public intoxication, and other unspecified offenses);

(b) The average daily population during the 30-day period in June;

(c) The date and count for the greatest number of confined inmates during the 30-day period in June;

(d) The number of new admissions into jail, and final discharges from jail during the month of June;

(e) From July 1 of the previous year to June 30 of the current collection year: the number of inmate deaths while confined, the number of deaths attributed to suicide, and the number of confined inmates that attempted suicide;

(f) At midyear, the number of correctional staff employed by the facility and their occupation (*e.g.,* administration, jail operations, educational staff, etc.);

(g) At midyear, the number of jail operations employees who had received the basic detention officer certification and how many had received 40 hours of in-service training; and

(h) At midyear, the total rated capacity of jail facilities.

This collection is the only national effort devoted to describing and understanding annual changes in the tribal jail population. The collection enables BJS, tribal correctional authorities and administrators, legislators, researchers, and jail planners to track growth in the number of jails and their capacities nationally, as well as to track changes in the demographics and supervision status of the tribal jail population and the prevalence of crowding.

5. *An estimate of the total number of respondents and the amount of time*

estimated for an average respondent to respond:

Reporting mode	Purpose of contact	Number of responses	Average reporting time (min)	Total burden hours (hrs)
Mail, Fax, Email, telephone	Data collection	84	75	105
Email and telephone	Verify facility operational status and point-of-contact	84	2	3
Email and telephone	Data quality follow-up validation	84	7	10
Total		84	84	118

The questionnaire will be sent to 84 Indian country correctional facilities operated by tribal authorities or the Bureau of Indian Affairs (BIA). Based on prior years' reporting, we estimate a reporting time of 75 minutes for the SJIC questionnaire. If needed, jail respondents will also be contacted by email or telephone to verify data quality issues. Thus, we expect that in any data collection year 84 SJIC respondents will have an average reporting time of 2 minutes to verify facility operational status and point-of-contact, 75 minutes for the data collection, and an additional 7 minutes for data quality follow-up validation, for a total burden 84 minutes per facility. Annually, this results in a total burden estimate for SJIC of 118 hours.

If additional information is required, contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E.405A, Washington, DC 20530.

Dated: January 30, 2019.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2019–00845 Filed 2–1–19; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF JUSTICE

[OMB Number 1121–NEW]

Agency Information Collection Activities; Proposed Collection Comments Requested; New collection: Census of Tribal Law Enforcement Agencies (CTLEA)

AGENCY: Bureau of Justice Statistics, Department of Justice.

ACTION: 60-day notice.

SUMMARY: The Department of Justice (DOJ), Office of Justice Programs, Bureau of Justice Statistics, will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 60 days until April 5, 2019.

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 Steven W. Perry, Statistician, Institutional Research & Special Projects Unit, Bureau of Justice Statistics, 810 Seventh Street NW, Washington, DC 20531 (email: *Steven.W.Perry@usdoj.gov*; telephone: 202–307–0777).

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 Statistics, 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:* New collection.

(2) *The Title of the Form/Collection:* Census of Tribal Law Enforcement Agencies (CTLEA).

(3) *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* The applicable form number(s) for this collection is CTLEA–18. The applicable component within the Department of Justice is the Bureau of Justice Statistics, in the Office of Justice Programs.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* This information collection is a census of the 279 tribal law enforcement agencies operating in Indian country and serving tribal lands. Enacted in 2010, the Tribal Law and Order Act (TLOA) requires the Bureau of Justice Statistics (BJS) to (1) establish and implement a tribal data collection system, (2) consult with Indian tribes to establish and implement this data collection system, and (3) annually report to Congress the data collected and analyzed in accordance with the act (Pub. L. 111–211, 124 Stat. 2258, § 251(b)). Indian country includes federally recognized reservations, tribal communities, and identified trust lands. Criminal jurisdiction in Indian country varies by type of crime committed, whether the offender or victim is a tribal member, and the state in which the offense occurred. This information collection helps fulfill this mandate and meet the agency's mission.

Abstract: Tribal law enforcement agencies share concurrent jurisdiction for all criminal matters among tribal members occurring on tribal lands. They often act as the first responders for serious felony crimes committed in Indian country, until the appropriate federal and state law enforcement official arrive upon the scene. Tribal law enforcement agencies are authorized and operated by tribes to enforce tribal laws, statutes and criminal codes. Tribal police officers are responsible for ensuring public safety on reservations, trust lands and tribal communities. Although tribal law enforcement agencies now number 279, unlike their Federal, State and local counterparts,

they have been the subject of only limited studies and no comprehensive recurring statistical collection.

As part of the CTLEA questionnaire development process, during FY 2016 and FY 2017, BJS implemented a comprehensive and culturally centered strategy to gather input from both federal agencies and tribal law enforcement agencies on the proposed content for the CTLEA questionnaire. First, various DOJ policy and grant making components were invited to provide recommendations on their critical data needs to improve program planning and resource allocation. Second, BJS hosted a two day tribal justice expert panel in Phoenix, Arizona that included participants from the Bureau of Indian Affairs, the FBI's Indian Country Crimes Unit, tribal law enforcement agencies, and Alaska Native villages. Third, the CTLEA draft questionnaire content was then submitted for review by various tribal law enforcement agencies, including those in both Public Law (Pub. L.) 280 and non-Public Law 280 jurisdictions and BIA agencies.[1]

BJS conducted cognitive testing during July—August 2018 of the CTLEA survey to ensure: (1) Question ordering and item clarity, (2) availability of data types requested, and (3) verification of the estimated respondent burden. The full data collection period, which is anticipated to commence April–August 2019, pending OMB approval.

The CTLEA will collect data on the administrative and operational characteristics of the tribal law enforcement agencies, with the goal of producing national statistics on tribal law enforcement agency staffing; sources of funding; calls for service and arrests; training; coordination and collaboration with Federal, State and local agencies; technology use; and, access to regional and national criminal justice databases. These data will allow BJS to establish baselines for future trend analyses and comparisons with future surveys of tribal law enforcement agencies.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimated 279 tribal law enforcement agencies—including tribal operated police departments (229), conservation/wildlife enforcement agencies (44), and tribal university or college police (6)—that serve or work on tribal lands will be asked to take part in the CTLEA. Based on the survey development and cognitive testing activities, an average of 30 minutes per respondent is needed to complete the CTLEA–18 form per respondent. BJS anticipates that nearly all of the approximately 279 respondents will fully complete the questionnaire.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated public burden associated with this collection is 174.5 hours. It is estimated that respondents will take 30 minutes to complete a questionnaire (279 × 30 = 139.5 hours) and additional verification or validation of responses for about 50% of the respondents will require 15 minutes (140 × 15 minutes = 35 hours). The total burden hours for CTLEA respondent data collection:

TABLE 1—2018 CTLEA ESTIMATED RESPONDENT BURDEN

Total number of respondents	Time to complete CTLEA–18		Time to complete Non-response follow-up		Total CTLEA–18 respondent burden (hours)
(a) CTLEA universe, N = 279	30 minutes X N = 279 139.5 hours	..... + ...	15 minutes X n = 140 35 hours	=	174.5
(b) Non-response follow-up estimated at 50% of CTLEA universe, n = 140					

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E.405A, Washington, DC 20530.

Dated: January 30, 2019.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2019–00853 Filed 2–1–19; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF JUSTICE

[OMB Number 1121–NEW]

Office of Justice Programs; Agency Information Collection Activities; Proposed eCollection eComments Requested; New Collection; Fourth National Incidence Studies of Missing, Abducted, Runaway and Thrownaway Children (NISMART–4)

AGENCY: Office of Justice Programs, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Department of Justice (DOJ), Office of Justice Programs, Office of Juvenile Justice and Delinquency Prevention, will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 30 days until March 6, 2019.

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

[1] Public Law 83–280, August 15, 1953, codified as 18 U.S.C. 1162, 28 U.S.C. 1360, and 25 U.S.C. 1321–1326). Due to the sovereign status of federally recognized tribes in the United States, crimes committed in Indian country are often subject to concurrent jurisdiction among multiple criminal justice agencies. More than 300 tribes in the United States are under Public Law 83–280 jurisdictions (commonly referred to as Pub. L. 280), which established a method whereby the federal government could transfer mandatory jurisdiction over crimes in Indian country to states or states could acquire optional jurisdiction in whole or in part over Indian country within their boundaries. Sixteen states have established either mandatory or optional jurisdictions over crimes in Indian country.

California, Minnesota (except the Red Lake Reservation), Nebraska, Oregon (except the Warm Springs Reservation), and Wisconsin. Ten states have acquired optional jurisdiction over crimes in Indian country: Arizona, Florida, Idaho, Iowa, Montana, Nevada, North Dakota, South Dakota, Utah, and Washington. In states where Public Law 280 does not apply, the federal government retains criminal jurisdiction for major crimes committed in Indian country. Federal jurisdiction in Indian country is established under the Indian Country Crimes Act (18 U.S.C. 1152), the Indian Country Major Crimes Act (18 U.S.C. 1153), and the Assimilative Crimes Act (18 U.S.C. 13).

instrument with instructions or additional information, please contact Benjamin Adams, Social Science Analyst, Office of Juvenile Justice and Delinquency Prevention, 810 Seventh Street NW, Washington, DC 20531 (email: *benjamin.adams@usdoj.gov*; telephone: 202–616–3687).

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 Office of Juvenile Justice and Delinquency Prevention, including whether the information shall have practical utility;

—Evaluate whether the accuracy of the agency's estimate of the burden on the proposed collection of information, including the validity of the methodology and assumptions that were used;

—Evaluate whether and if so how the quality, utility, and clarity of the information collected can be enhanced; and

—Minimize the burden of the collection of information on those who are to respond, including 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:* New collection.

(2) *The Title of the Form/Collection:* Fourth National Incidence Studies of Missing, Abducted, Runaway and Thrownaway Children (NISMART–4).

(3) *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* Not applicable (new collection).

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* State, county, and local law enforcement agencies (LEAs), state Missing Child Clearinghouses (MCCs), and the National Center on Missing and Exploited Children (NCMEC). *Abstract:* The Fourth National Incidence Studies of Missing, Abducted, Runaway and Thrownaway Children (NISMART–4) will include three pilot studies and one national data collection. The three pilot studies will test methodologies for collecting information from law enforcement agencies on child victims of stranger abductions, parental abductions, and other types of missing children, respectively. The pilot test data will be used solely to evaluate the effectiveness of the proposed survey methodologies. The national study will collect data on the number and characteristics of children abducted by strangers (*i.e.,* ''stereotypical kidnappings''). OJJDP will use the information gathered in the national study in published reports and statistics. The reports will be made available to the U.S. Congress, Executive Office of the President, practitioners, researchers, students, the media, others interested in missing children statistics, and the general public via the OJJDP website.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:*

Burden Hours for Law Enforcement Survey—Stereotypical Kidnappings (LES–SK) Pilot: OJJDP expects 20 law enforcement investigators to spend an average of 40 minutes completing an online case detail survey and 20 minutes completing the telephone debriefing about the online survey (20 × 60 minutes = 20 hours). In addition, OJJDP expects the NCMEC database administrator to spend 5 hours pulling 20 stereotypical kidnappings cases from the NCMEC database for use in testing the online survey (1 × 5 hours = 5 hours). The total amount of time for the LES–SK pilot is 25 hours.

Burden Hours for Law Enforcement Survey—Family Abductions (LES–FA) Pilot: The sample size for Components 1 and 2 of the pilot is 30 law enforcement investigators who will be asked to search their database for cases of family abductions occurring in a 1-year period. OJJDP estimates the search will take an average of 3 hours and that 28 will comply (28 × 3 hours = 84 hours), 2 will decline (2 × 3 minutes = 6 minutes). OJJDP estimates that database administrators for NCMEC and the MCCs associated with states in the sample will all agree to conduct database searches for the agencies in Component 1 and Component 2 and that these searches will take an average of 3 hours (31 × 4 hours = 124 hours). OJJDP estimates that all 5 agencies selected for telephone debriefing in Component 1 will participate and the interviews will take an average of 20 minutes to complete (5 × 20 minutes = 1.67 hours). OJJDP expects that all 10 of the law enforcement investigators selected to complete the Component 3 case detail telephone survey will participate and that the interview will take 30 minutes (10 × 30 minutes = 5 hours). OJJDP estimates that 18 of the 20 investigators selected to complete the Component 3 case detail online survey will comply and that the instrument will take an average of 15 minutes (18 × 15 minutes = 4.5 hours), 2 will decline (2 × 3 minutes = 6 minutes). OJJDP expects that all 18 investigators who complete the online survey will agree to participate in the 20 minute debriefing telephone interview (18 × 20 minutes = 6 hours). The total amount of time for the LES–FA pilot is 225.4 hours.

Burden Hours for Law Enforcement Survey—Missing Children (LES–MC) Pilot: The sample size for Components 1 and 2 of the pilot is 30 law enforcement investigators who will be asked to search for case of missing children occurring in a 1-month period. OJJDP estimates the search will take an average of 3 hours and that 28 will comply (28 × 3 hours = 84 hours), 2 will decline (2 × 3 minutes = 6 minutes). OJJDP estimates that database administrators for NCMEC and the MCCs associated with states in the sample will all agree to conduct database searches and that these searches will take an average of 4 hours (31 × 4 hours = 124 hours). OJJDP estimates that all five agencies selected for telephone debriefing in Component 1 will participate and the interviews will take an average of 20 minutes to complete (5 × 20 minutes = 1.67 hours). OJJDP expects that all 10 of the law enforcement investigators selected to complete the Component 3 case detail telephone survey will participate and that the interview will take 30 minutes (10 × 30 minutes = 5 hours). OJJDP estimates that 18 of the 20 investigators selected to complete the Component 3 case detail online survey will comply and that the instrument will take an average of 15 minutes (18 × 15 minutes = 4.5 hours), 2 will decline (2 × 3 minutes = 6 minutes). OJJDP expects that all 18 investigators who complete the online survey will agree to participate in the 20 minute debriefing telephone interview (18 × 20 minutes = 6 hours). The total amount of time for the LES–MC pilot is 225.4 hours.

Burden Hours for National Law Enforcement Survey—Stereotypical Kidnappings (LES–SK): A total of 4,727 law enforcement agencies are included in the national stratified cluster sample of 400 PSUs (Primary Sampling Units). All of these agencies will receive the mail screener. OJJDP estimates that 2,836 (60 percent) of the law enforcement agencies will complete the screener by mail, based on the response rate for the mail screener obtained for

NISMART–3. The great majority of these will have no stereotypical kidnapping cases during the 1-year timeframe of the survey and OJJDP estimates the average time to complete the mail screener to be 15 minutes (2,836 × 15 minutes = 709.05 hours), 1,891 will not respond by mail (1,891 × 3 minutes = 94.54 hours). OJJDP estimates that 1,229 (26 percent) of the law enforcement agencies will complete the mail screener by telephone, based on the percentage of mail screeners completed by telephone in NIMSART–3. OJJDP estimates that the time to complete the screener by telephone will be 4 minutes (1,229 × 4 minutes =81.9 hours), and 662 will not respond (662 × 3 minutes = 33.1 hours). OJJDP estimates that 204 cases will be identified that appear to meet the definition of a qualifying stereotypical kidnapping case. The estimate is based on the number of cases identified in NISMART–3 for telephone followup from the mail screener and searches of other databases. Investigators of these cases will be asked to complete the online survey about case details. OJJDP estimates that 161 (79 percent) of the law enforcement officers will complete the case detail online instrument (estimate again based on the percentage of investigators who completed this component for NISMART–3) with 145 (90 percent) completing online. OJJDP estimates that the instrument will take an average of 40 minutes to complete (145 × 40 minutes = 96.6 hours), 59 will not respond online (59 × 3 minutes = 2.95 hours). OJJDP estimates that 16 (10 percent) of the 161 law enforcement officers who complete the detailed case survey will do it via telephone interview and that the interview will take 60 minutes (16 × 60 minutes = 16 hours), and that 43 will not respond (43 × 3 minutes = 2.15 hours). OJJDP estimates the time for NCMEC and state MCCs database administrators to conduct a database search of any stereotypical kidnapping cases in their states to be 4 hours and expect that all NCMEC and the state MCCs in the 49 states where the sampled PSUs are located will participate (50 × 4 hour = 200 hours). The total amount of time for the National LES–SK study is 1,236.5 hours.

(6) *An estimate of the total public burden (in hours) associated with the collection:* There are an estimated 1,712 total burden hours (1,259 hours for law enforcement investigators and 453 hours for NCMEC and MCC database administrators) associated with the three pilot studies and the national LES–SK study.

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E.405A, Washington, DC 20530.

Dated: January 30, 2019.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2019–00850 Filed 2–1–19; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF JUSTICE

U.S. Marshals Service

[OMB Number 1105–0097]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension with No Changes, of a Previously Approved Collection; Leased/Charter/Contract Personnel Expedited Clearance Request

AGENCY: U.S. Marshals Service, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Department of Justice (DOJ), U.S. Marshals Service (USMS), will submit the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection was previously published in the **Federal Register** on November 1, 2018, allowing for a 60-day comment period.

DATES: Comments are encouraged and will be accepted for an additional 30 days until March 6, 2019.

FOR FURTHER INFORMATION CONTACT: If you have additional comments, particularly with respect to the estimated public burden or associated response time, have suggestions, need a copy of the proposed information collection instrument with instructions, or desire any other additional information, please contact Nicole Timmons either by mail at CG–3, 10th Floor, Washington, DC 20530–0001, by email at *Nicole.Timmons@usdoj.gov,* or by telephone at 202–236–2646. Written comments and/or suggestions can also be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20503 or sent to *OIRA_submissions@omb.eop.gov*.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension with No Change, of a Currently Approved Collection.

(2) *The Title of the Form/Collection:* Leased/Charter/Contract Personnel Expedited Clearance Request.

(3) *The agency form number, if any, and the applicable component of the Department sponsoring the collection: Form number:* USM–271. *Component:* U.S. Marshals Service, U.S. Department of Justice.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or households. *Abstract:* This form is used to be completed by people applying to become contract personnel. It is required so that USMS can perform an expedited background check before workers may be hired to transport USMS and Bureau of Prisons prisoners.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimated 180 respondents will utilize the form, and it will take each respondent approximately 5 minutes to complete the form.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The estimated annual public burden associated with this collection is 15 hours. It is estimated that applicants will take 5 minutes to complete a Form USM–271. In order to calculate the public burden for Form USM–271, USMS multiplied 5 by 180 and divided

by 60 (the number of minutes in an hour), which equals 15 total annual 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: January 30, 2019.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2019–00841 Filed 2–1–19; 8:45 am]

BILLING CODE 4410–14–P

LIBRARY OF CONGRESS

Copyright Office

[Docket No. 2019–2]

Copyright Restoration of Works in Accordance with the Uruguay Round Agreements Act

AGENCY: U.S. Copyright Office, Library of Congress.

ACTION: Publication of list identifying copyrights restored under the Uruguay Round Agreements Act for which a Notice of Intent to Enforce restored copyrights was filed in the U.S. Copyright Office.

SUMMARY: The U.S. Copyright Office is publishing a list of works for which it has received and processed a Notice of Intent to Enforce copyrights restored under the Uruguay Round Agreements Act. The Office is required by law to publish such lists to provide a public record of works in which copyrights have been restored and whose owners have notified the Office of their intent to enforce those copyrights. In addition, publication triggers the statutory 12-month grace period within which reliance parties may continue to exploit existing copies of the identified works.

DATES: February 4, 2019.

FOR FURTHER INFORMATION CONTACT: Regan A. Smith, General Counsel and Associate Register of Copyrights, at *regans@copyright.gov*; or Kevin R. Amer, Senior Counsel for Policy and International Affairs, at *kamer@copyright.gov.* Each may be reached by telephone at 202–707–8350.

SUPPLEMENTARY INFORMATION:

I. Background

The Uruguay Round Agreements Act (''URAA'')[1] provides for the restoration of copyright in certain works of foreign origin that previously were in the public domain in the United States. Enacted in 1994 to implement U.S. obligations under the Agreement on Trade-Related Aspects of Intellectual Property Rights (''TRIPS'') of the World Trade Organization (''WTO''), the URAA extends copyright to works that are protected in nations adhering to certain international copyright agreements to which the United States is a party, but that were unprotected in the United States for any of three reasons: (1) Noncompliance with formalities imposed at any time by United States copyright law, including failure of renewal, publishing the work without a proper notice, or failure to comply with any manufacturing requirements; (2) lack of subject matter protection in the case of sound recordings fixed before February 15, 1972; or (3) lack of national eligibility (*i.e.,* the work is from a country with which the United States did not have copyright relations at the time of the work's publication).[2] A work meeting these criteria is protected ''for the remainder of the term of copyright that the work would have otherwise been granted in the United States if the work never entered the public domain in the United States.''[3]

Under the URAA, copyright in restored works vests automatically on the date of restoration.[4] That date was January 1, 1996, if the work's source country was already a member of the WTO or the Berne Convention for the Protection of Literary and Artistic Works (''Berne Convention'') as of that date. Otherwise, the date of restoration is the earliest of (1) the date the source country becomes a WTO member, (2) the date of the country's adherence to the Berne Convention, the WIPO Copyright Treaty, or the WIPO Performances and Phonograms Treaty, or (3) the date when the President issues a proclamation extending copyright restoration to that country.[5] For a published work, the ''source country'' is the eligible country in which the work is first published or, in the case of a work published on the same day in multiple countries, the eligible country with the most significant contacts with the work.[6] For an unpublished work, the source country is (1) the eligible country in which the author or rightholder is a national or domiciliary, (2) if the work has multiple authors or rightholders, the country in which the majority of foreign authors or rightholders are nationals or domiciliaries, or (3) the nation other than the United States with the most significant contacts with the work, in cases where the majority of authors or rightholders are not foreign.[7]

Although the copyright owner may immediately enforce the restored copyright against individuals who infringe his or her rights on or after the date of restoration, the copyright owner's right to enforce the restored copyright is delayed against ''reliance parties.'' Typically, a reliance party is one who was already using the work before the source country became eligible for copyright restoration.[8] Before a copyright owner can enforce a restored copyright against a reliance party, the copyright owner must file a Notice of Intent to Enforce the copyright (''NIE'') with the Copyright Office or serve an NIE on such a party.[9] Thereafter, reliance parties may continue to exploit existing copies of the work for a twelve-month grace period.[10]

An NIE may be filed in the Copyright Office within twenty-four months after the date of restoration of copyright.[11] NIEs appropriately filed with the Copyright Office and published in the **Federal Register** serve as constructive notice to all reliance parties.[12] Alternatively, an owner may serve an NIE on an individual reliance party at any time after the date of restoration.[13] Such notices, however, are effective only against the party served and other reliance parties who have actual knowledge of the notice and its contents.[14]

The Copyright Office is directed to ''publish in the **Federal Register**, commencing not later than 4 months after the date of restoration for a particular nation and every 4 months thereafter for a period of 2 years, lists identifying restored works and the ownership thereof if a notice of intent to enforce a restored copyright has been filed.''[15] The Office does not research the facts stated in an NIE to determine whether a work is or is not eligible for restoration or whether the submitter has asserted a valid claim of copyright ownership. Nor does the Office adjudicate between competing parties who have filed NIEs for the same

[1] Public Law 103–465, 108 Stat. 4809 (1994).

[2] 17 U.S.C. 104A(h)(6).

[3] *Id.* 104A(a)(1)(B).

[4] *Id.* 104A(a)(1)(A).

[5] *Id.* 104A(h)(1)–(2).

[6] *Id.* 104(h)(8)(C).

[7] *Id.* 104A(h)(8)(B).

[8] *Id.* 104A(h)(4).

[9] *Id.* 104A(d)(2).

[10] *Id.* 104A(d)(2)(A)(ii), (B)(ii).

[11] *Id.* 104A(d)(2)(A)(i).

[12] *Id.* 104A(c).

[13] *Id.* 104A(e)(2)(A).

[14] *Id.* 104A(c).

[15] *Id.* 104A(e)(1)(B)(i).

works.[16] Accordingly, the Office's publication of a list of works for which an NIE has been filed indicates only that one or more parties have claimed rights in those works; it does not represent a determination by the Office that those claims are valid. In all cases, the validity of such a claim is governed by the terms of the applicable law, including the URAA, as applied to the relevant facts.

II. List of Works for Which a Notice of Intent To Enforce Was Received

On July 24, 2018, an NIE was filed with the Copyright Office on behalf of Fakhria Zahir, who claims ownership of restored copyrights in 447 sound recordings. The NIE identifies Afghanistan as the source country for each of these works. Afghanistan became a WTO member on July 26, 2016, prior to its adherence to any of the other international agreements relevant to copyright restoration under the statute.[17] Therefore, U.S. copyrights in eligible works for which Afghanistan is the source country were restored on that date. Because the NIE was filed with the Office within twenty-four months after restoration, it is timely for purposes of securing publication in the **Federal Register**.[18]

Accordingly, the Office is publishing the following list of works identified in the NIE:

Aasheq Shodam Gunaham Hameen Ast
Abroha Bar Qolaha
Abroha Gul Ha
Afsoos
Agar Bahar Beyayad
Agar Bahar Biyayad (home recording version)
Agar Ein Asoman Setara
Agar Ishq Bashad
Agar Maikhara Wa Mastam
Agar Penhan Bowad Paida
Agar Sabza Bodam
Agar Sabza Boodam (home recording version)
Agar Tu Yarake Man Bashi (home recording version)
Agar tu Yarakeman Bashi
Agar Ze Khalq Malamat
Agar Ze Khalq Malamat (home recording version)
Aghaz Gashta Zendagi (Choon Sahar)
Ah Chee Khosh Amadi
Ahange Zindagi
Ahesta Bero
Ai Yar Khoob Royan
Aiy Bewafa Bewafa
Aiy Dusitan Eh Dusitan
Aiy Naigarai Man
Aiy Padesha Khoban
Akherin Shame Aashenaye Maa
Akhir ay Darya
Akhir Ay Darya (home recording version)
Amad Nafase Sobho
Amrahan Judayee Maslahat Neist
Asheqam Asheq Ba Royat
Ashiq Shodam Gowaham
Ashiq Shudayie Hay Dil
Ashiqe Royat Man
Ashko Haye Man Hamchon
Asoman Ay Asoman
Asoman Khaleest
Asoman Khalist (home recording version)
Awaleen Eshqam Tu Boodi (home recording version)
Awaleen Ishqam To Bodi
Awara Bechara Qalbe Man
Awara Bechara Qalbe Man (home recording version)
Ay Aahe Sahargah Tu
Ay Badida am Tarik
Ay Bekhabar Az Darde Man
Ay Bekhabar Az Darde Man (home recording version)
Ay Bewafa Ay Bewafa
Ay Bote Berahem
Ay Bulbule Khosh Elhan
Ay Dil Ay Dil
Ay Dil Tu Gerya Kam Kon
Ay dozdida chashm
Ay Gulezare Man
Ay Hamwatan Ay Neroyee
Ay Ishq
Ay Ishq Tu Wai Ra Na
Ay Jane Man Asirat
Ay Jane Man Asirat (home recording version)
Ay Ke Az Kelke Honar
Ay ke az Yaar Neshan
Ay Mahe Kenhanie Man
Ay Naame Ghamat Taranaye Man
Ay Name Ghamat Taranaye Man (home recording version)
Ay Nazanin Az Ishqe Tu
Ay Nazanin Dar Eshqe Tu (home recording version)
Ay Negahat Sabztar
Ay Nilagoon Daryaye Man
Ay Padshahe Khooban
Ay Qawme Ba Haj Rafta
Ay Rashke Gul Ha
Ay Rasht Gulha
Ay Sarban Ahesta Raw
Ay Sarban Ahesta Raw (home recording version)
Ay Sholay Azin
Ay Surode Wapasinam
Ay Tere Ghamat Ra
Ay Yare Khobe Man
Ay Yare Khobe Man (home recording version)
Aya sayad rahme kon
Az An Roz Ke Payman
Az Asheeyaan Juda Gashta
Az Bara-e Gham-e Man
Az Baraye Ghame Man
Az Baraye Ghame Man (home recording version)
Az Bast Yadeh Tu
Az Beygonai Tu
Az Dastat Feghan Feghan
Az Ghamat ai Nazinin (home recording version)
Az Ghamat Ay Nazaneen
Az Naazo chi Mekhandani
Az Parda Beeroon Nashaw
Az Peshe Man Beraw
Az Peshe Man Beraw (home recording version)
Az Safar Khosh Amadi
Az Tangnaye Mahbase Tariki
Az Tu Duram
Azizam Ba Yadat Shabhaye
Ba Aan Hama Qawlo Qararo Payman
Ba An Hama Qawl o Qarar
Ba Asoman Begoyed
Ba Atashin Khoye Khod
Ba Azmai Tuba Istakhara Konam
Ba Azme Toba
Ba Daghe Na Moradi Sokhtam
Ba dile man sharar afroz
Ba Juz To Monese Digar
Ba Khabar Bash Ba Khabar
Ba Khod Guftam
Ba Khoda Tang Ast Dilam
Ba Khoda Tang Ast Dilam (home recording version)
Ba Kodam Dar Rawam Man
Ba Saghar Naqel Kard
Ba Saghar Naqel Kard (home recording version)
Ba Sange Gham Zadi
Ba Zameen Pasa
Bacha Nasho Ay Dil
Bad az ein ke Raqib
Bada Ha Khaleest (home recording version)
Bada Ha Khalist
Badwayet Konom
Badwayit Konom (home recording version)
Bahar Amad
Bahar Ast O Saman
Bahare Jawaneyam Raft
Bahare Man Hazar Az Naw
Bahd Az Khuda Yagana Khudaye
Bairaway Da Ghareebaan
Bar Khatere Azada
Baramd Az Pase Koh
Barayam Gerya kon Imshab
Bas Kai Jafa Zekhar O Gul (home recording version)
Baske Jafa Ze Khar o Gul
Baz Amadi Ay Jane Man

[16] Under the URAA, however, a material false statement knowingly made with respect to any restored copyright identified in an NIE ''shall make void all claims and assertions made with respect to such restored copyright.'' *Id.* 104A(e)(3).

[17] *See Afghanistan and the WTO,* World Trade Organization, *https://www.wto.org/english/thewto_e/countries_e/afghanistan_e.htm* (last visited Jan. 29, 2019); U.S. Copyright Office, *Circular 38A: International Copyright Relations of the United States,* at 4 (2019), *available at https://www.copyright.gov/circs/circ38a.pdf* (noting Afghanistan's adherence to the Berne Convention as of Jun. 2, 2018). Afghanistan has not been the subject of a presidential proclamation of copyright restoration.

[18] Due to unintended delays in the routing and processing of this NIE, publication has been delayed beyond the four-month period set forth in the statute.

Baz Amadi Ay Jane Man (home recording version)
Baz Ayo Kenaram Beneshin
Baz Mekhaham Tura Ay Ishqe Man
Bazi To Kardi
Be Tu Gul Gashte Chaman
Bego Ke Gul Naferestad
Begzar bigiriam Man
Begzar Ta Begeryam
Begzarad Begzarad Omre Man
Begzarad Begzarad Omre Man (home recording version)
Begzaro Ta Begeryam
Beman Ay Shab
Benazam Qalbe Pakat
Berawed Ay Areefan
Bewafa Yaram
Bewafa Yaram (home recording version)
Bewafai Makon Ay Negaram
Beyayed Beyayed Ba Maidane
Beyayed Beyayed Ke Gulzar
Beyayed Beyayed Ke Gulzar (home recording version)
Bia Berem Ba Sangeran
Bimaram o Ghair Az Jigare
Biyayed Biyayed
Bodana Jan Bodana
Borida Bad Paye Man
Borida Bad Paye Man (home recording version)
Bosa Ha Talab Mekonad
Bote Nazaninam
Boye Khush Bahar
Boye To Khizad Hanoz
Boye To Khizad Hanoz (home recording version)
Bulbule Shoridah
Chal Akela Chal Akela
Chal Akela Chal Akela (home recording version)
Chal Chal Mere Saathi
Chashm Ba Rahat Dil ba Yadat
Chashmak Bezan Setara
Chashme Seya Dari
Che Behoda Che Sada
Che Garmi Chi Khubi Sharabi
Che Khahe Goft
Che Khelaf Sar Zad Az Ma
Che Khelaf Sar Zad Az Ma (home recording version)
Che Shod ke Rekht o ba Ham
Chera Dishab Ba Soye Man
Chi Shab Ha Ba Yadat
Chon darakht farwardin
Da Jamhoriat Zamong
Danam Chera Chashmane Tu
Dar Chee Konai Emshaw
Dar Damane Sahra
Dar Konje Dilam
Darakht Yaar Darakht Sabz
Dast Az Talab Nadaram
Delat Mekhast Baraye Tu
Dele Ma Har Chee Risho
Dil Ze Sawdaye Du Chashme
Dilaizar Raika Man
Dilakam Hay Dilakam
Dilakam Hay Dilakam (home recording version)
Dilam Dar Ashiqi Awara Shod
Dilat Mekhat Barayie Tu
Dilbara Gar tu Yaareman Bashi
Dile Devana
Dil-e Diwana
Dile Ma Har Chi Resh
Door Az Tu Har Shab
Dostat Daram Wallah Bellah
Dostet Darom Hamisha
Dozde Ishqam Man o Deshab
Ein Chi Ishqest
Ein Shero Ra Baraye Tu
Elahi Man Namedanam (home recording version)
Ellahi Man Namidanam
Emroz Farda
Emshab Shoda Am Mast
Emshab Shodaim mast
Eshqe Tu Bar Man
Faqat Soze Delam Ra
Gah Dar Aghoshe Ein
Gah Dar Aghoshe Ein (home recording version)
Gar Chi Chashme Tu
Gar chi Mastim O Kharabim
Gar Koni Yak Nezara
Gar Zolfe Porayshanat
Gar Zuif Preshanatu (home recording version)
Garchi Mastim
Goftam Ke Mekhwaham Tura
Gofti Ke Mibosam Tora
Goftom Ke Naro
Gozasht Anke Tu Sarkhile
Gul Sabo Ba Dosh Amad
Gule Sangam Gule Sangam
Gule Sangam Gule Sangam (home recording version)
Haasha Ke Man ba Mowsum
Hai Sharmaon Kis Kis Ko Bataon
Hai Yare Khobe Man
Hama Roz Az To
Hama Yaranam Ba Porayshani
Hama Yaranam Ba Preshani (home recording version)
Hamash Dardo Hamash Ranj
Hamash Dardo Hamash Ranjo Hamash Gham
Hamcho Nai Menalam
Hanoz Bar Labe Man
Har Chando Ke Door
Har Chando Ke Door (home recording version)
Hargez Hargez
Hargez Kasai Baroz
Hargez Kase Ba Roz
Harja Ke Safar Kardam
Harja Ke Safar Kardam (home recording version)
Hawaye Ishqe To Az Sar
Hosnat Robayad Aab o taTaab
Imshab az Bada kharabam
Imshab Ba Bame Asoman
Imshab Ba Qesaee Dile Man
Imshab Ba Qesaee Dile Man (home recording version)
Imshab Ba Yade Roye Tu
Ishq Mani
Ishq o Mehrat
Ishqai Bemanee Dil Barey
Ishqe Man Ba Tu Bood
Its Now or Never
Jeena Yahan Marna Yahan
Jeena Yahan Marna Yahan (home recording version)
Kaash Ay Tanha Omide Zendagi
Kajakee Abroyet
Kajaki Abroyat Nesh Kazhdum
Kame Na Randayem
Karda Am Nala Base
Kas Ra Khabar Nabasha
Kashke Kashke
Kasho Bodam Lala
Kasrah Khabar Nabsha
Kay Bashad o Kay
Khabar Dari Ke Dein
Khal Ba Konje Lab Yaki
Khanda Ba Lab Haye Tura
Kharabam Ze Masti
Khodat Medani Guleman
Khodat Medani Guleman (home recording version)
Khuda Bowad Hamrahet
Khuda Bowad Yaaret
Khuda Bowad Yaret (home recording version)
Khwab Az Chashmanam Raboodi
Kist Dar Shahro Ke
Kistam Man Rahnaward
Kitna Nazuk Hai Dil
Kojaye Delbare Man
Laili Laili Laili Jaan (home recording version)
Laili Laili Laili Jan
Lar Sha Nangarhar Ta
Lewanai Zuma
Magar Khuda Ze Raqiban
Mah Ham Ze Rah Rasid
Mah Ham Ze Rah Rasid (home recording version)
Maihan ay Maihan
Man Agar Dewanaham
Man Bare Sangeenam
Man Dar in Wayrana Manzil
Man Dar Saraye Tu
Man Gholame Qamaram
Man Ghulame Qamaram (home recording version)
Man Masto To Deewana
Man Na Goyam Kai Tu Bai Mehro Wafayee
Man Nadanistam
Man Nadanistam (home recording version)
Man Nagoyam Ke Mara Az Qafas
Man nainawazam
Man Randa Ze Maikhana
Mana Goyum Kai Mara Az Qafas Azad Konai
Mara An Roz Geryan Afaridan
Mara Chun Qatrayie Ashke
Mara Dil Khoon Kardi
Mara Mara May Bede
Maranjan Delam Ra
Maranjan Dilam Ra (home recording version)
Marge man
Marge Man Roze Faraa
Mashooqa basaman shod

Mashoqa Ba Saman Shud (home recording version)
Mast Shodam Saqi
Megom Ke Dostet Darom
Megum Ke Dostet Darum (home recording version)
Megzarat
Mera Hum Dum Milgaya
Merawam Khasta o Afsorda
Merawi Az Man Labrize Feghanam
Merawi az Man o Labreze
Meri Gagan
Mikhandam Agar Imshab
Milga Yah Sultan Edo
Mobarak Mobarak Jamhoori Ma
Mordam Az Dard
Na Dil Maftoon Dilbande
Na Dil Maftoon
Na Hum Tume Jaane
Na sorode Na Soroure
Nabari goman ke mofteh
Nala Ba Dil Shod Gereh
Nala Kon Ai Dile Shorida
Namedanam Ba Roye Ki Bekhandam
Namekhaham Tura
Namikhwaham To Ra
Naro Naro Az Peyshim
Nazanine
Ne Ne Hargez Hargez
Negah Kon Negah Kon
Oba Darta Rawram, Saba Darta Pakham
Oba Dirta Rawlom
Oh Bano Bano Jana
Oh Na Razi Janan Zama
Oh Na Razi Janan Zama (home recording version)
Omaid Zindagi
Paida Shodo Paida Shod
Pas Azin Zari Makon
Pen Dashtam Gulai Khaterai Mani
Pendashotam Hamisha Gule
Pere Rased o Fasele Jawani
Piri Raseed
Piri Rasido Fasle Jawani
Porkon Peyala Ra
Poshida Chon Jan Merawi
Poshida Choon Jan Mirawi
Pyar Ka Qabil Narahai
Qadah Ra Sar Konid
Qadah Ra Sar Konid (home recording version)
Que Sera Sera
Rakra Sharab Da Sro Labaano Sanam
Raqs Bokon Shor Bede
Raw Sar Bene Ba Balin
Raw Sar Bene Ba Balin (home recording version)
Royhai Nahaistan Gujast
Roz o Shabam (Ze hadesat)
Roz o Shabam (Ze hadesat) (home recording version)
Sad Rah Dar Intezarat
Sad Rah Dar Intezarat (home recording version)
Sahar megoft o bulbul
Sakhi Jaan Merawai
Saqiya Mara Daryab
Sar Sare Poshta
Sayad Nasasat Ze Kafas Azadam
Setara Dida Fero Bast
Shab Cho Dar Bastam
Shab Hai Zulmani
Shab Haye Rawshan
Shab Haye Zolmani
Shabe Ra Ba Man
Shabe Ze Shabha
Shadi Koned Ay Dostan
Shadi Koned Hai Dostan (home recording version)
Shekast Ahde Man o Goft
Shekast Ahde Mano Goft
Shekayat Daram
Shekayat Darum (home recoring version)
Shudam Dewana Dewana
Sorma Kadi
South of the Border
Soze Qalbam Jawedani
Surma Kadi Bemorom Sura Kadi
Surode Shabangah
Ta Ba Jafayat Khosham
Taal Mile
Tan Ha Tui
Tanha Shodam Tanha
Tanha Tarin Marde Zaminam
Tanha Toye
Tanha Toye Tanha Toye (home recording version)
Tel De Wae Naseeb
Toba Toba az Shabe Hijran
Tu Ba Mani To Ba Mani
Tu Ba Mani To Ba Mani (home recording version)
Tu Ba Yak Dashte Pur Az Gul
Tu Barayem Moqadasi
Tu Barayem Moqadasi (home recording version)
Tu Dani Tu Ze Chi Jawhar
Tu Darakhtai Parwardi
Tu Gar Ba Man Yar Shawi
Tu Gule Naaze Hama
Tura Afsoone Chashmanam
Tura Sad Bar Goftam
Tura Sad Bar Guftam (home recording version)
Untitled 1—Ahmad Zahir talking to friends and saying even though we don't see each other often, our friendship and closeness remain in our hearts. He plays a song for all of his friends.
Untitled 2—Ahmad Zahir improv at family gathering
Untitled 3—Ahmad Zahir improv in Pashto, followed by a song
Untitled 4—Ahmad Zahir being humorous and goofing off with a friend, singing a humorous song
Untitled 5—Ahmad Zahir freestyle jam session
Untitled 6—Ahmad Zahir and Fakhria Zahir composing a message for Fakhria's parents
Untitled 7—Ahmad Zahir talking about a poem, starts to sing 'Har Chando Ki Door As Tu o Peshe Degaranam' which means 'No matter how far I am from you'
Wai Baran Baran
Waqte ke Dil Tangast
Way man Behoda ham
Yade Aan Sarwe Rawan
Yade Rozogare Shirin
Yak Dil Miga Boro (Sultane Qalbha)
Yar Az Dile Man Khabar
Yar Ba Ma Bewafaee
Yarab Ghame Be Rahmye Janan
Yarake Man Chura Khosh
You Are My Sunshine
Zabanam Ra Namefahmi
Ze Bas Ba Yade Tu Har
Ze Dastam Bar Namekhezad
Ze Dastam Bar Namekhizad
Ze Hamrahan Jedayee
Ze Jane Man Chi Mikhahi
Ze Sang Nest Qable Man
Ze Sango Nist Qalbeman
Zeba Negaram Ba Man
Zebaam Kai Barkhast
Zindagi Akher Sarayad
Zindagi Chist
Zindagi Kuch Bhi Nahi Sirf Kahaani Hai
Zindagy Akher Sarayad

Dated: January 30, 2019.

Regan A. Smith,

General Counsel and Associate Register of Copyrights.

[FR Doc. 2019–00874 Filed 2–1–19; 8:45 am]

BILLING CODE 1410–30–P

NATIONAL FOUNDATION FOR THE ARTS AND THE HUMANITIES

Institute of Museum and Library Services

Notice of Proposed Information Collection Request: Guidelines for IMLS Grants to States Five-Year Evaluation

AGENCY: Institute of Museum and Library Services, National Foundation for the Arts and the Humanities.

ACTION: Notice; request for comments on this collection of information.

SUMMARY: The Institute of Museum and Library Services (IMLS), as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act. This pre-clearance consultation program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed.

A copy of the proposed information collection request can be obtained by contacting the individual listed below in the **ADDRESSES** section of this notice.

DATES: Written comments must be submitted to the office listed in the addressee section below on or before March 31, 2019.

IMLS is particularly interested in comments that help the agency to:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; 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 submissions of responses.

ADDRESSES: Send comments to: Dr. Sandra Webb, Director, Office of Grants Policy and Management, Institute of Museum and Library Services, 955 L'Enfant Plaza North SW, Suite 4000, Washington, DC 20024–2135. Dr. Webb can be reached by Telephone: 202–653–4718, Fax: 202–653–4608, or by email at *swebb@imls.gov,* or by teletype (TTY/TDD) for persons with hearing difficulty at 202–653–4614.

FOR FURTHER INFORMATION CONTACT: Teri DeVoe, Associate Deputy Director for Grants to States, Office of Library Services, Institute of Museum and Library Services, 955 L'Enfant Plaza North SW, Suite 4000, Washington, DC 20024–2135. She can be reached by Telephone: 202–653–4778, Fax: 202–653–4602, or by email at *tdevoe@imls.gov,* or by teletype (TTY/TDD) for persons with hearing difficulty at 202–653–4614.

SUPPLEMENTARY INFORMATION:

I. Background

The Institute of Museum and Library Services is the primary source of federal support for the nation's libraries and museums. We advance, support, and empower America's museums, libraries, and related organizations through grant making, research, and policy development. Our vision is a nation where museums and libraries work together to transform the lives of individuals and communities. To learn more, visit *www.imls.gov.*

Current Actions: The Grants to States program is the largest grant program administered by IMLS. Through this program, IMLS provides financial assistance to develop library services throughout the States, U.S. Territories, and the Freely Associated States. IMLS funds support projects that, among other purposes, promote literacy and education; enhance and expand the services and resources provided by all types of libraries; enhance the skills of the current and future library workforce and leadership; develop public-private partnerships with other agencies and community-based organizations; and target library services to individuals with diverse geographic, cultural and socio-economic backgrounds, individuals with disabilities, and individuals from other underserved communities. The program recognizes the increasing importance of information technology by emphasizing programs that teach digital literacy skills; develop library services that provide all users with access to information through local, State, regional, national, and international collaborations and networks; and establish or enhance electronic and other linkages among and between libraries and other entities.

A State Library Administrative Agency (''SLAA'') is the official agency of a State charged by law with the extension and development of public library services throughout the State. To receive funds under the Grants to States program, each SLAA must submit to the Director of IMLS a State Plan detailing certain goals, assurances, and procedures for a five-year period. A State Plan is a document that identifies a State's library needs, sets forth the activities to be taken toward meeting the identified needs supported with the assistance of Federal funds made available under subchapter II (Library Services and Technology, ''LSTA'') and provides assurances that the officially designated SLAA has the fiscal and legal authority and capability to administer all aspects of any award under the Grants to States program. The State Plan must also provide assurances for establishing the State's policies, priorities, criteria, and procedures necessary to the implementation of all programs under the LSTA.

IMLS authorizing legislation directs State Library Administrative Agencies (SLAAs) to ''independently evaluate, and report to the Director regarding, the activities assisted under this subchapter, prior to the end of the Five Year Plan.'' This evaluation provides SLAAs an opportunity to measure progress in meeting the goals set in their approved Five Year Plans with a framework to synthesize information across all state reports in telling a national story.

This action is to seek approval for the instructions for the Guidelines for IMLS Grants to States Five-Year Evaluation for the next three years.

Agency: Institute of Museum and Library Services.

Title: Guidelines for IMLS Grants to States Five-Year Evaluation.

OMB Number: 3137–0090.

Frequency: Once every five years.

Affected Public: State Library Administrative Agencies.

Number of Respondents: 59.

Estimated Average Burden per Response: 90 hours.

Estimated Total Annual Burden: 5,310 hours.

Total Annualized Capital/Startup Costs: n/a.

Total Annual Costs: $148,361.

Public Comments Invited: Comments submitted in response to this notice will be summarized and/or included in the request for OMB's clearance of this information collection.

Dated: January 29, 2019.

Kim Miller,

Grants Management Specialist, Institute of Museum and Library Services.

[FR Doc. 2019–00809 Filed 2–1–19; 8:45 am]

BILLING CODE 7036–01–P

NATIONAL SCIENCE FOUNDATION

Notice of Intent To Seek Approval To Renew an Information Collection

AGENCY: National Science Foundation.

ACTION: Notice and request for comments.

SUMMARY: The National Science Foundation (NSF) is announcing plans to renew clearance of this collection. In accordance with the requirements of the Paperwork Reduction Act of 1995, we are providing opportunity for public comment on this action. After obtaining and considering public comment, NSF will prepare the submission requesting OMB clearance of this collection for no longer than 3 years.

DATES: Written comments should be received by April 5, 2019 to be assured of consideration. Comments received after that date will be considered to the extent practicable.

ADDRESSES: Written comments regarding the information collection and requests for copies of the proposed information collection request should be addressed to Suzanne Plimpton, Reports

Clearance Officer, National Science Foundation, 2415 Eisenhower Avenue, Suite 18000W, Alexandria, VA 22314, or by email to *splimpto@nsf.gov.*

FOR FURTHER INFORMATION CONTACT: Suzanne Plimpton on (703) 292–7556 or send email to *splimpto@nsf.gov.* Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339, which is accessible 24 hours a day, 7 days a week, 365 days a year (including federal holidays).

SUPPLEMENTARY INFORMATION:

Comments: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information shall have practical utility; (b) the accuracy of the Agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information on respondents, including through the use of automated collection techniques or other forms of information technology; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Title of Collection: ''Biological Sciences Proposal Classification Form.''

OMB Approval Number: 3145–0203.

Expiration Date of Approval: March 31, 2019.

Type of Request: Intent to seek approval to renew an information collection for three years.

Proposed Project: Five organizational units within the Directorate of Biological Sciences of the National Science Foundation will use the Biological Sciences Proposal Classification Form. They are the Division of Biological Infrastructure (DBI), the Division of Environmental Biology (DEB), the Division of Molecular and Cellular Biosciences (MCB), the Division of Integrative Organismal Systems IOS) and Emerging Frontiers (EF). All scientists submitting proposals to these units will be asked to complete an electronic version of the Proposal Classification Form. The form consists of brief questions about the substance of the research and the investigator's previous federal support. Each division will have a slightly different version of the form. In this way, submitters will only confront response choices that are relevant to their discipline.

Use of the Information: The information gathered with the Biological Sciences Proposal Classification Form serves two main purposes. The first is facilitation of the proposal review process. Since peer review is a key component of NSF's grant-making process, it is imperative that proposals are reviewed by scientists with appropriate expertise. The information collected with the Proposal Classification Form helps ensure that the proposals are evaluated by specialists who are well versed in appropriate subject matter. This helps maintain a fair and equitable review process.

The second use of the information is program evaluation. The Directorate is committed to investing in a range of substantive areas. With data from this collection, the Directorate can calculate submission rates and funding rates in specific areas of research. Similarly, the information can be used to identify emerging areas of research, evaluate changing infrastructure needs in the research community, and track the amount of international research. As the National Science Foundation is committed to funding cutting-edge science, these factors all have implications for program management.

The Directorate of Biological Sciences has a continuing commitment to monitor its information collection in order to preserve its applicability and necessity. Through periodic updates and revisions, the Directorate ensures that only useful, non-redundant information is collected. These efforts will reduce excessive reporting burdens.

Burden on the Public: The Directorate estimates that an average of five minutes is expended for each proposal submitted. An estimated 6,500 responses are expected during the course of one year for a total of 542 public burden hours annually.

Expected Respondents: Individuals.

Estimated Number of Responses: 6,500.

Estimated Number of Respondents: 6,500.

Estimated Total Annual Burden on Respondents: 542 hours.

Frequency of Responses: On occasion.

Dated: January 30, 2019.

Suzanne H. Plimpton,

Reports Clearance Officer, National Science Foundation.

[FR Doc. 2019–00834 Filed 2–1–19; 8:45 am]

BILLING CODE 7555–01–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 March 6, 2019. 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

1. *Applicant: Permit Application: 2019–017.* Robert Sanders, Department of Biology, Temple University, 1900 N 12th Street, Philadelphia, PA 19122.

Activity for Which Permit is Requested: Introduce Non-indigenous Species into Antarctica. The applicant would use cultures of the bacteria as a food source during a study of Antarctic mixotrophic phytoplankton aboard the research vessel Laurence M. Gould. The bacterial culture is a non-pathogenic marine species (*Photobacterium angustum*) obtained from American Type Culture Collection. This bacterial

species would be used as it has been shown to have the ability to incorporate a thymidine substitute that can be used to identify which phytoplankton have ingested the bacteria. The feeding experiments would be conducted in sealed plastic containers kept isolated from the environment. At the conclusion of the experiments, any sample or culture remaining, including filtered seawater, would be destroyed by autoclaving on the ship. Supplies and equipment would be sterilized at the end of each experiment by autoclaving or using ethanol. The applicant and permit agents are experienced in using sterile techniques and in maintaining safe practices with microbial cultures.

Location: West Antarctic Peninsula region.

Dates of Permitted Activities: April 10–May 31, 2019.

2. *Applicant:* Permit Application: 2019–018. Daniel P. Zitterbart, Woods Hole Oceanographic Institution, 266 Woods Hole Road, Woods Hole, MA 02543–1050.

Activity for Which Permit is Requested: Take. The permit applicant proposes to place short-term deployment tags on humpback whales (*Megaptera novaeangliae*) for the purposes of studying their foraging ecology. The applicant would deploy digital acoustic recording tags (DTAGs) onto humpback whales to record the three-dimensional movement of the animals, and the presence of feeding lunges. DTAGs contain a 3-axis accelerometer and magnetometer that record the pitch, yaw, and heading of the whale at a high sampling rate (> 50 Hz), as well as a pressure sensor that records the depth of the animal. A FastLoc® (Wildtrack Telemetry Systems Ltd) GPS tag will also be attached to the DTAG, allowing the position of the whale to be recorded throughout the deployment. To deploy the tag, a zodiac will be used to approach the whale, with the tag lowered onto the back of the whale using a carbon-fibre pole. Effort will be made to tag animals that are determined to be in transit or resting, and not currently feeding. The tags would be released from the whales after several hours and would be retrieved by the researchers. The applicant proposes to tag up to five adult or sub-adult humpack whales during the permit period (no calves would be tagged). Up to 70 additional whales, all ages, would potentially be approached and disturbed during the tagging efforts. The applicant and agents would also conduct water and oceanographic sampling, as well as deploy an echosounder and hydrophone, in order to study the availability of prey and oceanographic conditions during whale foraging. The study would be conducted during an expedition aboard a tour vessel operated by Polar Latitudes, Inc.

Location: West Antarctic Peninsula region.

Dates of Permitted Activities: March 1–20, 2019.

Suzanne H. Plimpton,

Reports Clearance Officer, National Science Foundation.

[FR Doc. 2019–00879 Filed 2–1–19; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on the Medical Uses of Isotopes: Meeting Notice

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of meeting.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) will convene a teleconference meeting of the Advisory Committee on the Medical Uses of Isotopes (ACMUI) on February 26, 2019, to discuss the draft report of the ACMUI Training and Experience Subcommittee. This report will include the subcommittee's recommendation on training and experience requirements for authorized users under title 10 *Code of Federal Regulations* (10 CFR) 35.300, ''Use of unsealed byproduct material for which a written directive is required,'' that is necessary for safety. Meeting information, including a copy of the agenda and handouts, will be available at *http://www.nrc.gov/reading-rm/doc-collections/acmui/meetings/2019.html.* The agenda and handouts may also be obtained by contacting Ms. Kellee Jamerson using the information below.

DATES: The teleconference meeting will be held on Tuesday, February 26, 2019, 10:00 a.m. to 12:00 p.m. Eastern Time.

FOR FURTHER INFORMATION CONTACT: Any member of the public who wishes to participate in the teleconference should contact Ms. Jamerson using the contact information below or may register for the GoToWebinar at *https://register.gotowebinar.com/register/3062144677756975362* for the February 26, 2019, meeting.

Contact Information: Kellee Jamerson, email: *Kellee.Jamerson@nrc.gov,* telephone: (301) 415–7408.

SUPPLEMENTARY INFORMATION:

Conduct of the Meeting

Dr. Christopher Palestro, ACMUI Chairman, will preside over the meeting. Dr. Palestro will conduct the meeting in a manner that will facilitate the orderly conduct of business. The following procedures apply to public participation in the meeting:

1. Persons who wish to provide a written statement should submit an electronic copy to Ms. Jamerson at the contact information listed above. All submittals must be received by February 21, 2019, 3 business days prior to the February 26, 2019, meeting, and must pertain to the topic on the agenda for the meeting.

2. Questions and comments from members of the public will be permitted during the meeting at the discretion of the Chairman.

3. The draft transcript and meeting summary will be available on ACMUI's website *http://www.nrc.gov/reading-rm/doc-collections/acmui/meetings/2019.html* on or about April 9, 2019.

This meeting will be held in accordance with the Atomic Energy Act of 1954, as amended (primarily Section 161a); the Federal Advisory Committee Act (5 U.S.C. App); and the Commission's regulations in 10 CFR part 7.

Dated: January 30, 2019.

Russell E. Chazell,

Federal Advisory Committee Management Officer.

[FR Doc. 2019–00908 Filed 2–1–19; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2019–0001]

Sunshine Act Meetings

TIME AND DATE: Weeks of February 4, 11, 18, 25, March 4, 11, 2019.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and Closed.

MATTERS TO BE CONSIDERED:

Week of February 4, 2019

There are no meetings scheduled for the week of February 4, 2019.

Week of February 11, 2019—Tentative

There are no meetings scheduled for the week of February 11, 2019.

Week of February 18, 2019—Tentative

There are no meetings scheduled for the week of February 18, 2019.

Week of February 25, 2019—Tentative

There are no meetings scheduled for the week of February 25, 2019.

Week of March 4, 2019—Tentative

There are no meetings scheduled for the week of March 1, 2019.

Week of March 11, 2019—Tentative

There are no meetings scheduled for the week of March 11, 2019.

CONTACT PERSON FOR MORE INFORMATION: For more information or to verify the status of meetings, contact Denise McGovern at 301–415–0681 or via email at *Denise.McGovern@nrc.gov.* The schedule for Commission meetings is subject to change on short notice.

The NRC Commission Meeting Schedule can be found on the internet at: *http://www.nrc.gov/public-involve/public-meetings/schedule.html.*

The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings, or need this meeting notice or the transcript or other information from the public meetings in another format (*e.g.,* Braille, large print), please notify Kimberly Meyer-Chambers, NRC Disability Program Manager, at 301–287–0739, by videophone at 240–428–3217, or by email at *Kimberly.Meyer-Chambers@nrc.gov.* Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

Members of the public may request to receive this information electronically. If you would like to be added to the distribution, please contact the Nuclear Regulatory Commission, Office of the Secretary, Washington, DC 20555 (301–415–1969), or by email at *Wendy.Moore@nrc.gov* or *Diane.Garvin@nrc.gov.*

Dated at Rockville, Maryland, this 31st day of January, 2019.

For the Nuclear Regulatory Commission.

Denise L. McGovern,

Policy Coordinator, Office of the Secretary.

[FR Doc. 2019–01043 Filed 1–31–19; 4:15 pm]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 40–8838; NRC–2019–0027]

U.S. Department of the Army; Jefferson Proving Ground

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Draft environmental assessment and draft finding of no significant impact; notice of availability and request for comments.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing for public comment a draft environmental assessment (EA) and draft finding of no significant impact (FONSI) for a proposed amendment of NRC source materials license SUB–1435 for the Jefferson Proving Ground (JPG) from ''possession only for decommissioning'' to ''possession only.'' The proposed amendment of the U.S. Department of the Army (Army)'s license would also include an exemption from the NRC's decommissioning timeliness requirements in the regulations. The draft EA, ''Draft Environmental Assessment for the Proposed Amendment of Materials License SUB–1435, Jefferson Proving Ground, Southeastern Indiana (Jefferson, Ripley, and Jennings Counties),'' documents the NRC staff's environmental review of the license amendment application.

DATES: Submit comments by March 6, 2019. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received before this date.

ADDRESSES: You may submit comments by any of the following methods:

- *Federal Rulemaking Website:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2019–0027. Address questions about Docket IDs in *Regulations.gov* to Ms. Krupskaya Castellon; telephone: 301–287–9221; email: *Krupskaya.Castellon@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* Office of Administration, Mail Stop: TWFN–7–A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Program Management, Announcements and Editing Staff.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Christine Pineda, Office of Nuclear Material Safety and Safeguards, telephone: 301–415–6789; email: *Christine.Pineda@nrc.gov;* U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2019–0027 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2019–0027.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*Begin Web-based ADAMS Search.*'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced in this document (if that document is available in ADAMS) is provided the first time that a document is referenced. The ADAMS Accession Number for the draft EA is ML19008A310. The document can also be accessed directly at *https://www.nrc.gov/docs/ML1900/ML19008A310.pdf.*
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID NRC–2019–0027 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at: *http://www.regulations.gov* as well as enter the comment submissions into the ADAMS Public Documents collection. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into the ADAMS Public Documents collection.

II. Introduction

Jefferson Proving Ground (JPG) was established in 1940 on 224 square kilometers (km^2) [55,265 acres (ac)] in parts of Jefferson, Ripley, and Jennings

counties in southeastern Indiana for the production and specification testing of conventional ammunition components. The nearest population center is Madison, Indiana, located approximately 8 kilometers (km) [5 miles (mi)] south of JPG. The site was used by the Army between 1941 and 1994 for munitions testing and, during that time, more than 24 million rounds were fired. Approximately 1.5 million rounds did not detonate upon impact, remaining as unexploded ordnance (UXO) on or beneath the ground surface, along with an additional 3 to 5 million rounds with live detonators, primers, or fuses. As part of its munitions testing program, the Army also test-fired depleted uranium (DU) projectiles into the 8.4-square kilometers (km^2) [2,080-acres (ac)] DU Impact Area, which is located within the JPG installation. The DU test firings began on March 18, 1984, and concluded on May 2, 1994. The Army estimates that a high density of high-explosive UXO is present in the DU Impact Area.

The NRC is considering a request for an amendment to the Army's source materials license SUB–1435. The license authorizes possession only by the Army of up to 80,000 kilograms (kg) [176,370 pounds (lb)] of DU metal, alloy, and/or other forms, kept onsite, for the purpose of decommissioning, in the restricted area known as the ''Depleted Uranium Impact Area'' (DU Impact Area) at the JPG site in southeastern Indiana. The NRC is considering a license amendment that would modify the license from ''possession only for decommissioning'' to ''possession only'' and an exemption from the NRC's decommissioning timeliness requirements in Title 10 of the *Code of Federal Regulations* (10 CFR) Paragraph 40.42(d). The need for this NRC licensing action is to ensure the safe possession of radioactive materials (in the form of DU). The Army needs to delay remediation of the DU Impact Area because remediation is prohibitively expensive and poses a risk of potential explosions due to the presence of a large amount of UXO.

In accordance with NRC's regulations in 10 CFR part 51, ''Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions,'' that implement the National Environmental Policy Act of 1969, as amended (NEPA) (42 U.S.C. 4321 *et seq.*), the NRC staff has prepared a draft EA documenting its environmental review of the license amendment application (ADAMS Accession Numbers: ML17004A186, and ML18156A002). Based on the environmental review, the NRC has made a preliminary determination that the proposed action will not significantly affect the quality of the human environment and that a FONSI is therefore appropriate.

By this notice, the NRC is requesting public comment on the draft FONSI and supporting draft EA.

III. Summary of Draft Environmental Assessment

The draft EA is publicly available in ADAMS using ADAMS Accession Number ML19008A310, or at this link: *https://www.nrc.gov/docs/ML1900/ML19008A310.pdf.* A summary description of the proposed action and expected environmental impacts is provided below.

Description of the Proposed Action

The proposed action is for the NRC to (1) amend Condition 9 of materials license SUB–1435 to change the authorized use of licensed material from ''possession only for decommissioning'' to ''possession only'' for a 20-year term and (2) grant an exemption from the NRC's decommissioning timeliness requirements in 10 CFR 40.42(d) for the term of the license. Under the proposed action and in accordance with current license conditions, the licensed DU material would remain onsite in the restricted area known as the DU Impact Area at JPG. In accordance with a Memorandum of Agreement (MOA) established in 2000 with the U.S. Fish and Wildlife Service and the U.S. Air Force, the Army would continue to maintain institutional control and implement land use restrictions over an area of approximately 206-km^2 [50,950-ac], which includes the DU Impact Area. Under the terms of the MOA, the Army would remain responsible for remediation of all contamination resulting from Army activities, including the ultimate remediation and control of all DU in the NRC-licensed DU Impact Area.

Environmental Impacts of the Proposed Action

In the draft EA, the NRC staff assessed the potential environmental impacts from the proposed license amendment and exemption to the following resource areas: land use; geology and soils; water resources; ecological resources; climatology, meteorology, and air quality; environmental justice; and public and occupational health. The NRC staff also considered the cumulative impacts from past, present, and reasonably foreseeable future actions when combined with the proposed action.

All potential impacts from the proposed action were determined to be SMALL, as described in the EA. The NRC staff concluded that approval of the proposed action would not result in a significant increase in short-term or long-term radiological risk to public health or the environment. Furthermore, the NRC staff found that there would be no significant negative cumulative impact to any resource area from the proposed action when added to other past, present, and reasonably foreseeable future actions, and that a positive cumulative ecological impact would likely result from the continued management of the Big Oaks National Wildlife Refuge over the proposed action's 20-year duration.

Environmental Impacts of the Alternatives to the Proposed Action

As an alternative to the proposed action, the NRC staff considered denial of the proposed action (*i.e.,* the ''no-action'' alternative). Under the no-action alternative, the NRC would not grant the license amendment or exemption, and the Army would need to comply with the terms of its current license, which authorizes possession only for decommissioning. Under this alternative, the Army would need to submit a decommissioning plan. The NRC staff concluded that decommissioning activities for a 20-year duration would be restricted due to the presence of UXO and, therefore, the potential impacts of the no-action alternative over a period of 20 years would be SMALL and similar or identical to the impacts of the proposed action.

IV. Draft Finding of No Significant Impact

In accordance with the NEPA and 10 CFR part 51, the NRC staff has conducted an environmental review of a request for an amendment to NRC source materials license SUB–1435 that would change the authorized use of licensed material from ''possession only for decommissioning'' to ''possession only'' and for an exemption from the NRC's decommissioning timeliness requirements in 10 CFR 40.42(d). Based on its environmental review of the proposed action, as documented in the draft EA, the NRC staff has preliminarily determined that granting the requested license amendment and exemption would not significantly affect the quality of the human environment. Therefore, the NRC staff has preliminarily determined, pursuant to 10 CFR 51.31, that preparation of an environmental impact statement is not required for the proposed action and a

FONSI is appropriate. Pursuant to 10 CFR 51.33(a), the NRC staff is making the draft FONSI and draft EA available for public review and comment.

Dated at Rockville, Maryland, this 30th day of January 2019.

For the U.S. Nuclear Regulatory Commission.

Andrew Pretzello,

Acting Director, Division of Fuel Cycle Safety, Safeguards, and Environmental Review, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2019–00878 Filed 2–1–19; 8:45 am]

BILLING CODE 7590–01–P

OFFICE OF PERSONNEL MANAGEMENT

Submission for Review: Request for Case Review for Enhanced Disability Annuity Benefit, RI 20–123

AGENCY: Office of Personnel Management.

ACTION: 60-Day Notice and request for comments.

SUMMARY: The Retirement Services, Office of Personnel Management (OPM) offers the general public and other federal agencies the opportunity to comment on a revised information collection request (ICR), Request for Case Review for Enhanced Disability Annuity Benefit, RI 20–123.

DATES: Comments are encouraged and will be accepted until April 5, 2019.

ADDRESSES: You may submit comments, identified by docket number and title, by the following method:

• *Federal Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

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

FOR FURTHER INFORMATION CONTACT: A copy of this ICR with applicable supporting documentation, may be obtained by contacting the Retirement Services Publications Team, Office of Personnel Management, 1900 E Street NW, Room 3316–L, Washington, DC 20415, Attention: Cyrus S. Benson, or sent by email to *Cyrus.Benson@opm.gov* or faxed to (202) 606–0910 or reached via telephone at (202) 606–4808.

SUPPLEMENTARY INFORMATION: As required by the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. chapter 35) as amended by the Clinger-Cohen Act (Pub. L. 104–106), OPM is soliciting comments for this collection (OMB No. 3206–0254). The Office of Management and Budget is particularly interested in comments that:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

Form RI 20–123 is used by retirees separated for disability and the survivors of retirees separated for disability to request that Retirement Operations review the computations of disability annuities to include the formulae provided in law for individuals who performed service as law enforcement officers, firefighters, nuclear materials carriers, air traffic controllers, Congressional employees, and Capitol and Supreme Court police.

Analysis

Agency: Retirement Services, Office of Personnel Management.

Title: Request for Case Review for Enhanced Disability Annuity Benefit.

OMB Number: 3206–0254.

Frequency: On occasion.

Affected Public: Individuals or Households.

Number of Respondents: 100.

Estimated Time per Respondent: 5 minutes.

Total Burden Hours: 25.

Office of Personnel Management.

Alexys Stanley,

Regulatory Affairs Analyst.

[FR Doc. 2019–00796 Filed 2–1–19; 8:45 am]

BILLING CODE 6325–38–P

POSTAL SERVICE

Temporary Emergency Committee of the Board of Governors; Sunshine Act Meeting

FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT: 84 FR 500.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: Thursday, February 7, 2019 at 10:30 a.m.; and Friday, February 8, 2019 at 9:00 a.m.

PLACE: Columbus, Ohio, at the Sheraton Columbus Hotel at Capitol Square, 75 East State Street, Columbus, OH 43215, in the Legislative Room.

STATUS: Thursday, February 7, 2019—Closed; Friday, February 8, 2019—Open.

CHANGES IN THE MEETING: Time of closed session changed and one item removed from open session agenda.

REVISED TIME AND MATTERS TO BE CONSIDERED:

Thursday, February 7, 2019 at 10:00 a.m. (Closed)

1. Strategic Issues.
2. Financial Matters.
3. Compensation and Personnel Matters.
4. Executive Session—Discussion of prior agenda items and Board governance.

Friday, February 8, 2019 at 9:00 a.m. (Open)

1. Remarks of the Chairman of the Temporary Emergency Committee of the Board.
2. Remarks of the Postmaster General and CEO.
3. Approval of Minutes of Previous Meetings.
4. Committee Reports.
5. Quarterly Financial Report.
6. Quarterly Service Performance Report.
7. Approval of Tentative Agenda for April meetings.

A public comment period will begin immediately following the adjournment of the open session on February 8, 2019. During the public comment period, which shall not exceed 30 minutes, members of the public may comment on any item or subject listed on the agenda for the open session above. Registration of speakers at the public comment period is required. Speakers may register online at *https://www.surveymonkey.com/r/USPS-BOG-Question.* Onsite registration will be available until thirty minutes before the meeting starts. No more than three minutes shall be allotted to each speaker. The time allotted to each speaker will be determined after

registration closes. Participation in the public comment period is governed by 39 CFR 232.1(n).

CONTACT PERSON FOR MORE INFORMATION: Acting Secretary of the Board, U.S. Postal Service, 475 L'Enfant Plaza SW, Washington, DC 20260–1000. Telephone: (202) 268–4800.

Michael J. Elston,

Acting Secretary.

[FR Doc. 2019–01105 Filed 1–31–19; 4:15 pm]

BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–85000; File No. SR–NASDAQ–2018–079]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change To Amend Nasdaq Rules 5705 and 5710 To Adopt a Disclosure Requirement for Certain Securities

January 29, 2019.

On November 29, 2018, The Nasdaq Stock Market LLC (''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 with respect to amend Nasdaq Rules 5705 and 5710 to adopt a disclosure requirement for certain securities. The proposed rule change was published for comment in the **Federal Register** on December 19, 2018.[3] The Commission has received no comment letters regarding the proposed rule change.

Section 19(b)(2) of the Act [4] provides that, within 45 days of 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 disapproved. The 45th day after publication of the notice for this proposed rule change is February 2, 2019. 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 the proposed rule change. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[5] designates March 19, 2019, 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–NASDAQ–2018–079).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[6]

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019–00803 Filed 2–1–19; 8:45 am]

BILLING CODE 8011–01–P

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 84812 (December 13, 2018), 83 FR 65184.

[4] 15 U.S.C. 78s(b)(2).

[5] *Id.*

[6] 17 CFR 200.30–3(a)(31).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–84982; File No. SR–FINRA–2018–039]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change Relating to FINRA Rule 4570 (Custodian of Books and Records)

January 11, 2019.

On November 15, 2018, Financial Industry Regulatory Authority, Inc. (''FINRA'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change relating to FINRA Rule 4570 (Custodian of Books and Records). The proposed rule change was published for comment in the **Federal Register** on November 30, 2018.[3] The Commission has received no comment letters regarding the proposed rule change.

Section 19(b)(2) of the Act[4] provides that, within 45 days of 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 find 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 disapproved. The 45th day after publication of the notice for this proposed rule change is January 14, 2019. 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 the proposed rule change.[5] Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[6] designates February 28, 2019, 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–FINRA–2018–39).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[7]

Brent J. Fields,

Secretary.

[FR Doc. 2019–00805 Filed 2–1–19; 8:45 am]

BILLING CODE 8011–01–P

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 84646 (November 26, 2018), 83 FR 61689.

[4] 15 U.S.C. 78s(b)(2).

[5] We also note that by letter dated December 27, 2018, FINRA consented to extending to February 28, 2019 the time period for Commission action on SR–FINRA–2018–039. *See http://www.finra.org/sites/default/f2018-39-Extension-1.pdf.*

[6] *Id.*

[7] 17 CFR 200.30–3(a)(31).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–84999; File No. SR–MSRB–2019–01]

Self-Regulatory Organizations; Municipal Securities Rulemaking Board; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Extend the Effective Date of Previously-Approved Amendments to Rule G–21 and New Rule G–40

January 29, 2019.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act'') [1] and Rule 19b–4 thereunder,[2] notice is hereby given that on January 28, 2019 the Municipal Securities Rulemaking Board (''MSRB'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the MSRB. The Commission is publishing this notice to

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The MSRB filed with the Commission a proposed rule change to extend the February 7, 2019, effective date of previously-approved amendments to Rule G–21, on advertising by brokers, dealers or municipal securities dealers, and new Rule G–40, on advertising by municipal advisors (''proposed rule change'').[3] The MSRB has designated the proposed rule change for immediate effectiveness. The new effective date of the amendments to Rule G–21 and new Rule G–40 will be announced in an MSRB Notice to be published on the MSRB's website no later than 60 days following publication of the proposed rule change in the **Federal Register**. The effective date to be announced will be not later than 180 days following publication of the MSRB Notice.

The text of the proposed rule change is available on the MSRB's website at *www.msrb.org/Rules-and-Interpretations/SEC-Filings/2019-Filings.aspx,* at the MSRB's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the MSRB included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The MSRB has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The MSRB proposes to extend the effective date of amendments to Rule G–21 and new Rule G–40 (collectively ''advertising rules''). On May 7, 2018, the Commission approved the amendments with an effective date of February 7, 2019.[4]

The amendments to Rule G–21 (i) provide more specific content standards for advertisements by brokers, dealers or municipal securities dealers (collectively, dealers), (ii) revise the rule's general standards for advertisements, and (iii) reconcile analogous provisions relating to the definition of ''form letter'' in Rule G–21 with the definition of correspondence in FINRA Rule 2210, on communications. The amendments also include a technical amendment in paragraph (e) to streamline the rule.

New Rule G–40 includes general provisions, addresses professional advertisements by municipal advisors, and requires principal approval, in writing, for advertisements by municipal advisors before their first use. The general provisions (i) define key terms, including the term ''advertisement,'' (ii) provide content standards, such as the requirement that an advertisement be based on the principles of fair dealing and good faith and be fair and balanced, and (iii) provide general standards for advertisements, namely that a municipal advisor shall not publish or disseminate an advertisement that the municipal advisor knows or has reason to know contains any untrue statement of material fact or is otherwise false or misleading.

In setting an effective date of February 7, 2019, the MSRB was seeking to provide dealers and municipal advisors sufficient time to establish and implement effective processes and procedures to comply with the advertising rules. Consistent with that intent, the MSRB planned to provide guidance relating to: A municipal advisor's use of case studies and municipal advisory client lists; Rule G–40's content standards; and the use of social media.[5] The MSRB is seeking to extend the effective date of the amendment to Rule G–21 and new Rule G–40 because additional time is needed to finalize its initial guidance and any related rule changes concerning the use of social media under MSRB advertising rules and, subsequently, allow dealers and municipal advisors to establish and implement effective policies and procedures for compliance with the advertising rules.

Accordingly, the MSRB submits this proposed rule change to extend the effective date of the amendments to Rule G–21 and new Rule G–40.

2. Statutory Basis

The MSRB believes that the proposed rule change is consistent with Section 15B(b)(2)(C) of the Act,[6] which provides that the MSRB's rules shall:

> be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in municipal securities and municipal financial products, to remove impediments to and perfect the mechanism of a free and open market in municipal securities and municipal financial products, and, in general, to protect investors, municipal entities, obligated persons, and the public interest.

The proposed rule change does not alter any rule language but extends the effective date of the amendments to Rule G–21 and new Rule G–40, which were previously approved by the Commission. The MSRB believes that by extending the effective date until after the guidance concerning the use of social media under MSRB advertising rules is finalized, dealers and municipal advisors will be afforded the time necessary to develop effective compliance procedures. Therefore, the proposed rule change will promote effective compliance with MSRB advertising rules and help prevent fraudulent and manipulative practices, promote just and equitable principles of trade, and protect investors, municipal entities, obligated persons and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

Section 15B(b)(2)(C) of the Act[7] requires that MSRB rules be designed not to impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The MSRB does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the Act. The proposed rule change will not alter any rule language and will, instead, only extend the effective date of the amendments to Rule G–21 and new Rule G–40.

Additionally, Section 15B(b)(2)(L)(iv) of the Act, requires that MSRB rules not impose a regulatory burden on small municipal advisors that is not necessary or appropriate in the public interest and for the protection of investors, municipal entities, and obligated persons, provided that there is robust

[3] *See* Release No. 34–83177 (May 7, 2018); 83 FR 21794 (May 10, 2018) (File No. SR–MSRB–2018–01). The SEC also approved a technical amendment to Rule G–42, on duties of non-solicitor municipal advisors. The compliance date for this amendment to Rule G–42 would remain February 7, 2019.

[4] *Id.*

[5] See Letter from Pamela K. Ellis, Associate General Counsel, MSRB, dated April 30, 2018, available at *http://msrb.org/~/media/Files/SEC-Filings/2018/MSRB-2018-01%20MSRB%20Letter%20to%20SEC.ashx?.*

[6] 15 U.S.C. 78*o*–4(b)(2)(C).

[7] *Id.*

protection of investors against fraud.[8] The MSRB believes that the proposed rule change is consistent with Section 15B(b)(2)(L)(iv) of the Act in that, while the proposed rule change would affect all municipal advisors, including small municipal advisors, any regulatory burden that results is necessary and appropriate in order to promote regulatory consistency of advertising standards.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Pursuant to Section 19(b)(3)(A)[9] of the Act and Rule 19b–4(f)(6)[10] thereunder, the MSRB has designated the proposed rule change as one that effects a change that: (i) Does not significantly affect the protection of investors or the public interest; (ii) does not impose any significant burden on competition; and (iii) by its terms, does not become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate. A proposed rule change filed under Rule 19b–4(f)(6) normally does not become operative until 30 days after the date of filing.[11] However, Rule 19b–4(f)(6)(iii)[12] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest.[13] The MSRB has requested that the Commission designate the proposed rule change operative upon filing,[14] as specified in Rule 19b–4(f)(6)(iii),[15] which would make the proposed rule change operative on January 28, 2019.

The MSRB notes that the proposed rule change does not contain any amendments to the text of MSRB rules but extends the effective date of the amendments to Rule G–21 and new Rule G–40, which were previously approved by the Commission. The MSRB believes that by extending the effective date until after the guidance concerning the use of social media under MSRB advertising rules is finalized, dealers and municipal advisors will be afforded the time necessary to develop effective compliance procedures. Further, the MSRB has stated that, in light of a 30-day operative period that would conclude after the original effective date of February 7, 2019, an earlier operative date would provide regulatory certainty to dealers and municipal advisors that the effective date for compliance with the amendments to Rule G–21 and new Rule G–40 is extended.

The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. The proposed rule change will help promote effective compliance with the amendments to Rule G–21 and new Rule G–40. Waiver of the 30-day operative period will provide certainty to dealers and municipal advisors that the effective date for compliance with the amendments to Rule G–21 and new Rule G–40 is extended in advance of February 7, 2019 and avoid confusion in the market. Accordingly, the Commission hereby waives the 30-day operative delay specified in Rule 19b–4(f)(6)(iii) and designates the proposed rule change to be operative upon filing.[16]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–MSRB–2019–01 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

All submissions should refer to File Number SR–MSRB–2019–01. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the MSRB. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–MSRB–2019–01 and should be submitted on or before February 25, 2019.

For the Commission, pursuant to delegated authority.[17]

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019–00802 Filed 2–1–19; 8:45 am]

BILLING CODE P

[8] 15 U.S.C. 78*o*–4(b)(2)(L)(iv).

[9] 15 U.S.C. 78s(b)(3)(A).

[10] 17 CFR 240.19b–4(f)(6).

[11] *Id.*

[12] 17 CFR 240.19b–4(f)(6)(iii).

[13] In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file a proposed rule change, along with a brief description and text of such proposed rule change, at least five business days prior to the date of filing, or such shorter time as designated by the Commission. The Commission has designated a shorter time for delivery of such written notice.

[14] *See* SR–MSRB–2018–10.

[15] 17 CFR 240.19b–4(f)(6)(iii).

[16] For the purpose of waiving the 30-day operative delay for this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[17] 17 CFR 200.30–3(a)(12).

DEPARTMENT OF STATE

[Public Notice: 10663]

Notice of Public Meeting; Correction

AGENCY: Department of State.

ACTION: Notice; correction.

SUMMARY: The Department of State published a document in the **Federal Register** of Friday, December 21, 2018, giving notice of a public meeting to prepare for the sixth session of the International Maritime Organization's (IMO) Sub-Committee on Pollution Prevention and Response (PPR 6). The document contained an incorrect date and call-in number.

FOR FURTHER INFORMATION CONTACT: Ms. Melissa Perera, 202–372–1446, or *Melissa.E.Perera@uscg.mil.*

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of Friday, December 21, 2018, Vol. 83, No. 245, on page 65783 in the second column under ''Notice of Public Meeting'', correct the first sentence to read:

The Department of State will conduct an open meeting at 1:00 p.m. Eastern Standard Time on Tuesday, February 12, 2019, in Room 6I10–01–A of the Douglas A. Munro Coast Guard Headquarters Building at St. Elizabeth's, 2703 Martin Luther King Jr. Avenue SE, Washington, DC 20593.

Additionally, in the third column, correct the third full sentence regarding the teleconference phone line to read:

To access the teleconference line, participants should call (202) 475–4000 and use Participant Code: 796 771 84.

Joel C. Coito,

Coast Guard Liaison Officer, Office of Ocean and Polar Affairs, Department of State.

[FR Doc. 2019–00902 Filed 2–1–19; 8:45 am]

BILLING CODE 4710–09–P

DEPARTMENT OF STATE

[Public Notice 10614]

60-Day Notice of Proposed Information Collection: Courier Drop-Off List for U.S. Passport Applications

ACTION: Notice of request for public comment.

SUMMARY: The Department of State is seeking Office of Management and Budget (OMB) approval for the information collection described below. In accordance with the Paperwork Reduction Act of 1995, we are requesting comments on this collection from all interested individuals and organizations. The purpose of this notice is to allow 60 days for public comment preceding submission of the collection to OMB.

DATES: The Department will accept comments from the public up to April 5, 2019.

ADDRESSES: You may submit comments by any of the following methods:

- *Web:* Persons with access to the internet may comment on this notice by going to *www.Regulations.gov*. You can search for the document by entering ''Docket Number: DOS–2018–0054'' in the Search field. Then click the ''Comment Now'' button and complete the comment form.
- *Email: PPTFormsOfficer@state.gov*.
- *Regular Mail:* Send written comments to: PPT Forms Officer, U.S. Department of State, CA/PPT/S/PMO, 44132 Mercure Cir, P.O. Box 1199, Sterling, VA 20166–1199.

You must include the DS form number (if applicable), information collection title, and the OMB control number in any correspondence.

SUPPLEMENTARY INFORMATION:

- *Title of Information Collection:* Courier Drop-Off List for U.S. Passport Applications.
- *OMB Control Number:* 1405–0222.
- *Type of Request:* Revision of a Currently Approved Collection.
- *Originating Office:* Bureau of Consular Affairs, Passport Services, Office of Program Management and Operational Support (CA/PPT/S/PMO).
- *Form Number:* DS–4283.
- *Respondents:* Business or Other For-Profit Organizations.
- *Estimated Number of Respondents:* 670 respondents per year.
- *Estimated Number of Responses:* 238,554 responses per year.
- *Average Time per Response:* 10 minutes.
- *Total Estimated Burden Time:* 39,759 annual hours.
- *Frequency:* Daily.
- *Obligation to Respond:* Required to Obtain or Retain a Benefit.

We are soliciting public comments to permit the Department to:

- Evaluate whether the proposed information collection is necessary for the proper functions of the Department.
- Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected.
- Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Please note that comments submitted in response to this Notice are public record. Before including any detailed personal information, you should be aware that your comments as submitted, including your personal information, will be available for public review.

Abstract of Proposed Collection

The information collected on the DS–4283 is used to facilitate the issuance of passports to U.S. nationals with imminent travel plans who hire private courier companies to deliver their applications to one of twelve Department domestic passport agencies. The Department asks courier company employees to complete the DS–4283 for each service type and submit the form with passport applications delivered in bulk to passport agencies in a designated drop-off box. Passport agencies use the form to track the submission of applications that a courier drops off. The form serves as a record of receipt of documents submitted to the Department and as an acknowledgment of who delivered these documents. The DS–4283 is part of a Department effort to facilitate the delivery of passport applications by private courier companies while maintaining the integrity of the passport application process.

Methodology

This form is used to track the processing of passport applications delivered in bulk to passport agencies by private courier companies. Courier employees are asked to attach the form onto sealed envelopes or packages containing passport applications which they deliver in bulk to designated drop-off facilities at one of twelve passport agencies for processing.

Rachel M. Arndt,

Deputy Assistant Secretary for Passport Services, Bureau of Consular Affairs, Department of State.

[FR Doc. 2019–00842 Filed 2–1–19; 8:45 am]

BILLING CODE 4710–06–P

DEPARTMENT OF TRANSPORTATION

Notice of Final Federal Agency Actions on Proposed Highway Projects in Texas

AGENCY: Texas Department of Transportation (TxDOT), Federal Highway Administration (FHWA), U.S. Department of Transportation.

ACTION: Notice of limitation on claims for judicial review of actions by TxDOT and Federal agencies.

SUMMARY: This notice announces actions taken by TxDOT and Federal agencies that are final. The environmental review, consultation, and other actions required by applicable Federal environmental laws for these projects

are being, or have been, carried-out by TxDOT pursuant to a Memorandum of Understanding dated December 16, 2014, and executed by FHWA and TxDOT. The actions relate to various proposed highway projects in the State of Texas. These actions grant licenses, permits, and approvals for the projects.

DATES: By this notice, TxDOT is advising the public of final agency actions subject to 23 U.S.C. 139(l)(1). A claim seeking judicial review of TxDOT and Federal agency actions on the highway project will be barred unless the claim is filed on or July 11, 2019. If the Federal law that authorizes judicial review of a claim provides a time period of less than 150 days for filing such a claim, then that shorter time period still applies.

FOR FURTHER INFORMATION CONTACT: Carlos Swonke, Environmental Affairs Division, Texas Department of Transportation, 125 East 11th Street, Austin, Texas 78701; telephone: (512) 416–2734; email: *carlos.swonke@txdot.gov.* TxDOT's normal business hours are 8:00 a.m.–5:00 p.m. (central time), Monday through Friday.

SUPPLEMENTARY INFORMATION: Notice is hereby given that TxDOT and Federal agencies have taken final agency actions by issuing licenses, permits, and approvals for the highway projects in the State of Texas that are listed below.

The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Categorical Exclusion (CE), Environmental Assessment (EA), or Environmental Impact Statement (EIS) issued in connection with the projects and in other key project documents. The CE, EA, or EIS and other key documents for the listed projects are available by contacting TxDOT at the address provided above.

This notice applies to all TxDOT and Federal agency decisions as of the issuance date of this notice and all laws under which such actions were taken, including but not limited to:

1. *General:* National Environmental Policy Act (NEPA) [42 U.S.C. 4321–4351]; Federal-Aid Highway Act [23 U.S.C. 109].

2. *Air:* Clean Air Act, 42 U.S.C. 7401–7671(q).

3. *Land:* Section 4(f) of the Department of Transportation Act of 1966 [49 U.S.C. 303]; Landscaping and Scenic Enhancement (Wildflowers), 23 U.S.C. 319.

4. *Wildlife:* Endangered Species Act [16 U.S.C. 1531–1544 and Section 1536], Marine Mammal Protection Act [16 U.S.C. 1361], Fish and Wildlife Coordination Act [16 U.S.C. 661–667(d)], Migratory Bird Treaty Act [16 U.S.C. 703–712].

5. *Historic and Cultural Resources:* Section 106 of the National Historic Preservation Act of 1966, as amended [54 U.S.C. 300101 *et seq.*]; Archeological Resources Protection Act of 1977 [16 U.S.C. 470(aa)–11]; Archeological and Historic Preservation Act [54 U.S.C. 312501 *et seq.*]; Native American Grave Protection and Repatriation Act (NAGPRA) [25 U.S.C. 3001–3013].

6. *Social and Economic:* Civil Rights Act of 1964 [42 U.S.C. 2000(d)–2000(d)(1)]; American Indian Religious Freedom Act [42 U.S.C. 1996]; Farmland Protection Policy Act (FPPA) [7 U.S.C. 4201–4209].

7. *Wetlands and Water Resources:* Clean Water Act, 33 U.S.C. 1251–1377 (Section 404, Section 401, Section 319); Land and Water Conservation Fund (LWCF), 16 U.S.C. 4601–4604; Safe Drinking Water Act (SDWA), 42 U.S.C. 300(f)–300(j)(6); Rivers and Harbors Act of 1899, 33 U.S.C. 401–406; Wild and Scenic Rivers Act, 16 U.S.C. 1271–1287; Emergency Wetlands Resources Act, 16 U.S.C. 3921, 3931; TEA–21 Wetlands Mitigation, 23 U.S.C. 103(b)(6)(m), 133(b)(11); Flood Disaster Protection Act, 42 U.S.C. 4001–4128.

8. *Executive Orders:* E.O. 11990 Protection of Wetlands; E.O. 11988 Floodplain Management; E.O. 12898, Federal Actions to Address Environmental Justice in Minority Populations and Low Income Populations; E.O. 11593 Protection and Enhancement of Cultural Resources; E.O. 13007 Indian Sacred Sites; E.O. 13287 Preserve America; E.O. 13175 Consultation and Coordination with Indian Tribal Governments; E.O. 11514 Protection and Enhancement of Environmental Quality; E.O. 13112 Invasive Species. (Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction.)

The projects subject to this notice are:

1. Bicentennial Boulevard Extension Project from SH 107 to Trenton Road, Hidalgo County, Texas. The proposed project would extend Bicentennial Boulevard from SH 107 to Trenton Road as a new location, four-lane facility. The length of the proposed project is approximately 2.86 miles. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Final Environmental Assessment approved on October 25, 2018, the Finding of No Significant Impact was issued on December 19, 2018, and other documents in the TxDOT project file. The EA and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT Pharr District Office at 600 W. US Expressway 83, Pharr, Texas 78577; telephone (956) 702–6102.

2. State Loop (SL) 336 South from Interstate Highway (IH) 45 to Farm to Market Road (FM) 1314 in Montgomery County, Texas. The proposed project would create a divided 4-lane facility by constructing a 2-lane roadway to the south of existing SL 336. The new lanes would serve as the east bound lanes, with the existing lanes being converted to serve west bound traffic. The project length is approximately 2.5 miles. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Categorical Exclusion Determination issued on September 28, 2018 and other documents in the TxDOT project file. The Categorical Exclusion Determination and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT Houston District Office located at 7600 Washington Avenue, Houston, Texas 77007; telephone (713) 802–5076.

3. Farm to Market Road (FM) 1488, Magnolia Relief Route, from existing FM 1488 west of Magnolia to proposed State Highway (SH) 249 east of Magnolia in Montgomery County, Texas. The proposed action would construct an east-west facility on new location to serve as a major arterial for the distribution of traffic around the city of Magnolia. This facility would consist of a four-lane divided facility. The project length is approximately 5.4 miles. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Final Environmental Assessment (EA) approved on October 23, 2018, the Finding of No Significant Impact (FONSI) issued on October 25, 2018, and other documents in the TxDOT project file. The EA, FONSI, and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT Houston District Office located at 7600 Washington Avenue, Houston, Texas 77007; telephone (713) 802–5076.

4. I–35 from the Guadalupe River to FM 1103, Comal County, Texas. The project includes operational improvements to the I–35 interchanges with FM 1103/Hubertus Road, Schwab Road, Engel Road, Solms Road, Loop 337/Rueckle Road, Business 35/Schmidt Avenue, Walnut Avenue, and FM 725. Improvements would include intersection improvements, ramp reconfigurations and the addition of auxiliary lanes along the I–35 mainlanes

and frontage road reconstruction. The project is approximately 9.25 miles in length. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Categorical Exclusion Determination issued on November 20, 2018. The Categorical Exclusion Determination and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT San Antonio District Office at 4615 NW Loop 410, San Antonio, TX 78229; telephone (210) 615–5839.

5. State Loop 1604 from IH 10 East to FM 1346 (Houston Street), Bexar County, Texas. The project would widen the existing 2-lane undivided roadway to a 4-lane divided roadway. The project is approximately 3.9 miles in length. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Categorical Exclusion Determination issued on November 30, 2018, and other documents in the TxDOT project file. The Categorical Determination and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT San Antonio District Office at 4615 NW Loop 410, San Antonio, TX 78229; telephone (210) 615–5839.

6. SH 46 from Farhills Drive to FM 3159, Comal County, Texas. The project would widen the roadway from its existing two-lane highway to two different configurations. The curbed with storm drain configuration, constructed in the more developed areas, would consist of six 11-foot travel lanes with a 16-foot raised median. The other configuration, a curbed with grasslined open-ditch configuration, would be constructed in less developed areas and would consist of six 11-foot travel lanes with a 16-foot raised median. The project is approximately 6 miles in length. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Final Environmental Assessment (EA) approved on October 26, 2018, Finding of No Significant Impact (FONSI) issued on October 26, 2018, and other documents in the TxDOT project file. The EA, FONSI and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT San Antonio District Office at 4615 NW Loop 410, San Antonio, TX 78229; telephone (210) 615–5839.

7. US 290/SH 71 West from State Loop 1 (MoPac) to west of RM 1826 and US 290 to Silvermine Drive, Travis County, Texas. The project, known as the Oak Hill Parkway (OHP) project, proposes improvements that include direct connectors at the intersection of US 290 and SH 71, controlled access along both highways in Oak Hill with frontage roads, and an overpass for US 290 at William Cannon Drive. New construction on roadway improvements would begin just east of Joe Tanner Lane where the existing mainlanes transition to an urban highway. The mainlanes would be elevated over William Cannon Drive, and the westbound mainlanes and frontage road would be located north of Williamson Creek. The mainlanes would be depressed under SH 71 and direct connectors would be provided, connecting eastbound SH 71 with US 290, and westbound US 290 to SH 71. Mainlanes would vary from four near William Cannon Drive to two near the western project limit. Grade-separated intersections would be constructed at Convict Hill Road, RM 1826, Scenic Brook Drive, and Circle Drive (Southview Road). Along SH 71, the direct connector ramps would extend past Scenic Brook Drive where the mainlanes would then transition to a five-lane (three lanes northbound, two lanes southbound) rural highway. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Final Environmental Impact Statement (FEIS) approved on December 21, 2018 and Record of Decision (ROD) issued on December 21, 2018, and other documents in the TxDOT project file. The FEIS, ROD and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT Austin District Office at 7901 North I–35, Austin, TX 78753; telephone (512) 832–7000. The EIS and ROD can also be viewed and downloaded from the following website: *www.oakhillparkway.com.*

8. SH 78 at Gaston Avenue in Dallas County, Texas. The proposed project would reconfigure the intersection of SH 78 (East Grand Avenue/Garland Road) at Gaston Avenue in the City of Dallas, Dallas County, Texas. The proposed facility would be reconfigured as a fully signalized, reverse T-intersection with East Grand Avenue intersecting Gaston Avenue and Garland Road. The length of the proposed project is approximately 0.76 miles. The purpose of the proposed project is to improve traffic operations and mobility, as well as to improve safety and to provide improved bicycle and pedestrian accommodations. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Final Categorical Exclusion Determination issued on December 21, 2018, and other documents in the TxDOT project file. The Categorical Exclusion Determination and other documents in the TxDOT file are available by contacting TxDOT at the address provided above or the TxDOT Dallas District Office at 4777 E. Highway 80, Mesquite, TX 75150; telephone: (214) 320–4480.

9. SH 158 at SH 137 in Glasscock County, Texas. The proposed project would construct an overpass on SH 158 over SH 137. The purpose of the project is to allow for traffic to move through the intersection with less congestion. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Categorical Exclusion Determination issued on September 4, 2018, and other documents in the TxDOT project file. The Categorical Exclusion Determination and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT San Angelo District Office at 4502 Knickerbocker Road, San Angelo, Texas 76904; telephone (325) 947–9266.

10. IH 10 from FM 3538 to FM 2761 in Colorado and Austin Counties, Texas. The proposed project would add an additional main lane in each direction along IH 10. The proposed project would also convert existing two way frontage roads to one way frontage roads. The purpose of the project is to improve mobility and increase safety along this section of I–10. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Categorical Exclusion Determination issued on November 8, 2018, and other documents in the TxDOT project file. The Categorical Exclusion Determination and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT Yoakum District Office at 403 Huck St., Yoakum, TX 77995; telephone (361) 293–4436.

11. SL 121 from FM 439 to I–35 in Bell County, Texas. The proposed project would widen SL 121 from 2 to 4 lane divided roadway with bike/pedestrian improvements. The proposed project is needed to improve traffic safety, alleviate congestion, improve access management, and to provide pedestrian/bicycle accommodations. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Categorical Exclusion Determination

issued on December 12, 2018 and other documents in the TxDOT project file. The Categorical Exclusion Determination and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT Waco District Office at 100 S Loop Dr., Waco, TX 76704; telephone (254) 867–2705.

12. SH6/SL340 from US 84 to IH 35 in McLennan County, Texas. The proposed project would construct continuous frontage roads and four overpasses. The proposed project length is 2.68 miles. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Categorical Exclusion Determination issued December 14, 2018, and other documents in the TxDOT project file. The Categorical Exclusion Determination and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT Waco District Office at 100 S Loop Dr., Waco, TX 76704; telephone (254) 867–2705.

13. Loop 338 Overpass at East Yukon Rd, Ector County, Texas. The proposed improvements would include the construction of an overpass on SL 338 at the intersection of E. Yukon Rd. The project would be approximately 2.0 miles in length. The project would help improve mobility on Loop 338. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Categorical Exclusion Determination issued on September 7, 2018, and other documents in the TxDOT project file. The Categorical Exclusion Determination and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT Odessa District Office at 3901 East Highway 80, Odessa, Texas 79761; telephone (432) 498–4746.

14. Loop 250 at CR 1150 and CR 60, Midland County, Texas. The proposed project consists of extending main lanes and constructing access ramps and two overpasses between the existing frontage roads, on SL 250 from 0.5 miles west of County Road (CR) 1150 to 0.5 miles east of CR 60. The project would be approximately 1.0 mile in length. The project would help improve mobility on Loop 250 at the intersections of CR 1150 and CR 60. The actions by TxDOT and Federal agencies and the laws under which such actions were taken are described in the Categorical Exclusion Determination issued on September 19, 2018, and other documents in the TxDOT project file. The Categorical Exclusion Determination and other documents in the TxDOT project file are available by contacting TxDOT at the address provided above or the TxDOT Odessa District Office at 3901 East Highway 80, Odessa, Texas 79761, (432) 498–4746.

Authority: 23 U.S.C. 139(l)(1).

Issued on January 29, 2019.

Michael T. Leary,

Director, Planning and Program Development, Federal Highway Administration.

[FR Doc. 2019–00865 Filed 2–1–19; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service (IRS), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning Testimony or Production of Records in a Court or Other Proceeding.

DATES: Written comments should be received on or before April 5, 2019 to be assured of consideration.

ADDRESSES: Direct all written comments to Laurie Brimmer, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the regulation should be directed to Martha R. Brinson, at (202) 317–5753, or at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet at *Martha.R.Brinson@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Testimony or Production of Records in a Court or Other Proceeding.

OMB Number: 1545–1850.

Regulation Project Number: TD 9178.

Abstract: Final regulation provide specific instructions and to clarify the circumstances under which more specific procedures take precedence. The final regulation extend the application of the regulation to former IRS officers and employees as well as to persons who are or were under contract to the IRS. The final regulation affect current and former IRS officers, employees and contractors, and persons who make requests or demands for disclosure.

Current Actions: There is no change to this existing regulation.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for profit organizations, and farms. Businesses and other for-profit organizations, Individuals and households, Not-for-Profit institutions, and Farms.

Estimated Number of Respondents: 1,400.

Estimated Time per Respondent: 1 hour.

Estimated Total Annual Burden Hours: 1,400.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. Comments will be of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information has practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: January 29, 2019.

Laurie Brimmer,

Senior Tax Analyst.

[FR Doc. 2019–00870 Filed 2–1–19; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 706–CE

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on information collections, as required by the Paperwork Reduction Act of 1995. Currently, the IRS is soliciting comments concerning Form 706–CE, Certificate of Payment of Foreign Death Tax.

DATES: Written comments should be received on or before April 5, 2019 to be assured of consideration.

ADDRESSES: Direct all written comments to Laurie Brimmer, Internal Revenue Service, Room 6529, 1111 Constitution Avenue NW, Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Charles G. Daniel at (202) 317–5754, at Internal Revenue Service, Room 6529, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet at *Charles.G.Daniel@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Certificate of Payment of Foreign Death Tax.

OMB Number: 1545–0260.

Form Number: 706–CE.

Abstract: Form 706–CE is used by the executors of estates to certify that foreign death taxes have been paid so that the estate may claim the foreign death tax credit allowed by Internal Revenue Code section 2014. The information is used by IRS to verify that the proper credit has been claimed.

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension of a previously approved collection.

Affected Public: Individual or households.

Estimated Number of Responses: 2,250.

Estimated Time per Response: 1 hour, 44 minutes.

Estimated Total Annual Burden Hours: 3,870 hours.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: January 29, 2019.

Laurie Brimmer,

Senior Tax Analyst.

[FR Doc. 2019–00881 Filed 2–1–19; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 8905

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on information collections, as required by the Paperwork Reduction Act of 1995. Currently, the IRS is soliciting comments concerning Form 8905, Certification of Intent To Adopt a Pre-approved Plan.

DATES: Written comments should be received on or before April 5, 2019 to be assured of consideration.

ADDRESSES: Direct all written comments to Laurie Brimmer, Internal Revenue Service, room 6529, 1111 Constitution Avenue NW, Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Charles G. Daniel at (202) 317–5754, at Internal Revenue Service, Room 6529, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet at *Charles.G.Daniel@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Certification of Intent To Adopt a Pre-approved Plan.

OMB Number: 1545–2011.

Form Number: 8905.

Abstract: Use Form 8905 to treat an employer's plan as a pre-approved plan and therefore eligible for the six-year remedial amendment cycle of Part IV of Revenue Procedure 2005–66, 2005–37 I.R.B. *509.* This form is filed with other document(s).

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension of a previously approved collection.

Affected Public: Businesses and other for-profit organizations, Farms.

Estimated Number of Responses: 29,000.

Estimated Time per Response: 2 hours, 50 minutes.

Estimated Total Annual Burden Hours: 82,360 hours.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to

minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: January 29, 2019.

Laurie Brimmer,

Senior Tax Analyst.

[FR Doc. 2019–00867 Filed 2–1–19; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Administration of Multiemployer Plan Participant Vote on an Approved Suspension of Benefits Under MPRA

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on information collections, as required by the Paperwork Reduction Act of 1995. Currently, the IRS is soliciting comments concerning suspension of benefits under the Multiemployer Pension Reform Act of 2014—Administration of Multiemployer Plan Participant Vote.

DATES: Written comments should be received on or before April 5, 2019 to be assured of consideration.

ADDRESSES: Direct all written comments to Laurie Brimmer, Internal Revenue Service, Room 6529, 1111 Constitution Avenue NW, Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Charles G. Daniel at (202) 317–5754, at Internal Revenue Service, Room 6529, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet at *Charles.G.Daniel@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Suspension of Benefits Under the Multiemployer Pension Reform Act of 2014—Administration of Multiemployer Plan Participant Vote.

OMB Number: 1545–2260.

Abstract: Respondents are sponsors of collectively bargained retirement trusts in significant financial distress. The MPRA allows a respondent to apply to Treasury for approval to suspend benefit payments. If an application is approved, Treasury must then administer a vote by participants on whether to accept or reject the suspension. The regulation provides detailed voting procedures. The information collection is necessary to establish the voting process.

Current Actions: There are no changes being made at this time.

Type of Review: Extension of a previously approved collection.

Affected Public: Businesses and other for-profits.

Estimated Number of Responses: 28.

Estimated Time per Response: 500 hours.

Estimated Total Annual Burden Hours: 14,000 hours.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: January 29, 2019.

Laurie Brimmer,

Senior Tax Analyst.

[FR Doc. 2019–00849 Filed 2–1–19; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 14411

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on information collections, as required by the Paperwork Reduction Act of 1995. Currently, the IRS is soliciting comments concerning Form 14411, Systemic Advocacy Issue Submission form.

DATES: Written comments should be received on or before April 5, 2019 to be assured of consideration.

ADDRESSES: Direct all written comments to Laurie Brimmer, Internal Revenue Service, room 6529, 1111 Constitution Avenue NW, Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Charles G. Daniel at (202) 317–5754, at Internal Revenue Service, room 6529, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet at *Charles.G.Daniel@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Systemic Advocacy Issue Submission.

OMB Number: 1545–1832.

Form Number: 14411.

Abstract: Systemic Advocacy Issue Submission Form, is an optional use form for taxpayers (individual and business), tax professionals, trade and business associations, etc. to submit systemic problems. These problems may pertain to experiences with the Internal Revenue Service's processes procedures or make legislative recommendations.

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension of a previously approved collection.

Affected Public: Business or other for-profit organizations, individuals, not-for-profit institutions, farms, Federal, State, Local or Tribal governments.

Estimated Number of Responses: 420.

Estimated Time per Response: 48 minutes.

Estimated Total Annual Burden Hours: 336 hours.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: January 29, 2019.

Laurie Brimmer,

Senior Tax Analyst.

[FR Doc. 2019–00848 Filed 2–1–19; 8:45 am]

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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 493

Clinical Laboratory Improvement Amendments of 1988 (CLIA) Proficiency Testing Regulations Related to Analytes and Acceptable Performance; Proposed Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 493

[CMS–3355–P]

RIN 0938–AT55

Clinical Laboratory Improvement Amendments of 1988 (CLIA) Proficiency Testing Regulations Related to Analytes and Acceptable Performance

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS; Centers for Disease Control and Prevention (CDC), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would update proficiency testing (PT) regulations under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) to address current analytes (that is, substances or constituents for which the laboratory conducts testing) and newer technologies. This proposed rule would also make additional technical changes to PT referral regulations to more closely align them with the CLIA statute.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on April 5, 2019.

ADDRESSES: In commenting, please refer to file code CMS–3355–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3355–P, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3355–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Sarah Bennett, CMS, (410) 786–3531; Caecilia Blondiaux, CMS, (410) 786–2190; or Nancy Anderson, CDC, (404) 498–2741

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that website to view public comments.

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I. Background

On October 31, 1988, Congress enacted the Clinical Laboratory Improvement Amendments of 1988 (Pub. L. 100–578) (CLIA'88), codified at 42 U.S.C. 263a, to ensure the accuracy and reliability of testing in all laboratories, including, but not limited to, those that participate in Medicare and Medicaid, that test human specimens for purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment, or the assessment of health, of human beings. The Secretary established the initial regulations implementing CLIA on February 28, 1992 at 42 CFR part 493 (57 FR 7002). Those regulations required, among other things, for laboratories conducting moderate or high-complexity testing to enroll in an approved proficiency testing (PT) program for each specialty, subspecialty, and analyte or test for which the laboratory is certified under CLIA. PT referral was further addressed by enactment of the Taking Essential Steps for Testing Act of 2012 (Pub. L. 112–202, December 4, 2012) (TEST Act) and our implementing regulations (79 FR 25435 and 79 FR 27105). As of January 2017, there were 246,143 CLIA-certified laboratories, of which 36,777 Certificate of Compliance and Certificate of Accreditation laboratories were required to enroll in a U.S. Department of Health and Human Services (HHS)-approved PT program and comply with the PT regulations.

Testing has evolved significantly since 1992, and technology is now more accurate and precise than the methods in use at the time the PT regulations became effective for all laboratories in 1994. In addition, many tests for analytes for which PT was not initially required are now in routine clinical use. For example, tests for cardiac markers, such as troponins, and the hemoglobin A1c test commonly used to monitor glycemic control in persons with diabetes, were not routinely performed prior to 1992. Recognizing these changes, we are proposing revisions to our existing PT regulations in this proposed rule.

As part of the process for developing our proposals to revise the PT regulations, HHS requested input from the Clinical Laboratory Improvement Advisory Committee (CLIAC) regarding appropriate revisions to the regulations. CLIAC is the official federal advisory committee charged with advising HHS regarding appropriate regulatory standards for ensuring accuracy, reliability and timeliness of laboratory testing. Questions posed to CLIAC at the September 2008 CLIAC meeting and their recommendations are documented in the meeting summary on the CLIAC website at *https://ftp.cdc.gov/pub/CLIAC_meeting_presentations/pdf/CLIAC_Summary/cliac0908_summary.pdf.*

In response to our request for input, CLIAC established a PT Workgroup that included laboratory experts, representatives from accreditation organizations, state surveyors, and PT program officials. The CLIAC PT Workgroup provided information and data to CLIAC for their deliberation in making recommendations to HHS regarding appropriate revisions to subparts H and I of the CLIA regulations. These recommendations addressed updating the list of required PT analytes; revising the scoring criteria for acceptable performance for current and proposed analytes; changes to specialties or subspecialties, including microbiology, that do not have required

PT analytes; and clarification of the PT referral requirements. The questions posed to CLIAC at the September 2010 CLIAC meeting and their recommendations are documented in the meeting summary on the CLIAC website at *http://wwwn.cdc.gov/cliac/pdf/cliac0910.pdf.*

After the September 2010 CLIAC meeting, CMS and CDC met to review and consider the recommendations. Following this, the two agencies collaborated to develop a process to revise the list of required PT analytes. That is, CMS and CDC reviewed current analytes listed in subpart I to determine which analytes should be retained in the regulations and which should be deleted. In addition, CMS and CDC examined analytes not currently listed in subpart I to determine if any additional analytes should be added to subpart I.

As discussed in section II of this proposed rule, a systematic approach was taken in order to update the required PT analytes, using various factors in selecting candidate analytes. A variety of PT-related and test volume data were subsequently collected from HHS-approved PT programs and various sources as described below, and analyzed by CMS and CDC.

As discussed in section II.B.2. of this proposed rule, CMS and CDC used those data and applied the criteria in a step-wise approach to determine the analytes included in this proposed rule. Following selection of those candidate analytes, CMS and CDC sought feedback from PT programs on the following topics: Current PT program practices using ''peer grouping'' to determine target values; the potential to include new analytes as required PT; mechanism for grading current of analytes; possible changes to the criteria for acceptable performance; and potential changes to microbiology subspecialties, including the replacement of the types of service as outlined currently at §§ 493.911(a), 493.913(a), 493.915(a), 493.917(a) and 493.919(a), with the candidate analytes and the replacement of the list of specific organisms for each microbiology subspecialty at the above citations with our proposal to adopt a general list of types of microorganisms for each microbiology subspecialty.

Specifically, with CDC's expertise and assistance, we then developed an approach and rationale, as discussed in section II.B.10. of this proposed rule, for revising PT acceptance limits based upon empirical data, including clinical relevance. CMS and CDC worked to determine the acceptance limits, that is, the symmetrical tolerance (plus and minus) around the target value (as defined in § 493.2), to propose for both new and existing required analytes. As a result of this work, we ultimately decided to propose stating acceptance limits as percentages whenever possible.

We then again sought industry input. For each analyte, we requested that PT programs consider our potential new acceptance limits and provide data simulations using real PT data as a means of pilot testing our potential acceptance limits. We received simulation data from several PT programs, which facilitated the development of the acceptance limits proposed in this rule. We note that acceptance limits are intended to be used for scoring PT performance by PT programs and are not intended to be used by individual laboratories to satisfy the requirement at § 493.1253(b) to establish performance specifications.

II. Provisions of the Proposed Regulations

This section provides an overview of our proposed revisions to the CLIA definitions and PT requirements in subpart A—General Provisions, § 493.2 Definitions; subpart H—Participation in Proficiency Testing for Laboratories Performing Nonwaived Testing; and subpart I—Proficiency Testing Programs for Nonwaived Testing.

A. Proposed Changes to Microbiology PT

1. Categories of Testing

Subpart I of the CLIA regulations includes PT requirements for each subspecialty of microbiology, §§ 493.911 through 493.919, which describe ''Types of services offered by laboratories'' for each subspecialty. In addition, since the regulations do not specify required analytes for microbiology as they do for other specialties, they include descriptions of levels or extents (for example, identification to the genus level only, identification to the genus and species level) used to determine the type of laboratory for PT purposes. CLIAC discussed the usefulness and limitations of the types of services listed in subpart I in helping laboratories enroll properly or in helping surveyors conduct laboratory inspections. It was noted that the types of services listed in subpart I do not allow for reporting growth or no growth, presence or absence, or presumptive identification of microorganisms on PT samples, which are common ways that physician office laboratories report patient results. Based on input from the PT Workgroup, CLIAC suggested revision of the regulations to include broad categories for the types of PT required for each microbiology subspecialty to allow flexibility for inclusion of new technologies.

After deliberation, CLIAC made the following recommendations:

- A system for categorizing types of service should be maintained in the regulations to help laboratories determine what PT they need to perform and assist surveyors in monitoring PT performance and patient testing.
- The regulations should include four categories of testing for each microbiology subspecialty, as applicable: Stain(s), susceptibility and resistance testing, antigen and/or toxin detection, and microbial identification or detection.

Based on these recommendations, we conducted a review of the PT modules offered by HHS-approved PT programs and consulted with CDC microbiology subject matter experts who concurred that not all four recommended categories above are applicable to each microbiology subspecialty nor do PT programs have PT available for each category. If at some point in the future PT becomes available, we may propose to include additional categories of testing to microbiology subspecialties in future rulemaking. Based on these recommendations and our review, we are proposing to modify §§ 493.911 through 493.919 to remove the types of services listed for each microbiology subspecialty and to add the recommended categories of testing for each microbiology subspecialty as described in the bullets below. We believe that the revised microbiology PT regulations would better reflect current practices in microbiology.

- Section 493.911(a): For bacteriology, we are proposing that the categories required include, as applicable: Gram stain including bacterial morphology; direct bacterial antigen detection; bacterial toxin detection; detection and identification of bacteria which includes one of the following: Detection of growth or no growth in culture media or identification of bacteria to the highest level that the laboratory reports results on patient specimens; and antimicrobial susceptibility or resistance testing on select bacteria.
- Section 493.913(a): For mycobacteriology, we are proposing that the categories for which PT is required include, as applicable: Acid-fast stain; detection and identification of mycobacteria which includes one of the following: Detection of growth or no growth in culture media or identification of mycobacteria; and

antimycobacterial susceptibility or resistance testing.

- Section 493.915(a): For mycology, we are proposing that the categories for which PT is required include, as applicable: Direct fungal antigen detection; detection and identification of fungi and aerobic actinomycetes which includes one of the following—detection of growth or no growth in culture media or identification of fungi and aerobic actinomycetes; and antifungal susceptibility or resistance testing.
- Section 493.917(a): For parasitology, we are proposing that the categories for which PT is required include, as applicable: Direct parasite antigen detection; and detection and identification of parasites which includes one of the following—detection of the presence or absence of parasites or identification of parasites.
- Section 493.919(a): For virology, we are proposing that the categories for which PT is required include, as applicable: Viral antigen detection; detection and identification of viruses; and antiviral susceptibility or resistance testing.

In all of these subspecialties, as outlined in sections II.B.5., II.B.7., and II.B.8. of this proposed rule, we are also proposing to revise the requirements for evaluation of a laboratory's performance at §§ 493.911(b) through 493.919(b) to be consistent with these categories.

We are not proposing to include antigen and toxin detection in the mycobacteriology subspecialty because no PT program currently offers applicable PT modules. We are not proposing to include stains and antiparasitic susceptibility or resistance testing in the subspecialty of parasitology because no PT program offers applicable PT modules. We invite the public to comment on these proposals and specifically on the proposed categories of testing for the subspecialties listed above. If public comments indicate that applicable PT modules are available for antigen and toxin detection or for stains and antiparasitic susceptibility or resistance testing, we may finalize their inclusion in the final rule, as applicable. If at some point in the future, PT becomes available for mycobacteriology antigen and toxin detection testing, and stains and antiparasitic susceptibility or resistance testing, we may propose to include this category of testing for PT in future rulemaking.

2. Major Groups of Microorganisms

Each subspecialty of microbiology, §§ 493.911 through 493.919, currently includes a list of the types of microorganisms that might be included in an HHS approved PT program over time. Several PT programs have suggested to HHS that the regulations should include a more general list of types of organisms that must be included in required PT instead of a specific list. CLIAC considered whether there needs to be a more general list of organisms in the regulations to assure a variety of challenges are offered over the course of the year. Following their deliberation, CLIAC made the following recommendation:

- Require PT for a general list of types of organisms in each subspecialty. For example, in bacteriology, the groups listed should include gram-negative bacilli, gram-positive bacilli, gram-negative cocci, and gram-positive cocci.

Generally, we have found that PT programs include only those organisms listed in the current regulations, and do not include additional organisms outside of the current regulatory list. By restructuring to a more general list of organisms, it will be clearer that PT programs are able to be flexible in selecting which samples to provide to laboratories for PT, especially as new organisms are identified as being clinically important. Therefore, we are proposing to remove the lists of specific example organisms from each microbiology subspecialty, §§ 493.911 through 493.919, and to add the following list of types of organisms to each.

- § 493.911(a)(3): For bacteriology, we are proposing that the annual program content must include representatives of the following major groups of medically important aerobic and anaerobic bacteria if appropriate for the sample sources: Gram-negative bacilli; gram-positive bacilli; gram-negative cocci; and gram-positive cocci. The more general list of types of organisms will continue to cover the six major groups of bacteria currently listed in the regulations.
- § 493.913(a)(3): For mycobacteriology, we are proposing that the annual program content must include *Mycobacterium tuberculosis* complex and *Mycobacterium* other than tuberculosis (MOTT), if appropriate for the sample sources.
- § 493.915(a)(3): For mycology, we are proposing that annual program content must include the following major groups of medically important fungi and aerobic actinomycetes if appropriate for the sample sources: Yeast or yeast-like organisms; molds that include dematiaceous fungi, dermatophytes, dimorphic fungi, hyaline hyphomycetes, and mucormycetes; and aerobic actinomycetes.
- § 493.917(a)(3): For parasitology, we are proposing that the annual program content must include intestinal parasites and blood and tissue parasites, if appropriate for the sample sources.
- § 493.919(a)(3): For virology, we are proposing that the annual program content must include respiratory viruses, herpes viruses, enterovirus, and intestinal viruses, if appropriate for the sample sources.

3. Declaration of Patient Reporting Practices

The PT requirements at § 493.801(b) specify that laboratories must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. CLIAC considered this requirement as applied to microbiology and agreed that PT programs should instruct laboratories to perform all testing as they normally would on patient specimens, including reporting PT results for microorganism identification to the same level that would be reported on patient specimens. CLIAC deliberated on this issue and made the following recommendation:

- Laboratories should declare their patient reporting practices for organisms included in each PT challenge. However, PT programs should only gather this information as it is the inspecting agency's responsibility to review and take action if necessary.

We believe that laboratories should be instructed to report PT results for microbiology organism identification to the ''highest'' level that they report results on patient specimens to ensure that they do so to the ''same'' level that they report results on patient specimens. As a result, we are proposing to amend §§ 493.801(b), 493.911(b), 493.913(b), 493.915(b), 493.917(b), and 493.919(b), to state that laboratories must report PT results for microbiology organism identification to the highest level that they report results on patient specimens. If finalized, this proposal should address an issue we identified during the PT program reapproval process in which we found laboratories inappropriately deciding whether to participate in a PT event based on the reporting criteria required by the PT program.

4. Gram Stain PT

CLIAC considered whether required PT for Gram stains should include both stain reaction and morphology. CLIAC concluded it should and recommended:

• PT results for Gram stains should include both stain reaction and morphology.

We agree with this recommendation because knowing the bacterial morphology is essential for accurate identification of specific groups of bacteria. Therefore, we are proposing the following in § 493.911:

• Section 493.911(a): The addition of required morphology for Gram stains.

• Section 493.911(b): The evaluation of a laboratory's performance would be modified to include bacterial morphology as one part of the performance criterion for scoring the Gram stain.

5. Mixed Culture Requirement

The current CLIA requirements for bacteriology § 493.911(b)(1), mycobacteriology § 493.913(b)(1), and mycology § 493.915(b)(1) specify that at least 50 percent of the PT samples in an annual program must be mixtures of the principal organism and appropriate normal flora. The purpose of this requirement is to simulate the findings that would occur with actual patient specimens. In bacteriology, this 50 percent mixed culture requirement must be met for two required sample types, those that require laboratories to report only organisms that the testing laboratory considers to be a principal pathogen that is clearly responsible for a described illness (excluding immuno-compromised patients) and those that require laboratories to report all organisms present. The CLIA requirements for mycobacteriology and mycology PT do not specify two sample types, but include the 50 percent requirement for cultures containing a mixture of the principal organism and appropriate normal flora. None of the 50 percent mixed culture requirements in these subspecialties applies to samples that would only contain normal flora and no reportable organisms.

CLIAC considered whether PT should include mixed cultures, and discussed the difficulties of having mixed cultures in challenges for antimicrobial susceptibility testing. CLIAC considered lowering the mixed culture requirement to 25 percent for all subspecialties in microbiology. Upon deliberation, CLIAC made the following recommendation:

• Lower the mixed culture requirement from 50 percent to 25 percent for PT challenges of both sample types (those that require laboratories to report only the principal pathogen and those that require laboratories to report all organisms present).

We agree it is appropriate to lower the mixed culture requirement from 50 percent to 25 percent for bacteriology, mycobacteriology, and mycology to better reflect actual patient samples. As a result, we are proposing changes as follows:

• Section 493.911(a)(2): In bacteriology, we are proposing to decrease the required mixed cultures from 50 percent to 25 percent for culture challenges that require laboratories to report only the principal pathogen and those that require laboratories to report all organisms present.

• Sections 493.913(a)(2) and 493.915(a)(2): In mycobacteriology and mycology, respectively, we are proposing to decrease the mixed culture requirement from 50 percent to 25 percent.

Since the requirements for parasitology and virology do not currently include requirements for mixed cultures (or mixed PT challenges), we do not propose to make any changes to these subspecialties.

6. Antimicrobial Susceptibility Testing

PT for antimicrobial susceptibility testing is currently required for bacteriology at § 493.911(b)(1) and mycobacteriology at § 493.913(b)(1), but it is not required for mycology, parasitology, or virology. For antimicrobial susceptibility testing in bacteriology at § 493.911(b)(3), at least one sample per testing event must include one gram-positive or gram-negative sample and for mycobacteriology at § 493.913(b)(3), at least one sample per testing event must include a strain of *Mycobacterium tuberculosis* with a predetermined pattern of susceptibility or resistance to the common antimycobacterial agents. In some instances, laboratories appreciate the opportunity to participate in additional susceptibility testing challenges as educational tools. Under the current regulations, some laboratories may perform the minimum required susceptibility testing on some organisms such as gram-positive cocci. When CLIAC discussed this issue, the point was made that by increasing the frequency and number of required susceptibility testing PT challenges for different groups of organisms, potential issues with patient testing in a laboratory may be detected sooner. CLIAC considered recommending increasing the susceptibility testing challenges to two per event and requiring one gram-positive and one gram-negative organism in each bacteriology testing event. CLIAC also considered whether PT should be required for resistance as well as susceptibility testing and whether these requirements should be extended to other microbiology subspecialties. Following this deliberation, CLIAC made the following recommendations:

• Required PT for antimicrobial susceptibility and/or resistance testing should be increased to two challenges per event for a total of six challenges per year in bacteriology and should include one gram-positive and one gram-negative organism in each event.

• PT should be required for laboratories that perform susceptibility and/or resistance testing in all microbiology subspecialties. It should include two challenges per event and should include resistant organisms.

In considering these recommendations, we reviewed the modules currently offered by PT programs that include susceptibility testing and noted that there is a limited number of applicable PT modules currently available for resistance testing. Also, no PT program currently offers applicable PT modules for antiparasitic susceptibility or resistance testing in the subspecialty of parasitology. We believe it could be beneficial to increase the number of challenges per event from one to two for each microbiology subspecialty to increase the likelihood of detection of a problem in a laboratory. Antiparasitic susceptibility or resistance testing is not included in the subspecialty of parasitology because no PT program currently offers applicable PT modules. Therefore, we are proposing the following:

• Section 493.911(a)(4): For bacteriology, we are proposing to require at least two PT samples per event for susceptibility or resistance testing, including one gram-positive and one gram-negative organism with a predetermined pattern of susceptibility or resistance to common antimicrobial agents.

• Section 493.913(a)(5): For mycobacteriology, we are proposing to require at least two PT samples per event for susceptibility or resistance testing, including mycobacteria that have a predetermined pattern of susceptibility or resistance to common antimycobacterial agents.

• Section 493.915(a)(4): For mycology, we are proposing to require at least two PT samples per event for susceptibility or resistance testing, including fungi that have a predetermined pattern of susceptibility or resistance to common antifungal agents.

• Section 493.919(a)(4): For virology, we are proposing to require at least two PT samples per event for susceptibility or resistance testing, including viruses that have a predetermined pattern of

susceptibility or resistance to common antiviral agents.

In each of these subspecialties, we are also proposing to revise the requirements for evaluation of a laboratory's performance at §§ 493.911(b), 493.913(b), 493.915(b), and 493.919(b) to account for the fact that PT would be required for susceptibility or resistance testing and that the scoring should be consistent with the testing performed.

7. Direct Antigen Testing

PT for direct antigen testing is only required for bacteriology and virology under §§ 493.911(a) and 493.919(a), respectively, not for the other microbiology subspecialties of mycobacteriology, mycology, and parasitology. Since this type of testing is commonly used for testing patient specimens especially in mycology and parasitology, CLIAC considered whether PT for direct antigen testing should be part of all of the microbiology subspecialty requirements. CLIAC indicated that direct antigen PT should be required in subspecialties where these methods are used and PT is available and made the following recommendation:

- PT for direct antigen testing should be required for all microbiology subspecialties.

We reviewed the modules currently offered by PT programs and determined there are a number of modules that include direct antigen testing for all microbiology subspecialties except mycobacteriology, for which this technology is not commonly used for testing patient specimens. In addition, we recognized that in bacteriology, PT for direct antigen testing to detect toxins produced by organisms such as *Clostridioides* (formerly *Clostridium) difficile* is also commonly available. Based on the information collected from the PT programs, availability of the modules, and importance to the health and safety of the public, we are proposing:

- To retain the requirement for direct antigen detection for:

++ Section 493.911(a)(1)(ii): Bacteriology.

++ Section 493.919(a)(1)(i): Virology.

And add the requirement for direct antigen testing detection for:

++ Section 493.915(a)(1)(i): Mycology.

++ Section 493.917(a)(1)(i): Parasitology.

- To require PT for bacterial toxin detection under § 493.911(a)(1)(iii). No changes are proposed for mycobacteriology.
- To add the evaluation criteria of a laboratory's performance for two of the affected subspecialties under §§ 493.911(b) and 493.917(b) to include performance and scoring criteria that address direct antigen and toxin detection. Evaluation of a laboratory's performance for direct antigen testing at § 493.917(b) would align with the other microbiology subspecialties and reflect current microbiology practices in reporting patient results. Evaluation of a laboratory's performance for bacterial toxin detection at § 493.911(b) would reflect the current practice of reporting patient test results (that is, absence or presence of bacterial toxin).

B. Proposed Changes to PT for Non-Microbiology Specialties and Subspecialties

1. Analytes Proposed for Addition to Subpart I

The CLIA statute requires the PT standards established by the Secretary to require PT for each examination and procedure for which the laboratory is certified ''except for examinations and procedures for which the Secretary has determined that a proficiency test cannot reasonably be developed'' (42 U.S.C. 263a(f)(3)(A)). In determining whether PT can reasonably be developed for a given analyte, we considered whether the estimated cost of PT is reasonable in comparison to the expected benefit. Considering CLIAC's recommendations regarding possible changes to the analytes for which PT is required, we attempted to maximize improvements to the effectiveness of PT to improve accuracy, reliability and timeliness of testing while minimizing costs to the laboratories. In addition, we recognize that it is not necessary to require PT for every analyte to derive benefits generalizable to all test methods. For example, systematic analytical problems on a multichannel analyzer might be detected by participation in PT for any of the analytes tested. Further, laboratories are already required under § 493.1236(c)(1) to verify the accuracy of any test or procedure they perform that is not included in subpart I at least twice annually. Also, based on the results of the national PT survey [1] conducted by CDC and the Association of Public Health Laboratories (APHL) in 2013, a large number of laboratories voluntarily purchased PT materials for many nonrequired analytes.[2] Keeping this in mind, as discussed in section II.B.2. of this proposed rule, we are proposing to add the most crucial analytes based upon the following criteria:

(1) Current availability of PT materials and the number of PT programs offering PT.

(2) Volume of patient testing performed nationwide.

(3) Impact on patient health and/or public health.

(4) Cost and feasibility of implementation.

2. Process for Ranking Analytes Proposed for Addition to Subpart I

We used a sequential process to narrow the list of eligible analytes for addition based on each of the four criteria listed above.

a. Current Availability of PT Materials and the Number of PT Programs Already Offering PT

We believe that the availability of these PT samples for a particular analyte is an appropriate criterion for narrowing the list of eligible analytes and that scaling up a program would be relatively less difficult than creating a PT sample for a particular analyte that had not previously been offered. For the reasons noted below, we believe that at least three PT programs offering PT samples for a particular analyte under consideration would provide a sufficient number of programs to offer immediate access to PT by laboratories and a reasonable starting point for the analytes under consideration. CMS and CDC want to ensure that the laboratories could choose the best PT program for the services that their laboratories offered as well as not create a market advantage for a small number of PT programs. To evaluate the current availability of PT materials and PT programs offering PT samples for a particular analyte, we analyzed the distribution of available PT programs for analytes for which PT is currently not required by subpart I of the CLIA regulations. The supporting data were collected from available sources, including data from PT program catalogs, and data routinely reported by PT programs, including enrollment data. We examined the number of PT programs offering these analytes at any number of events per year and any number of challenges per event. We initially determined the number of analytes under consideration for which PT was offered by at least two, three, or four of the eleven existing PT programs. We determined that limiting the

[1] Office of Management and Budget control number 0920–0961. Expiration date 4/30/2015.

[2] Earley, Marie C., J. Rex Astles, and Karen Breckenridge. Practices and Perceived Value of Proficiency Testing in Clinical Laboratories. Journal of Applied Laboratory Medicine 1, 4 (2017), pp. 415–420.

analytes under consideration to those for which PT was offered by at least three PT programs allowed a sufficient number of programs to offer immediate access to PT by laboratories and provided a reasonable starting point of 199 for the number of analytes under consideration (96 in routine chemistry, 27 in endocrinology, 28 in toxicology, 25 in general immunology, 21 in hematology, two for antibody identification). Expected impact on laboratories and PT programs was also taken into account (for example, minimizing the cost of purchasing and providing samples) when determining the minimum number of PT programs. Decreasing the minimum PT programs to two rather than three would increase the number of analytes under consideration to 303, but presumably decrease PT program availability and access for a given analyte. Conversely, increasing the minimum number of PT programs to four, while presumably increasing PT program availability and access for a given analyte, decreased the number of analytes under consideration to 164. This was the first cut, based upon available PT modules.

b. Volume of Patient Testing Being Performed Nationwide

For the second cut, we prioritized the remaining 199 analytes under consideration based upon estimated national testing volumes. We decided that an estimated national test volume of 500,000 per analyte annually was an appropriate threshold as it was based upon testing volumes of the majority (68 out of 81) of analytes currently listed in subpart I. For comparison, of the analytes that are currently required under subpart I, 63 had a total national test volume above 1,000,000; five had national test volumes between 500,000 and 1,000,000; and 13 had national test volumes below 500,000. We used 500,000 annual tests as a preliminary cut-off for retention on the list of analytes under consideration. We also retained analytes that were below the 500,000 threshold that we determined to be clinically important based on literature already footnoted in section II.B.2.b. of this proposed rule and consultation with CDC health experts. The following analytes with test volumes less than 500,000 that were retained are: Carbamazepine, alpha-1-antitrypsin, phenobarbital, hepatitis Be antigen, antibody identification, theophylline, gentamicin, and tobramycin.

In estimating national testing volumes to rank the remaining 199 analytes under consideration in this proposed rule, we were unable to identify a single source of available data for all patient testing being performed nationwide. We had complete data for Medicare reimbursements, as well as the most current MarketScan Commercial Claims and Encounters (CCAE) and MarketScan Medicaid Multi-state data sets (2009 Truven Health MarketScan® data, *https://truvenhealth.com/your-healthcare-focus/life-sciences/data_databases_and_online_toolsMarkets/Life-Sciences/Products/Data-Tools/MarketScan-Databases*) and extrapolated accordingly. We used data provided by an HHS-approved accreditation organization, specifically a list of the number of their accredited laboratories offering each tests we considered for addition to, or deletion from, subpart I in order to determine how many laboratories were performing testing for the proposed analytes. We also considered smaller representative data sets, including data sets obtained from a large healthcare network, a large reference laboratory, and a university hospital network in order to evaluate the trends in performing testing for the proposed analytes. We analyzed national trends in testing based upon Medicare Part B reimbursement data (*https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4698806/*) to determine the analytes in each specialty that are increasingly used for patient diagnosis and/or management. We concluded that the trends revealed in the data could continue to show increases in reimbursement for the proposed analytes.

We estimated the 2009 national test volumes based upon two data sets: (1) Medicare Part B reimbursement statistics (excluding waived testing); and (2) CCAE. For all analytes under consideration for the addition to subpart I, we used Current Procedural Terminology (CPT) codes from claims data. We identified all possible occurrences of a particular analyte and combined them into one count. For example, if bicarbonate could be performed in a panel and by itself, we included all possible occurrences.

A complete count was available for the Medicare Part B data, and for this sector no estimation of total counts was necessary. MarketScan data, which is a sample of approximately 40 million covered individuals, was necessary to estimate CCAE data and approximately 6.5 million covered individuals for Medicaid data. Therefore, we estimated the total number of tests in both of these categories for the entire United States. The Agency for Healthcare Research and Quality (AHRQ) [3] data showed that an estimated total of 181.5 million covered individuals enrolled in CCAE healthcare insurance; from this we derived a factor of 4.5 (181.5 million individuals/40 million individuals) by which to multiply the MarketScan CCAE estimates to extrapolate estimates for the entire U.S. Similarly, for the Medicaid estimates, we knew from CMS data that there were approximately 52.5 million individuals covered by Medicaid, so we derived a factor of 8.0 (52.5 million individuals/6.5 million individuals) by which to multiply the MarketScan Medicaid estimates to extrapolate estimates for the entire United States.

We note that these estimates did not account for some inpatient testing that was paid through capitation arrangements for inpatient testing. Testing paid directly by patients was also not counted because, in these cases, CPT codes would not be captured in the data because there was no request for reimbursement. Even with this limitation, we believe that these estimates provide a relative sense of the numbers of tests being performed annually per analyte. No other accurate data were available to us.

As noted above, for the second cut, based upon our estimates of national testing volumes, we decided that an estimated national test volume of 500,000 per analyte annually was an appropriate threshold as most of the analytes listed in subpart I had national testing volumes above this threshold. Together with the above-described analytes that were below the 500,000 threshold that we determined to be clinically important, this narrowed our list of potential analytes under consideration for addition to subpart I to 73, representing analytes in five specialties or subspecialties

c. Impact on Patient and/or Public Health

For the third cut, we considered the evidence available as to patient and public impact for each analyte. There was no standardized, generally accepted way available to us to assess the relative impact of testing for particular analytes on clinical care and public health. Therefore, we used the following parameters to get a relative sense of the importance of the analytes under consideration: A review of published laboratory practice guidelines (LPGs); a review of critical values; and a review of the analyte's classification by the Food and Drug Administration (FDA) (*http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/Search.cfm*). We accessed several data sources, including tests listed in the CDC Guide to Community Preventive Services

[3] *https://meps.ahrq.gov/mepstrends/hc_ins/.*

(*https://www.thecommunityguide.org*); National Healthcare Priorities/ Disparities reports (*https://www.ahrq.gov/research/findings/nhqrdr/index.html*); clinical practice guidelines including the National Guideline Clearinghouse (NGC) database available from AHRQ (*https://www.guideline.gov/*);[4] critical values available in publications;[5] and (CAP) Q-Probes.[6]

In order to assess patient and public impact for each analyte, we considered the evidence available related to each analyte under consideration. To do so, our first parameter was a review of published LPGs. We hypothesized that if there was a relatively large number of LPGs available for a particular analyte, that analyte would be important for health testing. To estimate the number of LPGs, we used the AHRQ's NGC database. For example, there were 60 LPGs listed in the NGC for LDL cholesterol, 31 for hemoglobin A1c, and 27 for troponin, all of which are proposed for addition in Table 1. However, this approach did not differentiate analytes for which there were conflicting recommendations. For example, there are controversies about the value of screening men with prostate specific antigen (PSA) testing, and there is an ongoing debate about the prudence of testing vitamin D in asymptomatic adults (Kopes-Kerr, 2013).[7 8 9]

Our second parameter was a review of critical values. Critical values are predetermined limits for specific analytes that when exceeded may suggest that immediate clinical intervention is required. We assessed analytes included on ''critical values'' lists to determine the analyte's relative importance in helping clinicians to make rapid life-altering decisions. This approach allowed us to gauge how important an accurate result could be because an incorrect result could lead to a life-threatening intervention or a failure to intervene. We reviewed published literature[10] and critical values posted online from 16 institutions including small hospitals, university hospitals, and reference laboratories.[11]

Our final parameter for assessing the clinical impact of an analyte was reviewing its medical device classification (Class I, II, or III) as categorized by the Food and Drug Administration's risk classification list. In a similar way, we assessed the public health importance of the eligible analytes by counting the number of recommendations for testing the analytes from CDC's Morbidity and Mortality Weekly Report, the Infectious Disease Society of America, and the Council of State and Territorial Epidemiologists for surveillance of health conditions related to the particular analyte under consideration. We found supporting evidence for national prioritization in some of the following: the U.S. Preventive Services Task Force (*https://www.uspreventiveservicestaskforce.org/Page/Name/recommendations*), the National Healthcare Quality and Disparities Report (*https://www.ahrq.gov/research/findings/nhqrdr/index.html*), the CDC Hormone Standardization Program (*https://www.cdc.gov/labstandards/hs.html*). For some analytes that have important public health impact, such as blood lead, we consulted with subject matter experts in the CDC National Center for Environmental Health, which promotes national testing and/or has standardization programs for some priority analytes, specifically estradiol and testosterone. CMS and CDC used this information to help determine which analytes should be included in this proposed rule.

Therefore, we used those parameters in an attempt to get a relative sense of the patient and public health impact of the analytes under consideration, but, using the data available to us, we found no standardized, generally accepted way to assess the relative impact of testing for particular analytes on clinical care and public health. After assessing patient and public health impact on a case-by-case basis for the third cut, we narrowed the analytes down to 34 for consideration of addition to the proposed list of analytes in subpart I.

d. Cost and Feasibility of Implementation

For the final analysis to determine whether an analyte would be proposed for inclusion in subpart I of the CLIA regulations, we focused upon feasibility and costs of conducting PT for each of the remaining 34 analytes under consideration. We provided each of the HHS-approved PT programs the opportunity to submit comments in writing related to: inclusion/deletion of analytes, grading schemes, method(s) for determining target values, evaluating data using peer groups, cost of including new analytes, and structure of microbiology PT. Analytes for which it would be difficult for the PT programs to scale up production to meet the CLIA required frequency of three events per year with five challenges per event were eliminated from consideration because we believe that the costs passed down to laboratories to purchase the PT would be overly burdensome. In other cases, the decisions were based on the difficulty of finding any suitable PT materials. Some potential analytes were eliminated because they were too unstable for product development or shipping or because the testing methodology was not sufficiently standardized to support PT, such as vitamin D testing. After assessing cost and feasibility of implementing PT on a case-by-case basis, we made the final cut, narrowing the analytes down to 29 potential analytes for the proposed list of analytes in subpart I.

3. Specific Analytes Proposed for Addition to Subpart I

Based upon the sequential process described above, information received from the PT programs and consultation between CDC and CMS, we narrowed the list down to 29 analytes that we are proposing to add to subpart I of the CLIA regulations (Table 1).

TABLE 1—ANALYTES PROPOSED FOR ADDITION TO SUBPART I

CLIA Regulation	Analytes
General Immunology, § 493.927.	Anti-HBs, Anti-HCV, C-reactive protein (high sensitivity).

[4] AHRQ's National Guideline Clearinghouse website accessed for this proposed rule, however, no longer exists on the internet effective July 16, 2018.

[5] Burtis, C. A., Ashwood, E. R., & Bruns, D. E. (2012). Tietz Textbook of Clinical Chemistry and Molecular Diagnostics. London: Elsevier Health Sciences.

[6] Laboratory critical values policies and procedures: a college of American Pathologists Q-Probes Study in 623 institutions. Howanitz PJ, Steindel SJ, Heard NV. Arch Pathol Lab Med. 2002 Jun;126(6):663–9.

[7] Barry, Micheael J. Screening for Prostate Cancer—The Controversy That Refuses to Die. New England Journal of Medicine 360;13 (March 2009).

[8] Eck, Leigh M. Should family physicians screen for vitamin D deficiency? yes: targeted screening in at-risk populations is prudent. American Family Physician 87, 8 (2013), pp. 541b.Fr.

[9] Kopes-Kerr, Colin. Should family physicians screen for vitamin D deficiency? no: screening is unnecessary, and routine supplementation makes more sense. American Family Physician 87, 8 (2013), pp. 540b.

[10] Wagar, Friedberg, Souers, and Stankovic, 2007, *https://www.ncbi.nlm.nih.gov/pubmed/18081434.*

[11] *www.mayomedicallaboratories.com/test-catalog/appendix/criticalvalues/index.html.*

TABLE 1—ANALYTES PROPOSED FOR ADDITION TO SUBPART I—Continued

CLIA Regulation	Analytes
Routine Chemistry, § 493.931.	B-natriuretic peptide (BNP), ProBNP, Cancer antigen (CA) 125, Carbon dioxide, Carcinoembryonic antigen, Cholesterol, low density lipoprotein, Ferritin, Gamma glutamyl transferase, Hemoglobin A1c, Phosphorus, Prostate specific antigen, total, Total iron binding capacity, Troponin I, Troponin T.
Endocrinology, § 493.933.	Estradiol, Folate, serum, Follicle stimulating hormone, Luteinizing hormone, Progesterone, Prolactin, Parathyroid hormone, Testosterone, Vitamin B12.
Toxicology, § 493.937.	Acetaminophen, serum, Salicylate, Vancomycin.

4. Analytes Proposed for Removal From Subpart I

Recognizing that changes in the practice of clinical medicine have resulted in less frequent use of certain analytes, we used the same process to review the existing list of analytes in subpart I to determine which should be retained. In addition to requesting CLIAC's recommendations, we generally used the same criteria for retention of an analyte in subpart I as those used for determining which PT analytes to propose adding, however, as such PT testing was already available on the market, we did not consider the availability of PT material or the feasibility of implementation; therefore, we believe that PT programs already have the mechanism(s) in place to manufacture and ship PT for these analytes.

5. Process for Ranking and Assessing Existing Analytes and Proposals for Removal From Subpart I

a. Estimating Nationwide Testing Volume

We generally used the same rationale to select currently required analytes to propose for deletion. Specifically, we used the same threshold of 500,000 tests performed annually as an initial criterion for considering PT analytes. Those estimated to be lower than this threshold were considered for deletion from required PT. In particular, we focused on PT for several of the therapeutic drugs (ethosuximide, quinidine, primidone, and procainamide and its metabolite, N-acetyl procainamide). New drugs that are more effective or safer have entered the market since 1992, and may have replaced use of the therapeutic drugs that were included in the 1992 regulations. If so, we would expect to see a continued decline in the volume of testing for the use of such drugs. In addition to identifying decreases in testing for these drugs, we looked for probable causes of those decreases. These decreases in testing could be a result of new and emerging tests, including methodologies, replacing older tests, new technology, and changes to the way that the medical community orders laboratory testing. For example, the decrease in testing for LDH isoenzymes could be explained by the increased reliance on better alternative cardiac markers, especially troponin.[12] For some of the anticonvulsant drugs, there may have been changes in medical practice, including alternative drugs and other treatments, possibly decreasing the need to measure them.[13] We identified 13 currently required analytes with national test volumes that were less than our 500,000 annual test volume threshold.

b. Estimated Impact on Patient and Public Health

For any analyte still under consideration for removal, we performed literature reviews to determine if testing for alternative analytes or other diagnostic strategies had begun to supplant testing for the considered analyte. We took into account testing trends over the past 10 years[14] and we attempted to project expected testing trends. We then assessed the critical importance of candidates for deletion from subpart I based upon the number of guidelines available in the AHRQ NGC and the same sources used for considering inclusion in subpart I, bearing in mind that for all analytes and tests that are not listed in subpart I, laboratories must demonstrate accuracy twice per year as specified at § 493.1236(c)(1). We also considered the potential impact on clinical medicine and public health of deleting these analytes. Based on our literature review and consultation with CDC health experts, we decided not to propose the elimination of eight analytes based upon their critical importance for patient testing: carbamazepine, alpha-1-antitrypsin, phenobarbital, hepatitis Be antigen (HBeAg), antibody identification, theophylline, gentamicin and tobramycin. These are used for making important health decisions, for example, diagnosing hepatitis B (HBeAg), performing crossmatching for blood transfusions (antibody identification), or assessing compliance with medication for critically ill asthmatic patients (theophylline).

6. Analytes Proposed for Deletion From Subpart I

Based upon the sequential process described above, we propose that the following analytes be deleted from subpart I: At § 493.931 LDH isoenzymes and at § 493.937 ethosuximide, quinidine, primidone, and procainamide (and its metabolite, N-acetyl procainamide).

7. Determining Criteria for Acceptable Performance

''Criteria for Acceptable Performance'', as that term is used in §§ 493.923, 493.927, 493.931, 493.933, 493.937, 493.941, and 493.959, is defined by the target value and acceptance limits. Criteria for acceptable performance is meant for PT scoring only and not intended to be used to set acceptability criteria for a laboratory's verification or establishment of performance specifications.

8. Setting Target Values

Under § 493.2, ''target value'' for quantitative tests are currently generally defined as either the mean of all participant responses after removal of outliers (those responses greater than 3 standard deviations from the original mean) or the mean established by definitive or reference methods acceptable for use in the National Reference System for the Clinical Laboratory (NRSCL) by the National Committee for the Clinical Laboratory Standards (NCCLS). However, in instances where definitive or reference methods are not available or a specific method's results demonstrate bias that is not observed with actual patient specimens, as determined by a defensible scientific protocol, a comparative method or a method group (''peer'' group) may be used. If the method group is less than 10 participants ''target value'' means the overall mean after outlier removal (as defined above) unless acceptable scientific reasons are available to indicate that such an evaluation is not appropriate.

We recognize, based on input from PT programs, that peer grouping is generally the way that target values are

[12] Shahangian, Alspach, Astles, Yesupriya, and Dettwyler, 2014, *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4698806/*.

[13] Krumholz, et al, 2015) (NICE, 2012, *https://www.nice.org.uk/guidance/cg137*).

[14] Shahangian, Alspach, Astles, Yesupriya, and Dettwyler, 2014 *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4698806/*.

set for most analytes. Therefore, in this rule, we are proposing to continue allowing PT programs to use peer grouping to set the target values. In addition, we propose removing the reference to the NRSCL and NCCLS, while retaining the other options for setting target values.

9. Changing Acceptance Limits

Because there have been improvements in technology resulting in better sensitivity, specificity, and precision, routinely using peer grouping to set target values means that the acceptance limits (AL) that were originally specified in each specialty and subspecialty of the CLIA'88 regulations in subpart I effectively allow for a more tolerant acceptance criteria for most analytes than would occur if targets were set by a reference method or overall mean. Based on feedback from several HHS-approved PT programs, we believe that it would be appropriate to update the ALs to reflect advancements in technology and analytical accuracy since the PT regulations were implemented in 1992. While narrowing limits may increase miss rates per challenge, we do not expect a high unsuccessful rate based on the data simulations provided by the PT programs. We expect the rates of unsatisfactory events would be low based on the simulation data, and that the rates of unsuccessful events (two consecutive or two out of three testing events being unsatisfactory) would be even lower; therefore, we believe it is reasonable to propose tighter limits given current analytic accuracy. We used all data available to us to minimize the negative consequences of the proposed changes (for example, too many unsuccessful performances) to acceptance limits, including simulations provided by PT programs.

10. Changes to Percentage Acceptance Limits (ALs)

a. Basis for Using Fixed Percentage PT ALs

Currently, the CLIA regulations at §§ 493.927(c)(2), 493.931(c)(2), 493.933(c)(2), 493.937(c)(2), and 493.941(c)(2) prescribe a variety of ALs, including: A multiple of the standard deviation (SD) of results from the mean of other participants in the peer group; fixed limit as a percentage of the assigned value; fixed limit in concentration units; and a mixture of percentage and concentration units, depending on the concentration of the analyte. For all new and currently required non-microbiology analytes, we propose to use fixed ALs, preferably as percentage limits rather than concentration units.

There are 53 analytes (existing or proposed) for which we are proposing a percentage-based AL, for which biological variability data were published. For several analytes (for example, therapeutic drugs) there were no biological variability data because these analytes do not occur naturally in the body. Where there were such data, we used AL to get as close to, or below, an accuracy goal for the test that was based on biological variability data, and then we simulated several percentage-based ALs to see if their results would have passed or failed at each simulation. We wanted to get miss rates (that is, percent of laboratories that did not meet the criteria for acceptable performance per PT challenge) of somewhere in the 1 to 2 percent range as was observed in the data provided by the PT programs for current ALs. Of the 53 analytes, 34 of the proposed ALs were tighter than or equal to biological variability limits. For 19 analytes, the limits we are proposing are looser (greater) than the limits required to meet accuracy based upon biological variability. For these 19 analytes, using ALs based upon biological variability would be untenable because the current analytical accuracy for such testing would not be expected to be able to meet such limits. White blood cell differential is the only remaining analyte that would have ALs in SD. In this case there were no biological variability data available.

In general, fixed ALs, either in percentages or concentration units, are preferred to SDs for PT, for several important reasons: They can be tied directly to objective goals for performance, such as goals for analytical accuracy and technical expectations; they are constant in all PT events and do not vary because of statistical randomness, masked outliers, or small sample size; they assure the same evaluation criteria are used by all PT programs and discourage opportunities for participants to ''shop'' for PT programs with less stringent criteria for which it is easier to achieve acceptable performance; they do not unfairly result in tighter effective ALs for peer groups that use analyzers that have tighter analytical precision; they can combine a fixed percentage and a fixed absolute concentration to allow for more robust evaluation while also fairly evaluating low analyte concentrations; and they are commonly used worldwide in other PT and external quality assessment programs.

Our analysis of existing PT and external quality assessment programs showed that ALs using two or three SDs have been used in PT in a wide variety of settings for several reasons, such as: Limited experience with PT or matrix effects for a particular analyte; lack of consensus on criteria for acceptable performance; inertia with no compelling pressure for change; and analytical performance so poor that multiples of the overall SD are considered to be the only fair approach. In our opinion, all of these reasons to some extent contributed to initial reliance on SD limits for certain analytes when CLIA'88 was implemented. We also note that while regulations promulgated under CLIA'67 used ALs of three SD for several analytes, regulations finalized under CLIA'88 replaced these with fixed limits and PT programs were able to successfully make the transition. Therefore, we believe it is likely that the proposed changes from SD-based ALs to fixed ALs will not be problematic.

Therefore, as discussed in section II.B. of this proposed rule, we are proposing to amend certain analytes in §§ 493.927, 493.931, 493.933, 493.937, and 493.941 to include fixed ALs with or without percentages. Three analytes have only concentration-based ALs (that is, no percentage-based ALs): pH, potassium and sodium.

b. Adding Fixed Concentration Units to Fixed Percentage Units

A percentage-based criterion can be unnecessarily stringent at low concentrations—either because of technical feasibility or because medical needs at the low concentration do not require such tight precision [15]. Thus, when percentage-based fixed criteria are used for ALs, it may be necessary to place a minimum on the percentage as currently occurs with the criterion for acceptable performance for glucose (§ 493.931) for which the AL switches from 10 percent to 6 mg/dL below a concentration of 60 mg/dL. The combined ALs direct PT programs to score with whichever of the specifications is more tolerant; at lower limits of the analytical range this will be the fixed concentration limit. Therefore, to allow for more fair and realistic ALs, we propose to use combinations of percentage and concentration limits as appropriate. These combination limits are similar to limits that already exist in CLIA'88 regulations for glucose and other analytes.

Therefore, we are proposing to amend certain analytes in §§ 493.927, 493.931, 493.933, 493.937, 493.941 and 493.959

[15] Thompson, Michael. Variation of precision with concentration in an analytical system. Analyst, 113, (1988), pp. 1579–1587.

to include percentage-based ALs with or without additional fixed ALs.

c. Establishing ALs Based on Analytical Accuracy Goals for Proposed New and Several Current Analytes

For the newly proposed analytes and several current analytes for which current ALs are in units other than percentages such as three SDs or concentration units, we are proposing to change the ALs to percentages. Over the years, there have been many proposed criteria for establishing goals for analytical performance.[16] [17] The various possible approaches were reviewed and a hierarchy was established based upon a 1999 consensus conference.[18] These strategies were reconsidered in the 2014 European Federation of Clinical Chemistry and Laboratory Medicine Strategic Conference in Milan. Participants in both conferences acknowledged that the ability of a test method to meet clinical needs is the highest priority and the most defensible approach would be clinical trials in which patient outcomes could be compared using different analytical accuracy goals. This approach was not feasible for many reasons. Although clinical outcomes studies would be the most rigorous basis for establishing analytical performance goals, these are seldom possible, leaving the natural dispersion of levels for each analyte (biological variability) as the next best scientifically defensible approach for establishing analytical accuracy goals.[19] The less the biological variability, the more stringent the analytical accuracy needs to be. This approach makes sense for two of the most important reasons to conduct patient testing: Diagnosis of disease, that is, differentiating an abnormal result from a normal one, and monitoring a patient's progress during treatment. In the former case, we believe that the ''within-group'' biological variability is the important limiting factor defining an appropriate error goal for a test method. Furthermore, for monitoring progress, we believe the most important factor is the ''within individual'' variability. It was not possible for us to differentiate how analytes are being used or will be used clinically, with respect to diagnosis versus monitoring. Therefore, we accounted for both needs and used an approach that accounted for both kinds of biological variability to estimate analytical accuracy goals as the basis for our proposals for acceptance limits in percentages.[20] The advantage of using analytical accuracy goals that are expressed in terms of percentages is that they can be directly related to ALs in a mathematical way expressed as percentages.

We have assumed that a laboratory that can meet the clinical needs for test accuracy based upon biological variability should perform successfully on PT most or all of the time. Therefore, whenever possible, we have used publically available estimates of allowed total error based upon estimates of biological variability[21] to approximate the proposed AL. CDC has shown in an a recent poster[22] that it is possible to design ALs based upon such accuracy goals, and it is possible to simulate the ability of a PT program to identify laboratories that cannot meet such goals, while minimizing the likelihood of misidentifying laboratories that are meeting analytical accuracy goals based upon biological variability.

Therefore, we are proposing to amend ALs for certain current analytes as well as establish ALs for analytes proposed for addition in §§ 493.927, 493.931, 493.933, 493.937, 493.941 and 493.959 based on analytical accuracy goals.

d. Tightening Existing Percentage ALs as Needed

There have been significant improvements in laboratories' performance in PT for the great majority of analytes[23] and PT unsatisfactory rates have dropped for all types of laboratories. The improvements are such that, for many analytes, laboratories that began to use PT to comply with CLIA'88 now perform as well as the hospital and independent laboratories which were previously required to perform PT under CLIA'67. Howerton, et al.[24] showed that for almost all analytes examined, PT performance improved somewhat after CLIA'88 was implemented, but the improvements were greater for laboratories that were not previously required to perform PT. The rates of unsatisfactory PT are now roughly the same for analytes listed in subpart I, regardless of the laboratory type, and this is consistent with CLIA's intent to ensure accurate clinical testing regardless of the setting where testing is performed. There are several factors contributing to the improvements in PT performance, including improved analytical methods being used in all settings; technological advances resulting in improved precision, sensitivity and specificity; and increased familiarity with handling preparation, and reporting of PT samples. Therefore, for the reasons above as well as supporting simulation data date from the PT programs, we are proposing to make criteria for acceptable performance for existing analytes listed in subpart I tighter so they are in closer agreement with analytical accuracy goals which are based upon biological variability and simulation data.

Therefore, based on the simulation data, we are proposing to tighten ALs for certain current analytes in §§ 493.927, 493.931, 493.933, 493.937, 493.941 and 493.959.

e. Simulating the Impact of New ALs on Unacceptable Scores for Challenges and Unsatisfactory Rates for Events

We evaluated a very specific PT data set to help CMS and CDC set appropriate limits. The total simulations reproduced PT that covered 2 years, representing 30 challenges (three events per year; five challenges per event; 2 years) of each proposed new analyte and for the analytes for which we propose to modify ALs. We reviewed the aggregated percentage of unacceptable scores for each PT challenge using retrospective data. We then reviewed the simulation data which applied two or three new ALs for each of 84 analytes (consisting of 27 new analytes and 57 existing analytes). Based on the simulation data, we were able to make informed decisions to help us create or adjust the ALs.

Based upon our analysis of the simulation results, we further refined the proposed ALs and added potential

[16] Tonks, David B. A study of the accuracy and precision of clinical chemistry determinations in 170 Canadian laboratories. Clinical Chemistry 9, 2 (1963), pp. 217–233.

[17] Cotlove, Ernest, Eugene K. Harris, and George Z. Williams. Biological and analytic components of variation in long-term studies of serum constituents in normal subjects. Clinical Chemistry 16, 12 (1970), pp. 1028–1032.

[18] Fraser, Callum. The 1999 Stockholm consensus conference on quality specifications in laboratory medicine. Clinical Chemistry and Laboratory Medicine 53, 6 (2015), pp. 837–840.

[19] Burtis, Carl A., Edward R. Ashwood, David E. Bruns, Ed. Tietz textbook of clinical chemistry and molecular diagnostics. (Chapter 2 Selection and analytical evaluation of methods with statistical techniques, pp. 17), Elsevier Saunders, Philadelphia, P.A., (2012).

[20] Burtis, Carl A., Edward R. Ashwood, David E. Bruns, Ed. Tietz textbook of clinical chemistry and molecular diagnostics. (Chapter 17 Preanalytic variables and biological variation, pp. 470–471), Elsevier Saunders, Philadelphia, P.A., (2006).

[21] *https://www.westgard.com/biodatabase1.htm.*

[22] Astles, Tholen, and Mitchell, 2016, *https://www.aacc.org/science-and-practice/annual-meeting-abstracts-archive.*

[23] Howerton, Krolak, Manasterski, and Handsfield, 2010.

[24] Howerton D1, Krolak JM, Manasterski A, Handsfield JH. Arch Pathol Lab Med. 2010 May;134(5):751–8. Proficiency testing performance in US laboratories: results reported to the Centers for Medicare & Medicaid Services, 1994 through 2006.

absolute concentrations in lieu of percentage ALs, as was described previously. We then requested narrowly tailored data from PT programs as described above using retrospective PT data and peer group data for scoring, as they ordinarily would do. We focused on unsatisfactory scores with the data so that we could calculate the unsatisfactory rate per analyte among all participating laboratories that might occur with each proposed AL. The final simulations were conducted by several of the PT programs and this set of data was used to determine the ALs proposed in this rule.

We compared the unacceptable scores for each challenge and each proposed AL to determine at which concentrations it would be necessary to switch to a fixed concentration AL. Using this approach, we were able to identify an AL for each analyte and, in some cases, an additional concentration-based AL. This approach enabled us to identify an AL that would be sensitive enough to identify poor performing laboratories, yet not so sensitive that it will incorrectly identify laboratories that are likely meeting requirements for accuracy.

f. Limitation in Our Ability To Predict the Number of New Unsatisfactory and Unsuccessful Scores

It is not possible for us to predict the precise effect of the proposed changes on the number of unsatisfactory and unsuccessful scores. The occurrence of an unsatisfactory score for a PT event depends upon at least two of five challenges being graded as unacceptable or outside the criteria for acceptable for performance. PT programs select different combinations of samples for each event and it is impossible to predict how their selection could be modelled statistically. Finally, the distribution of unsatisfactory and unsuccessful PT scores is not randomly distributed across all participants.

C. Additional Proposed Changes

We are proposing to amend § 493.2 to modify the definition of an existing term and define new terms as follows:

- *Target value:* We are removing the reference to NRSCL and NCCLS and retaining the other options for setting target values are retained in this proposed rule.
- *Acceptance Limit:* We are proposing to define this term to mean the symmetrical tolerance (plus and minus) around the target value.
- *Unacceptable score:* We are proposing to define this term to mean PT results that are outside the criteria for acceptable performance for a single challenge or sample.
- *Peer group:* We are proposing to define this term as a group of laboratories whose testing process utilizes similar instruments, methodologies, and/or reagent systems and is not to be assigned using the reagent lot number. PT programs should assign peer groups based on their own policies and procedures and not based on direction from any manufacturer.

We are also proposing the following revisions to the regulation text at subpart A:

- Sections 493.20 and 493.25: We are proposing to amend the regulations to reflect that if moderate and high complexity laboratories also perform waived tests, compliance with § 493.801(a) and (b)(7) are not applicable. However, we propose to continue to require compliance with § 493.801(b)(1) through (6) to align the regulations with the CLIA statute (42 U.S.C. 263a(i)(4)), which does not exclude waived tests from the ban on improper PT referral.

We are also proposing the following revision to the regulation text at subpart H:

- Section 493.861: We are amending the satisfactory performance criteria for failure to attain an overall testing event score for unexpected antibody detection from ''at least 80 percent'' to ''100 percent.'' We are proposing this change because it is critical for laboratories to identify any unexpected antibody when crossmatching blood to protect the public health and not impact patient care.

We are also proposing the following revisions to the regulation text at subpart I:

- Section 493.901(a): We are proposing to require that each HHS-approved PT program have a minimum of ten laboratory participants before offering any PT analyte. We recognize that PT programs do not grade results when there are fewer than ten laboratory participants. This would require the laboratory to perform additional steps to verify the accuracy of their results. If at any time a PT program does not meet the minimum requirement of 10 participating laboratories for an analyte or module, HHS may withdraw approval for that analyte, specialty or subspecialty. This change reduces some burden on laboratories that have incurred the expense of enrolling in a PT program but do not receive a score or receive an artificial score requiring the laboratory to take additional steps to verify the accuracy of the analyte as required by § 493.1236(b)(2).
- Section 493.901(c)(6): We are proposing to add the requirement that PT programs limit the participants' online submission of PT data to one submission or that a method be provided to track changes made to electronically reported results. Many PT programs currently allow laboratories an option to report PT results electronically while some other PT programs allow laboratories to only report PT results electronically with no other reporting option such as facsimile or mailed PT submission forms. However, at this time, the PT programs who do participate in the online reporting have no mechanism to review an audit trail for the submitted result. In some cases of PT referral, it has been discovered that laboratories have sent PT samples to another CLIA certified laboratory for testing, received results from the other laboratory, and then changed their online reported results to the PT program since those results can be modified up until the PT event close date. In an effort to assist in PT referral investigations and determinations, an audit trail that includes all instances of reported results would aid in determining if a laboratory compared PT results obtained from another laboratory and changed their previously submitted results.
- Section 493.901(c)(8): We are proposing to add to the requirement previously found at § 493.901 that contractors performing administrative responsibilities as described in §§ 493.901 and 493.903 must be a private nonprofit organization or a federal or state agency or nonprofit entity acting as a designated agent for the federal or state agency. Several PT programs have divided their administrative and technical responsibilities into separate entities or have had the administrative responsibilities performed by a contractor. We were made aware that administrative responsibilities were being performed by a for-profit entity. Because the CLIA statute (42 U.S.C. 263a(f)(3)(C)) requires PT programs to be administered by a private nonprofit organization or a state, we are proposing to amend § 493.901 to state that all functions and activities related to administering the PT program must be performed by a private nonprofit organization or state.
- Section 493.901(e): We are proposing to add the requirement that HHS may perform on-site visits for all initial PT program applications for HHS approval and periodically for previously HHS-approved PT programs either during the reapproval process or as necessary to review and verify the

policies and procedures represented in its application and other information, including, but not limited to, review and examination of documents and interviews of staff.

• Section 493.901(f): We are proposing to add an additional requirement to the regulation that specifies CMS may require a PT program to reapply for approval using the process for initial applications if widespread or systemic problems are encountered during the reapproval process. The initial application for the approval as an HHS PT program requires more documentation in the application process than that which is required of PT programs seeking HHS reapproval.

• Section 493.903(a)(3): It has come to our attention that PT programs may have on occasion modified a laboratory's PT result submission by adding information such as the testing methodology which was inadvertently omitted by the laboratory. Therefore, we are proposing to add the requirement that PT programs must not change or add any information on the PT result submission for any reason including, but not limited to, the testing methodology, results, data, or units.

• Section 493.905: We are proposing to add that HHS may withdraw the approval of a PT program at any point in the calendar year if the PT program provides false or misleading information that is necessary to meet a requirement for program approval or if the PT program has failed to correct issues identified by HHS related to PT program requirements. We are also proposing to add a requirement that the PT program may request reconsideration should CMS determine that false or misleading information was provided of if the PT program has failed to correct issues identified by HHS related to PT program requirements.

• Sections 493.911 through 493.919: We are proposing, as discussed in section II.A.1. of this proposed rule, to modify the regulation by removing the types of services listed for each microbiology subspecialty. We are also proposing to remove specific lists of example organisms from each microbiology subspecialty and replace the list with broader categories of organisms.

• Section 493.911(a): For bacteriology, as discussed in sections II.A.1. and V.C. of this proposed rule, we are proposing that the categories required include Gram stain including bacterial morphology; direct bacterial antigen detection; bacterial toxin detection; detection and identification of bacteria; and antimicrobial susceptibility or resistance testing on select bacteria.

• Section 493.911(a)(3): We are proposing that the bacteriology annual PT program content described must include representatives of the following major groups of medically important aerobic and anaerobic bacteria if appropriate for the sample sources: Gram-negative bacilli; gram-positive bacilli; gram-negative cocci; and gram-positive cocci.

• Section 493.913(a): We are proposing to include required PT for acid-fast stain; detection and identification of mycobacteria; and antimycobacterial susceptibility or resistance testing.

• Section 493.913(a)(3): For mycobacteriology, we are proposing that the annual program content must include *Mycobacterium tuberculosis* complex and *Mycobacterium* other than tuberculosis (MOTT), if appropriate for the sample sources.

• Section 493.915(a): For mycology, we are proposing to require PT for direct fungal antigen detection; detection and identification of fungi and aerobic actinomycetes; and antifungal susceptibility or resistance testing.

• Section 915(a)(3): We are we are proposing that annual program content must include the following major groups of medically important fungi and aerobic actinomycetes if appropriate for the sample sources: Yeast or yeast like organisms; molds that include dematiaceous fungi, dermatophytes, dimorphic fungi, hyaline hyphomycetes, and mucormycetes; and aerobic actinomycetes.

• Section 493.917(a): For parasitology, we are proposing to require PT for direct parasite antigen detection and detection and identification of parasites.

• Section 493.917(a)(3): We are proposing that the annual program content must include intestinal parasites and blood and tissue parasites, if appropriate for the sample source.

• Section 493.919(a): For virology, we are proposing to require PT for viral antigen detection; detection and identification of viruses to the highest level that the laboratory reports results on patient specimens; and antiviral susceptibility or resistance testing.

• Section 493.919(a)(3): We are proposing that the annual program content must include respiratory viruses, herpes viruses, enterovirus, and intestinal viruses, if appropriate for the sample source.

• Sections 493.911(b)(1), 493.913(b)(1), 493.915(b)(1), 493.917(b)(1), 493.919(b)(1), 493.923(b)(1), 493.927(c)(1), 493.931(c)(1), 493.933(c)(1), 493.937(c)(1), 493.941(c)(1), and 493.959(d)(1): We are proposing to amend these provisions to clarify that for the purpose of achieving consensus, PT programs must attempt to grade using both participant and referee laboratories before determining that the sample is ungradable. We believe that this change will enhance consistency among the PT programs when grading samples. The current regulations noted above allow for scoring either with participants or with referees before calling a sample ungradable.

• Sections 493.923(a), 493.927(a), 493.931(a), 493.933(a), 493.937(a), 493.941(a), and 493.959(b): We are proposing to amend these provisions to remove the option that PT samples, ''at HHS' option, may be provided to HHS or its designee for on-site testing''.

• Section 493.927: We are proposing to amend, as discussed in sections II.B.8 through II.B.10. of this proposed rule, the criteria for acceptable PT performance to permit scoring of quantitative test results for the following immunology analytes: Antinuclear antibody; antistreptolysin O; rheumatoid factor; and rubella. For these analytes, we have determined that there are one or more test systems that currently report results in quantitative units; therefore, we are adding ALs based on percentages or target values in addition to retaining the qualitative target values. We propose to make this allowance in CLIA for reporting PT which reflects current practice.

• Section 493.931(b): We are making a technical change to the description for creatine kinase isoenzymes to be CK–MB isoenzymes, which may be measured either by electrophoresis or by direct mass determination, for example using an immunoassay.

• Section 493.933: We propose to add the following analytes: Estradiol, folate (serum), follicle stimulating hormone, luteinizing hormone, progesterone, prolactin, parathyroid hormone, testosterone, and vitamin B12.

• Section 493.937(a): We are proposing to revise this provision by including the requirement that annual PT programs must provide samples that cover the full range of values that could occur in patient specimens. We are proposing this amendment so that PT programs must provide samples across a toxicology sample's entire reportable range rather than just provide samples within a sample's therapeutic range.

• Section 493.941: We are differentiating the criteria for units of reporting of the analyte prothrombin time. Currently the analyte prothrombin time can be reported in seconds and/or

INR (international normalized ratio), so we are proposing to amend the criteria for acceptable performance to reflect both units of reporting and proposing to add the requirement that laboratories must report prothrombin time for PT the same way they report it for patient results; if patient results are reported in seconds or as INR results, they should report the same way to PT programs. If the laboratory reports patient results both in seconds and as INR, they should be reported the same way to the PT programs. We are also proposing to add criteria for acceptable performance for directly measured INR for prothrombin time. In addition, we propose to require laboratories that perform both cell counts and differentials to conduct PT for both (that is, the ''or'' would be changed to an ''and''). Finally, we are proposing to change the criteria for acceptable performance for ''cell identification'' from 90 percent to 80 percent. We are proposing this change as the requirement of five samples per event does not allow for a score of 90 percent (that is, five samples would allow for scores of 0 percent, 20 percent, 40 percent, 60 percent, 80 percent, or 100 percent). PT for cell identification is currently required in § 493.941. Further, § 493.851(a) states that ''failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory performance for the testing event.'' If the requirement for acceptable performance remains at 90 percent, a laboratory can only have satisfactory performance if they receive 100 percent; however, § 493.851(a) allows satisfactory performance for both 80 percent and 100 percent.

- Section 493.959: We are proposing to change the criteria for acceptable performance for unexpected antibody detection from 80 percent accuracy to 100 percent accuracy. We are proposing this change because it is critical for laboratories to identify any unexpected antibody when crossmatching blood in order to protect the public health and not impact patient care.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to publish a 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval.

To fairly evaluate whether an information collection should be approved by OMB, PRA section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our burden estimates.
- The quality, utility, and clarity of the information to be collected.
- Our effort to minimize the information collection burden on the affected public, including the use of automated collection techniques.

We are soliciting public comment on each of the section 3506(c)(2)(A)-required issues for the following information collection requirements (ICRs).

The requirements and burden will be submitted to OMB under (OMB control number 0938-New).

A. Clarification for Reporting of Microbiology Organism Identification

We are proposing to clarify a requirement at §§ 493.801(b), 493.911(b), 493.913(b), 493.915(b), 493.917(b), and 493.919(b), to emphasize the point that, as currently required, laboratories must report PT results for microbiology organism identification to the highest level that they report results on patient specimens. In accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2), we believe the reporting of microbiology organism identification is a usual and customary practice when reporting PT results to PT programs. We are able to determine how many laboratories provide services in microbiology; however, we are unable to determine if the laboratories are enrolled in the appropriate PT outside of the survey process, or if the microbiology PT samples for which the laboratory is enrolled are required under subpart I. There are no data systems that capture this information. We estimate the number of laboratories that are not currently reporting microbiology organisms to the highest level that they report results on patient specimens to be about 10 percent of 36,777 laboratories which is 368 laboratories. We estimate it would take 20 minutes for a laboratory to fill this information on the PT submission form. Each laboratory would report this information 3 times a year which would take approximately 1 hour. The total annual burden is 368 hours (368 laboratories × 1 hour). A Clinical Laboratory Technologists/Technicians would perform this task at an hourly wage of $25.59 as published in 2017 by the Bureau of Labor Statistics (*https://www.bls.gov/oes/current/oes_nat.htm*). The wage rate would be $51.18 to include overhead and fringe benefits. The total cost would be $18,834 (368 hours × $51.18).

B. Submission of PT Data by Laboratories

At § 493.901(c)(6), we are proposing to add the requirement that PT programs limit the participants' online submission of PT data to one submission or that a method be provided to track changes made to electronically reported results. In an effort to assist in PT referral investigations and determinations, an audit trail that includes all instances of reported results would aid in determining if a laboratory compared PT results obtained from another laboratory and changed their previously submitted results. In accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2), we believe the ability for the PT programs to track this data already exists in their software; however, they may need to make minor modifications to their software in order to meet this requirement. If a PT program would need to update their software, we would estimate that the cost would be 15 hours for software modification. The total burden is 135 hours (9 PT programs × 15 hours). However, this would not be an annual burden, rather it would only occur once when the requirement is implemented. A Software Developer, System Software would perform this task at an hourly wage of $107.48 as published in 2017 by the Bureau of Labor Statistics (*https://www.bls.gov/oes/current/oes_nat.htm*). The wage rate would be $107.48 to include overhead and fringe benefits. The total high estimated cost would be $14,510 (135 hours × $107.48). For those PT programs who already have this mechanism in place, there would be no additional burden or cost to meet this requirement.

C. Optional On-Site Visits to PT Programs

At § 493.901(e), we propose to add the requirement that HHS may require on-site visits for all initial PT program applications for HHS approval and periodically for previously HHS-approved PT programs either during the reapproval process or as necessary to review and verify the policies and procedures represented in its application and other information, including, but not limited to, review and examination of documents and interviews of staff. There is no collection of information requirements associated with this proposed requirement because the documentation is already being collected and maintained by the PT program as

normal course of business and is a usual and customary practice in accordance with implementing regulations at 42 CFR 493, subpart I.

D. PT Program Reapproval

At § 493.901(f), we propose to specify that we may require a PT program to reapply for approval using the process for initial applications if widespread or systemic problems are encountered during the reapproval process. If a PT program would need to reapply for approval using the initial application process, we would estimate that the cost would be 10 hours for document collection. The total burden is 90 hours (9 PT programs × 10 hour). However, this would not be an annual burden, rather it would only occur under the circumstances outlined above, and we believe that these would only occur rarely. An Office/Administrative Support Worker would perform this task at an hourly wage of $17.96 as published in 2017 by the Bureau of Labor Statistics (*https://www.bls.gov/oes/current/oes_nat.htm*). The wage rate would be $35.92 to include overhead and fringe benefits. The total cost would be $3,233 (90 hours × $35.92).

E. Withdrawal of Approval of a PT Program

At § 493.905, we propose to add that HHS may withdraw the approval of a PT program at any point in the calendar year if the PT program provides false or misleading information that is necessary to meet a requirement for program approval or if the PT program has failed to correct issues identified by HHS related to PT program requirements. We are also proposing to add a requirement that the PT program may request reconsideration. We believe this is excepted because of it being an administrative action per 5 CFR 1320.4(a)(2).

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Regulatory Impact Analysis

A. Statement of Need

Proficiency testing (PT) has long been recognized as a critical component of a quality management system. It was first required at a national level for some clinical laboratories under CLIA'67. When CLIA'88 was enacted, and its implementing regulations were finalized in 1992, all clinical laboratories that perform nonwaived testing became subject to the CLIA PT requirements. Since that time, there have been many changes in the practice of laboratory medicine and improvements in the analytical accuracy of test methods, such that HHS decided to assess the need to revise the PT regulations. For example, a number of analytes and tests now used for making clinical decisions were not recognized or commonly used at the time the CLIA PT requirements were published on February 28, 1992 at 42 CFR part 493 (57 FR 7002). Improvements in analytical accuracy required revisions to the criteria for acceptable performance to reflect the current practices. We based our decision to update the regulations and incorporate the changes proposed in this rule upon advice from the CLIAC.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

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). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any one year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. A regulatory impact analysis (RIA) is required for economically-significant regulatory actions that are likely to impose costs or benefits of $100 million or more in any given year.

This proposed regulation is economically significant within the meaning of section 3(f)(1) of the Executive Order since the estimated cost alone is likely to exceed the $150 million annual threshold. However, our upper limit of estimated impact is under the threshold of $150 million for the year of 2018 under Unfunded Mandates Reform Act (UMRA). The proposed rule, if finalized, would revise the CLIA PT requirements and would affect approximately 36,777 clinical laboratories now subject to participation in PT, resulting in some financial implications. In addition, this proposed rule, if finalized, would cause the seven existing CLIA-approved PT programs to incur some costs as they modify their programs to meet the requirements specified in this proposed rule. It may also have an effect on some state PT requirements. We prepared the RIA and found that it did not meet the UMRA threshold for a significant regulatory action.

The RFA requires agencies to analyze options for regulatory relief of small entities if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we assume that the great majority of clinical laboratories and PT programs are small entities, either by virtue of being nonprofit organizations or by meeting the Small Business Administration definition of a small business by having revenues of less than $7.5 million to $38.5 million in any one year. For purposes of the RFA, we believe that approximately 82 percent of clinical laboratories qualify as small entities based on their nonprofit status as reported in the American Hospital Association Fast Fact Sheet, updated January 2017 (*https://www.aha.org/system/files/2018-01/fast-facts-us-hospitals-2017_0.pdf*) and 100 percent of PT programs are nonprofit organizations. Individuals and states are not included in the definition of a small entity. We are voluntarily preparing a Regulatory Impact Analysis and are requesting public comments in this area to assist us in making this determination in the final rule.

In addition, section 1102(b) of the Social Security Act (the Act) requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. We do not expect this proposed rule, if finalized, would have a significant impact on small rural hospitals. Such hospitals often provide very limited laboratory services and may refer testing for the analytes we propose to add, to larger laboratories. For the small rural hospitals that have laboratories and perform testing for the analytes, we expect that our proposals will add minimal effort since they should already have PT policies and procedures in place. We are unable to estimate the number of laboratories that support small rural hospitals. We are requesting public comments in this area to assist us in making this determination in the final rule.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any one year of $100 million in 1995 dollars, updated annually for inflation. In 2018, that threshold is approximately $150 million.[25] We do not anticipate this proposed rule would impose an unfunded mandate on states, tribal governments, or the private sector of more than $150 million annually. We request comments from states, tribal governments, and the private sector on this assumption.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. The proposed changes would not have a substantial direct effect on state and local governments, preempt state law, or otherwise have a federalism implication and there is no change in the distribution of power and responsibilities among the various levels of government. We do not believe that this rule would impose substantial direct compliance costs on state and local governments that are not required by statute. We do not believe that a significant number of laboratories affected by these proposals are operated by state or local governments. Therefore, the proposed modifications in these areas would not cause additional costs to state and local governments.

We are proposing to require that each HHS-approved PT program have a minimum of ten laboratory participants before offering any PT analyte. This change reduces some burden on laboratories that have incurred the expense of enrolling in a PT program but do not receive a score or receive an artificial score requiring the laboratory to take additional steps to verify the accuracy of the analyte as required by § 493.1236(b)(2). PT programs will determine if it is economically feasible to offer those analytes or if they should market their products to laboratories. Both of these activities are outside the scope of our authority.

C. Anticipated Effects

This proposed rule, if finalized, would impact approximately 36,777 clinical laboratories (total of Certificate of Compliance and Certificate of Accreditation laboratories, as of January 2017) required to participate in PT under the CLIA regulations implemented by the February 28, 1992 final rule, seven current HHS-approved PT programs, and to a lesser extent, *in vitro* diagnostics (IVD) manufacturers, healthcare providers, laboratory surveyors, and patients. Although complete data are not available to calculate all estimated costs and benefits that would result from the changes proposed in this rule, we are providing an analysis of the potential impact based on available information and certain assumptions. Implementation of these proposed requirements in a final rule would result in changes that are anticipated to have quantifiable impacts on laboratories and non-quantifiable impacts on laboratories, PT programs, and others mentioned above. In estimating the quantifiable impacts, we separated the laboratory specialties into two broad categories that include: (1) Proposed PT changes to the microbiology specialty; and (2) proposed PT changes to non-microbiology specialties. This was done because the PT requirements for microbiology differ from those than for other laboratory specialties, and laboratories that are certified to perform microbiology testing may be impacted differently than those that perform non-microbiology clinical testing. In each microbiology subspecialty PT participation is required based on the types of services offered by a laboratory and an overall score is given per that subspecialty. In the other specialties and subspecialties, PT participation is required and scores are given based on specific required analytes listed in the regulations.

For both the microbiology PT changes and addition of proposed analytes to subpart I, we anticipate minimal burden to laboratories as CLIA already requires that laboratories must verify the accuracy of tests not currently listed in subpart I at least twice annually. We believe many laboratories meet this requirement by participating in proficiency testing voluntarily. However, we do not have a way of estimating how many of these participating laboratories actually meet the requirement through additional verification. Information on the costs of voluntary participation is also not reported. Although we cannot precisely predict how the proposed changes may qualitatively affect clinical laboratories, we do not expect there to be major changes in how they function. We have quantified the costs we expect laboratories to incur but there may be costs associated with other administrative functions related to PT ordering, result reporting, and record keeping that we are not able to estimate. As stated above, we are unable to estimate the number of laboratories voluntarily enrolled in PT which is not currently required in subpart I. Cost of adding a new analyte would range from $0.39 to $86.50; however, the majority of the costs/analyte are less than $5.00 per analyte.

1. Quantifiable Impacts for Laboratories

CDC receives catalogs from all CLIA-approved PT programs annually. We estimated material costs for purchasing PT based on the range of 2017 catalog prices from the seven CLIA-approved PT programs. In estimating the costs for performing PT for all laboratory specialties that would be affected by this regulatory change, we assumed that the average national CMS reimbursement rate for Part B Medicare (CMS Virtual Research Data Center: *https://www.resdac.org/cms-data/request/cms-virtual-research-data-center*) was a reasonable estimate of the cost the laboratory incurs when testing each sample (or challenge) because this amount represents the average reimbursement to laboratories performing patient testing for that analyte or test. We also assume the cost for testing patient samples is the same as the cost for testing PT samples.

We calculate that, on average, the impact would be between $721 and

[25] Bush, Laina. HHS Memo on Annual Update to the Unfunded Mandate Reform Act Threshold for 2017, March 24, 2017.

$3,218 per laboratory, with laboratories having fewer analytes bearing a smaller burden.

a. Impacts of Proposed PT Changes to the Microbiology Specialty

Proposed changes to the microbiology specialty include changes in each of the subspecialties (bacteriology, mycobacteriology, mycology, parasitology, and virology) that would replace the types of services offered and the examples of organisms to be included over time with a proposed list of categories of tests and groups of microorganisms for which PT is required. In addition, changes are being proposed for each individual subspecialty that would require specific PT for certain microbiology tests and procedures. These changes, if finalized, could have a cost impact on laboratories. However, as stated in § 493.801(a)(2)(ii) and § 493.1236(c)(1), for tests or procedures performed by the laboratory that are not listed in the CLIA regulations subpart I, Proficiency Testing Programs for Nonwaived Testing, a laboratory must verify the accuracy of that test or procedure at least twice annually. Although we can estimate how many microbiology laboratories voluntarily enroll in PT with HHS-approved PT programs to meet this requirement, we cannot estimate how many laboratories meet this requirement through other accuracy verification methods. The numbers of laboratories reported in Table 2 and Table 3 represent those laboratories the CDC was able to verify as voluntarily enrolled in PT for those types of microbiology tests not currently included in subpart I. The number of laboratories affected by this change as well as the cost can be estimated by adding the M1 (that is, laboratories already participating in required microbiology PT) and M2 (that is, laboratories not participating in a PT program for proposed microbiology PT) number in Table 2 and Table 3. For the 7,160 affected microbiology laboratories, the estimated cost of the proposed quantifiable changes to required PT for each microbiology subspecialty follows.

To estimate the costs that would be incurred by laboratories to purchase PT materials for the proposed changes to the microbiology specialty, if finalized, we compiled a range of PT material cost estimates per each challenge using 2017 catalog pricing for each PT program. For this analysis we refer to the PT catalog offerings as ''modules''. In microbiology, PT programs offer different types of modules. Independent modules such as stain(s), antigen detection, or toxin detection are intended for reporting a result for a single type of test. Many microbiology modules include challenges that address different types of testing. These modules, such as urine culture, may include individual PT challenges for Gram stain, bacterial identification, and antimicrobial susceptibility testing. In many cases, estimating the challenge cost was difficult because PT programs' pricing varies and in some cases the PT challenge cost per microbiology test depends upon whether the test is offered as an individual module or as part of a collection of multiple types of PT challenges in a module. In addition, to accurately estimate the challenge cost, we had to account for differences in the frequency at which the PT programs currently offer their modules and challenges. For example, one PT program may offer an antigen detection module at a frequency of two events per year, and three samples per event (six total samples per year); while another offers a similar module at three events per year, and five samples per event (15 total samples per year). Based upon the module type and frequency, we estimated the total low and high challenge cost for PT material using the range of 2017 catalog prices from the seven CLIA-approved PT programs. Details are explained under each subsection. We acknowledge that these estimated ranges may be higher than the actual costs of requiring additional PT since laboratories may already voluntarily purchase PT to meet the biannual CLIA requirement for verifying the accuracy of testing.

In estimating the number of microbiology laboratories that would be impacted by each of the proposed changes, we determined the numbers of Certificate of Compliance (CoC) and Certificate of Accreditation (CoA) laboratories for each microbiology subspecialty using the CMS Online Survey Certification & Reporting System (OSCAR)/Quality Improvement and Evaluation System (QIES) database. To categorize the laboratories as described below, the OSCAR/QIES database was used to determine the accreditation organization for each CoA laboratory.

For the analysis of the impact on laboratories by the proposed microbiology PT changes, we used two laboratory categories:

- Laboratories participating in a PT program for already required microbiology PT (Category M1).
- Laboratories not participating in a PT program for proposed microbiology PT (Category M2).

Category M1: Laboratories Already Participating in Required Microbiology PT

For proposed changes or additions to required microbiology PT, we used data from the PT program event summaries provided to CDC by the PT programs to estimate the total number of laboratories performing the already required PT. We then used that number to estimate how many laboratories would be affected by proposed changes or additions to the required PT.

Category M2: Laboratories not Participating in a PT Program for Proposed Microbiology PT

As stated, we used Certificate of Accreditation data to facilitate the estimation of the number of laboratories that would be subject to proposed microbiology PT and are not already participating in a PT program. Of the seven CLIA-approved accreditation organizations, data were provided by COLA showing how many of the 7,414 COLA-accredited laboratories offer testing for four of the new microbiology tests we are proposing to add to the list for required PT. We used these data to estimate the percentage of COLA-accredited laboratories that provide testing for these microbiology tests. We assumed that COLA-accredited laboratories are similar to CoC laboratories and laboratories accredited by accreditation organizations other than the College of American Pathologists (CAP). Therefore, we assumed that the percentage of COLA-accredited laboratories that perform a specific microbiology test could be used to approximate the total number of laboratories that perform the test using the OSCAR/QIES data. For the proposed microbiology PT changes, the number of CAP-accredited laboratories was considered negligible because they are already required to purchase PT for all testing performed and were not included in the total. We analyzed each proposed change for the microbiology specialty for each category and added our estimates to obtain the total projected impact to all affected laboratories.

(1) Effects of the Proposed PT Changes in the Bacteriology Subspecialty

In the bacteriology subspecialty, the proposed changes that may have a cost impact include the determination of bacterial morphology as part of the Gram stain module, the addition of bacterial toxin detection as required PT, and the addition of a second antimicrobial susceptibility or resistance testing challenge per year.

Gram stain reaction is currently required in the PT regulations and all PT programs that offer a Gram stain PT module also offer the determination of bacterial morphology as part of the same module. We know the numbers of total laboratories enrolled in the PT program modules that require Gram stain reporting from the PT program event summaries. To determine the number of laboratories that would be impacted by this proposed change, if finalized, we calculated the number enrolled in Gram stain PT who do not report the bacterial morphology PT portion of the Gram stain module. Since this change would require that laboratories already performing PT report bacterial morphology in addition to Gram stain reaction on each challenge, we estimate the cost impact would be minimal. Since laboratories are already participating in Gram stain PT and we know the numbers of laboratories not currently participating in the determination of bacterial morphology, the range of estimated costs was determined by using the number of category M1 laboratories that perform Gram stain; the estimate of the cost the laboratory incurs when testing each challenge, using the average national CMS reimbursement rate for Part B Medicare; the low price and high price per challenge for PT (based on PT program catalog variations); and the number of challenges required per year using one challenge for the low estimate and 15 challenges for the high estimate (Tables 2 and 3).

To evaluate the impact of requiring PT for bacterial toxin detection, we determined the total number of category M2 laboratories for bacteriology. Laboratories performing voluntary PT for bacterial toxin detection are already meeting the proposed PT requirements. Since CAP-accredited laboratories are already required to perform PT if they perform bacterial toxin detection, we assumed they are already meeting the proposed PT requirements and did not include them in our estimate. The range of estimated costs was determined by using the number of category M2 impacted laboratories that perform bacterial toxin detection; the estimate of the cost the laboratory incurs when testing each challenge, using the average national CMS reimbursement rate for Part B Medicare; the low price and high price per challenge for PT (based on PT program catalog variations); and the number of challenges required per year using one challenge for the low estimate and 15 challenges for the high estimate (Tables 2 and 3).

Currently, one sample or challenge per testing event is required for antimicrobial susceptibility testing in bacteriology. To evaluate the proposed impact of increasing the required antimicrobial susceptibility or resistance testing from currently required one challenge per year to a proposed two challenges per year, we calculated the total number of category M1 laboratories already participating in PT for antimicrobial susceptibility testing. The range of estimated costs was determined by using the number of category M1 laboratories that currently perform antimicrobial susceptibility testing; the estimate of the cost the laboratory incurs when testing each challenge, using the average national CMS reimbursement rate for Part B Medicare; the low price and high price per challenge for PT (based on PT program catalog variations); and the number of challenges required per year using one challenge for the low estimate (Tables 2 and 3). Considering all of the potential cost impacts, the range of estimated impact for the proposed bacteriology subspecialty changes for the first year would be $101,785 to $2,599,552.

(2) Effects of the Proposed PT Changes in the Mycobacteriology Subspecialty

In the mycobacteriology subspecialty, the proposed changes that may have a cost impact include the addition of a second antimycobacterial susceptibility or resistance testing challenge per year. The same type of analysis that was performed to evaluate the proposed impact of increasing the required bacterial antimicrobial susceptibility or resistance testing from one challenge to two challenges per year was performed to evaluate the proposed impact of increasing the required antimycobacterial susceptibility or resistance testing from one challenge to two challenges per year (Tables 2 and 3). The range of estimated impact for the proposed mycobacteriology subspecialty changes for the first year would be $12,558 to $39,420.

(3) Effects of the Proposed PT Changes in the Mycology Subspecialty

In the mycology subspecialty, the proposed changes that may have a cost impact include the addition of required PT for direct fungal antigen detection, detection of growth or no growth in culture media, and the addition of two antifungal susceptibility or resistance testing challenges per year. To evaluate the impact of the proposed regulated PT for direct fungal antigen detection, we determined the total number of category M2 laboratories for mycology. Laboratories performing voluntary PT for direct fungal antigen detection are already meeting the proposed PT requirements. Since CAP-accredited laboratories are already required to perform PT if they perform direct fungal antigen detection, we assumed they are already meeting the proposed PT requirements and did not include them in our estimate. The range of estimated costs was determined by using the number of category M2 impacted laboratories that perform direct fungal antigen detection; the estimate of the cost the laboratory incurs when testing each challenge, using the average national CMS reimbursement rate for Part B Medicare; the low price and high price per challenge for PT (based on PT program catalog variations); and the number of challenges required per year using one challenge for the low estimate and 15 challenges for the high estimate (Tables 2 and 3).

The proposal to add detection of growth or no growth in culture media to the mycology PT identification would impact laboratories that are currently performing dermatophyte identification using dermatophyte test medium to determine the presence or absence of dermatophytes in a patient specimen. We calculated the impact of this proposal using the same methodology as was performed to determine the impact of the proposal to include direct fungal antigen detection (Tables 2 and 3).

Because COLA did not indicate that any of their accredited laboratories participate in antifungal susceptibility or resistance testing, we assumed that no CoC or CoA laboratories other than those accredited by CAP would be required to participate in PT for antifungal susceptibility or resistance testing. Therefore, the cost impact of the proposed change to include two antifungal susceptibility or resistance testing challenges per year was calculated using the total number of category M1 laboratories that participate in CAP PT for antifungal susceptibility testing, the only program that offers challenges, as the number of impacted laboratories. The range of estimated costs was determined by using the number of CAP category M1 impacted laboratories that perform antifungal susceptibility or resistance testing; the estimate of the cost the laboratory incurs when testing each challenge; based on the average national CMS reimbursement rate for Part B Medicare; the low price and high price per challenge for PT (based on PT program catalog variations); and the number of challenges required per year using one challenge for the low estimate (Tables 2 and 3). Considering all of the potential cost impacts, the range of estimated impact for the proposed mycology

subspecialty changes for the first year would be $41,235 to $422,406.

(4) Effects of the Proposed PT Changes in the Parasitology Subspecialty

In the parasitology subspecialty, the proposed change that may have a cost impact is the addition of required PT for direct parasite antigen detection. To evaluate the potential impact of this addition, we determined the total number of category M2 laboratories for parasitology. Laboratories performing voluntary PT for direct parasite antigen detection are already meeting the proposed PT requirements. Since CAP-accredited laboratories are already required to perform PT if they perform direct parasite antigen detection, we assumed they are already meeting the proposed PT requirements and did not include them in our estimate. The range of estimated costs was determined by using the number of category M2 impacted laboratories that perform direct parasite antigen detection; the estimate of the cost the laboratory incurs when testing each challenge, using the average national CMS reimbursement rate for Part B Medicare; the low price and high price per challenge for PT (based on PT program catalog variations); and the number of challenges required per year using one challenge for the low estimate and 15 challenges for the high estimate (Tables 2 and 3). Considering all of the potential cost impacts, the range of estimated impact for the proposed parasitology subspecialty changes for the first year would be $14,151 to $678,696.

(5) Effects of the Proposed PT Changes in the Virology Subspecialty

In the virology subspecialty, the proposed change that may have a cost impact includes the addition of two antiviral susceptibility or resistance testing challenges per year. Because COLA did not indicate that any of their accredited laboratories participate in antiviral susceptibility or resistance testing, we assumed that no CoC or CoA laboratories other than those accredited by CAP would be required to participate in PT for antiviral susceptibility or resistance testing. Therefore, the cost impact of the proposed change to include two antiviral susceptibility or resistance testing challenges per year was calculated using the total number of category M1 laboratories that participate in CAP PT for antiviral susceptibility or resistance testing, the only program that had subscribers to a PT module, as the number of impacted laboratories. The range of estimated costs was determined by using the number of CAP category M1 impacted laboratories that perform antiviral susceptibility or resistance testing; the estimate of the cost the laboratory incurs when testing each challenge, using the average national CMS reimbursement rate for Part B Medicare; the low price and high price per challenge for PT (based on PT program catalog variations); and the number of challenges required per year using one challenge for the low estimate (Tables 2 and 3). Considering all of the potential cost impacts, the range of estimated impact for the proposed virology subspecialty changes for the first year would be $216,318 to $314,145.

TABLE 2—LOW ESTIMATE FOR PROPOSED MICROBIOLOGY PT REGULATORY CHANGES

Proposed PT regulation change	Total number of affected M1 laboratories	Total number of affected M2 laboratories	Labor *	Supply/ material cost **	Total low impact for one challenge	Total low impact for microbiology regulation changes
Gram Stain including Morphology	26	0	$4.54	$4.67	$239.46	$386,047
Bacterial Toxin Detection	0	1,542	14.22	11.44	39,567.72	
Antimicrobial susceptibility and/or resistance testing	3,281	0	9.89	9.00	61,978.09	
Antimycobacterial susceptibility or resistance testing	454	0	4.33	23.33	12,557.64	
Direct fungal antigen detection	0	96	14.22	16.00	2,901.12	
Detection of growth or no growth in culture media—dermatophytes (DTM)	0	527	8.16	16.00	12,732.32	
Antifungal susceptibility or resistance testing	0	369	9.89	24.80	*** 12,800.61	
Direct parasite antigen detection	0	533	14.22	12.33	14,151.15	
Antiviral susceptibility or resistance testing	332	0	230.11	95.67	[3] 108,158.96	

* Average national CMS reimbursement rate for Part B Medicare (CMS Virtual Research Data Center: *https://www.resdac.org/cms-data/request/cms-virtual-research-data-center*).
** Low 2017 PT catalog price per challenge.
*** Total low impact is multiplied by two for the proposal to add two new susceptibility or resistance testing challenges.

TABLE 3—HIGH IMPACT FOR PROPOSED MICROBIOLOGY PT REGULATIONS

Proposed PT regulation change	Total number of affected M1 laboratories	Total number of affected M2 laboratories	Labor [1]	Supply/ material cost [2]	Total high impact/for one challenge	Total high impact/for 15 challenges	Total high impact for microbiology regulation changes
Gram Stain including Morphology	26	0	$4.54	$15.00	$508.04	$7,620.60	$4,054,219
Bacterial Toxin Detection	0	1,542	14.22	91.50	163,020.24	2,445,303.60	
Antimicrobial susceptibility and/or resistance testing	3,281	0	9.89	34.80	146,627.89	N/A	
Antimycobacterial susceptibility or resistance testing	454	0	4.33	82.50	39,420.82	N/A	
Direct fungal antigen detection	0	96	14.22	31.80	4,417.92	66,268.80	
Detection of growth or no growth in culture media—dermatophytes (DTM)	0	527	8.16	33.00	21,691.32	325,369.80	
Antifungal susceptibility or resistance testing	0	369	9.89	31.80	[3] 15,383.61	N/A	
Direct parasite antigen detection	0	533	14.22	70.67	45,246.37	678,695.55	
Antiviral susceptibility or resistance testing	332	0	230.11	243.00	[3] 157,072.52	N/A	

[1] Average national CMS reimbursement rate for Part B Medicare (CMS Virtual Research Data Center: *https://www.resdac.org/cms-data/request/cms-virtual-research-data-center*).
[2] High 2017 PT catalog price per challenge.
[3] Total low impact is multiplied by two for the proposal to add two new susceptibility or resistance testing challenges.

b. Impacts of Proposed PT Changes to the Non-Microbiology Specialties/Subspecialties

The proposed changes in specialties and subspecialties other than microbiology include adding 29 new analytes at the frequency of three events per year and five challenges per event. According to CLIA, laboratories with Certificates of Compliance and Certificates of Accreditation are required to perform PT. There are 36,777 clinical laboratories that will be affected (19,287 Certificate of Compliance and 17,490 Certificate of Accreditation laboratories). This will be a new burden for some laboratories, but many laboratories are already paying for PT of these analytes. As previously mentioned, in §§ 493.801(a)(2)(ii) and 493.1236(c)(1), for tests or procedures performed by the laboratory that are not listed in the CLIA regulations subpart I, the laboratory must verify the accuracy of that test or procedure at least twice annually. Since laboratories may voluntarily enroll in PT as one way to meet this requirement, we assume the added burden would be minimal. We have evidence from laboratories that responded to our national PT survey (Earley, Astles, and Breckenridge, 2017) that of those who were not already required by the CAP to perform PT on more than the CLIA-required analytes, 39 percent purchased PT for 1 to 5 analytes, 17 percent for 6 to 10 analytes, 10 percent for 11 to 20 analytes, and 10 percent for more than 20 analytes. We estimated the costs for proposed analytes by grouping all affected laboratories into four categories, calculating the number of laboratories in each category and calculated the costs using the analyte price and test reimbursement rate. We also propose to tighten acceptance limits of several currently-required analytes, which may have an impact on laboratories, but the cost impact is not included in our estimate. In addition, we are proposing to delete five currently-required analytes (ethosuximide, LDH isoenzymes, primidone, procainamide/NAPA, and quinidine) that are infrequently performed. As such, we do not anticipate this being a substantial cost savings since laboratories may continue to use PT voluntarily as a way of meeting the biannual accuracy verification requirement.

Three issues had to be considered to estimate the costs for PT materials for proposed analytes: PT programs may offer analytes as an individual analyte or as part of a module that combines multiple analytes; some of the proposed analytes may already be offered but at a frequency other than the CLIA-required frequency ($3 \times 5 = 15$ samples per year); and the extent to which laboratories already use PT varies—that is, laboratories accredited by the CAP are required to enroll in PT for each test they perform. For all these reasons, laboratories enrolled in different PT programs will be impacted differently. Based on this observation and our inability to make estimates at the level of individual laboratories, we accounted for each of these variations when calculating the costs incurred.

To account for the different prices each PT program charges for different analytes, either alone or in different combinations, we used a range of estimates based upon the programs' unit costs for PT currently offered. We used two approaches to estimate the cost of individual PT analytes. If the analyte was offered individually by the PT program, we used that price. However, if the analyte was not offered individually, we divided the panel price by the total number of analytes in the panel to estimate the cost per analyte, which is used as individual analyte price. For the lower cost estimate, we selected the lowest individual analyte price among all PT programs. For the higher cost estimate, we used the highest individual analyte price. In some cases, PT programs offer PT for the proposed analytes at different frequencies, that is, different numbers of events per year and different numbers of challenges per event. Therefore, to accurately estimate the future unit costs, we had to calculate the increased frequency for each analyte in order to achieve three events/year with five challenges per event.

The proposed rule will have different impacts on CoA laboratories mainly because the CAP has strict requirements for PT participation that exceed CLIA minimal requirements, while other accreditation organizations may not. Therefore, our analysis starts with CAP-accredited laboratories as CAP is not only a large accreditation organization but also the largest PT program. In estimating the number of affected laboratories resulting from the proposed PT changes, if finalized, we acknowledged that any CAP-accredited laboratory that offers patient testing for one of the CAP PT program analytes must enroll in the relevant program for that analyte. However, CAP-accredited laboratories are permitted to enroll in PT from other CAP-approved PT programs for certain analytes and only for specific programs. Laboratories not accredited by the CAP may purchase PT materials from any CMS-approved PT program, including the CAP PT program. Therefore, we have designated four categories to estimate the cost impact, if the proposed changes are finalized:

- *Category 1: Laboratories accredited by the CAP that purchase material from the CAP PT program:* The CAP provided us with the number of their accredited laboratories that are enrolled in their PT program for each proposed analyte. The cost increase was calculated on a per analyte basis by multiplying the cost per sample (PT material + CMS reimbursement amount) by the increase in frequency of samples and the number of laboratories that purchase PT from the CAP PT program.
- *Category 2: CAP-accredited laboratories that purchase PT materials from other PT programs:* For the analytes we considered adding, CAP-accredited laboratories are already required by CAP to enroll in a CAP-approved PT program. Ordinarily CAP-accredited laboratories enroll in the CAP PT program but they are permitted to enroll in PT from other CAP-approved PT programs. Using the data the CAP provided, we calculated the total number of CAP-accredited laboratories enrolled in one of the other PT programs provided through PT Program A, PT Program D, PT Program E, or PT Program G. The cost increase in this category was calculated on a per analyte basis. We were able to obtain the enrollment distribution of the CAP-accredited laboratories in each of the non-CAP PT programs. The enrollment of laboratories not accredited by the CAP in each of the non-CAP PT programs (Category 4) was also available. Because the methodology to calculate Category 2 is the same as Category 4, we combine these two categories by using the enrollment of all laboratories (CAP-accredited laboratories and laboratories not accredited by the CAP) in each of the non-CAP PT program in the calculation.
- *Category 3: Laboratories not already enrolled in a PT program:* To derive the minimum and maximum number of laboratories not already enrolled in a PT program that may provide testing for the proposed analytes, we began by estimating that there are 29,927 laboratories that perform nonwaived testing and are not accredited by the CAP in the United States. To facilitate the calculations, we presumed that laboratories not accredited by the CAP will not purchase CAP PT. From the OSCAR/QIES database, we derived the number of laboratories not accredited by the CAP that provide testing in each specialty and reasoned that this was the maximum number of laboratories not

accredited by the CAP that might provide testing for each analyte.

COLA provided us with the percentages of the approximately 7,414 COLA-accredited laboratories that perform testing for each proposed analyte. We determined that COLA-accredited laboratories are similar to CoC laboratories in terms of their annual test volumes. Therefore, we assumed that the percentage of COLA-accredited laboratories that test each proposed analyte could be used to estimate the number of CoC and CoA (other than CAP- or COLA-accredited) laboratories that test each analyte.

We used the percentage of CAP-accredited laboratories that participate in PT for each proposed analyte to estimate the maximum number of CoC and CoA (other than CAP and COLA) laboratories that test each analyte. This percentage was much higher for many of the analytes when compared to the laboratories accredited by organizations other than the CAP. Since CAP-accredited laboratories are often either hospital-based or commercial laboratories that already participate in PT for the additional analytes, approximations for high estimates may substantially overestimate the number of laboratories impacted.

Using the above information, we calculated low and high estimates for the total number of non-CAP-accredited, CoC and CoA laboratories that may provide testing for each proposed analyte.

For each proposed analyte, we calculated the number of CAP-accredited laboratories that buy from non-CAP PT programs by subtracting the CAP-accredited laboratories enrolled in CAP PT from the total number of CAP-accredited laboratories.

We derived a low estimate of the total number of laboratories not accredited by the CAP and not enrolled in one of the non-CAP PT programs for each analyte. Negative estimates were taken as ''0''. This represents our low estimate of the number of laboratories that will need to purchase PT for each analyte.

To obtain the high estimate for the number of laboratories not accredited by the CAP and not enrolled in one of the non-CAP PT programs, we took the high estimate of CoA laboratories not accredited by the CAP and CoC laboratories and subtracted the number of this subset of CoA laboratories already known to be enrolled in PT. For the high estimate of the number of laboratories not accredited by CAP and not enrolled in one of the non-CAP PT programs, we also used an additional criterion of the number of laboratories in the respective specialty from OSCAR/QIES to limit the estimate at the number of laboratories in the specialty. If this number was less than the high estimate of CoC laboratories and CoA laboratories accredited by a program other than the CAP, then the high estimate was calculated by subtracting the number of laboratories not accredited by CAP and not enrolled in one of the non-CAP PT programs from the total number of laboratories in the specialty.

The cost increase in this category was calculated on a per analyte basis. The minimum cost per sample that was the lowest across all eight non-CAP PT programs and the maximum cost per sample that was the highest across all eight non-CAP PT programs were used for these calculations. The minimum cost increase was calculated by multiplying the minimum cost per sample, including the CMS reimbursement amount, by the number of laboratories that are not purchasing PT from any PT program. The same calculation was made using the maximum cost per sample for the maximum cost increase.

• *Category 4: Laboratories not accredited by the CAP and enrolled in PT programs other than the CAP PT program:* We obtained the number of laboratories enrolled in PT programs other than the CAP PT program and subtracted the number of CAP-accredited laboratories enrolled in a non-CAP PT program per analyte for this category. The cost increase in this category was calculated on a per analyte basis. The estimated cost increases were calculated for each of the non-CAP PT programs for which information was available. The minimum increase was calculated for each of the PT programs by multiplying the cost per sample, including the CMS reimbursement amount, by the increase in frequency of samples and the number of laboratories that purchase PT from that individual program. To determine the maximum increase, the same calculation was made using the highest cost per analyte including the CMS reimbursement amount.

c. Results

We estimate that the overall impact of adding requirements for the proposed analytes in the specialties and subspecialties other than microbiology will range from $26 to $114 million for the first year (Table 4), if these proposed changed are finalized. Because of their larger number, and the fact that non-CAP accredited laboratories tend not to enroll in non-required PT as frequently as CAP-accredited laboratories do, we estimate that non-CAP accredited laboratories that are not enrolled in any PT program will have an impact between $16 and $100 million for the first year. We also estimate that laboratories that are enrolled in PT programs other than CAP will have a relatively minor impact, $5.4 million for the first year (Table 4).

TABLE 4—ESTIMATED IMPACT FOR PROPOSED NON-MICROBIOLOGY PT REGULATIONS FOR THE FIRST YEAR IN 2017 DOLLARS

Category	Low estimate	High estimate
1. Laboratories accredited by CAP that purchase material from the CAP PT program	4,516,673	4,516,673.
2. Laboratories accredited by CAP that purchase PT materials from other PT programs	Included in Category 4	Included in Category 4.
3. Laboratories not accredited by CAP that not already enrolled in other PT programs	16,248,746	100,303,499.
4. Laboratories not accredited by CAP enrolled in other PT programs (category 2 and 4 combined).	5,351,565	4,103,686.
Total increased cost	$26,116,984	$114,275,423.

For each of the four categories of affected laboratories previously described, Table 5 shows the total estimated range of annual cost for the proposed changes (including both microbiology and non-microbiology) in undiscounted 2017 dollars and discounted at 3 percent and 7 percent to translate expected costs in any given future years into present value terms. The base year is 2017 for the calculations displayed in Table 5 and we assume inflation-adjusted costs in future years to be the same as costs in the base year.

TABLE 5—TOTAL ESTIMATED ANNUAL COSTS FOR PROPOSED PT REGULATIONS

[All specialties in both microbiology and non-microbiology]

	Undiscounted (2017 $)			Discounted at 3 percent			Discounted at 7 percent		
	Primary	Low #	High &	Primary	Low	High	Primary	Low	High
2019	$72,416,336	$26,503,031	$118,329,642	$68,259,342	$24,981,649	$111,537,036	$63,251,232	$23,148,774	$103,353,692
2020	72,416,336	26,503,031	118,329,642	66,271,206	24,254,028	108,288,385	59,113,301	21,634,368	96,592,236
2021	72,416,336	26,503,031	118,329,642	64,340,977	23,547,600	105,134,354	55,246,076	20,219,035	90,273,117
2022	72,416,336	26,503,031	118,329,642	62,466,968	22,861,748	102,072,188	51,631,847	18,896,294	84,367,399
2023	72,416,336	26,503,031	118,329,642	60,647,542	22,195,871	99,099,212	48,254,062	17,660,088	78,848,037

Total low cost is the sum of Table 2 (microbiology) and Table 4 (non-microbiology).
& Total high cost is the sum of Table 3 (microbiology) and Table 4 (non-microbiology).

2. Non-Quantifiable Impacts

If the changes proposed in this rule are finalized, a number of non-quantifiable impacts will also result for PT programs and laboratories. We solicit comments and data to facilitate the determination of quantifiable estimates in the final rule.

As with any currently required PT, if finalized, the proposed regulation would not require approved PT programs to offer additional analytes. Several programs already offer the analytes or tests that would be required by laboratories, and in these cases, we expect minimal impact on the PT programs. If the proposed changes outlined in this rule are finalized, we expect there will initially be some increased expenditures for PT programs to implement the changes, even if they are only scaling up currently offered PT. At the same time, PT programs will also increase revenue received if they increase the PT analytes or tests they offer. We have no way to estimate how many programs may choose to offer additional PT analytes or tests, but we assume that most will implement the changes included in the final rule. For some programs, this would mean offering an analyte or test for the first time, while for others it would mean increasing the yearly number of events and/or challenges per event. The costs would be relatively less for the programs that are already offering the PT analytes or tests, including those currently offering challenges at less than the PT frequency required under CLIA. There are also differences in what the PT programs charge laboratories for PT which would change the impact of the final rule. In part, these differences depend upon the total number of samples distributed per year and how the PT is packaged; some PT is sold as modules that group several related analytes together. Because CLIA-approved PT programs are required to maintain non-profit status, any increased revenue that results from an expanded PT menu will not be turned into profit. We have attempted to account for the quantifiable impacts in our estimates for laboratories.

If the proposed analyte deletions are finalized, some PT programs may cease offering the deleted analytes, others may continue to offer them at a frequency less than that required under CLIA, and still others may continue to offer them at the PT frequency required under CLIA. For these reasons, we are unable to estimate the cost impact to PT programs for this change. We solicit comments and data that would help us estimate the impact of the PT changes on PT programs in the final rule.

Although we cannot precisely predict how the proposed changes may affect clinical laboratories, we do not expect there to be major changes in how they function. We have quantified the costs we expect laboratories to incur but there may be costs associated with other administrative functions related to PT ordering, result reporting, and record keeping that we are not able to estimate. For those laboratories that currently purchase PT for the five analytes we propose to delete, we cannot estimate the lowered expenditure for laboratories that stop buying PT materials and must begin doing something else to verify accuracy. Based upon our focus groups and surveys, we know there are a variety of things laboratories may do to externally verify accuracy, ranging from splitting samples with other laboratories to purchasing PT materials voluntarily. Also, we do not know the extent to which split samples are tested, or how many patient samples might be tested in this way; there is no stated minimum number of specimens that must be tested semi-annually to verify accuracy. Therefore, we have not attempted to estimate the costs for alternative approaches that may be adopted to verify accuracy for the deleted analytes. Regardless of how laboratories might be impacted, we expect that they will not spend more than they currently spend on PT for the analytes we propose to delete, but we cannot estimate this. By not attempting to estimate the number of laboratories that may stop buying PT material for the deleted analytes, we may be slightly overestimating the net impact.

3. Benefits

While we cannot quantify the benefits that the proposed changes will bring, if finalized, we believe that the changes will facilitate more rapid identification of unacceptable practices in laboratories, especially for those laboratories that have not previously participated in PT. There are very few published reports that have investigated the impact of PT performance on testing accuracy or patient outcomes. In part this is because performing PT is now a standard practice for most analytes we are considering to add, so it is not possible to separate cohorts of PT users from non-users.[26 27 28 29] In addition, remediation after identification of problems should also occur more quickly and clinical test results of marginal or inferior quality are less likely to be used as analytical systems will improve. All of these things will serve to minimize the potential adverse impact to patients and benefiting physicians and healthcare providers that could occur with inaccurate testing.

PT performance partially reflects daily clinical laboratory performance (Stull, Hearn, Hancock, Handsfield, and Collins, 1998). Updating acceptance limits will benefit laboratories by helping to ensure the accuracy and reliability of testing and providing a mechanism for laboratories to be held accountable for clinically appropriate patient test results, which directly affects the public's health (Astles, Tholen, and Mitchell, 2016). Both

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[27] Parsons PJ Reilly AA Esernio-Jenssen D et al. Evaluation of blood lead proficiency testing: comparison of open and blind paradigms. Clin Chem. 2001;47:322–330.

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clinical laboratories and patients can benefit from continued monitoring of PT to help assess the success of intervention efforts to improve the overall quality of clinical laboratory testing.[30]

Another benefit that may result from adding new PT analytes and tests and updating the limits for acceptable PT performance under CLIA includes the generation of additional information on test performance and sources of errors that PT programs can share with laboratories (Howerton, Krolak, Manasterski, and Handsfield, 2010). Such information can also be used as a source of training and can help to maintain the competency of testing personnel (Garcia, et al., 2014).

Last, while we do not anticipate that the changes being proposed in this rule would incur any costs on the IVD industry, we expect the IVD industry to potentially benefit by the changes made in this proposed rule when finalized. Having the ability to track PT results for the added analytes will enable better and faster detection of problems with product manufacturing, including reagent problems. We are aware that some IVD manufacturers enroll in PT and are able to track the performance of the peer groups using their instruments in summary reports issued by the PT programs.

Ultimately, we believe that laboratories, healthcare providers, patients, and the IVD industry will benefit from improved analytical performance (Howerton, Krolak, Manasterski, and Handsfield, 2010) that is expected to occur when this rule becomes finalized.

D. Alternatives Considered

In proposing these changes, several alternatives were considered. We considered the possibility of changing either the required frequency of PT events per year or changing the number of required PT challenges per event. Responses from our national survey did not support changing either parameter, nor did CLIAC recommend any changes to the required PT frequency or number of challenges per event. We did not perceive a benefit from either reducing or increasing the number of events per year. Reducing the number of events to two per year and keeping all other factors the same would cost less compared to the proposed rule, but it would delay the potential time it takes to identify a poor performing laboratory as ''unsuccessful'' to at least 12 months, instead of the current 8 months. Increasing the number of events might help to identify a laboratory with testing issues slightly earlier, but increasing the number of events would increase costs. We are proposing to continue to require five challenges per event, with a passing score generally defined as a minimum of four challenges falling within the criteria for acceptable performance. A minimum of five challenges per event are necessary to follow the approach taken in the final regulation implementing CLIA '88 which states that a minimum event score should be 80 percent to be successful allowing for one missed result per event.

For the microbiology specialty, we considered the possibility of including required PT analytes in each subspecialty at a frequency of three events per year with five challenges per event. We determined that the increase in required PT would result in an additional impact of over $5.3 million to laboratories that would be required to perform susceptibility or resistance testing for 15 challenges per year. For the non-microbiology specialties and subspecialties, we could have opted not to add any new PT analytes, but testing of the analytes we are proposing to add is widespread and is important in clinical decision making and public health testing. We also considered adding all analytes for which there was at least one existing PT program, but we believed this alternative would have been excessively burdensome as it would mean adding hundreds of new required analytes which may not be necessary to identify problematic laboratory performance. We could have left the acceptance limits as they were established in CLIA '88, but we believe those are outdated given advancements in technology. We considered retaining the definition of peer group established in CLIA '88, but we decided this would be too expensive and ultimately unworkable because it would require PT programs to perform commutability testing using analyzers from multiple peer groups every time a new batch of PT materials was created. We are requesting public comments related to alternative changes to be considered to assist us in finalizing this rule.

E. Accounting Statement and Table

We have prepared the following accounting statement showing the classification of expenditures associated with the provisions of this proposed rule.

TABLE 6—ACCOUNTING TABLE

Category	Primary estimate	Minimum estimate	Maximum estimate	Units			Source citation
				Year dollars	Discount rate %	Period covered	
Benefits							
Qualitative	• More effective detection of laboratories that provide inaccurate laboratory test results. • Increased confidence in laboratory test results.						Preamble and Impact Analysis.
Costs							
Annualized Monetized $/year	$72,416,336 70,307,122 67,678,819	$26,503,031 25,731,098 24,769,188	$118,329,642 114,883,148 110,588,450	2017 2017 2017	0 3 7	2019–2028 2019–2028 2019–2028	Impact Analysis.

[30] Bainbridge, J., C.L. Wilkening, W. Rountree, R. Louzao, J. Wong, N. Perza, A. Garcia, T.N. Denny The Immunology Quality Assessment Proficiency Testing Program for CD3+4+ and CD3+8+ Lymphocyte Subsets: A ten year review via longitudinal mixed effects modeling. NIH Public Access Author Manuscript (July 2014).

F. Regulatory Reform Analysis Under E.O. 13771

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017 and requires that the costs associated with significant new regulations ''shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.'' This proposed rule, if finalized, is considered an E.O. 13771 regulatory action. We estimate that this rule would generate $58.0 million in annualized costs in 2016 dollars, discounted at 7 percent relative to year 2016 over a perpetual time horizon. Details on the estimated costs of this rule can be found in the preceding analyses.

G. Conclusion

We estimate that the cost to laboratories to participate in PT for the analytes and tests proposed in this rule would cost between $26,503,031 and $118,329,642 in 2017 dollars. Although the effect of the changes proposed will increase laboratory costs, implementation of these changes in a final rule will increase the confidence of laboratory professionals and the end-users of test results, including physicians and other healthcare providers, patients, and the public, in the reliability and accuracy of test results.

We have determined that this rule would not have a significant economic impact on a substantial number of small entities or a significant impact in the operations of a substantial number of small rural hospitals and for these reasons, we are not preparing analyses for either the RFA or section 1102(b) of the Act.

In accordance with the provisions of Executive Order 12866, this proposed regulation was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 493

Administrative practice and procedure, Grant programs—health, Health facilities, Laboratories, Medicaid, Medicare, Penalties, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR part 493 as set forth below:

PART 493—LABORATORY REQUIRMENTS

■ 1. The authority citation for part 493 is revised to read as follows:

Authority: 42 U.S.C. 263a, 1302, 1395x(e), the sentence following 1395x(s)(11) through 1395x(s)(16).

■ 2. Section 493.2 is amended by—
■ a. Adding the definitions of ''Acceptance limit'' and ''Peer group'' in alphabetical order;
■ b. Revising the definition of ''Target value''; and
■ c. Adding the definition of ''Unacceptable score'' in alphabetical order.

The additions and revision read as follows:

§ 493.2 Definitions.

* * * * *

Acceptance limit is the symmetrical tolerance (plus and minus) around the target value.

* * * * *

Peer group is a group of laboratories whose testing process utilizes similar instruments, methodologies, and/or reagent systems and is not to be assigned using the reagent lot number level.

* * * * *

Target value for quantitative tests is:

(1) If the peer group consists of 10 participants or greater:

(i) The mean of all participant responses after removal of outliers (that is, those responses greater than three standard deviations from the original mean, as applicable); or

(ii) The mean established by a definitive method or reference methods; or

(iii) The mean of a peer group, in instances when a definitive method or reference methods are not available; or

(iv) If the peer group consists of fewer than 10 participants, ''target value'' means the overall mean after outlier removal (as defined in paragraph (1) of this definition) unless acceptable scientific reasons are available to indicate that such an evaluation is not appropriate.

(2) [Reserved]

* * * * *

Unacceptable score is a PT result that is outside of the criteria for acceptable performance for a single challenge or sample.

* * * * *

■ 3. Section 493.20 is amended by revising paragraph (c) to read as follows:

§ 493.20 Laboratories performing tests of moderate complexity.

* * * * *

(c) If the laboratory also performs waived tests, compliance with § 493.801(a) and (b)(7) and subparts J, K, and M of this part is not applicable to the waived tests. However, the laboratory must comply with the requirements in § 493.15(e), §§ 493.801(b)(1) through (6), 493.1771, 493.1773, and 493.1775.

■ 4. Section 493.25 is amended by revising paragraph (d) to read as follows:

§ 493.25 Laboratories performing tests of high complexity.

* * * * *

(d) If the laboratory also performs waived tests, compliance with §§ 493.801(a) and 493.801(b)(7) and subparts J, K, and M of this part are not applicable to the waived tests. However, the laboratory must comply with the requirements in §§ 493.15(e), 493.801(b)(1) through (6), 493.1771, 493.1773, and 493.1775.

■ 5. Section 493.801 is amended by—
■ a. Redesignating paragraphs (b)(3) through (6) as paragraphs (b)(4) through (7), respectively; and
■ b. Adding new paragraph (b)(3).

The addition reads as follows:

§ 493.801 Condition: Enrollment and testing of samples.

* * * * *

(b) * * *

(3) The laboratory must report PT results for microbiology organism identification to the highest level that it reports results on patient specimens.

* * * * *

■ 6. Section 493.861 is amended by revising paragraph (a) to read as follows:

§ 493.861 Standard; Unexpected antibody detection.

(a) Failure to attain an overall testing event score of at least 100 percent is unsatisfactory performance.

* * * * *

■ 7. Section 493.901 is amended by—
■ a. Redesignating paragraphs (a), (b), (c), and (d) as paragraphs (b), (c), (d), and (e), respectively;
■ b. Adding new paragraph (a);
■ c. Redesignating newly redesignated paragraphs (c)(6) and (7) as paragraphs (c)(7) and (8), respectively;
■ d. Adding new paragraph (c)(6);
■ e. Revising newly redesignated paragraph (c)(8);
■ f. Adding paragraph (c)(9);
■ g. Revising newly redesignated paragraph (e); and
■ h. Adding paragraph (f).

The additions and revisions read as follows:

§ 493.901 Approval of proficiency testing programs.

* * * * *

(a) Require a minimum of ten laboratory participants before offering a proficiency testing analyte;

* * * * *

(c) * * *

(6) For those results submitted electronically, a mechanism to track changes to any result reported to the proficiency testing program and the reason for the change;

* * * * *

(8) A process to resolve technical, administrative, and scientific problems about program operations; and

(9) A contractor performing administrative responsibilities as described in this section and § 493.903 must be a private nonprofit organization or a Federal or State agency, or an entity acting as a designated agent for the Federal or State agency.

* * * * *

(e) HHS may require on-site visits for all initial proficiency testing program applications for CMS approval and periodically or when problems are encountered for previously HHS-approved proficiency testing programs either during the reapproval process or as necessary to review and verify the policies and procedures represented in its application and other information, including, but not limited to, review and examination of documents and interviews of staff.

(f) HHS may require a proficiency testing program to reapply for approval using the process for initial applications if significant problems are encountered during the reapproval process.

■ 8. Section 493.903 is amended—

■ a. In paragraph (a)(1) by removing the period and adding ''; ''

■ b. In paragraph (a)(2) by removing ''; '' and adding in its place ''; and''; and

■ c. By adding paragraph (a)(3).

The addition reads as follows:

§ 493.903 Administrative responsibilities.

* * * * *

(a) * * *

(3) Not change submitted laboratory data and results for any proficiency testing event;

* * * * *

■ 9. Section 493.905 is revised to read as follows:

§ 493.905 Nonapproved proficiency testing programs.

(a) If a proficiency testing program is determined by HHS to fail to meet any criteria contained in §§ 493.901 through 493.959 for approval of the proficiency testing program, CMS will notify the program and the program must notify all laboratories enrolled of the nonapproval and the reasons for nonapproval within 30 days of the notification. CMS may disapprove any proficiency testing program that provides false or misleading information with respect to any information that is necessary to meet any criteria contained in §§ 493.901 through 493.959 for approval of the proficiency testing program.

(b) *Request for reconsideration.* Any PT program that is dissatisfied with a determination to disapprove the program, as applicable, may request that CMS reconsider the determination, in accordance with subpart D of part 488 of this chapter.

■ 10. Section 493.911 is revised to read as follows:

§ 493.911 Bacteriology.

(a) *Program content and frequency of challenge.* To be approved for proficiency testing for bacteriology, the annual program must provide a minimum of five samples per testing event. There must be at least three testing events provided to the laboratory at approximately equal intervals per year. The samples may be provided to the laboratory through mailed shipments. The specific organisms included in the samples may vary from year to year.

(1) The annual program must include, as applicable, samples for:

(i) Gram stain including bacterial morphology;

(ii) Direct bacterial antigen detection;

(iii) Bacterial toxin detection; and,

(iv) Detection and identification of bacteria which includes one of the following:

(A) Detection of growth or no growth in culture media;

(B) Identification of bacteria; and

(v) Antimicrobial susceptibility or resistance testing.

(2) An approved program must furnish HHS and its agents with a description of samples that it plans to include in its annual program no later than 6 months before each calendar year. The program must include bacteria commonly occurring in patient specimens and other important emerging pathogens. The program determines the reportable isolates and correct responses for antimicrobial susceptibility or resistance for any designated isolate. At least 25 percent of the samples must be mixtures of the principal organism and appropriate normal flora. Mixed cultures are samples that require reporting of one or more principal pathogens. Mixed cultures are not ''negative'' samples such as when two commensal organisms are provided in a PT sample with the intended response of ''negative'' or ''no pathogen present.'' The program must include the following two types of samples to meet the 25 percent mixed culture criterion:

(i) Samples that require laboratories to report only organisms that the testing laboratory considers to be a principal pathogen that is clearly responsible for a described illness (excluding immuno-compromised patients). The program determines the reportable isolates, including antimicrobial susceptibility or resistance for any designated isolate; and

(ii) Samples that require laboratories to report all organisms present. Samples must contain multiple organisms frequently found in specimens where multiple isolates are clearly significant or where specimens are derived from immuno-compromised patients. The program determines the reportable isolates.

(3) The content of an approved program must vary over time, as appropriate. The types of bacteria included annually must be representative of the following major groups of medically important aerobic and anaerobic bacteria, if appropriate for the sample sources:

(i) Gram-negative bacilli.

(ii) Gram-positive bacilli.

(iii) Gram-negative cocci.

(iv) Gram-positive cocci.

(4) For antimicrobial susceptibility or resistance testing, the program must provide at least two samples per testing event that include one Gram-positive and one Gram-negative organism that have a predetermined pattern of susceptibility or resistance to the common antimicrobial agents.

(b) *Evaluation of a laboratory's performance.* HHS approves only those programs that assess the accuracy of a laboratory's responses in accordance with paragraphs (b)(1) through (9) of this section.

(1) The program determines the reportable bacterial staining and morphological characteristics to be interpreted by Gram stain. The program determines the bacteria to be reported by direct bacterial antigen detection, bacterial toxin detection, detection of growth or no growth in culture media, identification of bacteria, and antimicrobial susceptibility or resistance testing. To determine the accuracy of each of the laboratory's responses, the program must compare each response with the response which reflects agreement of either 80 percent or more of ten or more referee laboratories or 80 percent or more of all participating laboratories. Both methods must be attempted before the program can choose to not grade a PT sample.

(2) A laboratory must identify the organisms to highest level that it performs these procedures on patient specimens.

(3) A laboratory's performance will be evaluated on the basis of the average of

its scores for paragraph (b)(4) through (8) of this section as determined in paragraph (b)(9) of this section.

(4) The performance criteria for Gram stain including bacterial morphology is staining reaction, that is, Gram positive or Gram negative and morphological description for each sample. The score is the number of correct responses for Gram stain reaction plus the number of correct responses for morphological description divided by 2 then divided by the number of samples to be tested, multiplied by 100.

(5) The performance criterion for direct bacterial antigen detection is the presence or absence of the bacterial antigen. The score is the number of correct responses divided by the number of samples to be tested, multiplied by 100.

(6) The performance criterion for bacterial toxin detection is the presence or absence of the bacterial toxin. The score is the number of correct responses divided by the number of samples to be tested multiplied by 100.

(7) The performance criterion for the detection and identification of bacteria includes one of the following:

(i) The performance criterion for the detection of growth or no growth in culture media is the presence or absence of bacteria or growth. The score is the number of correct responses divided by the number of samples to be tested multiplied by 100.

(ii) The performance criterion for the identification of bacteria is the total number of correct responses for bacterial identification submitted by the laboratory divided by the number of organisms present plus the number of incorrect organisms reported by the laboratory multiplied by 100 to establish a score for each sample in each testing event. Since laboratories may incorrectly report the presence of organisms in addition to the correctly identified principal organism(s), the scoring system must provide a means of deducting credit for additional erroneous organisms that are reported. For example, if a sample contained one principal organism and the laboratory reported it correctly but reported the presence of an additional organism, which was not considered reportable, the sample grade would be $1/(1 + 1) \times 100 = 50$ percent.

(8) For antimicrobial susceptibility or resistance testing, a laboratory must indicate which drugs are routinely included in its test panel when testing patient samples. A laboratory's performance will be evaluated for only those antimicrobials for which susceptibility or resistance testing is routinely performed on patient specimens. A correct response for each antimicrobial will be determined as described in paragraph (b)(1) of this section. Scoring for each sample is based on the number of correct susceptibility or resistance responses reported by the laboratory divided by the actual number of correct susceptibility or resistance responses determined by the program, multiplied by 100. For example, if a laboratory offers susceptibility or resistance testing using three antimicrobial agents, and the laboratory reports correct responses for two of the three antimicrobial agents, the laboratory's grade would be $2/3 \times 100 = 67$ percent.

(9) The score for a testing event in bacteriology is the average of the scores determined under paragraphs (b)(4) through (8) of this section based on the type of service offered by the laboratory.

■ 11. Section 493.913 is revised to read as follows:

§ 493.913 Mycobacteriology.

(a) *Program content and frequency of challenge.* To be approved for proficiency testing for mycobacteriology, the annual program must provide a minimum of five samples per testing event. There must be at least two testing events provided to the laboratory at approximately equal intervals per year. The samples may be provided through mailed shipments. The specific organisms included in the samples may vary from year to year.

(1) The annual program must include, as applicable, samples for:

(i) Acid-fast stain;

(ii) Detection and identification of mycobacteria which includes one of the following:

(A) Detection of growth or no growth in culture media; or

(B) Identification of mycobacteria; and

(iii) Antimycobacterial susceptibility or resistance testing.

(2) An approved program must furnish HHS and its agents with a description of the samples it plans to include in its annual program no later than 6 months before each calendar year. At least 25 percent of the samples must be mixtures of the principal mycobacteria and appropriate normal flora. The program must include mycobacteria commonly occurring in patient specimens and other important emerging mycobacteria. The program determines the reportable isolates and correct responses for antimycobacterial susceptibility or resistance for any designated isolate.

(3) The content of an approved program may vary over time, as appropriate. The mycobacteria included annually must contain species representative of the following major groups of medically important mycobacteria, if appropriate for the sample sources:

(i) *Mycobacterium tuberculosis* complex; and

(ii) *Mycobacterium* other than tuberculosis (MOTT).

(4) The program must provide at least five samples per testing event that include challenges that are acid-fast and challenges which do not contain acid-fast organisms.

(5) For antimycobacterial susceptibility or resistance testing, the program must provide at least two samples per testing event that have a predetermined pattern of susceptibility or resistance to the common antimycobacterial agents.

(b) *Evaluation of a laboratory's performance.* HHS approves only those programs that assess the accuracy of a laboratory's response in accordance with paragraphs (b)(1) through (7) of this section.

(1) The program determines the reportable mycobacteria to be detected by acid-fast stain. The program determines the mycobacteria to be reported by detection of growth or no growth in culture media, identification of mycobacteria, and for antimycobacterial susceptibility or resistance testing. To determine the accuracy of each of the laboratory's responses, the program must compare each response with the response that reflects agreement of either 80 percent or more of ten or more referee laboratories or 80 percent or more of all participating laboratories. Both methods must be attempted before the program can choose to not grade a PT sample.

(2) A laboratory must detect and identify the organism to the highest level that it performs these procedures on patient specimens.

(3) A laboratory's performance will be evaluated on the basis of the average of its scores for paragraph (b)(4) through (6) of this section as determined in paragraph (b)(7) of this section.

(4) The performance criterion for acid-fast stains is positive or negative or the presence or absence of acid-fast organisms. The score is the number of correct responses divided by the number of samples to be tested, multiplied by 100.

(5) The performance criterion for the detection and identification of mycobacteria includes one of the following:

(i) The performance criterion for the detection of growth or no growth in culture media is the presence or absence of bacteria or growth. The score is the number of correct responses divided by

the number of samples to be tested multiplied by 100.

(ii) The performance criterion for the identification of mycobacteria is the total number of correct responses for mycobacterial identification submitted by the laboratory divided by the number of organisms present plus the number of incorrect organisms reported by the laboratory multiplied by 100 to establish a score for each sample in each testing event. Since laboratories may incorrectly report the presence of mycobacteria in addition to the correctly identified principal organism(s), the scoring system must provide a means of deducting credit for additional erroneous organisms reported. For example, if a sample contained one principal organism and the laboratory reported it correctly but reported the presence of an additional organism, which was not considered reportable, the sample grade would be $1/(1 + 1) \times 100 = 50$ percent.

(6) For antimycobacterial susceptibility or resistance testing, a laboratory must indicate which drugs are routinely included in its test panel when testing patient samples. A laboratory's performance will be evaluated for only those antimycobacterial agents for which susceptibility or resistance testing is routinely performed patient specimens. A correct response for each antimycobacterial agent will be determined as described in paragraph (b)(1) of this section. Scoring for each sample is based on the number of correct susceptibility or resistance responses reported by the laboratory divided by the actual number of correct susceptibility or resistance responses as determined by the program, multiplied by 100. For example, if a laboratory offers susceptibility or resistance testing using three antimycobacterial agents and the laboratory reports correct responses for two of the three antimycobacterial agents, the laboratory's grade would be $2/3 \times 100 = 67$ percent.

(7) The score for a testing event in mycobacteriology is the average of the scores determined under paragraphs (b)(4) through (6) of this section based on the type of service offered by the laboratory.

■ 12. Section 493.915 is revised to read as follows:

§ 493.915 Mycology.

(a) *Program content and frequency of challenge.* To be approved for proficiency testing for mycology, the annual program must provide a minimum of five samples per testing event. There must be at least three testing events provided to the laboratory at approximately equal intervals per year. The samples may be provided through mailed shipments. The specific organisms included in the samples may vary from year to year.

(1) The annual program must include, as applicable, samples for:

(i) Direct fungal antigen detection;

(ii) Detection and identification of fungi and aerobic actinomycetes which includes one of the following:

(A) Detection of growth or no growth in culture media; or

(B) Identification of fungi and aerobic actinomycetes; and

(iii) Antifungal susceptibility or resistance testing.

(2) An approved program must furnish HHS and its agents with a description of the samples it plans to include in its annual program no later than 6 months before each calendar year. At least 25 percent of the samples must be mixtures of the principal organism and appropriate normal background flora. The program must include fungi and aerobic actinomycetes commonly occurring in patient specimens and other important emerging fungi. The program determines the reportable isolates and correct responses for antifungal susceptibility or resistance for any designated isolate.

(3) The content of an approved program must vary over time, as appropriate. The fungi included annually must contain species representative of the following major groups of medically important fungi and aerobic actinomycetes, if appropriate for the sample sources:

(i) Yeast or yeast-like organisms;

(ii) Molds that include;

(A) Dematiaceous fungi;

(B) Dermatophytes;

(C) Dimorphic fungi;

(D) Hyaline hyphomycetes;

(E) Mucormycetes; and

(iii) Aerobic actinomycetes.

(4) For antifungal susceptibility or resistance testing, the program must provide at least two challenges per testing event that include fungi that have a predetermined pattern of susceptibility or resistance to the common antifungal agents.

(b) *Evaluation of a laboratory's performance.* HHS approves only those programs that assess the accuracy of a laboratory's response, in accordance with paragraphs (b)(1) through (8) of this section.

(1) The program determines the reportable fungi to be reported by direct fungal antigen detection, detection of growth or no growth in culture media, identification of fungi and aerobic actinomycetes, and antifungal susceptibility or resistance testing. To determine the accuracy of a laboratory's responses, the program must compare each response with the response reflects agreement of either 80 percent or more of ten or more referee laboratories or 80 percent or more of all participating laboratories. Both methods must be attempted before the program can choose to not grade a PT sample.

(2) A laboratory must detect and identify the organisms to highest level that it performs these procedures on patient specimens.

(3) A laboratory's performance will be evaluated on the basis of the average of its scores for paragraphs (b)(4) through (6) of this section as determined in paragraph (b)(7) of this section.

(4) The performance criterion for direct fungal antigen detection is the presence or absence of the fungal antigen. The score is the number of correct responses divided by the number of samples to be tested, multiplied by 100.

(5) The performance criterion for the detection and identification of fungi and aerobic actinomycetes includes one of the following:

(i) The performance criterion for the detection of growth or no growth in culture media is the presence or absence of fungi or growth. The score is the number of correct responses divided by the number of samples to be tested multiplied by 100.

(ii) The performance criterion for the identification of fungi and aerobic actinomycetes is the total number of correct responses for fungal and aerobic actinomycetes identification submitted by the laboratory divided by the number of organisms present plus the number of incorrect organisms reported by the laboratory multiplied by 100 to establish a score for each sample in each testing event. Since laboratories may incorrectly report the presence of fungi and aerobic actinomycetes in addition to the correctly identified principal organism(s), the scoring system must provide a means of deducting credit for additional erroneous organisms that are reported. For example, if a sample contained one principal organism and the laboratory reported it correctly but reported the presence of an additional organism, which was not considered reportable, the sample grade would be $1/(1 + 1) \times 100 = 50$ percent.

(6) For antifungal susceptibility or resistance testing, a laboratory must indicate which drugs are routinely included in its test panel when testing patient samples. A laboratory's performance will be evaluated for only those antifungal agents for which

susceptibility or resistance testing is routinely performed on patient specimens. A correct response for each antifungal agent will be determined as described in paragraph (b)(1) of this section. Scoring for each sample is based on the number of correct susceptibility or resistance responses reported by the laboratory divided by the actual number of correct susceptibility or resistance responses as determined by the program, multiplied by 100. For example, if a laboratory offers susceptibility or resistance testing using three antifungal agents and the laboratory reports correct responses for two of the three antifungal agents, the laboratory's grade would be $2/3 \times 100 = 67$ percent.

(7) The score for a testing event is the average of the sample scores as determined under paragraphs (b)(4) through (6) of this section.

■ 13. Section 493.917 is revised to read as follows:

§ 493.917 Parasitology.

(a) *Program content and frequency of challenge.* To be approved for proficiency testing in parasitology, the annual program must provide a minimum of five samples per testing event. There must be at least three testing events provided to the laboratory at approximately equal intervals per year. The samples may be provided through mailed shipments. The specific organisms included in the samples may vary from year to year.

(1) The annual program must include, as applicable, samples for:

(i) Direct parasite antigen detection; and

(ii) Detection and identification of parasites which includes one of the following:

(A) Detection of presence or absence of parasites; or

(B) Identification of parasites.

(2) An approved program must furnish HHS and its agents with a description of the samples it plans to include in its annual program no later than 6 months before each calendar year. Samples must include both formalinized specimens and PVA (polyvinyl alcohol) fixed specimens as well as blood smears, as appropriate for a particular parasite and stage of the parasite. The majority of samples must contain protozoa or helminths or a combination of parasites. Some samples must be devoid of parasites.

(3) The content of an approved program must vary over time, as appropriate. The types of parasites included annually must be representative of the following major groups of medically important parasites, if appropriate for the sample sources:

(i) Intestinal parasites; and

(ii) Blood and tissue parasites.

(4) The program must provide at least five samples per testing event that include challenges which contain parasites and challenges that are devoid of parasites.

(b) *Evaluation of a laboratory's performance.* HHS approves only those programs that assess the accuracy of a laboratory's responses in accordance with paragraphs (b)(1) through (6) of this section.

(1) The program determines the reportable parasites to be detected by direct parasite antigen detection, detection of presence or absence of parasites, and identification of parasites. It may elect to establish a minimum number of parasites to be identified in samples before they are reported. Parasites found in rare numbers by referee laboratories are not considered in a laboratory's performance; such findings are neutral. To determine the accuracy of a laboratory's response, the program must compare each response with the response which reflects agreement of either 80 percent or more of ten or more referee laboratories or 80 percent or more of all participating laboratories. Both methods must be attempted before the program can choose to not grade a PT sample.

(2) A laboratory must detect and identify or concentrate and identify the parasites to the highest level that it performs these procedures on patient specimens.

(3) A laboratory's performance will be evaluated on the basis of the average of its scores for paragraphs (b)(4) through (5) of this section as determined in paragraph (b)(6) of this section.

(4) The performance criterion for direct parasite antigen detection is the presence or absence of the parasite antigen. The score is the number of correct responses divided by the number of samples to be tested, multiplied by 100.

(5) The performance criterion for the detection and identification of parasites includes one of the following:

(i) The performance criterion for the detection of presence or absence of parasites is the presence or absence of parasites. The score is the number of correct responses divided by the number of samples to be tested, multiplied by 100.

(ii) The performance criterion for the identification of parasites is the total number of correct responses for parasite identification submitted by the laboratory divided by the number of parasites present plus the number of incorrect parasites reported by the laboratory multiplied by 100 to establish a score for each sample in each testing event. Since laboratories may incorrectly report the presence of parasites in addition to the correctly identified principal organism(s), the scoring system must provide a means of deducting credit for additional erroneous organisms that are reported and not found in rare numbers by the program's referencing process. For example, if a sample contained one principal organism and the laboratory reported it correctly but reported the presence of an additional organism, which was not considered reportable, the sample grade would be $1/(1 + 1) \times 100 = 50$ percent.

(6) The score for a testing event is the average of the sample scores as determined under paragraphs (b)(4) through (5) of this section.

■ 14. Section 493.919 is revised to read as follows:

§ 493.919 Virology.

(a) *Program content and frequency of challenge.* To be approved for proficiency testing in virology, a program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The samples may be provided to the laboratory through mailed shipments. The specific organisms included in the samples may vary from year to year.

(1) The annual program must include, as applicable, samples for:

(i) Viral antigen detection;

(ii) Detection and identification of viruses; and

(iii) Antiviral susceptibility or resistance testing.

(2) An approved program must furnish HHS and its agents with a description of the samples it plans to include in its annual program no later than 6 months before each calendar year. The program must include other important emerging viruses and viruses commonly occurring in patient specimens. The program determines the reportable isolates and correct responses for antiviral susceptibility or resistance for any designated isolate.

(3) The content of an approved program must vary over time, as appropriate. If appropriate for the sample sources, the types of viruses included annually must be representative of the following major groups of medically important viruses:

(i) Respiratory viruses;

(ii) Herpes viruses;

(iii) Enterovirus; and

(iv) Intestinal viruses.

(4) For antiviral susceptibility or resistance testing, the program must

provide at least two challenges per testing event that include viruses that have a predetermined pattern of susceptibility or resistance to the common antiviral agents.

(b) *Evaluation of laboratory's performance.* HHS approves only those programs that assess the accuracy of a laboratory's response in accordance with paragraphs (b)(1) through (7) of this section.

(1) The program determines the viruses to be reported by direct viral antigen detection, detection and identification of viruses, and antiviral susceptibility or resistance testing. To determine the accuracy of a laboratory's response, the program must compare each response with the response which reflects agreement of either 80 percent or more of ten or more referee laboratories or 80 percent or more of all participating laboratories. Both methods must be attempted before the program can choose to not grade a PT sample.

(2) A laboratory must detect and identify the viruses to the highest level that it performs these procedures on patient specimens.

(3) A laboratory's performance will be evaluated on the basis of the average of its scores for paragraphs (b)(4) through (6) of this section as determined in paragraph (b)(7) of this section.

(4) The performance criterion viral antigen detection is the presence or absence of the viral antigen. The score is the number of correct responses divided by the number of samples to be tested, multiplied by 100.

(5) The performance criterion for the detection and identification of viruses is the total number of correct responses for viral detection and identification submitted by the laboratory divided by the number of viruses present plus the number of incorrect virus reported by the laboratory multiplied by 100 to establish a score for each sample in each testing event. Since laboratories may incorrectly report the presence of viruses in addition to the correctly identified principal organism(s), the scoring system must provide a means of deducting credit for additional erroneous organisms that are reported. For example, if a sample contained one principal organism and the laboratory reported it correctly but reported the presence of an additional organism, which was not considered reportable, the sample grade would be $1/(1 + 1) \times 100 = 50$ percent.

(6) For antiviral susceptibility or resistance testing, a laboratory must indicate which drugs are routinely included in its test panel when testing patient samples. A laboratory's performance will be evaluated for only those antiviral agents for which susceptibility or resistance testing is routinely performed patient specimens. A correct response for each antiviral agent will be determined as described in paragraph (b)(1) of this section. Scoring for each sample is based on the number of correct susceptibility or resistance responses reported by the laboratory divided by the actual number of correct susceptibility or resistance responses as determined by the program, multiplied by 100. For example, if a laboratory offers susceptibility or resistance testing using three antiviral agents and the laboratory reports correct responses for two of the three antiviral agents, the laboratory's grade would be $2/3 \times 100 = 67$ percent.

(7) The score for a testing event is the average of the sample scores as determined under paragraphs (b)(4) and (6) of this section.

■ 15. Section 493.923 is amended by revising paragraphs (a) and (b)(1) to read as follows:

§ 493.923 Syphilis serology.

(a) *Program content and frequency of challenge.* To be approved for proficiency testing in syphilis serology, a program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The samples may be provided through mailed shipments. An annual program must include samples that cover the full range of reactivity from highly reactive to non-reactive.

(b) * * *

(1) To determine the accuracy of a laboratory's response for qualitative and quantitative syphilis tests, the program must compare the laboratory's response with the response that reflects agreement of either 80 percent or more of ten or more referee laboratories or 80 percent or more of all participating laboratories. Both methods must be attempted before the program can choose to not grade a PT sample.

* * * * *

■ 16. Section 493.927 is amended by revising paragraphs (a), (b), and (c)(1) and (2) to read as follows:

§ 493.927 General immunology.

(a) *Program content and frequency of challenge.* To be approved for proficiency testing for immunology, the annual program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The annual program must provide samples that cover the full range of reactivity from highly reactive to nonreactive. The samples may be provided through mailed shipments.

(b) *Challenges per testing event.* The minimum number of challenges per testing event the program must provide for each analyte or test procedure is five. Analytes or tests for which laboratory performance is to be evaluated include:

Alpha-l antitrypsin.
Alpha-fetoprotein (tumor marker).
Antinuclear antibody.
Antistreptolysin O.
Anti-human immunodeficiency virus (HIV).
Complement C3.
Complement C4.
C-reactive protein (high sensitivity).
HBsAg.
Anti-HBc.
HBeAg.
Anti-HBs.
Anti-HCV.
IgA.
IgG.
IgE.
IgM.
Infectious mononucleosis.
Rheumatoid factor.
Rubella.

(c) * * *

(1) To determine the accuracy of a laboratory's response for quantitative and qualitative immunology tests or analytes, the program must compare the laboratory's response for each analyte with the response that reflects agreement of either 80 percent or more of ten or more referee laboratories or 80 percent or more of all participating laboratories. The proficiency testing program must indicate the minimum concentration that will be considered as indicating a positive response. Both methods must be attempted before the program can choose to not grade a PT sample.

(2)(i) For quantitative immunology analytes or tests, the program must determine the correct response for each analyte by the distance of the response from the target value. After the target value has been established for each response, the appropriateness of the response must be determined by using either fixed criteria or the number of standard deviations (SDs) the response differs from the target value.

Criteria for Acceptable Performance

The criteria for acceptable performance are—

Analyte or test	Criteria for acceptable performance
Alpha-1 antitrypsin	Target value ±20% or positive or negative.
Alpha-fetoprotein (tumor marker)	Target value ±20% or positive or negative.
Antinuclear antibody	Target value ±3 SD or positive or negative.
Antistreptolysin O	Target value ±3 SD or positive or negative.
Anti-Human Immunodeficiency virus (HIV)	Reactive (positive) or nonreactive (negative).
Complement C3	Target value ±15% or positive or negative.
Complement C4	Target value ±5 mg/dL or 20% (greater) or positive or negative.
C-reactive protein (HS)	Target value ±1 mg/dL or 30% (greater).
HBsAg	Reactive (positive) or nonreactive (negative).
anti-HBc	Reactive (positive) or nonreactive (negative).
HBeAg	Reactive (positive) or nonreactive (negative).
Anti-HBs	Reactive (positive) or nonreactive (negative).
Anti-HCV	Reactive (positive) or nonreactive (negative).
IgA	Target value ±15%.
IgE	Target value ±20%.
IgG	Target value ±20%.
IgM	Target value ±20%.
Infectious mononucleosis	Positive or negative.
Rheumatoid factor	Target value ±3 SD or positive or negative.
Rubella	Target value ±3 SD or positive or negative or immune or nonimmune.

* * * * *

■ 17. Section 493.931 is amended by revising paragraphs (a), (b), and (c)(1) and (2) to read as follows:

§ 493.931 Routine chemistry.

(a) *Program content and frequency of challenge.* To be approved for proficiency testing for routine chemistry, a program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The annual program must provide samples that cover the clinically relevant range of values that would be expected in patient specimens. The specimens may be provided through mailed.

(b) *Challenges per testing event.* The minimum number of challenges per testing event a program must provide for each of the following analyte or test procedure is five serum, plasma or blood samples.

Analyte or Test Procedure

Alanine aminotransferase (ALT/SGPT)
Albumin
Alkaline phosphatase
Amylase
Aspartate aminotransferase (AST/SGOT)
Bilirubin, total
Blood gas (pH, pO2, and pCO2)
B-natriuretic peptide (BNP)
proBNP
Calcium, total
Carbon dioxide
Chloride
Cholesterol, total
Cholesterol, high density lipoprotein
Cholesterol, low density lipoprotein
Creatine kinase (CK)
CK–MB isoenzymes
Creatinine
Ferritin
Gamma glutamyl transferase
Glucose (Excluding measurements on devices cleared by FDA for home use)
Hemoglobin A1c
Iron, total
Lactate dehydrogenase (LDH)
Magnesium
Phosphorus
Potassium
Prostate specific antigen, total
Sodium
Total iron binding capacity
Total Protein
Triglycerides
Troponin I
Troponin T
Urea Nitrogen
Uric Acid

(c) * * *

(1) To determine the accuracy of a laboratory's response for qualitative and quantitative chemistry tests or analytes, the program must compare the laboratory's response for each analyte with the response that reflects agreement of either 80 percent or more of ten or more referee laboratories or 80 percent or more of all participating laboratories. Both methods must be attempted before the program can choose to not grade a PT sample.

(2) For quantitative chemistry tests or analytes, the program must determine the correct response for each analyte by the distance of the response from the target value. After the target value has been established for each response, the appropriateness of the response must be determined by using either fixed criteria based on the percentage difference from the target value or the number of standard deviations (SD) the response differs from the target value.

Criteria for Acceptable Performance

The criteria for acceptable performance are—

Analyte or test	Criteria for acceptable performance
Alanine aminotransferase (ALT/SGPT)	Target value ±15%.
Albumin	Target value ±8%.
Alkaline phosphatase	Target value ±20%.
Amylase	Target value ±10%.
Aspartate aminotransferase (AST/SGOT)	Target value ±15%.
Bilirubin, total	Target value ±20%.
Blood gas pCO2	Target value ±5 mm Hg or ±8% (greater).
Blood gas pO2	Target value ±15 mmHg or 15% (greater).
Blood gas pH	Target value ±0.04.
B-natriuretic peptide (BNP)	Target value ±30%.
Pro B-natriuretic peptide (proBNP)	Target value ±30%.
Calcium, total	Target value ±1.0 mg/dL.
Carbon dioxide	Target value ±20%.

Analyte or test	Criteria for acceptable performance
Chloride	Target value ±5%.
Cholesterol, total	Target value ±10%.
Cholesterol, high density lipoprotein	Target value ±20%.
Cholesterol, low density lipoprotein (direct measurement)	Target value ±20%.
Creatine kinase (CK)	Target value ±20%.
CK–MB isoenzymes	MB elevated (presence or absence) or Target value ±25% (greater).
Creatinine	Target value ±0.2 mg/dL or ±10% (greater).
Ferritin	Target value ±20%.
Gamma glutamyl transferase	Target value ±5 U/L or ±15% (greater).
Glucose (excluding measurements devices cleared by FDA for home use.).	Target value ±8% (greater).
Hemoglobin A1c	Target value ±10%.
Iron, total	Target value ±15%.
Lactate dehydrogenase (LDH)	Target value ±15%.
Magnesium	Target value ±15%.
Phosphorus	Target value ±0.3 mg/dL or ±10% (greater).
Potassium	Target value ±0.3 mmol/L.
Prostate Specific Antigen, total	Target value ±0.2 ng/dL or 20% (greater).
Sodium	Target value ±4 mmol/L.
Total Iron Binding Capacity (direct measurement)	Target value ±20%.
Total Protein	Target value ±8%.
Triglycerides	Target value ±15%.
Troponin I	Target value ±0.9 ng/mL or 30% (greater).
Troponin T	Target value ±0.2 ng/mL or 30% (greater).
Urea nitrogen	Target value ±2 mg/dL or ±9% (greater).
Uric acid	Target value ±10%.

* * * * *

■ 18. Section 493.933 is amended by revising paragraphs (a), (b), and (c)(1) and (2) to read as follows:

§ 493.933 Endocrinology.

(a) *Program content and frequency of challenge.* To be approved for proficiency testing for endocrinology, a program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The annual program must provide samples that cover the clinically relevant range of values that would be expected in patient specimens. The samples may be provided through mailed shipments.

(b) *Challenges per testing event.* The minimum number of challenges per testing event a program must provide for each analyte or test procedure is five serum, plasma, blood, or urine samples.

Analyte or Test

Cancer antigen (CA) 125
Carcinoembryonic antigen (CEA)
Cortisol
Estradiol
Folate, serum
Follicle stimulating hormone
Free thyroxine
Human chorionic gonadotropin (excluding urine pregnancy tests done by visual color comparison categorized as waived tests)
Luteinizing hormone
Parathyroid hormone
Progesterone
Prolactin
Testosterone
T3 Uptake
Triiodothyronine
Thyroid-stimulating hormone
Thyroxine
Vitamin B12

(c) * * *

(1) To determine the accuracy of a laboratory's response for qualitative and quantitative endocrinology tests or analytes, a program must compare the laboratory's response for each analyte with the response that reflects agreement of either 80 percent or more of ten or more referee laboratories or 80 percent or more of all participating laboratories. Both methods must be attempted before the program can choose to not grade a PT sample.

(2) For quantitative endocrinology tests or analytes, the program must determine the correct response for each analyte by the distance of the response from the Target value. After the Target value has been established for each response, the appropriateness of the response must be determined by using either fixed criteria based on the percentage difference from the Target value or the number of standard deviations (SDs) the response differs from the Target value.

Criteria for Acceptable Performance

The criteria for acceptable performance are—

Analyte or test	Criteria for acceptable performance
Cancer antigen (CA) 125	Target value ±20%.
Carcinoembryonic antigen (CEA)	Target value ±15%.
Cortisol	Target value ±20%.
Estradiol	Target value ±30%.
Folate, serum	Target value ±1 ng/mL or ±30% (greater).
Follicle stimulating hormone	Target value ±2 IU/L or ±18% (greater).
Free thyroxine	Target value ±0.3 ng/dL or ±15% (greater).
Human chorionic	Target value ±18% or positive or negative.
Gonadotropin (excluding urine pregnancy tests done by visual color comparison categorized as waived tests).	
Luteinizing hormone	Target value ±20%.
Parathyroid hormone	Target value ±30%.
Progesterone	Target value ±25%.

Analyte or test	Criteria for acceptable performance
Prolactin	Target value ±20%.
Testosterone	Target value ±20 ng/dL or ±30% (greater).
T3 uptake	Target value ±18%.
Triiodothyronine	Target value ±30%.
Thyroid-stimulating hormone	Target value ±20% or 0.2 mIU/L (greater).
Thyroxine (greater)	Target value ±20% or 1.0 mcg/dL.
Vitamin B12	Target value ±25%.

* * * * *

■ 19. Section 493.937 is amended by revising paragraphs (a), (b), and (c)(1) and (2) to read as follows:

§ 493.937 Toxicology.

(a) *Program content and frequency of challenge.* To be approved for proficiency testing for toxicology, the annual program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The annual program must provide samples that cover the full range of values that could occur in patient specimens and that cover the level of clinical significance for the particular drug. The samples may be provided through mailed shipments.

(b) *Challenges per testing event.* The minimum number of challenges per testing event a program must provide for each analyte or test procedure is five serum, plasma, or blood samples.

Analyte or Test Procedure

Acetaminophen, serum
Alcohol (blood)
Blood lead
Carbamazepine
Digoxin
Gentamicin
Lithium
Phenobarbital
Phenytoin
Salicylate
Theophylline
Tobramycin
Valproic Acid
Vancomycin

(c) * * *

(1) To determine the accuracy of a laboratory's responses for quantitative toxicology tests or analytes, the program must compare the laboratory's response for each analyte with the response that reflects agreement of either 80 percent or more of ten or more referee laboratories or 80 percent or more of all participating laboratories. Both methods must be attempted before the program can choose to not grade a PT sample.

(2) For quantitative toxicology tests or analytes, the program must determine the correct response for each analyte by the distance of the response from the target value. After the target value has been established for each response, the appropriateness of the response must be determined by using fixed criteria based on the percentage difference from the target value.

Criteria for Acceptable Performance

The criteria for acceptable performance are:

Analyte or test	Criteria for acceptable performance
Acetaminophen	Target value ±15%.
Alcohol, blood	Target Value ±20%.
Blood lead	Target Value ±10% or 2 mcg/dL (greater).
Carbamazepine	Target Value ±20%.
Digoxin	Target Value ±15% or ±0.2 ng/mL (greater).
Gentamicin	Target Value ±25%.
Lithium	Target Value ±15%.
Phenobarbital	Target Value ±15%.
Phenytoin	Target Value ±15% or ±2 mcg/dL (greater).
Salicylate	Target Value ±15%.
Theophylline	Target Value ±20%.
Tobramycin	Target Value ±20%.
Valproic Acid	Target Value ±20%.
Vancomycin	Target Value ±15% or ±2 mcg/dL (greater).

* * * * *

■ 20. Section 493.941 is amended by revising paragraphs (a), (b), and (c)(1) and (2) to read as follows:

§ 493.941 Hematology (including routine hematology and coagulation).

(a) *Program content and frequency of challenge.* To be approved for proficiency testing for hematology, a program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The annual program must provide samples that cover the full range of values that would be expected in patient specimens. The samples may be provided through mailed shipments.

(b) *Challenges per testing event.* The minimum number of challenges per testing event a program must provide for each analyte or test procedure is five.

Analyte or Test Procedure

Cell identification
White blood cell differential
Erythrocyte count
Hematocrit (excluding spun microhematocrit)
Hemoglobin
Leukocyte count
Platelet count
Fibrinogen
Partial thromboplastin time
Prothrombin time (seconds or INR)

(c) * * *

(1) To determine the accuracy of a laboratory's responses for qualitative and quantitative hematology tests or analytes, the program must compare the laboratory's response for each analyte with the response that reflects agreement of either 80 percent or more of ten or more referee laboratories or 80 percent or more of all participating laboratories. Both methods must be attempted before the program can choose to not grade a PT sample.

(2) For quantitative hematology tests or analytes, the program must determine the correct response for each analyte by

the distance of the response from the target value. After the target value has been established for each response, the appropriateness of the response is determined using either fixed criteria based on the percentage difference from the target value or the number of standard deviations (SD) the response differs from the target value.

Criteria for Acceptable Performance

The criteria for acceptable performance are:

Analyte or test	Criteria for acceptable performance
Cell identification	80% or greater consensus on identification.
White blood cell differential	Target ±3SD based on the percentage of different types of white blood cells in the samples.
Erythrocyte count	Target ±4%.
Hematocrit (Excluding spun hematocrit)	Target ±4%.
Hemoglobin	Target ±4%.
Leukocyte count	Target ±5%.
Platelet count	Target ±25%.
Fibrinogen	Target ±20%.
Partial thromboplastin time	Target ±15%.
If a laboratory reports a prothrombin time in both INR and seconds, the INR should be reported to the PT provider program.	
Prothrombin time (seconds or INR)	Target ±15%.

* * * * *

■ 21. Section 493.959 is amended by revising paragraphs (b) and (d)(1) and (2) to read as follows:

§ 493.959 Immunohematology.

* * * * *

(b) *Program content and frequency of challenge.* To be approved for proficiency testing for immunohematology, a program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The annual program must provide samples that cover the full range of interpretation that would be expected in patient specimens. The samples may be provided through mailed shipments.

(d) * * *

(1) To determine the accuracy of a laboratory's response, a program must compare the laboratory's response for each analyte with the response that reflects agreement of either 100 percent of ten or more referee laboratories or 95 percent or more of all participating laboratories except for antibody identification. To determine the accuracy of a laboratory's response for antibody identification, a program must compare the laboratory's response for each analyte with the response that reflects agreement of either 95 percent or more of ten or more referee laboratories or 95 percent or more of all participating laboratories. Both methods must be attempted before the program can choose to not grade a PT sample.

(2) *Criteria for acceptable performance.*

The criteria for acceptable performance are—

Analyte or test	Criteria for acceptable performance
ABO group	100% accuracy.
D (Rho) typing	100% accuracy.
Unexpected antibody detection.	100% accuracy.
Compatibility testing	100% accuracy.
Antibody identification	80% + accuracy.

* * * * *

Dated: June 25, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: December 17, 2018.

Robert Redfield, MD

Director, Centers for Disease Control and Prevention and Administrator, Agency for Toxic Substances and Disease Registry

Dated: December 18, 2018.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2018–28363 Filed 2–1–19; 8:45 am]

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Part III

Environmental Protection Agency

40 CFR Part 63

National Emission Standards for Hazardous Air Pollutants: Hydrochloric Acid Production Residual Risk and Technology Review; Proposed Rules

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA–HQ–OAR–2018–0417; FRL–9988–70–OAR]

RIN 2060–AT74

National Emission Standards for Hazardous Air Pollutants: Hydrochloric Acid Production Residual Risk and Technology Review

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing amendments to the National Emission Standards for Hazardous Air Pollutants (NESHAP) for the Hydrochloric Acid (HCl) Production source category. The proposed action presents the results of the residual risk and technology reviews (RTRs) conducted as required under the Clean Air Act (CAA). The proposed amendments address the startup, shutdown, and malfunction (SSM) provisions of the rule, add electronic reporting, and update the reporting and recordkeeping requirements.

DATES: *Comments.* Comments must be received on or before March 21, 2019. Under the Paperwork Reduction Act (PRA), comments on the information collection provisions are best assured of consideration if the Office of Management and Budget (OMB) receives a copy of your comments on or before March 6, 2019.

Public Hearing. If anyone contacts us requesting a public hearing on or before February 11, 2019, we will hold a hearing. Additional information about the hearing, if requested, will be published in a subsequent **Federal Register** document and posted at *https://www.epa.gov/stationary-sources-air-pollution/hydrochloric-acid-production-national-emission-standards-hazardous.* See **SUPPLEMENTARY INFORMATION** for information on requesting and registering for a public hearing.

ADDRESSES: *Comments.* Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2018–0417, at *https://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* See **SUPPLEMENTARY INFORMATION** for detail about how the EPA treats submitted comments. *Regulations.gov* is our preferred method of receiving comments. However, the following other submission methods are also accepted:

- *Email: a-and-r-docket@epa.gov.* Include Docket ID No. EPA–HQ–OAR–2018–0417 in the subject line of the message.
- *Fax:* (202) 566–9744. Attention Docket ID No. EPA–HQ–OAR–2018–0417.
- *Mail:* To ship or send mail via the United States Postal Service, use the following address: U.S. Environmental Protection Agency, EPA Docket Center, Docket ID No. EPA–HQ–OAR–2018–0417, Mail Code 28221T, 1200 Pennsylvania Avenue NW, Washington, DC 20460.
- *Hand/Courier Delivery:* Use the following Docket Center address if you are using express mail, commercial delivery, hand delivery, or courier: EPA Docket Center, EPA WJC West Building, Room 3334, 1301 Constitution Avenue NW, Washington, DC 20004. Delivery verification signatures will be available only during regular business hours.

FOR FURTHER INFORMATION CONTACT: For questions about this proposed action, contact Nathan Topham, Sector Policies and Programs Division (Mail Code D243–02), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–0483; fax number: (919) 541–4991; and email address: *topham.nathan@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) 541–2076; 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 Marcia Mia, Office of Enforcement and Compliance Assurance, U.S. Environmental Protection Agency, EPA WJC South Building (Mail Code 2227A), 1200 Pennsylvania Avenue NW, Washington, DC 20460; telephone number: (202) 564–7042; and email address: *mia.marcia@epa.gov.*

SUPPLEMENTARY INFORMATION:

Public hearing. Please contact Adrian Gates at (919) 541–4860 or by email at *gates.adrian@epa.gov* to request a public hearing, to register to speak at the public hearing, or to inquire as to whether a public hearing will be held.

Docket. The EPA has established a docket for this rulemaking under Docket ID No. EPA–HQ–OAR–2018–0417. All documents in the docket are listed in *Regulations.gov.* Although listed, 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. Publicly available docket materials are available either electronically in *Regulations.gov* or in hard copy at the EPA Docket Center, Room 3334, EPA WJC West Building, 1301 Constitution Avenue NW, Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the EPA Docket Center is (202) 566–1742.

Instructions. Direct your comments to Docket ID No. EPA–HQ–OAR–2018–0417. The EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *https://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be CBI or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *https://www.regulations.gov* or email. This type of information should be submitted by mail as discussed below.

The EPA may publish any comment received to its public docket. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the Web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www2.epa.gov/dockets/commenting-epa-dockets.*

The *https://www.regulations.gov* website allows you to submit your comment anonymously, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to the EPA without going through *https://www.regulations.gov,* your email

address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comment and with any digital storage media you submit. If the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment. Electronic files should not include special characters or any form of encryption and be free of any defects or viruses. For additional information about the EPA's public docket, visit the EPA Docket Center homepage at *https://www.epa.gov/dockets.*

Submitting CBI. Do not submit information containing CBI to the EPA through *https://www.regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information on any digital storage media that you mail to the EPA, mark the outside of the digital storage media as CBI and then identify electronically within the digital storage media the specific information that is claimed as CBI. In addition to one complete version of the comments that includes information claimed as CBI, you must submit a copy of the comments that does not contain the information claimed as CBI directly to the public docket through the procedures outlined in *Instructions* above. If you submit any digital storage media that does not contain CBI, mark the outside of the digital storage media clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and the EPA's electronic public docket without prior notice. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 Code of Federal Regulations (CFR) part 2. Send or deliver information identified as CBI only to the following address: OAQPS Document Control Officer (C404–02), OAQPS, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, Attention Docket ID No. EPA–HQ–OAR–2018–0417.

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:

AEGL acute exposure guideline level
AERMOD air dispersion model used by the HEM–3 model
CAA Clean Air Act
CalEPA California EPA
CBI Confidential Business Information
CFR Code of Federal Regulations
Cl_2 chlorine
EPA Environmental Protection Agency
ERPG Emergency Response Planning Guideline
ERT Electronic Reporting Tool
HAP hazardous air pollutant(s)
HCl hydrochloric acid
HEM–3 Human Exposure Model, Version 1.1.0
HF hydrogen fluoride
HI hazard index
HQ hazard quotient
IRIS Integrated Risk Information System
km kilometer
MACT maximum achievable control technology
mg/m^3 milligrams per cubic meter
MIR maximum individual risk
NAAQS National Ambient Air Quality Standards
NAICS North American Industry Classification System
NESHAP national emission standards for hazardous air pollutants
NTTAA National Technology Transfer and Advancement Act
OAQPS Office of Air Quality Planning and Standards
OECA Office of Enforcement and Compliance Assurance
OMB Office of Management and Budget
PB–HAP hazardous air pollutants known to be persistent and bio-accumulative in the environment
POM polycyclic organic matter
REL reference exposure level
RFA Regulatory Flexibility Act
RfC reference concentration
RfD reference dose
RTR residual risk and technology review
SAB Science Advisory Board
SSM startup, shutdown, and malfunction
TOSHI target organ-specific hazard index
tpy tons per year
TRIM.FaTE Total Risk Integrated Methodology: Fate, Transport, and Ecological Exposure model
UF uncertainty factor
UMRA Unfunded Mandates Reform Act
URE unit risk estimate

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I. General Information

A. Does this action apply to me?

Table 1 of this preamble lists the NESHAP and associated regulated industrial source categories that are the subject of this proposal. Table 1 is not intended to be exhaustive, but rather provides a guide for readers regarding the entities that this proposed action is likely to affect. The proposed standards, once promulgated, will be directly applicable to the affected sources. Federal, state, local, and tribal government entities will not be affected by this proposed action. As defined in the *Initial List of Categories of Sources Under Section 112(c)(1) of the Clean Air Act Amendments of 1990* (see 57 FR 31576, July 16, 1992) and

Documentation for Developing the Initial Source Category List (*see* EPA–450/3–91–030), the HCl Production source category includes any facility engaged in the production of HCl. The category includes, but is not limited to, production of hydrochloric acid via any of the following methods: (1) Production of HCl as a by-product in the manufacture of organic chemicals; (2) direct reaction of salts and sulfuric acid (Mannheim process); (3) reaction of a salt, sulfur dioxide, oxygen, and water (Hargreaves process); or (4) burning chlorine (Cl_2) in the presence of hydrogen gas. On September 18, 2001 (66 FR 48174), the Fume Silica Production source category was combined with the HCl Production source category. The Fume Silica Production source category is any facility engaged in the production of fume silica. Fume silica is a fine white powder used as a thickener, thixotropic, or reinforcing agent in inks, resins, rubber, paints, and cosmetics. The category includes the production of fume silica by the combustion of silicon tetrachloride in hydrogen-oxygen furnaces.

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

Source category	NESHAP	NAICS code [1]
HCl production and fume silica production	HCl	325180

[1] North American Industry Classification System.

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 action is available on the internet. Following signature by the EPA Administrator, the EPA will post a copy of this proposed action at *https://www.epa.gov/hydrochloric-acid-production-national-emission-standards-hazardous.* Following publication in the **Federal Register**, the EPA will post the **Federal Register** version of the proposal and key technical documents at this same website. Information on the overall residual RTR program is available at *https://www3.epa.gov/ttn/atw/rrisk/rtrpg.html.*

A redline version of the regulatory language that incorporates the proposed changes in this action is available in the docket for this action (Docket ID No. EPA–HQ–OAR–2018–0417).

II. Background

A. What is the statutory authority for this action?

The statutory authority for this action is provided by sections 112 and 301 of the CAA, as amended (42 U.S.C. 7401 *et seq.*). Section 112 of the CAA establishes a two-stage regulatory process to develop standards for emissions of hazardous air pollutants (HAP) from stationary sources. Generally, the first stage involves establishing technology-based standards and the second stage involves evaluating those standards that are based on maximum achievable control technology (MACT) to determine whether additional standards are needed to address any remaining risk associated with HAP emissions. This second stage is commonly referred to as the ''residual risk review.'' In addition to the residual risk review, the CAA also requires the EPA to review standards set under CAA section 112 every 8 years to determine if there are ''developments in practices, processes, or control technologies'' that may be appropriate to incorporate into the standards. This review is commonly referred to as the ''technology review.'' When the two reviews are combined into a single rulemaking, it is commonly referred to as the ''risk and technology review.'' The discussion that follows identifies the most relevant statutory sections and briefly explains the contours of the methodology used to implement these statutory requirements. A more comprehensive discussion appears in the document titled *CAA Section 112 Risk and Technology Reviews: Statutory Authority and Methodology* in the docket for this rulemaking.

In the first stage of the CAA section 112 standard setting process, the EPA promulgates technology-based standards under CAA section 112(d) for categories of sources identified as emitting one or more of the HAP listed in CAA section 112(b). Sources of HAP emissions are either major sources or area sources, and CAA section 112 establishes different requirements for major source standards and area source standards. ''Major sources'' are those that emit or have the potential to emit 10 tons per year (tpy) or more of a single HAP or 25 tpy or more of any combination of HAP. All other sources are ''area sources.'' For major sources, CAA section 112(d)(2) provides that the technology-based NESHAP must reflect the maximum degree of emission reductions of HAP achievable (after considering cost, energy requirements, and non-air quality health and environmental impacts). These standards are commonly referred to as MACT standards. CAA section 112(d)(3) also establishes a minimum control level for MACT standards, known as the MACT ''floor.'' The EPA must also consider control options that are more stringent than the floor. Standards more stringent than the floor are commonly referred to as beyond-the-floor standards. In certain instances, as provided in CAA section 112(h), the EPA may set work practice standards where it is not feasible to prescribe or enforce a numerical emission standard. For area sources, CAA section 112(d)(5) gives the EPA discretion to set standards based on generally available control technologies or management practices (GACT standards) in lieu of MACT standards.

The second stage in standard-setting focuses on identifying and addressing any remaining (*i.e.,* ''residual'') risk according to CAA section 112(f). For source categories subject to MACT standards, section 112(f)(2) of the CAA requires the EPA to determine whether promulgation of additional standards is needed to provide an ample margin of safety to protect public health or to prevent an adverse environmental effect. Section 112(d)(5) of the CAA provides that this residual risk review is not required for categories of area sources subject to GACT standards. Section 112(f)(2)(B) of the CAA further expressly preserves the EPA's use of the two-step approach for developing standards to address any residual risk and the Agency's interpretation of ''ample margin of safety'' developed in the *National Emissions Standards for Hazardous Air Pollutants: Benzene Emissions from Maleic Anhydride Plants, Ethylbenzene/Styrene Plants, Benzene Storage Vessels, Benzene Equipment Leaks, and Coke By-Product Recovery Plants* (Benzene NESHAP) (54 FR 38044, September 14, 1989). The EPA notified Congress in the Risk Report that the Agency intended to use the Benzene NESHAP approach in making CAA section 112(f) residual risk determinations (EPA–453/R–99–001, p. ES–11). The EPA subsequently adopted this approach in its residual risk determinations and the United States

Court of Appeals for the District of Columbia Circuit (the Court) upheld the EPA's interpretation that CAA section 112(f)(2) incorporates the approach established in the Benzene NESHAP. See *NRDC* v. *EPA,* 529 F.3d 1077, 1083 (D.C. Cir. 2008).

The approach incorporated into the CAA and used by the EPA to evaluate residual risk and to develop standards under CAA section 112(f)(2) is a two-step approach. In the first step, the EPA determines whether risks are acceptable. This determination ''considers all health information, including risk estimation uncertainty, and includes a presumptive limit on maximum individual lifetime [cancer] risk (MIR) [1] of approximately 1 in 10 thousand.'' 54 FR 38045, September 14, 1989. If risks are unacceptable, the EPA must determine the emissions standards necessary to reduce risk to an acceptable level without considering costs. In the second step of the approach, the EPA considers whether the emissions standards provide an ample margin of safety to protect public health ''in consideration of all health information, including the number of persons at risk levels higher than approximately 1 in 1 million, as well as other relevant factors, including costs and economic impacts, technological feasibility, and other factors relevant to each particular decision.'' *Id.* The EPA must promulgate emission standards necessary to provide an ample margin of safety to protect public health. After conducting the ample margin of safety analysis, we consider whether a more stringent standard is necessary to prevent, taking into consideration costs, energy, safety, and other relevant factors, an adverse environmental effect.

CAA section 112(d)(6) separately requires the EPA to review standards promulgated under CAA section 112 and revise them ''as necessary (taking into account developments in practices, processes, and control technologies)'' no less often than every 8 years. In conducting this review, which we call the ''technology review,'' the EPA is not required to recalculate the MACT floor. *Natural Resources Defense Council (NRDC)* v. *EPA,* 529 F.3d 1077, 1084 (D.C. Cir. 2008). *Association of Battery Recyclers, Inc.* v. *EPA,* 716 F.3d 667 (D.C. Cir. 2013). The EPA may consider cost in deciding whether to revise the standards pursuant to CAA section 112(d)(6).

[1] Although defined as ''maximum individual risk,'' MIR refers only to cancer risk. MIR, one metric for assessing cancer risk, is the estimated risk if an individual were exposed to the maximum level of a pollutant for a lifetime.

B. What is this source category and how does the current NESHAP regulate its HAP emissions?

As described in section I.A of this preamble, the HCl Production source category includes facilities that are engaged in the production of HCl. In the initial list of source categories, Fume Silica Production was listed as a distinct source category. While developing the NESHAP for HCl Production, the EPA determined that HAP emissions from fume silica production were attributable to HCl production at these facilities. Therefore, during the proposal and promulgation of the NESHAP for HCl Production, the Fume Silica Production source category was subsumed into the HCl Production source category and the resulting HCl Production source category now includes HCl production at fume silica production facilities as well as other facilities producing HCl that were previously included in the source category.

The HCl Production NESHAP covers sources located at major sources of HAP emissions. HCl production facilities are typically co-located at plant sites that include various other chemical manufacturing processes such as pesticide or organic chemical manufacturing. The HCl production facility is the basic unit defined in the NESHAP. Specifically, the rule defines an HCl production facility as the collection of unit operations and equipment associated with the production of liquid HCl product of 30 weight percent or greater. The production of liquid HCl product occurs through the absorption of gaseous HCl into either water or an aqueous HCl solution. The HCl production facility includes HCl storage tanks (as defined in 40 CFR 63.9075), HCl transfer operations that load the HCl product into a tank truck, rail car, ship, or barge, and equipment leaks. A plant site could have several separate and distinct HCl production facilities. The affected source includes all HCl production facilities at the same site.

An HCl production facility begins at the point where a gaseous stream containing HCl [2] enters an absorber and ends at the point where the liquid HCl product is loaded into a tank truck, rail car, ship, or barge, at the point the HCl product enters another process on the plant site, or at the point the HCl product leaves the plant site via pipeline. The gaseous stream leaving the absorption column contains HCl that was not absorbed into the liquid in the tower and any Cl_2 present in the inlet stream. If the outlet stream is directly discharged to the atmosphere or if it is routed through other control devices before being discharged to the atmosphere, it is considered an HCl process vent from an HCl production facility. If the outlet stream is routed (or recycled) to another process, it is not regulated under the HCl Production NESHAP, but could be regulated under a separate NESHAP related to the process to which it is routed. For example, if an HCl process vent emission stream is routed to a hazardous waste combustor regulated under 40 CFR part 63, subpart EEE, as supplemental combustion air, that process vent stream is subject to 40 CFR part 63, subpart EEE rather than the HCl Production NESHAP.

[2] For purposes of the HCl Production NESHAP, how the gaseous HCl is produced does not affect applicability of the rule to the source. The source category only addresses the production of liquid HCl.

C. What data collection activities were conducted to support this action?

The EPA used a variety of resources to obtain data about facilities and their emissions for use in our risk assessment. We used the EPA's Enforcement and Compliance History Online (ECHO) database to develop a list of potentially subject facilities. Using this list, we searched state environmental agency websites and correspondence with industry to obtain copies of title V permits to confirm whether facilities have HCl production subject to the NESHAP. Once the facility list was finalized, the EPA used the 2014 National Emissions Inventory (NEI) to get emissions data for each facility. We compared the NEI data to title V permits to provide additional information regarding the applicability of the HCl Production NESHAP. There were some instances in which sources listed in title V permits did not include HAP emissions in the NEI. As discussed in the memorandum titled *HCl RTR Modeling File Data Source Documentation,* which is available in the docket for this action, these gaps were filled using average data from other emission points for which data were available. Further discussion of the methodology used to develop the emissions dataset for the risk assessment can be found in the memorandum titled *HCl RTR Modeling File Data Source Documentation,* which is available in the docket for this action. Industry representatives provided data corrections where facility ownership or emission point parameters from the NEI were incorrect.

D. What other relevant background information and data are available?

We used information from the Reasonably Available Control Technology (RACT), Best Available Control Technology (BACT), and Lowest Achievable Emission Rate (LAER) Clearinghouse (RBLC) database, reviewed title V permits for each HCl production facility, and reviewed regulatory actions related to emissions controls at similar sources that could be applicable to HCl production. We reviewed the RBLC to identify potential additional control technologies. No additional control technologies applicable to HCl production were found using the RBLC. Additional information related to the original promulgation and subsequent amendments of the NESHAP is available in Docket ID No. EPA–HQ–OAR–2002–0057.

III. Analytical Procedures and Decision-Making

In this section, we describe the analyses performed to support the proposed decisions for the RTR and other issues addressed in this proposal.

A. How do we consider risk in our decision-making?

As discussed in section II.A of this preamble and in the Benzene NESHAP, in evaluating and developing standards under CAA section 112(f)(2), we apply a two-step approach to determine whether or not risks are acceptable and to determine if the standards provide an ample margin of safety to protect public health. As explained in the Benzene NESHAP, ''the first step judgment on acceptability cannot be reduced to any single factor'' and, thus, ''[t]he Administrator believes that the acceptability of risk under section 112 is best judged on the basis of a broad set of health risk measures and information.'' 54 FR 38046, September 14, 1989. Similarly, with regard to the ample margin of safety determination, ''the Agency again considers all of the health risk and other health information considered in the first step. Beyond that information, additional factors relating to the appropriate level of control will also be considered, including cost and economic impacts of controls, technological feasibility, uncertainties, and any other relevant factors.'' *Id.*

The Benzene NESHAP approach provides flexibility regarding factors the EPA may consider in making determinations and how the EPA may weigh those factors for each source category. The EPA conducts a risk assessment that provides estimates of the MIR posed by the HAP emissions from each source in the source category, the hazard index (HI) for chronic exposures to HAP with the potential to cause noncancer health effects, and the hazard quotient (HQ) for acute exposures to HAP with the potential to cause noncancer health effects.[3] The assessment also provides estimates of the distribution of cancer risk within the exposed populations, cancer incidence, and an evaluation of the potential for an adverse environmental effect. The scope of the EPA's risk analysis is consistent with the EPA's response to comments on our policy under the Benzene NESHAP where the EPA explained that:

> [t]he policy chosen by the Administrator permits consideration of multiple measures of health risk. Not only can the MIR figure be considered, but also incidence, the presence of non-cancer health effects, and the uncertainties of the risk estimates. In this way, the effect on the most exposed individuals can be reviewed as well as the impact on the general public. These factors can then be weighed in each individual case. This approach complies with the *Vinyl Chloride* mandate that the Administrator ascertain an acceptable level of risk to the public by employing his expertise to assess available data. It also complies with the Congressional intent behind the CAA, which did not exclude the use of any particular measure of public health risk from the EPA's consideration with respect to CAA section 112 regulations, and thereby implicitly permits consideration of any and all measures of health risk which the Administrator, in his judgment, believes are appropriate to determining what will 'protect the public health'.

See 54 FR 38057, September 14, 1989. Thus, the level of the MIR is only one factor to be weighed in determining acceptability of risk. The Benzene NESHAP explained that ''an MIR of approximately one in 10 thousand should ordinarily be the upper end of the range of acceptability. As risks increase above this benchmark, they become presumptively less acceptable under CAA section 112, and would be weighed with the other health risk measures and information in making an overall judgment on acceptability. Or, the Agency may find, in a particular case, that a risk that includes MIR less than the presumptively acceptable level is unacceptable in the light of other health risk factors.'' *Id.* at 38045. Similarly, with regard to the ample margin of safety analysis, the EPA stated in the Benzene NESHAP that: ''EPA believes the relative weight of the many factors that can be considered in selecting an ample margin of safety can only be determined for each specific source category. This occurs mainly because technological and economic factors (along with the health-related factors) vary from source category to source category.'' *Id.* at 38061. We also consider the uncertainties associated with the various risk analyses, as discussed earlier in this preamble, in our determinations of acceptability and ample margin of safety.

The EPA notes that it has not considered certain health information to date in making residual risk determinations. At this time, we do not attempt to quantify the HAP risk that may be associated with emissions from other facilities that do not include the source category under review, mobile source emissions, natural source emissions, persistent environmental pollution, or atmospheric transformation in the vicinity of the sources in the category.

The EPA understands the potential importance of considering an individual's total exposure to HAP in addition to considering exposure to HAP emissions from the source category and facility. We recognize that such consideration may be particularly important when assessing noncancer risk, where pollutant-specific exposure health reference levels (*e.g.,* reference concentrations (RfCs)) are based on the assumption that thresholds exist for adverse health effects. For example, the EPA recognizes that, although exposures attributable to emissions from a source category or facility alone may not indicate the potential for increased risk of adverse noncancer health effects in a population, the exposures resulting from emissions from the facility in combination with emissions from all of the other sources (*e.g.,* other facilities) to which an individual is exposed may be sufficient to result in increased risk of adverse noncancer health effects. In May 2010, the Science Advisory Board (SAB) advised the EPA ''that RTR assessments will be most useful to decision makers and communities if results are presented in the broader context of aggregate and cumulative risks, including background concentrations and contributions from other sources in the area.''[4]

In response to the SAB recommendations, the EPA incorporates

[3] The MIR is defined as the cancer risk associated with a lifetime of exposure at the highest concentration of HAP where people are likely to live. The HQ is the ratio of the potential exposure to the HAP to the level at or below which no adverse chronic noncancer effects are expected; the HI is the sum of HQs for HAP that affect the same target organ or organ system.

[4] Recommendations of the SAB RTR Panel are provided in their report, which is available at: *http://yosemite.epa.gov/sab/sabproduct.nsf/4AB3966E263D943A8525771F00668381/$File/EPA-SAB-10-007-unsigned.pdf.*

cumulative risk analyses into its RTR risk assessments, including those reflected in this proposal. The Agency (1) conducts facility-wide assessments, which include source category emission points, as well as other emission points within the facilities; (2) combines exposures from multiple sources in the same category that could affect the same individuals; and (3) for some persistent and bioaccumulative pollutants, analyzes the ingestion route of exposure. In addition, the RTR risk assessments consider aggregate cancer risk from all carcinogens and aggregated noncancer HQs for all noncarcinogens affecting the same target organ or target organ system.

Although we are interested in placing source category and facility-wide HAP risk in the context of total HAP risk from all sources combined in the vicinity of each source, we are concerned about the uncertainties of doing so. Estimates of total HAP risk from emission sources other than those that we have studied in depth during this RTR review would have significantly greater associated uncertainties than the source category or facility-wide estimates. Such aggregate or cumulative assessments would compound those uncertainties, making the assessments too unreliable.

B. How do we perform the technology review?

Our technology review focuses on the identification and evaluation of developments in practices, processes, and control technologies that have occurred since the MACT standards were promulgated. Where we identify such developments, we analyze their technical feasibility, estimated costs, energy implications, and non-air environmental impacts. We also consider the emission reductions associated with applying each development. This analysis informs our decision of whether it is ''necessary'' to revise the emissions standards. In addition, we consider the appropriateness of applying controls to new sources versus retrofitting existing sources. For this exercise, we consider any of the following to be a ''development'':

- Any add-on control technology or other equipment that was not identified and considered during development of the original MACT standards;
- Any improvements in add-on control technology or other equipment (that were identified and considered during development of the original MACT standards) that could result in additional emissions reduction;
- Any work practice or operational procedure that was not identified or considered during development of the original MACT standards;
- Any process change or pollution prevention alternative that could be broadly applied to the industry and that was not identified or considered during development of the original MACT standards; and
- Any significant changes in the cost (including cost effectiveness) of applying controls (including controls the EPA considered during the development of the original MACT standards).

In addition to reviewing the practices, processes, and control technologies that were considered at the time we originally developed the NESHAP, we review a variety of data sources in our investigation of potential practices, processes, or controls to consider. See sections II.C and II.D of this preamble for information on the specific data sources that were reviewed as part of the technology review.

C. How do we estimate post-MACT risk posed by the source category?

In this section, we provide a complete description of the types of analyses that we generally perform during the risk assessment process. In some cases, we do not perform a specific analysis because it is not relevant. For example, in the absence of emissions of HAP known to be persistent and bioaccumulative in the environment (PB–HAP), we would not perform a multipathway exposure assessment. Where we do not perform an analysis, we state that we do not and provide the reason. While we present all of our risk assessment methods, we only present risk assessment results for the analyses actually conducted (see section IV.B of this preamble).

The EPA conducts a risk assessment that provides estimates of the MIR for cancer posed by the HAP emissions from each source in the source category, the HI for chronic exposures to HAP with the potential to cause noncancer health effects, and the HQ for acute exposures to HAP with the potential to cause noncancer health effects. The assessment also provides estimates of the distribution of cancer risk within the exposed populations, cancer incidence, and an evaluation of the potential for an adverse environmental effect. The seven sections that follow this paragraph describe how we estimated emissions and conducted the risk assessment. The docket for this rulemaking contains the following document which provides more information on the risk assessment inputs and models: *Residual Risk Assessment for the Hydrochloric Acid Production Source Category in Support of the 2018 Risk and Technology Review Proposed Rule.* The methods used to assess risk (as described in the seven primary steps below) are consistent with those described by the EPA in the document reviewed by a panel of the EPA's SAB in 2009,[5] and described in the SAB review report issued in 2010. They are also consistent with the key recommendations contained in that report.

1. How did we estimate actual emissions and identify the emissions release characteristics?

As discussed in the memorandum titled, *HCl RTR Modeling File Data Source Documentation,* emissions data for sources subject to the HCl Production NESHAP were gathered primarily from the 2014 NEI. We compared the NEI data for each facility to title V permits to determine which emission points listed in the NEI are subject to the HCl Production NESHAP and made corrections when data were missing from the NEI or appeared to be incorrect. For example, if the flow rate for an emission point was missing, we calculated this release characteristic using the stack velocity and cross-sectional area of the stack. Each correction we made is discussed in the memorandum and supporting documents, available in the docket for this action. Industry provided a few corrections of facility ownership and emission point parameters, which are also available in the docket for this action.

2. How did we estimate MACT-allowable emissions?

The available emissions data in the RTR emissions dataset include estimates of the mass of HAP emitted during a specified annual timeperiod. These ''actual'' emission levels are often lower than the emission levels allowed under the requirements of the current MACT standards. The emissions allowed under the MACT standards are referred to as the ''MACT-allowable'' emissions. We discussed the consideration of both MACT-allowable and actual emissions in the final Coke Oven Batteries RTR (70 FR 19998–19999, April 15, 2005) and in the proposed and final Hazardous Organic NESHAP RTR (71 FR 34428, June 14, 2006, and 71 FR 76609,

[5] U.S. EPA. *Risk and Technology Review (RTR) Risk Assessment Methodologies: For Review by the EPA's Science Advisory Board with Case Studies—MACT I Petroleum Refining Sources and Portland Cement Manufacturing,* June 2009. EPA–452/R–09–006. *https://www3.epa.gov/airtoxics/rrisk/rtrpg.html.*

December 21, 2006, respectively). In those actions, we noted that assessing the risk at the MACT-allowable level is inherently reasonable since that risk reflects the maximum level facilities could emit and still comply with national emission standards. We also explained that it is reasonable to consider actual emissions, where such data are available, in both steps of the risk analysis, in accordance with the Benzene NESHAP approach (54 FR 38044, September 14, 1989).

We were unable to use the NEI data to calculate allowable emissions based on the concentration-based standard. We attempted to calculate allowable emission rates using the flow rates in the NEI and the concentration based standards for HCl and Cl_2. For a number of sources, the calculated allowable emission values were substantially lower than actual emissions. This discrepancy could be due to incorrect flow rates in the NEI, conservatively high estimates of actual emissions, or actual emission estimates including HCl and Cl_2 emissions from sources not subject to the HCl NESHAP. We determined these estimates of allowable emission rates would not be appropriate. Instead, we estimated allowable emission rates by applying a factor of ten to actual emissions for process vents, material storage and loading, and storage tanks. Based on our engineering judgement, this factor of ten provides a very conservative estimate of allowable emission rates. Indeed, correspondence with industry suggests the allowable emission rates estimated using this method may be higher than facility-wide permitted emission rates for some facilities. Facilities typically operate below the level of the standard to provide a buffer between actual emission levels and the level of the standard. While we were not able to calculate the exact magnitude of this buffer for this source category, we believe that using a multiplier of 10 ensures we are not underestimating allowable emission rates. For more detail about the MACT-allowable emission levels, see the memorandum, *HCl RTR Modeling File Data Source Documentation,* which is available in the docket for this action. The standard for equipment leaks requires facilities to operate a leak detection and repair (LDAR) program. Consistent with other source categories with LDAR standards, we estimated that allowable emissions for equipment leaks are equal to actual emissions, since both actual and allowable emissions reflect the use of an LDAR program. Our estimates of actual and allowable emissions are further discussed in the memorandum titled *HCl RTR Modeling File Data Source Documentation.*

3. How do we conduct dispersion modeling, determine inhalation exposures, and estimate individual and population inhalation risk?

Both long-term and short-term inhalation exposure concentrations and health risk from the source category addressed in this proposal were estimated using the Human Exposure Model (HEM–3).[6] The HEM–3 performs three primary risk assessment activities: (1) Conducting dispersion modeling to estimate the concentrations of HAP in ambient air, (2) estimating long-term and short-term inhalation exposures to individuals residing within 50 kilometers (km) of the modeled sources, and (3) estimating individual and population-level inhalation risk using the exposure estimates and quantitative dose-response information.

a. Dispersion Modeling

The air dispersion model AERMOD, used by the HEM–3 model, is one of the EPA's preferred models for assessing air pollutant concentrations from industrial facilities.[7] To perform the dispersion modeling and to develop the preliminary risk estimates, HEM–3 draws on three data libraries. The first is a library of meteorological data, which is used for dispersion calculations. This library includes 1 year (2016) of hourly surface and upper air observations from 824 meteorological stations, selected to provide coverage of the United States and Puerto Rico. A second library of United States Census Bureau census block[8] internal point locations and populations provides the basis of human exposure calculations (U.S. Census, 2010). In addition, for each census block, the census library includes the elevation and controlling hill height, which are also used in dispersion calculations. A third library of pollutant-specific dose-response values is used to estimate health risk. These are discussed below.

b. Risk From Chronic Exposure to HAP

In developing the risk assessment for chronic exposures, we use the estimated annual average ambient air concentrations of each HAP emitted by each source in the source category. The HAP air concentrations at each nearby census block centroid located within 50 km of the facility are a surrogate for the chronic inhalation exposure concentration for all the people who reside in that census block. A distance of 50 km is consistent with both the analysis supporting the 1989 Benzene NESHAP (54 FR 38044, September 14, 1989) and the limitations of Gaussian dispersion models, including AERMOD.

For each facility, we calculate the MIR as the cancer risk associated with a continuous lifetime (24 hours per day, 7 days per week, 52 weeks per year, 70 years) exposure to the maximum concentration at the centroid of each inhabited census block. We calculate individual cancer risk by multiplying the estimated lifetime exposure to the ambient concentration of each HAP (in micrograms per cubic meter ($\mu g/m^3$)) by its unit risk estimate (URE). The URE is an upper-bound estimate of an individual's incremental risk of contracting cancer over a lifetime of exposure to a concentration of 1 microgram of the pollutant per cubic meter of air. For residual risk assessments, we generally use UREs from the EPA's Integrated Risk Information System (IRIS). For carcinogenic pollutants without IRIS values, we look to other reputable sources of cancer dose-response values, often using California EPA (CalEPA) UREs, where available. In cases where new, scientifically credible dose-response values have been developed in a manner consistent with EPA guidelines and have undergone a peer review process similar to that used by the EPA, we may use such dose-response values in place of, or in addition to, other values, if appropriate. The pollutant-specific dose-response values used to estimate health risk are available at *https://www.epa.gov/fera/dose-response-assessment-assessing-health-risks-associated-exposure-hazardous-air-pollutants.*

To estimate individual lifetime cancer risks associated with exposure to HAP emissions from each facility in the source category, we sum the risks for each of the carcinogenic HAP[9] emitted

[6] For more information about HEM–3, go to *https://www.epa.gov/fera/risk-assessment-and-modeling-human-exposure-model-hem.*

[7] U.S. EPA. Revision to the *Guideline on Air Quality Models: Adoption of a Preferred General Purpose (Flat and Complex Terrain) Dispersion Model and Other Revisions* (70 FR 68218, November 9, 2005).

[8] A census block is the smallest geographic area for which census statistics are tabulated.

[9] The EPA's 2005 *Guidelines for Carcinogen Risk Assessment* classifies carcinogens as: ''carcinogenic to humans,'' ''likely to be carcinogenic to humans,'' and ''suggestive evidence of carcinogenic potential.'' These classifications also coincide with the terms ''known carcinogen, probable carcinogen, and possible carcinogen,'' respectively, which are the terms advocated in the EPA's *Guidelines for Carcinogen Risk Assessment,* published in 1986 (51 FR 33992, September 24, 1986). In August 2000, the document, *Supplemental Guidance for Conducting Health Risk Assessment of Chemical Mixtures*

by the modeled facility. We estimate cancer risk at every census block within 50 km of every facility in the source category. The MIR is the highest individual lifetime cancer risk estimated for any of those census blocks. In addition to calculating the MIR, we estimate the distribution of individual cancer risks for the source category by summing the number of individuals within 50 km of the sources whose estimated risk falls within a specified risk range. We also estimate annual cancer incidence by multiplying the estimated lifetime cancer risk at each census block by the number of people residing in that block, summing results for all of the census blocks, then dividing this result by a 70-year lifetime.

To assess the risk of noncancer health effects from chronic exposure to HAP, we calculate either an HQ or a target organ-specific hazard index (TOSHI). We calculate an HQ when a single noncancer HAP is emitted. Where more than one noncancer HAP is emitted, we sum the HQ for each of the HAP that affects a common target organ or target organ system to obtain a TOSHI. The HQ is the estimated exposure divided by the chronic noncancer dose-response value, which is a value selected from one of several sources. The preferred chronic noncancer dose-response value is the EPA RfC defined as ''an estimate (with uncertainty spanning perhaps an order of magnitude) of a continuous inhalation exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime'' (*https://iaspub.epa.gov/sor_internet/registry/termreg/searchandretrieve/glossariesandkeywordlists/search.do?details=&vocabName=IRIS%20Glossary*). In cases where an RfC from the EPA's IRIS is not available or where the EPA determines that using a value other than the RfC is appropriate, the chronic noncancer dose-response value can be a value from the following prioritized sources, which define their dose-response values similarly to the EPA: (1) The Agency for Toxic Substances and Disease Registry (ATSDR) Minimum Risk Level (*http://www.atsdr.cdc.gov/mrls/index.asp*); (2) the CalEPA Chronic Reference Exposure Level (REL) (*http://oehha.ca.gov/air/crnr/notice-adoption-air-toxics-hot-spots-program-guidance-manual-preparation-health-risk-0*); or (3), as noted above, a scientifically credible dose-response value that has been developed in a manner consistent with EPA guidelines and has undergone a peer review process similar to that used by the EPA. The pollutant-specific dose-response values used to estimate health risks are available at *https://www.epa.gov/fera/dose-response-assessment-assessing-health-risks-associated-exposure-hazardous-air-pollutants.*

c. Risk From Acute Exposure to HAP That May Cause Health Effects Other Than Cancer

For each HAP for which appropriate acute inhalation dose-response values are available, the EPA also assesses the potential health risks due to acute exposure. For these assessments, the EPA makes conservative assumptions about emission rates, meteorology, and exposure location. We use the peak hourly emission rate,[10] worst-case dispersion conditions, and, in accordance with our mandate under section 112 of the CAA, the point of highest off-site exposure to assess the potential risk to the maximally exposed individual.

To characterize the potential health risks associated with estimated acute inhalation exposures to a HAP, we generally use multiple acute dose-response values, including acute RELs, acute exposure guideline levels (AEGLs), and emergency response planning guidelines (ERPG) for 1-hour exposure durations, if available, to calculate acute HQs. The acute HQ is calculated by dividing the estimated acute exposure by the acute dose-response value. For each HAP for which acute dose-response values are available, the EPA calculates acute HQs.

An acute REL is defined as ''the concentration level at or below which no adverse health effects are anticipated for a specified exposure duration.''[11] Acute RELs are based on the most sensitive, relevant, adverse health effect reported in the peer-reviewed medical and toxicological literature. They are designed to protect the most sensitive individuals in the population through the inclusion of margins of safety. Because margins of safety are incorporated to address data gaps and uncertainties, exceeding the REL does not automatically indicate an adverse health impact. AEGLs represent threshold exposure limits for the general public and are applicable to emergency exposures ranging from 10 minutes to 8 hours.[12] They are guideline levels for ''once-in-a-lifetime, short-term exposures to airborne concentrations of acutely toxic, high-priority chemicals.'' *Id.* at 21. The AEGL–1 is specifically defined as ''the airborne concentration (expressed as ppm (parts per million) or mg/m^3 (milligrams per cubic meter)) of a substance above which it is predicted that the general population, including susceptible individuals, could experience notable discomfort, irritation, or certain asymptomatic nonsensory effects. However, the effects are not disabling and are transient and reversible upon cessation of exposure.'' The document also notes that ''Airborne concentrations below AEGL–1 represent exposure levels that can produce mild and progressively increasing but transient and nondisabling odor, taste, and sensory irritation or certain asymptomatic, nonsensory effects.'' *Id.* AEGL–2 are defined as ''the airborne concentration (expressed as parts per million or milligrams per cubic meter) of a substance above which it is predicted that the general population, including susceptible individuals, could experience irreversible or other serious, long-lasting adverse health effects or an impaired ability to escape.'' *Id.*

ERPGs are ''developed for emergency planning and are intended as health-based guideline concentrations for

(EPA/630/R–00/002), was published as a supplement to the 1986 document. Copies of both documents can be obtained from *https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=20533&CFID=70315376&CFTOKEN=71597944.* Summing the risk of these individual compounds to obtain the cumulative cancer risk is an approach that was recommended by the EPA's SAB in their 2002 peer review of the EPA's National Air Toxics Assessment (NATA) titled *NATA—Evaluating the National-scale Air Toxics Assessment 1996 Data—an SAB Advisory,* available at *http://yosemite.epa.gov/sab/sabproduct.nsf/214C6E915BB04E14852570CA007A682C/$File/ecadv02001.pdf.*

[10] In the absence of hourly emission data, we develop estimates of maximum hourly emission rates by multiplying the average actual annual emissions rates by a factor (either a category-specific factor or a default factor of 10) to account for variability. This is documented in *Residual Risk Assessment Hydrochloric Acid Production Source Category in Support of the 2018 Risk and Technology Review Proposed Rule* and in Appendix 5 of the report: *Analysis of Data on Short-term Emission Rates Relative to Long-term Emission Rates.* Both are available in the docket for this rulemaking.

[11] CalEPA issues acute RELs as part of its Air Toxics Hot Spots Program, and the 1-hour and 8-hour values are documented in *Air Toxics Hot Spots Program Risk Assessment Guidelines, Part I, The Determination of Acute Reference Exposure Levels for Airborne Toxicants,* which is available at *http://oehha.ca.gov/air/general-info/oehha-acute-8-hour-and-chronic-reference-exposure-level-rel-summary.*

[12] National Academy of Sciences, 2001. *Standing Operating Procedures for Developing Acute Exposure Levels for Hazardous Chemicals,* page 2. Available at *https://www.epa.gov/sites/production/files/2015-09/documents/sop_final_standing_operating_procedures_2001.*pdf. Note that the National Advisory Committee for Acute Exposure Guideline Levels for Hazardous Substances ended in October 2011, but the AEGL program continues to operate at the EPA and works with the National Academies to publish final AEGLs (*https://www.epa.gov/aegl*).

single exposures to chemicals.'' [13] *Id.* at 1. The ERPG–1 is defined as ''the maximum airborne concentration below which it is believed that nearly all individuals could be exposed for up to 1 hour without experiencing other than mild transient adverse health effects or without perceiving a clearly defined, objectionable odor.'' *Id.* at 2. Similarly, the ERPG–2 is defined as ''the maximum airborne concentration below which it is believed that nearly all individuals could be exposed for up to one hour without experiencing or developing irreversible or other serious health effects or symptoms which could impair an individual's ability to take protective action.'' *Id.* at 1.

An acute REL for 1-hour exposure durations is typically lower than its corresponding AEGL–1 and ERPG–1. Even though their definitions are slightly different, AEGL–1s are often the same as the corresponding ERPG–1s, and AEGL–2s are often equal to ERPG–2s. The maximum HQs from our acute inhalation screening risk assessment typically result when we use the acute REL for a HAP. In cases where the maximum acute HQ exceeds 1, we also report the HQ based on the next highest acute dose-response value (usually the AEGL–1 and/or the ERPG–1).

For this source category, we used the default factor of 10 for the acute inhalation screening and refined screening assessment. In our acute inhalation screening risk assessment, acute impacts are deemed negligible for HAP for which acute HQs are less than or equal to 1 (even under the conservative assumptions of the screening assessment), and no further analysis is performed for these HAP. In cases where an acute HQ from the screening step is greater than 1, we consider additional site-specific data to develop a more refined estimate of the potential for acute exposures of concern. For this source category, the data refinements consisted of determining the highest HQ value that occurs outside facility boundaries. These refinements are discussed more fully in the *Residual Risk Assessment for the Hydrochloric Acid Production Source Category in Support of the Risk and Technology Review 2018 Proposed Rule,* which is available in the docket for this source category.

[13] *ERPGS Procedures and Responsibilities,* March 2014. American Industrial Hygiene Association. Available at: *https://www.aiha.org/get-involved/AIHAGuidelineFoundation/EmergencyResponsePlanningGuidelines/Documents/ERPG%20Committee%20Standard%20Operating%20Procedures%20%20-%20March%202014%20Revision%20%28Updated%2010-2-2014%29.pdf.*

4. How do we conduct the multipathway exposure and risk screening assessment?

The EPA conducts a tiered screening assessment examining the potential for significant human health risks due to exposures via routes other than inhalation (*i.e.,* ingestion). We first determine whether any sources in the source category emit any PB–HAP, as identified in the EPA's Air Toxics Risk Assessment Library (See Volume 1, Appendix D, at *http://www2.epa.gov/fera/risk-assessment-and-modeling-air-toxics-risk-assessment-reference-library*).

For the HCl Production source category, we did not identify emissions of any PB–HAP. Because we did not identify PB–HAP emissions, no further evaluation of multipathway risk was conducted for this source category.

5. How do we conduct the environmental risk screening assessment?

a. Adverse Environmental Effect, Environmental HAP, and Ecological Benchmarks

The EPA conducts a screening assessment to examine the potential for an adverse environmental effect as required under section 112(f)(2)(A) of the CAA. Section 112(a)(7) of the CAA defines ''adverse environmental effect'' as ''any significant and widespread adverse effect, which may reasonably be anticipated, to wildlife, aquatic life, or other natural resources, including adverse impacts on populations of endangered or threatened species or significant degradation of environmental quality over broad areas.''

The EPA focuses on eight HAP, which are referred to as ''environmental HAP,'' in its screening assessment: Six PB–HAP and two acid gases. The PB–HAP included in the screening assessment are arsenic compounds, cadmium compounds, dioxins/furans, polycyclic organic matter (POM), mercury (both inorganic mercury and methyl mercury), and lead compounds. The acid gases included in the screening assessment are HCl and hydrogen fluoride (HF).

HAP that persist and bioaccumulate are of particular environmental concern because they accumulate in the soil, sediment, and water. The acid gases, HCl and HF, are included due to their well-documented potential to cause direct damage to terrestrial plants. In the environmental risk screening assessment, we evaluate the following four exposure media: Terrestrial soils, surface water bodies (includes water-column and benthic sediments), fish consumed by wildlife, and air. Within these four exposure media, we evaluate nine ecological assessment endpoints, which are defined by the ecological entity and its attributes. For PB–HAP (other than lead), both community-level and population-level endpoints are included. For acid gases, the ecological assessment evaluated is terrestrial plant communities.

An ecological benchmark represents a concentration of HAP that has been linked to a particular environmental effect level. For each environmental HAP, we identified the available ecological benchmarks for each assessment endpoint. We identified, where possible, ecological benchmarks at the following effect levels: Probable effect levels, lowest-observed-adverse-effect level, and no-observed-adverse-effect level. In cases where multiple effect levels were available for a particular PB–HAP and assessment endpoint, we use all of the available effect levels to help us to determine whether ecological risks exist and, if so, whether the risks could be considered significant and widespread.

For further information on how the environmental risk screening assessment was conducted, including a discussion of the risk metrics used, how the environmental HAP were identified, and how the ecological benchmarks were selected, see Appendix 9 of the *Residual Risk Assessment for the Hydrochloric Acid Production Source Category in Support of the Risk and Technology Review 2018 Proposed Rule,* which is available in the docket for this action.

b. Environmental Risk Screening Methodology

For the environmental risk screening assessment, the EPA first determined whether any facilities in the HCl Production source category emitted any of the environmental HAP. For the HCl Production source category, we identified emissions of HCl. Because one or more of the environmental HAP evaluated (HCl) is emitted by at least one facility in the source category, we proceeded to the second step of the evaluation.

c. PB–HAP Methodology

The environmental screening assessment includes six PB–HAP, arsenic compounds, cadmium compounds, dioxins/furans, POM, mercury (both inorganic mercury and methyl mercury), and lead compounds. With the exception of lead, the environmental risk screening assessment for PB–HAP consists of three tiers. The first tier of the environmental

risk screening assessment uses the same health-protective conceptual model that is used for the Tier 1 human health screening assessment. TRIM.FaTE model simulations were used to back-calculate Tier 1 screening threshold emission rates. The screening threshold emission rates represent the emission rate in tpy that results in media concentrations at the facility that equal the relevant ecological benchmark. To assess emissions from each facility in the category, the reported emission rate for each PB–HAP was compared to the Tier 1 screening threshold emission rate for that PB–HAP for each assessment endpoint and effect level. If emissions from a facility do not exceed the Tier 1 screening threshold emission rate, the facility ''passes'' the screening assessment, and, therefore, is not evaluated further under the screening approach. If emissions from a facility exceed the Tier 1 screening threshold emission rate, we evaluate the facility further in Tier 2.

In Tier 2 of the environmental screening assessment, the screening threshold emission rates are adjusted to account for local meteorology and the actual location of lakes in the vicinity of facilities that did not pass the Tier 1 screening assessment. For soils, we evaluate the average soil concentration for all soil parcels within a 7.5-km radius for each facility and PB–HAP. For the water, sediment, and fish tissue concentrations, the highest value for each facility for each pollutant is used. If emission concentrations from a facility do not exceed the Tier 2 screening threshold emission rate, the facility ''passes'' the screening assessment and typically is not evaluated further. If emissions from a facility exceed the Tier 2 screening threshold emission rate, we evaluate the facility further in Tier 3.

Like in the multipathway human health risk assessment, in Tier 3 of the environmental screening assessment, we examine the suitability of the lakes around the facilities to support life and remove those that are not suitable (*e.g.,* lakes that have been filled in or are industrial ponds), adjust emissions for plume-rise, and conduct hour-by-hour time-series assessments. If these Tier 3 adjustments to the screening threshold emission rates still indicate the potential for an adverse environmental effect (*i.e.,* facility emission rate exceeds the screening threshold emission rate), we may elect to conduct a more refined assessment using more site-specific information. If, after additional refinement, the facility emission rate still exceeds the screening threshold emission rate, the facility may have the potential to cause an adverse environmental effect.

To evaluate the potential for an adverse environmental effect from lead, we compared the average modeled air concentrations (from HEM–3) of lead around each facility in the source category to the level of the secondary National Ambient Air Quality Standards (NAAQS) for lead. The secondary lead NAAQS is a reasonable means of evaluating environmental risk because it is set to provide substantial protection against adverse welfare effects which can include ''effects on soils, water, crops, vegetation, man-made materials, animals, wildlife, weather, visibility and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values and on personal comfort and well-being.''

d. Acid Gas Environmental Risk Methodology

The environmental screening assessment for acid gases evaluates the potential phytotoxicity and reduced productivity of plants due to chronic exposure to HF and HCl. The environmental risk screening methodology for acid gases is a single-tier screening assessment that compares modeled ambient air concentrations (from AERMOD) to the ecological benchmarks for each acid gas. To identify a potential adverse environmental effect (as defined in section 112(a)(7) of the CAA) from emissions of HF and HCl, we evaluate the following metrics: The size of the modeled area around each facility that exceeds the ecological benchmark for each acid gas, in acres and km^2; the percentage of the modeled area around each facility that exceeds the ecological benchmark for each acid gas; and the area-weighted average screening value around each facility (calculated by dividing the area-weighted average concentration over the 50-km modeling domain by the ecological benchmark for each acid gas). For further information on the environmental screening assessment approach, see Appendix 9 of the *Residual Risk Assessment for the Hydrochloric Acid Production Source Category in Support of the Risk and Technology Review 2018 Proposed Rule,* which is available in the docket for this action.

6. How do we conduct facility-wide assessments?

To put the source category risks in context, we typically examine the risks from the entire ''facility,'' where the facility includes all HAP-emitting operations within a contiguous area and under common control. In other words, we examine the HAP emissions not only from the source category emission points of interest, but also emissions of HAP from all other emission sources at the facility for which we have data. For this source category, we conducted the facility-wide assessment using a dataset compiled from the 2014 NEI. The source category records of that NEI dataset were removed, evaluated, and updated as described in section II.C of this preamble: What data collection activities were conducted to support this action? Once a quality assured source category dataset was available, it was placed back with the remaining records from the NEI for that facility. The facility-wide file was then used to analyze risks due to the inhalation of HAP that are emitted ''facility-wide'' for the populations residing within 50 km of each facility, consistent with the methods used for the source category analysis described above. For these facility-wide risk analyses, the modeled source category risks were compared to the facility-wide risks to determine the portion of the facility-wide risks that could be attributed to the source category addressed in this proposal. We also specifically examined the facility that was associated with the highest estimate of risk and determined the percentage of that risk attributable to the source category of interest. The *Residual Risk Assessment for the Hydrochloric Acid Production Source Category in Support of the Risk and Technology Review 2018 Proposed Rule,* available through the docket for this action, provides the methodology and results of the facility-wide analyses, including all facility-wide risks and the percentage of source category contribution to facility-wide risks.

For this source category, we conducted the facility-wide assessment using a dataset that the EPA compiled from the 2014 NEI. We used the NEI data for the facility and did not adjust any category or ''non-category'' data. Therefore, there could be differences in the dataset from that used for the source category assessments described in this preamble. We analyzed risks due to the inhalation of HAP that are emitted ''facility-wide'' for the populations residing within 50 km of each facility, consistent with the methods used for the source category analysis described above. For these facility-wide risk analyses, we made a reasonable attempt to identify the source category risks, and these risks were compared to the facility-wide risks to determine the portion of facility-wide risks that could be attributed to the source category

addressed in this proposal. We also specifically examined the facility that was associated with the highest estimate of risk and determined the percentage of that risk attributable to the source category of interest. The *Residual Risk Assessment for the Hydrochloric Acid Production Source Category in Support of the Risk and Technology Review 2018 Proposed Rule,* available through the docket for this action, provides the methodology and results of the facility-wide analyses, including all facility-wide risks and the percentage of source category contribution to facility-wide risks.

7. How do we consider uncertainties in risk assessment?

Uncertainty and the potential for bias are inherent in all risk assessments, including those performed for this proposal. Although uncertainty exists, we believe that our approach, which used conservative tools and assumptions, ensures that our decisions are health and environmentally protective. A brief discussion of the uncertainties in the RTR emissions dataset, dispersion modeling, inhalation exposure estimates, and dose-response relationships follows below. Also included are those uncertainties specific to our acute screening assessments, multipathway screening assessments, and our environmental risk screening assessments. A more thorough discussion of these uncertainties is included in the *Residual Risk Assessment for the Hydrochloric Acid Production Source Category in Support of the Risk and Technology Review 2018 Proposed Rule,* which is available in the docket for this action. If a multipathway site-specific assessment was performed for this source category, a full discussion of the uncertainties associated with that assessment can be found in Appendix 11 of that document, *Site-Specific Human Health Multipathway Residual Risk Assessment Report.*

a. Uncertainties in the RTR Emissions Dataset

Although the development of the RTR emissions dataset involved quality assurance/quality control processes, the accuracy of emissions values will vary depending on the source of the data, the degree to which data are incomplete or missing, the degree to which assumptions made to complete the datasets are accurate, errors in emission estimates, and other factors. The emission estimates considered in this analysis generally are annual totals for certain years, and they do not reflect short-term fluctuations during the course of a year or variations from year to year. The estimates of peak hourly emission rates for the acute effects screening assessment were based on an emission adjustment factor applied to the average annual hourly emission rates, which are intended to account for emission fluctuations due to normal facility operations.

b. Uncertainties in Dispersion Modeling

We recognize there is uncertainty in ambient concentration estimates associated with any model, including the EPA's recommended regulatory dispersion model, AERMOD. In using a model to estimate ambient pollutant concentrations, the user chooses certain options to apply. For RTR assessments, we select some model options that have the potential to overestimate ambient air concentrations (*e.g.,* not including plume depletion or pollutant transformation). We select other model options that have the potential to underestimate ambient impacts (*e.g.,* not including building downwash). Other options that we select have the potential to either under or overestimate ambient levels (*e.g.,* meteorology and receptor locations). On balance, considering the directional nature of the uncertainties commonly present in ambient concentrations estimated by dispersion models, the approach we apply in the RTR assessments should yield unbiased estimates of ambient HAP concentrations. We also note that the selection of meteorology dataset location could have an impact on the risk estimates. As we continue to update and expand our library of meteorological station data used in our risk assessments, we expect to reduce this variability.

c. Uncertainties in Inhalation Exposure Assessment

Although every effort is made to identify all of the relevant facilities and emission points, as well as to develop accurate estimates of the annual emission rates for all relevant HAP, the uncertainties in our emission inventory likely dominate the uncertainties in the exposure assessment. Some uncertainties in our exposure assessment include human mobility, using the centroid of each census block, assuming lifetime exposure, and assuming only outdoor exposures. For most of these factors, there is neither an under nor overestimate when looking at the maximum individual risk or the incidence, but the shape of the distribution of risks may be affected. With respect to outdoor exposures, actual exposures may not be as high if people spend time indoors, especially for very reactive pollutants or larger particles. For all factors, we reduce uncertainty when possible. For example, with respect to census-block centroids, we analyze large blocks using aerial imagery and adjust locations of the block centroids to better represent the population in the blocks. We also add additional receptor locations where the population of a block is not well represented by a single location.

d. Uncertainties in Dose-Response Relationships

There are uncertainties inherent in the development of the dose-response values used in our risk assessments for cancer effects from chronic exposures and noncancer effects from both chronic and acute exposures. Some uncertainties are generally expressed quantitatively, and others are generally expressed in qualitative terms. We note, as a preface to this discussion, a point on dose-response uncertainty that is stated in the EPA's *2005 Guidelines for Carcinogen Risk Assessment;* namely, that ''the primary goal of EPA actions is protection of human health; accordingly, as an Agency policy, risk assessment procedures, including default options that are used in the absence of scientific data to the contrary, should be health protective'' (EPA's *2005 Guidelines for Carcinogen Risk Assessment,* page 1–7). This is the approach followed here as summarized in the next paragraphs.

Cancer UREs used in our risk assessments are those that have been developed to generally provide an upper bound estimate of risk. That is, they represent a ''plausible upper limit to the true value of a quantity'' (although this is usually not a true statistical confidence limit).[14] In some circumstances, the true risk could be as low as zero; however, in other circumstances the risk could be greater.[15] Chronic noncancer RfC and reference dose (RfD) values represent chronic exposure levels that are intended to be health-protective levels. To derive dose-response values that are intended to be ''without appreciable risk,'' the methodology relies upon an uncertainty factor (UF) approach (U.S. EPA, 1993 and 1994) which considers uncertainty, variability, and gaps in the available data. The UFs are applied to

[14] IRIS glossary (*https://ofmpub.epa.gov/sor_internet/registry/termreg/searchandretrieve/glossariesandkeywordlists/search.do?details=&glossaryName=IRIS%20Glossary*).

[15] An exception to this is the URE for benzene, which is considered to cover a range of values, each end of which is considered to be equally plausible, and which is based on maximum likelihood estimates.

derive dose-response values that are intended to protect against appreciable risk of deleterious effects.

Many of the UFs used to account for variability and uncertainty in the development of acute dose-response values are quite similar to those developed for chronic durations. Additional adjustments are often applied to account for uncertainty in extrapolation from observations at one exposure duration (*e.g.,* 4 hours) to derive an acute dose-response value at another exposure duration (*e.g.,* 1 hour). Not all acute dose-response values are developed for the same purpose, and care must be taken when interpreting the results of an acute assessment of human health effects relative to the dose-response value or values being exceeded. Where relevant to the estimated exposures, the lack of acute dose-response values at different levels of severity should be factored into the risk characterization as potential uncertainties.

Uncertainty also exists in the selection of ecological benchmarks for the environmental risk screening assessment. We established a hierarchy of preferred benchmark sources to allow selection of benchmarks for each environmental HAP at each ecological assessment endpoint. We searched for benchmarks for three effect levels (*i.e.,* no-effects level, threshold effect level, and probable effect level), but not all combinations of ecological assessment/environmental HAP had benchmarks for all three effect levels. Where multiple effect levels were available for a particular HAP and assessment endpoint, we used all of the available effect levels to help us determine whether risk exists and whether the risk could be considered significant and widespread.

Although we make every effort to identify appropriate human health effect dose-response values for all pollutants emitted by the sources in this risk assessment, some HAP emitted by this source category are lacking dose-response assessments. Accordingly, these pollutants cannot be included in the quantitative risk assessment, which could result in quantitative estimates understating HAP risk. To help to alleviate this potential underestimate, where we conclude similarity with a HAP for which a dose-response value is available, we use that value as a surrogate for the assessment of the HAP for which no value is available. To the extent use of surrogates indicates appreciable risk, we may identify a need to increase priority for an IRIS assessment for that substance. We additionally note that, generally speaking, HAP of greatest concern due to environmental exposures and hazard are those for which dose-response assessments have been performed, reducing the likelihood of understating risk. Further, HAP not included in the quantitative assessment are assessed qualitatively and considered in the risk characterization that informs the risk management decisions, including consideration of HAP reductions achieved by various control options.

For a group of compounds that are unspeciated (*e.g.,* glycol ethers), we conservatively use the most protective dose-response value of an individual compound in that group to estimate risk. Similarly, for an individual compound in a group (*e.g.,* ethylene glycol diethyl ether) that does not have a specified dose-response value, we also apply the most protective dose-response value from the other compounds in the group to estimate risk.

e. Uncertainties in Acute Inhalation Screening Assessments

In addition to the uncertainties highlighted above, there are several factors specific to the acute exposure assessment that the EPA conducts as part of the risk review under section 112 of the CAA. The accuracy of an acute inhalation exposure assessment depends on the simultaneous occurrence of independent factors that may vary greatly, such as hourly emissions rates, meteorology, and the presence of humans at the location of the maximum concentration. In the acute screening assessment that we conduct under the RTR program, we assume that peak emissions from the source category and worst-case meteorological conditions co-occur, and, thus, resulting in maximum ambient concentrations. These two events are unlikely to occur at the same time, making these assumptions conservative. We then include the additional assumption that a person is located at this point during this same time period. For this source category, these assumptions would tend to be worst-case actual exposures as it is unlikely that a person would be located at the point of maximum exposure during the time when peak emissions and worst-case meteorological conditions occur simultaneously.

f. Uncertainties in the Multipathway and Environmental Risk Screening Assessments

For each source category, we generally rely on site-specific levels of PB–HAP or environmental HAP emissions to determine whether a refined assessment of the impacts from multipathway exposures is necessary or whether it is necessary to perform an environmental screening assessment. This determination is based on the results of a three-tiered screening assessment that relies on the outputs from models—TRIM.FaTE and AERMOD—that estimate environmental pollutant concentrations and human exposures for five PB–HAP (dioxins, POM, mercury, cadmium, and arsenic) and two acid gases (HCl and hydrogen chloride). For lead, we use AERMOD to determine ambient air concentrations, which are then compared to the secondary NAAQS standard for lead. Two important types of uncertainty associated with the use of these models in RTR risk assessments and inherent to any assessment that relies on environmental modeling are model uncertainty and input uncertainty.[16]

Model uncertainty concerns whether the model adequately represents the actual processes (*e.g.,* movement and accumulation) that might occur in the environment. For example, does the model adequately describe the movement of a pollutant through the soil? This type of uncertainty is difficult to quantify. However, based on feedback received from previous EPA SAB reviews and other reviews, we are confident that the models used in the screening assessments are appropriate and state-of-the-art for the multipathway and environmental screening risk assessments conducted in support of RTR.

Input uncertainty is concerned with how accurately the models have been configured and parameterized for the assessment at hand. For Tier 1 of the multipathway and environmental screening assessments, we configured the models to avoid underestimating exposure and risk. This was accomplished by selecting upper-end values from nationally representative datasets for the more influential parameters in the environmental model, including selection and spatial configuration of the area of interest, lake location and size, meteorology, surface water, soil characteristics, and structure of the aquatic food web. We also assume an ingestion exposure scenario and values for human exposure factors that represent reasonable maximum exposures.

In Tier 2 of the multipathway and environmental screening assessments,

[16] In the context of this discussion, the term ''uncertainty'' as it pertains to exposure and risk encompasses both *variability* in the range of expected inputs and screening results due to existing spatial, temporal, and other factors, as well as *uncertainty* in being able to accurately estimate the true result.

we refine the model inputs to account for meteorological patterns in the vicinity of the facility versus using upper-end national values, and we identify the actual location of lakes near the facility rather than the default lake location that we apply in Tier 1. By refining the screening approach in Tier 2 to account for local geographical and meteorological data, we decrease the likelihood that concentrations in environmental media are overestimated, thereby increasing the usefulness of the screening assessment. In Tier 3 of the screening assessments, we refine the model inputs again to account for hour-by-hour plume rise and the height of the mixing layer. We can also use those hour-by-hour meteorological data in a TRIM.FaTE run using the screening configuration corresponding to the lake location. These refinements produce a more accurate estimate of chemical concentrations in the media of interest, thereby reducing the uncertainty with those estimates. The assumptions and the associated uncertainties regarding the selected ingestion exposure scenario are the same for all three tiers.

For the environmental screening assessment for acid gases, we employ a single-tiered approach. We use the modeled air concentrations and compare those with ecological benchmarks.

For all tiers of the multipathway and environmental screening assessments, our approach to addressing model input uncertainty is generally cautious. We choose model inputs from the upper end of the range of possible values for the influential parameters used in the models, and we assume that the exposed individual exhibits ingestion behavior that would lead to a high total exposure. This approach reduces the likelihood of not identifying high risks for adverse impacts.

Despite the uncertainties, when individual pollutants or facilities do not exceed screening threshold emission rates (*i.e.,* screen out), we are confident that the potential for adverse multipathway impacts on human health is very low. On the other hand, when individual pollutants or facilities do exceed screening threshold emission rates, it does not mean that impacts are significant, only that we cannot rule out that possibility and that a refined assessment for the site might be necessary to obtain a more accurate risk characterization for the source category.

The EPA evaluates the following HAP in the multipathway and/or environmental risk screening assessments, where applicable: Arsenic, cadmium, dioxins/furans, lead, mercury (both inorganic and methyl mercury), POM, HCl, and HF. These HAP represent pollutants that can cause adverse impacts either through direct exposure to HAP in the air or through exposure to HAP that are deposited from the air onto soils and surface waters and then through the environment into the food web. These HAP represent those HAP for which we can conduct a meaningful multipathway or environmental screening risk assessment. For other HAP not included in our screening assessments, the model has not been parameterized such that it can be used for that purpose. In some cases, depending on the HAP, we may not have appropriate multipathway models that allow us to predict the concentration of that pollutant. The EPA acknowledges that other HAP beyond these that we are evaluating may have the potential to cause adverse effects and, therefore, the EPA may evaluate other relevant HAP in the future, as modeling science and resources allow.

IV. Analytical Results and Proposed Decisions

A. What are the results of the risk assessment and analyses?

As described above, for the HCl Production source category, we conducted an inhalation risk assessment and an environmental risk screening assessment on the only two HAP emitted, HCl and Cl_2. No PB–HAP are emitted from this source category; therefore, a multipathway risk assessment was not warranted. We present results of the risk assessment briefly below and in more detail in the residual risk document titled *Residual Risk Assessment for the Hydrochloric Acid Production Source Category in Support of the Risk and Technology Review 2018 Proposed Rule,* which is available in the docket for this action.

1. Inhalation Risk Assessment Results

Table 2 of this preamble provides an overall summary of the results of the inhalation risk assessment.

TABLE 2—INHALATION RISK ASSESSMENT SUMMARY FOR HCL PRODUCTION SOURCE CATEGORY

	Cancer MIR (in 1 million)		Cancer incidence (cases per year)	Population with cancer risk of 1-in-1 million or more	Population with cancer risk of 10-in-1 million or more	Max chronic noncancer HI actuals (and allowables)
	Based on actual emissions	Based on allowable emissions				
Source Category	0	0	0	0	0	0.2 (actuals) 2 (allowables)
Whole Facility	600	.....	0.09	980,000	130,000	6

The inhalation risk modeling performed to estimate risks based on actual emissions relied primarily on emissions data from the NEI. For allowable emissions, the NEI data was used to calculate conservative estimates of emissions. The results of the inhalation cancer risk assessment, as shown in Table 2 of this preamble, indicate there is no quantifiable cancer risk posed by the source category since the two HAP emitted from the HCl Production source category are not known or suspected carcinogens. Neither the EPA nor the International Agency for Research on Cancer (IARC) has evaluated the weight of evidence with respect to human carcinogenicity for Cl_2. However, IARC has determined that hydrogen chloride is not classifiable as a human carcinogen. Likewise, the total estimated cancer incidence is 0 (zero) excess cancer cases per year and no people are estimated to have cancer risk associated with this source category. The maximum modeled chronic noncancer HI (TOSHI) value for the source category based on actual emissions is estimated to be 0.2, driven by emissions of Cl_2 from process vents. The target organ affected is the respiratory system. Exposure to HI levels will be less than 1 for populations in the vicinity of an HCl production facility as a result of emissions from this source category. The maximum chronic noncancer TOSHI would increase when based on allowable emissions, with a TOSHI as high as 2 (respiratory) driven by Cl_2 emissions from process vents at two facilities. Based on allowable emissions, 300 people are estimated to

have a noncancer HI above 1 at these two facilities.

2. Acute Risk Results

The screening and refined analyses for acute impacts was based on actual emissions, and to estimate the peak emission rates from the average rates, a default multiplier of 10 was used for emission points in the source category. The choice of a default multiplier of 10 is discussed in section III.C.3.c of this preamble. The results of the acute refined analysis indicate that the maximum off-facility-site acute HQ is 0.7, based on the REL value for HCl, and occurs at one facility. Refer to the document titled *HCl RTR Modeling File Data Source Documentation* (available in the docket for this action) for a detailed description of how the acute factors were developed for this source category. For more detailed acute risk results, refer to the residual risk document titled *Residual Risk Assessment for the Hydrochloric Acid Production Source Category in Support of the Risk and Technology Review 2018 Proposed Rule,* which is available in the docket for this action.

3. Multipathway Risk Screening Results

No PB–HAP (cadmium, dioxins, POM, mercury, arsenic, and lead) are emitted from this source category. Therefore, a multi-pathway assessment is not warranted.

4. Environmental Risk Screening Results

The only environmental HAP emitted by facilities in this source category is HCl. Results of the analysis for HCl indicate that, based on actual emissions, the maximum annual off-site concentration is below all ecological benchmarks for all facilities. Therefore, we do not expect an adverse environmental effect as a result of HAP emissions from this source category. For more detail on the environmental risk screening assessment, refer to the residual risk document titled *Residual Risk Assessment for the Hydrochloric Acid Production Source Category in Support of the Risk and Technology Review 2018 Proposed Rule,* which is available in the docket for this action.

5. Facility-Wide Risk Results

We performed an assessment of the facility-wide risks to provide context for the source category risks, using NEI data as described above. The maximum facility-wide cancer MIR is 600-in-1 million, mainly driven by ethylene oxide emissions from a variety of industrial processes, none of which are part of this source category. The total estimated cancer incidence from the facility-wide assessment is 0.09 excess cancer cases per year, or one excess case in every 11 years. We estimate that approximately 980,000 people have cancer risks greater than 1-in-1 million from exposure to HAP emitted from sources not subject to the HCl Production NESHAP. We estimate that the maximum facility-wide TOSHI is 6, mainly driven by emissions of trichloroethylene from chemical manufacturing processes that are not part of this source category. The target organs affected are kidney, immunological, developmental, neurological, reproductive, and liver. We estimate that approximately 760 people are exposed to noncancer HI levels above 1, based on facility-wide emissions (not subject to the HCl Production NESHAP) from the 19 facilities within this source category.

6. What demographic groups might benefit from this regulation?

To examine the potential for any environmental justice issues that might be associated with the source category, we performed a demographic analysis, which is an assessment of risk to individual demographic groups of the populations living within 5 km and within 50 km of the facilities. In the analysis, we evaluated the distribution of HAP-related cancer and noncancer risk from the HCl Production source category across different demographic groups within the populations living near facilities.[17]

Results of the demographic analysis indicate that, for 3 of the 11 demographic groups, minorities, African American, and below the poverty level, the percentage of the population living within 5 km of facilities in the source category is greater than the corresponding national percentage for the same demographic groups. When examining the risk levels of those exposed to emissions from HCl production facilities, we find that no one within 50 km (risk modeling domain) is exposed to a cancer risk because the two HAP emitted are not known carcinogens. Furthermore, no person is exposed to a noncancer TOSHI greater than 1 due to HAP emissions from the HCl Production source category.

The methodology and the results of the demographic analysis are presented in a technical report, *Risk and Technology Review—Analysis of Demographic Factors for Populations Living Near Hydrochloric Acid Production,* available in the docket for this action.

B. What are our proposed decisions regarding risk acceptability, ample margin of safety, and adverse environmental effect?

1. Risk Acceptability

As noted in section II.A of this preamble, the EPA sets standards under CAA section 112(f)(2) using ''a two-step standard-setting approach, with an analytical first step to determine an 'acceptable risk' that considers all health information, including risk estimation uncertainty, and includes a presumptive limit on MIR of 'approximately 1-in-10 thousand.' '' See 54 FR 38045, September 14, 1989. We weigh all health risk factors in our risk acceptability determination, including the cancer MIR, cancer incidence, the maximum noncancer TOSHI, the maximum acute noncancer HQ, the extent of noncancer risk, the distribution of cancer and noncancer risk in the exposed population, and the risk estimation uncertainties.

For this risk assessment, the EPA estimated risk based on actual and allowable emissions from HCl production sources. There are no quantifiable cancer risk or cancer incidence associated with this source category. Likewise, a TOSHI less than 1 indicates that the combined HAP affecting a particular target organ are not likely to cause adverse chronic noncancer health effects. Also, the acute refined assessment indicates little potential concern of acute noncancer health impacts. We identified no PB–HAP emitted from the source category, and, thus, no known potential for multi-pathway effects.

Considering all of the health risk information and factors discussed above, including the uncertainties discussed in section III of this preamble, the EPA proposes that the risks from the HCl Production source category are acceptable.

2. Ample Margin of Safety Analysis

As directed by CAA section 112(f)(2), we conducted an analysis to determine if the current emissions standards provide an ample margin of safety to protect public health. Under the ample margin of safety analysis, the EPA considers all health factors evaluated in the risk assessment and evaluates the cost and feasibility of available control technologies and other measures

[17] Demographic groups included in the analysis are: White, African American, Native American, other races and multiracial, Hispanic or Latino, children 17 years of age and under, adults 18 to 64 years of age, adults 65 years of age and over, adults without a high school diploma, people living below the poverty level, people living two times the poverty level, and linguistically isolated people.

(including the controls, measures, and costs reviewed under the technology review) that could be applied to this source category to further reduce the risks (or potential risks) due to emissions of HAP identified in our risk assessment. In this analysis, we considered the results of the technology review, risk assessment, and other aspects of our MACT rule review to determine whether there are any cost-effective controls or other measures that would reduce emissions further to provide an ample margin of safety with respect to the risks associated with these emissions.

As provided in more detail in section IV.D below, we did not identify any developments in processes, practices, or controls for HCl production facilities during our analysis for this proposal. Hydrochloric acid production facilities use scrubbers to control emissions of HCl and Cl_2. These devices are capable of achieving high levels of emission reductions and we did not identify additional technologies capable of further reducing emissions from HCl production facilities or any improvements to the existing technologies that would result in further reduction of emissions. Given that we did not identify any developments in practices, process, or control technologies and the low risks remaining after implementation of the NESHAP, we are proposing that the existing standards for the HCl Production source category provide an ample margin of safety.

Regarding the facility-wide risks due to ethylene oxide and trichloroethylene (described above), which are due to emission sources that are not part of the HCl Production source category, we intend to evaluate those facility-wide estimated emissions and risks further and may address these in a separate future action, as appropriate. In particular, the EPA is addressing ethylene oxide based on the results of the latest NATA released in August 2018, which identified the chemical as a potential concern in several areas across the country. The latest NATA estimates that ethylene oxide significantly contributes to potential elevated cancer risks in some census tracts across the U.S. (less than 1 percent of the total number of tracts). As noted on the EPA's NATA website, NATA is a screening tool for state, local, and tribal air agencies and the EPA suggests that NATA results be used cautiously.[18] These elevated risks are largely driven by an EPA risk value that was updated in late 2016. Although this updated risk value is also responsible for the elevated facility-wide risks calculated here, as noted earlier, these risks are due to emission sources that are not part of the HCl Production source category. Nevertheless, the EPA is interested in receiving public comments on the use of the update risk value for regulatory purposes.

The EPA will work with industry and state, local, and tribal air agencies as the EPA takes a two-pronged approach to address ethylene oxide emissions: (1) Reviewing CAA regulations for facilities that emit ethylene oxide—starting with air toxics emissions standards for miscellaneous organic chemical manufacturing facilities and commercial sterilizers; and (2) getting additional information on ethylene oxide emissions. This information will help the EPA as it evaluates opportunities to reduce ethylene oxide emissions as part of its regulations review, and will help the agency determine whether more immediate emission reduction steps are necessary in any particular locations. The EPA will post updates on its work to address ethylene oxide on its website at: *https://www.epa.gov/ethylene-oxide.*

3. Adverse Environmental Effect

The emissions data for this source category indicate the presence of one environmental HAP, HCl, emitted by sources within this source category. Based on the results of our environmental risk screening assessment, we conclude that there is not an adverse environmental effect as a result of HAP emissions from the HCl Production source category. Thus, we are proposing that it is not necessary to set a more stringent standard to prevent an adverse environmental effect.

C. What are the results and proposed decisions based on our technology review?

We did not identify any developments in processes, practices, or controls for HCl production facilities during our analysis for this proposal. We are not proposing any changes to the NESHAP based on our technology review. Scrubbers are used across the industry to control emissions of HCl and Cl_2, with similar performance among facilities. We reviewed the EPA's RACT/BACT/LAER Clearinghouse to identify possible developments and none were found. Additionally, we reviewed title V permits for all facilities and found no substantive differences in the control strategies employed for HCl production facilities. Finally, a search of peer reviewed literature did not yield any information regarding technology developments for HCl production.

D. What other actions are we proposing?

In addition to the proposed determinations regarding the RTRs described above, we are proposing some revisions to the NESHAP to address other issues. We are proposing revisions to the SSM provisions of the MACT rule in order to ensure that they are consistent with the Court decision in *Sierra Club* v. *EPA,* 551 F. 3d 1019 (D.C. Cir. 2008), which vacated two provisions that exempted sources from the requirement to comply with otherwise applicable CAA section 112(d) emission standards during periods of SSM. We also are proposing various changes to recordkeeping and reporting requirements and adding electronic reporting. Our analyses and proposed changes related to these issues are discussed below.

1. SSM Requirements

In its 2008 decision in *Sierra Club* v. *EPA,* 551 F.3d 1019 (D.C. Cir. 2008), the Court vacated portions of two provisions in the EPA's CAA section 112 regulations governing the emissions of HAP during periods of SSM. Specifically, the Court vacated the SSM exemption contained in 40 CFR 63.6(f)(1) and 40 CFR 63.6(h)(1), holding that under section 302(k) of the CAA, emissions standards or limitations must be continuous in nature and that the SSM exemption violates the CAA's requirement that some CAA section 112 standards apply continuously.

We are proposing the elimination of the SSM exemption in this rule which appears at 40 CFR 63.9005(a). Consistent with *Sierra Club* v. *EPA,* we are proposing standards in this rule that apply at all times. We are also proposing several revisions to Table 7 (the General Provisions Applicability Table) as explained in more detail below. For example, we are proposing to eliminate the incorporation of the General Provisions' requirement that the source develop an SSM plan. We also are proposing to eliminate and revise certain recordkeeping and reporting requirements related to the SSM exemption as further described below.

The EPA has attempted to ensure that the provisions we are proposing to eliminate are inappropriate,

[18] In particular, the EPA has identified limitations to consider when looking at the results (*e.g.,* data gaps, default assumptions, and regional differences in emissions data completeness). A number of other aspects of the results are also worth noting, such as the results apply best to larger areas, not specific places; apply only to the analysis year (when the source data were collected); and assume a person breathes the air toxics emitted in the analysis every day for 70 years. See *https://www.epa.gov/national-air-toxics-assessment/nata-limitations* for a more complete discussion.

unnecessary, or redundant in the absence of the SSM exemption. We are specifically seeking comment on whether we have successfully done so.

In proposing the standards in this rule, the EPA has taken into account startup and shutdown periods. For the reasons explained below, the EPA is not proposing alternate standards for those periods, but is instead proposing that the source meet the otherwise applicable standards during these periods. We have no data indicating that emissions are different during startup or shutdown. For add-on control systems, the HCl Production NESHAP requires the measurement of scrubber flow rate and pH parameter limits apply at all times, including during periods of startup and shutdown. The HCl Production NESHAP requires add-on control device operating parameters to be recorded at least once every 15 minutes. The HCl Production NESHAP specifies in 40 CFR 63.9040(c) that if an operating parameter is out of the allowed range, this is a deviation from the operating limit and must be reported as specified in 40 CFR 63.9050(d).

The EPA is also proposing that the otherwise applicable limits would apply during periods of malfunction. Periods of startup, normal operations, and shutdown are all predictable and routine aspects of a source's operations. Malfunctions, in contrast, are neither predictable nor routine. Instead they are, by definition, sudden, infrequent and not reasonably preventable failures of emissions control, process or monitoring equipment (40 CFR 63.2 [Definition of malfunction]). The EPA interprets CAA section 112 as not requiring emissions that occur during periods of malfunction to be factored into development of CAA section 112 standards and this reading has been upheld as reasonable by the Court in *U.S. Sugar Corp.* v. *EPA,* 830 F.3d 579, 606–610 (2016). Under CAA section 112, emissions standards for new sources must be no less stringent than the level ''achieved'' by the best controlled similar source and emissions standards for existing sources generally must be no less stringent than the average emission limitation ''achieved'' by the best performing 12 percent of sources in the category. There is nothing in CAA section 112 that directs the Agency to consider malfunctions in determining the level ''achieved'' by the best performing sources when setting emission standards. As the Court has recognized, the phrase ''average emissions limitation achieved by the best performing 12 percent of'' sources ''says nothing about how the performance of the best units is to be calculated.'' *Nat'l Ass'n of Clean Water Agencies* v. *EPA,* 734 F.3d 1115, 1141 (D.C. Cir. 2013). While the EPA accounts for variability in setting emissions standards, nothing in CAA section 112 requires the Agency to consider malfunctions as part of that analysis. The EPA is not required to treat a malfunction in the same manner as the type of variation in performance that occurs during routine operations of a source. A malfunction is a failure of the source to perform in a ''normal or usual manner'' and no statutory language compels the EPA to consider such events in setting CAA section 112 standards.

As the Court recognized in *U.S. Sugar Corp,* accounting for malfunctions in setting standards would be difficult, if not impossible, given the myriad different types of malfunctions that can occur across all sources in the category and given the difficulties associated with predicting or accounting for the frequency, degree, and duration of various malfunctions that might occur. *Id.* at 608; ''the EPA would have to conceive of a standard that could apply equally to the wide range of possible boiler malfunctions, ranging from an explosion to minor mechanical defects. Any possible standard is likely to be hopelessly generic to govern such a wide array of circumstances.'' As such, the performance of units that are malfunctioning is not ''reasonably'' foreseeable. See, *e.g. Sierra Club* v. *EPA,* 167 F.3d 658, 662 (D.C. Cir. 1999 [''The EPA typically has wide latitude in determining the extent of data-gathering necessary to solve a problem. We generally defer to an agency's decision to proceed on the basis of imperfect scientific information, rather than to invest the resources to conduct the perfect study].'') See also, *Weyerhaeuser* v. *Costle,* 590 F.2d 1011, 1058 (D.C. Cir. 1978) (''In the nature of things, no general limit, individual permit, or even any upset provision can anticipate all upset situations. After a certain point, the transgression of regulatory limits caused by 'uncontrollable acts of third parties,' such as strikes, sabotage, operator intoxication or insanity, and a variety of other eventualities, must be a matter for the administrative exercise of case-by-case enforcement discretion, not for specification in advance by regulation.''). In addition, emissions during a malfunction event can be significantly higher than emissions at any other time of source operation. For example, if an air pollution control device with 99-percent removal goes off-line as a result of a malfunction (as might happen if, for example, the bags in a baghouse catch fire) and the emission unit is a steady state type unit that would take days to shut down, the source would go from 99-percent control to zero control until the control device was repaired. The source's emissions during the malfunction would be 100 times higher than during normal operations. As such, the emissions over a 4-day malfunction period would exceed the annual emissions of the source during normal operations. As this example illustrates, accounting for malfunctions could lead to standards that are not reflective of (and significantly less stringent than) levels that are achieved by a well-performing non-malfunctioning source. It is reasonable to interpret CAA section 112 to avoid such a result. The EPA's approach to malfunctions is consistent with CAA section 112 and is a reasonable interpretation of the statute.

Although no statutory language compels the EPA to set standards for malfunctions, the EPA has the discretion to do so where feasible. For example, in the Petroleum Refinery Sector Risk and Technology Review, the EPA established a work practice standard for unique types of malfunction that result in releases from pressure relief devices or emergency flaring events because the EPA had information to determine that such work practices reflected the level of control that applies to the best performers. 80 FR 75178, 75211–14 (December 1, 2015). The EPA will consider whether circumstances warrant setting standards for a particular type of malfunction and, if so, whether the EPA has sufficient information to identify the relevant best performing sources and establish a standard for such malfunctions. We also encourage commenters to provide any such information.

In the event that a source fails to comply with the applicable CAA section 112(d) standards as a result of a malfunction event, the EPA would determine an appropriate response based on, among other things, the good faith efforts of the source to minimize emissions during malfunction periods, including preventative and corrective actions, as well as root cause analyses to ascertain and rectify excess emissions. The EPA would also consider whether the source's failure to comply with the CAA section 112(d) standard was, in fact, sudden, infrequent, not reasonably preventable and was not instead caused in part by poor maintenance or careless operation. 40 CFR 63.2 (definition of malfunction).

If the EPA determines in a particular case that an enforcement action against a source for violation of an emission

standard is warranted, the source can raise any and all defenses in that enforcement action and the federal district court will determine what, if any, relief is appropriate. The same is true for citizen enforcement actions. Similarly, the presiding officer in an administrative proceeding can consider any defense raised and determine whether administrative penalties are appropriate.

The EPA is not aware of circumstances that would allow for establishing different emissions standard for some or all malfunctions that may occur at HCl production facilities and, therefore, is not proposing an alternative standard that would apply during periods of malfunction.

In summary, the EPA's interpretation of the CAA and, in particular, CAA section 112, is reasonable and encourages practices that will avoid malfunctions. Administrative and judicial procedures for addressing exceedances of the standards fully recognize that violations may occur despite good faith efforts to comply and can accommodate those situations. *U.S. Sugar Corp.* v. *EPA,* 830 F.3d 579, 606–610 (2016).

2. 40 CFR 63.9005 General Duty

We are proposing to revise the General Provisions table (Table 7) entry for 40 CFR 63.6(e)(1)(i) by changing the ''yes'' in column 3 to a ''no.'' Section 63.6(e)(1)(i) describes the general duty to minimize emissions during periods of SSM. With the elimination of the SSM exemption, there is no need to differentiate between normal operations, startup and shutdown, and malfunction events in describing the general duty. We are proposing instead to add general duty regulatory text at 40 CFR 63.9005(b) that reflects the general duty to minimize emissions during all periods of operation. Therefore, the language the EPA is proposing for 40 CFR 63.9005(b) does not include that language from 40 CFR 63.6(e)(1).

We are also proposing to revise the General Provisions table (Table 7) entry for 40 CFR 63.6(e)(1)(ii) by changing the ''yes'' in column 3 to a ''no.'' This provision requires malfunctions to be corrected as quickly as practicable and minimize emissions consistent with safety and good air pollution control practices. Section 63.6(e)(1)(ii) imposes requirements that are not necessary with the elimination of the SSM exemption or are redundant with the general duty requirement being added at 40 CFR 63.9005(b).

3. SSM Plan

We are proposing to revise the General Provisions table (Table 7) entry for 40 CFR 63.6(e)(3) by changing the ''yes'' in column 3 to a ''no.'' Generally, these paragraphs require development of an SSM plan and specify SSM recordkeeping and reporting requirements related to the SSM plan. As noted, the EPA is proposing to remove the SSM exemptions. Therefore, affected units will be subject to an emission standard during such events. The applicability of a standard during such events will ensure that sources have ample incentive to plan for and achieve compliance as they do during periods of normal operation and, thus, planning requirements specific for SSM are no longer necessary.

4. Compliance With Standards

We are proposing to revise the General Provisions table (Table 7) entry for 40 CFR 63.6(f)(1) by changing the ''yes'' in column 3 to a ''no.'' The current language of 40 CFR 63.6(f)(1) exempts sources from non-opacity standards during periods of SSM. As discussed above, the Court in *Sierra Club* vacated the exemptions contained in 40 CFR 63.6(f)(1) and held that the CAA requires a standard to apply continuously. Consistent with *Sierra Club,* the EPA is proposing to revise standards in this rule to apply at all times.

5. 40 CFR 63.9020 Performance Testing

We are proposing to revise the General Provisions table (Table 7) entry for 40 CFR 63.7(e)(1) by changing the ''yes'' in column 3 to a ''no.'' Section 63.7(e)(1) describes performance testing requirements. The EPA is instead proposing to add a performance testing requirement at 40 CFR 63.9020(a)(3). The performance testing requirements we are proposing to add differ from the General Provisions performance testing provisions in several respects. Specifically, the new proposed performance testing requirements do not include the language in 40 CFR 63.7(e)(1) restating the SSM exemption. However, we are including similar language that precludes startup and shutdown periods from being considered ''representative'' for purposes of performance testing. As provided in 40 CFR 63.7(e)(1), we are including language in 40 CFR 63.9020(a)(3) providing that performance tests conducted under this subpart should not be conducted during malfunctions. This is because conditions during malfunctions are often not representative of normal operating conditions. The EPA is proposing to add language that requires the owner or operator to record the process information that is necessary to document operating conditions during the test and include in such records an explanation to support that such conditions represent normal operation. Section 63.7(e) requires that the owner or operator make available upon request by the Administrator such records ''as may be necessary to determine the condition of the performance test,'' but does not specifically require the information to be recorded. The regulatory text the EPA is proposing to add to this provision builds on that requirement and makes explicit the requirement to record the information.

6. Monitoring

We are proposing to revise the General Provisions table (Table 7) entry for 40 CFR 63.8(c)(1)(i) and (c)(1)(iii) by changing the ''yes'' in column 3 to a ''no.'' The cross-references to the general duty and SSM plan requirements in those subparagraphs are not necessary in light of the removal of the SSM exemption and other requirements of 40 CFR 63.8 that require good air pollution control practices (40 CFR 63.8(c)(1)) and that set out the requirements of a quality control program for monitoring equipment (40 CFR 63.8(d)).

We are proposing to revise the General Provisions table (Table 7) entry for 40 CFR 63.8(d)(3) by changing the ''yes'' in column 3 to a ''no.'' The final sentence in 40 CFR 63.8(d)(3) refers to the General Provisions' SSM plan requirement which is no longer applicable. The EPA is proposing to add to the rule at 40 CFR 63.9005(d)(5) text that is identical to 40 CFR 63.8(d)(3) except that the final sentence is replaced with the following sentence: ''The program of corrective action should be included in the plan required under § 63.8(d)(2).''

7. 40 CFR 63.9055 Recordkeeping

We are proposing to revise the General Provisions table (Table 7) entry for 40 CFR 63.10(b)(2)(i) by changing the ''yes'' in column 3 to a ''no.'' Section 63.10(b)(2)(i) describes the recordkeeping requirements during startup and shutdown. These recording provisions are no longer necessary because the EPA is proposing that recordkeeping and reporting applicable to normal operations will apply during startup and shutdown. In the absence of special provisions applicable to startup and shutdown, such as a startup and shutdown plan, there is no reason to

retain recordkeeping for startup and shutdown periods separate from the requirement that applies during normal operation.

We are proposing to revise the General Provisions table (Table 7) entry for 40 CFR 63.10(b)(2)(ii) by changing the ''yes'' in column 3 to a ''no.'' Section 63.10(b)(2)(ii) describes the recordkeeping requirements during a malfunction. The EPA is proposing to add such requirements to 40 CFR 63.9055. The regulatory text we are proposing to add differs from the General Provisions it is replacing; the General Provisions require the creation and retention of a record of the occurrence and duration of each malfunction of process, air pollution control, and monitoring equipment. The EPA is proposing that this requirement apply to any failure to meet an applicable standard and is requiring that the source record the date, time, and duration of the failure rather than the ''occurrence.'' The EPA is also proposing to add to 40 CFR 63.9055 a requirement that sources keep records that include a list of the affected source or equipment and actions taken to minimize emissions, an estimate of the quantity of each regulated pollutant emitted over the standard for which the source failed to meet the standard, and a description of the method used to estimate the emissions. Examples of such methods would include product-loss calculations, mass balance calculations, measurements when available, or engineering judgment based on known process parameters. The EPA is proposing to require that sources keep records of this information to ensure that there is adequate information to allow the EPA to determine the severity of any failure to meet a standard, and to provide data that may document how the source met the general duty to minimize emissions when the source has failed to meet an applicable standard.

We are proposing to revise the General Provisions table (Table 7) entry for 40 CFR 63.10(b)(2)(iv) by changing the ''yes'' in column 3 to a ''no.'' When applicable, the provision requires sources to record actions taken during SSM events when those actions were inconsistent with their SSM plan. The requirement is no longer appropriate if the EPA finalizes its proposal that SSM plans will no longer be required. The requirement previously applicable under 40 CFR 63.10(b)(2)(iv)(B) to record actions to minimize emissions and record corrective actions is now applicable in 40 CFR 63.9055.

We are proposing to revise the General Provisions table (Table 7) entry for 40 CFR 63.10(b)(2)(v) by changing the ''yes'' in column 3 to a ''no.'' When applicable, the provision requires sources to record actions taken during SSM events to show that actions taken were consistent with their SSM plan. The requirement is no longer appropriate because SSM plans will no longer be required.

8. 40 CFR 63.9050 Reporting

We are proposing to revise the General Provisions table (Table 7) entry for 40 CFR 63.10(d)(5) by changing the ''yes'' in column 3 to a ''no.'' Section 63.10(d)(5) describes the reporting requirements for startups, shutdowns, and malfunctions. To replace the General Provisions reporting requirement, the EPA is proposing to add reporting requirements to 40 CFR 63.9050(c)(5). The replacement language differs from the General Provisions requirement in that it eliminates periodic SSM reports as a stand-alone report. We are proposing language that requires sources that fail to meet an applicable standard at any time to report the information concerning such events in the semi-annual compliance report already required in 40 CFR 63.9050. We are proposing that the report must contain the number, date, time, duration, and the cause of such events (including unknown cause, if applicable), a list of the affected source or equipment, an estimate of the quantity of each regulated pollutant emitted over any emission limit, and a description of the method used to estimate the emissions.

Examples of such methods would include product-loss calculations, mass balance calculations, measurements when available, or engineering judgment based on known process parameters. The EPA is proposing this requirement to ensure that there is adequate information to determine compliance, to allow the EPA to determine the severity of the failure to meet an applicable standard, and to provide data that may document how the source met the general duty to minimize emissions during a failure to meet an applicable standard.

The proposed amendments eliminate the cross reference to 40 CFR 63.10(d)(5)(i) that contains the description of the previously required SSM report format and submittal schedule. These specifications are no longer necessary because the events will be reported in otherwise required reports with similar format and submittal requirements.

We are proposing to revise the General Provisions table (Table 7) entry for 40 CFR 63.10(d)(5)(ii) by changing the ''yes'' in column 3 to a ''no.'' Section 63.10(d)(5)(ii) describes an immediate report for startups, shutdown, and malfunctions when a source failed to meet an applicable standard, but did not follow the SSM plan. We will no longer require owners and operators to report when actions taken during a startup, shutdown, or malfunction were not consistent with an SSM plan, because plans would no longer be required.

We are proposing to revise the General Provisions table (Table 7) entry for 40 CFR 63.10(c)(15) by changing the ''yes'' in column 3 to a ''no.'' The EPA is proposing that 40 CFR 63.10(c)(15) no longer apply. When applicable, the provision allows an owner or operator to use the affected source's SSM plan or records kept to satisfy the recordkeeping requirements of the SSM plan, specified in 40 CFR 63.6(e), to also satisfy the requirements of 40 CFR 63.10(c)(10) through (12). The EPA is proposing to eliminate this requirement because SSM plans would no longer be required, and, therefore, 40 CFR 63.10(c)(15) would no longer be available to satisfy the requirements of 40 CFR 63.10(c)(10) through (12).

9. Electronic Reporting

Through this proposal, the EPA is proposing that owners and operators of HCl production facilities submit electronic copies of required performance test reports, performance evaluations, notifications of compliance status, site-specific monitoring plans, and semiannual compliance reports through the EPA's Central Data Exchange (CDX) using the Compliance and Emissions Data Reporting Interface (CEDRI). A description of the electronic data submission process is provided in the memorandum, *Electronic Reporting Requirements for New Source Performance Standards (NSPS) and National Emission Standards for Hazardous Air Pollutants (NESHAP) Rules,* available in Docket ID No. EPA–HQ–OAR–2018–0417. The proposed rule requires that performance test results collected using test methods that are supported by the EPA's Electronic Reporting Tool (ERT) as listed on the ERT website [19] at the time of the test be submitted in the format generated through the use of the ERT and that other performance test results be submitted in portable document format (PDF) using the attachment module of the ERT. Similarly, we are proposing that performance evaluation results of continuous monitoring systems and other performance evaluation results be

[19] *https://www.epa.gov/electronic-reporting-air-emissions/electronic-reporting-tool-ert.*

submitted in PDF using the attachment module of the ERT.

For performance test reports, performance evaluations, and semiannual compliance reports, the proposed rule requires that owners and operators submit information to CEDRI using the appropriate spreadsheet template. A draft version of the proposed templates for these reports is included in the docket for this rulemaking.[20] The EPA specifically requests comment on the content, layout, and overall design of the templates.

Additionally, the EPA has identified two broad circumstances in which electronic reporting extensions may be provided. In both circumstances, the decision to accept the claim of needing additional time to report is within the discretion of the Administrator, and reporting should occur as soon as possible. The EPA is providing these potential extensions to protect owners and operators from noncompliance in cases where they cannot successfully submit a report by the reporting deadline for reasons outside of their control. First, the situation where an extension may be warranted due to outages of the EPA's CDX or CEDRI, which precludes an owner or operator from accessing the system and submitting required reports, is addressed in 40 CFR 63.9050(m). Second, the situation where an extension may be warranted due to a force majeure event, which 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 an owner or operator from complying with the requirement to submit a report electronically as required by this rule, is addressed in 40 CFR 63.9050(n). Examples of such events are acts of nature, acts of war or terrorism, or equipment failure or safety hazards beyond the control of the facility.

The electronic submittal of the reports addressed in this proposed 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. Moreover, electronic reporting is consistent with the EPA's plan[21] to implement Executive Order 13563 and is in keeping with the EPA's agency-wide policy[22] developed in response to the White House's Digital Government Strategy.[23] For more information on the benefits of electronic reporting, see the memorandum, *Electronic Reporting Requirements for New Source Performance Standards (NSPS) and National Emission Standards for Hazardous Air Pollutants (NESHAP) Rules,* available in Docket ID No. EPA–HQ–OAR–2018–0417.

E. What compliance dates are we proposing?

The EPA is proposing that existing affected sources and affected sources that commenced construction or reconstruction on or before February 4, 2019 must comply with all of the amendments no later than 180 days after the effective date of the final rule. The final action is not expected to be a ''major rule'' as defined by 5 U.S.C. 804(2), so the effective date of the final rule will be the promulgation date as specified in CAA section 112(d)(10). For existing sources, we are proposing a change that would impact ongoing compliance requirements for 40 CFR part 63, subpart NNNNN. As discussed elsewhere in this preamble, we are proposing to change the requirements for SSM by removing the exemption from the requirements to meet the standard during SSM periods and by removing the requirement to develop and implement an SSM plan. Our experience with similar industries shows that this sort of regulated facility generally requires a time period of 180 days to read and understand the amended rule requirements; to evaluate their operations to ensure that they can meet the standards during periods of startup and shutdown as defined in the rule and make any necessary adjustments; and to update their operations to reflect the revised requirements. From our assessment of the timeframe needed for compliance with the revised requirements, the EPA considers a period of 180 days to be the most expeditious compliance period practicable, and, thus, is proposing that existing affected sources be in compliance with this regulation's revised requirements within 180 days of the regulation's effective date. We solicit comment on this proposed compliance period, and we specifically request submission of information from sources in this source category regarding specific actions that would need to be undertaken to comply with the proposed amended requirements, including the proposed amendments related to recordkeeping and reporting and the time needed to make the adjustments for compliance with them. We note that information provided may result in changes to the proposed compliance date. Affected sources that commence construction or reconstruction after February 4, 2019 must comply with all requirements of the subpart, including the amendments being proposed, no later than the effective date of the final rule or upon startup, whichever is later. All affected facilities would have to continue to meet the current requirements of 40 CFR part 63, subpart NNNNN, until the applicable compliance date of the amended rule.

V. Summary of Cost, Environmental, and Economic Impacts

A. What are the affected sources?

We anticipate that 19 HCl production facilities currently operating in the United States will be affected by these proposed amendments. The basis for our estimate of affected facilities are provided in the memorandum, *Industry Characterization for the Hydrochloric Acid Production NESHAP Residual Risk and Technology Review,* which is available in the docket for this action. We are not currently aware of any planned or potential new or reconstructed HCl production facilities.

B. What are the air quality impacts?

We do not anticipate that the proposed amendments to this subpart will impact air quality. We are not proposing changes to the standard that

[20] See *Electronic Reporting Templates for Hydrochloric Acid Production, Subpart NNNNN,* available at Docket ID No. EPA–HQ–OAR–2018–0417.

[21] EPA's *Final Plan for Periodic Retrospective Reviews,* August 2011. Available at: *https://www.regulations.gov/document?D=EPA-HQ-OA-2011-0156-0154.*

[22] *E-Reporting Policy Statement for EPA Regulations,* September 2013. Available at: *https://www.epa.gov/sites/production/files/2016-03/documents/epa-ereporting-policy-statement-2013-09-30.pdf.*

[23] *Digital Government: Building a 21st Century Platform to Better Serve the American People,* May 2012. Available at: *https://obamawhitehouse.archives.gov/sites/default/files/omb/egov/digital-government/digital-government.html.*

will result in additional emission reductions beyond the levels already achieved by the NESHAP.

C. What are the cost impacts?

The cost impacts from these proposed amendments are savings in costs to affected production facilities. One way to present cost estimates is in present value (PV terms). The PV for these proposed amendments is equal to a savings of $84,514 at a discount rate of 3 percent and a savings of $62,136 at a discount rate of 7 percent, discounted to 2016. The equivalent annualized value, which is an annualized value consistent with the PV estimates, is equal to $22,736 at a discount rate of 3 percent and $18,344 at a discount rate of 7 percent (2016 dollars). These calculations are documented in the Economic Impact Analysis for the Proposed HCl Production RTR, which is available in the docket for this rulemaking.

D. What are the economic impacts?

With cost savings occurring for affected facilities, we do not anticipate the proposed amendments to yield adverse economic impacts, including negative impacts on employment.

E. What are the benefits?

As discussed above, we do not anticipate the proposed amendments to this subpart to impact air quality. The electronic submittal of the reports addressed in this proposed 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.

VI. Request for Comments

We solicit comments on all aspects of this proposed action. In addition to general comments on this proposed action, we are also interested in additional data that may improve the risk assessments and other analyses. We are specifically interested in receiving any improvements to the data used in the site-specific emissions profiles used for risk modeling. Such data should include supporting documentation in sufficient detail to allow characterization of the quality and representativeness of the data or information. Section VII of this preamble provides more information on submitting data.

Prior to publication of this proposal, Dow Chemical submitted several suggestions for changes to the HCl Production NESHAP. Most of these changes relate to monitoring, recordkeeping, and reporting requirements. The correspondence from Dow,[24] including their suggested regulatory language, are available in the docket for this action. We are specifically seeking comment on one issue raised by Dow in their May 30, 2018, correspondence, which is available in the docket for this action. Dow states that a definition for ''maintenance vents'' should be added to the rule if the exemptions for periods of SSM are removed.[25] Dow claims that regular maintenance activities require opening equipment after the equipment is cleaned and purged, presumably during periods that the equipment is being shut down which would previously be exempt from the emissions limits, and that these activities that only emit to the atmosphere during periods of maintenance or inspection would become subject to the requirements of the NESHAP if the exemption is removed. Dow recommends that certain emission points that exist due solely to maintenance and inspection of equipment be defined as maintenance vents and that EPA set work practice standards that require thoroughly purging and degassing the equipment to a control device prior to opening it to the atmosphere. They submitted recommended regulatory text for the definition of ''maintenance vent'' and corresponding work practices. We are seeking comment on:

- The necessity of this change for the HCl Production NESHAP in light of our proposed removal of the SSM exemptions;
- The estimated frequency of these maintenance activities;
- The cost associated with making (or not making) this change;
- The emissions impact of making (or not making) this change;
- Whether the regulatory language recommended by Dow reflects the best performers across the industry; and
- Whether it is feasible to set a numerical emission limit rather than a work practice standard, as Dow suggests.

VII. Submitting Data Corrections

The site-specific emissions profiles used in the source category risk and demographic analyses and instructions are available for download on the RTR website at *https://www3.epa.gov/ttn/atw/rrisk/rtrpg.html.* The data files include detailed information for each HAP emissions release point for the facilities in the source category.

If you believe that the data are not representative or are inaccurate, please identify the data in question, provide your reason for concern, and provide any ''improved'' data that you have, if available. When you submit data, we request that you provide documentation of the basis for the revised values to support your suggested changes. To submit comments on the data downloaded from the RTR website, complete the following steps:

1. Within this downloaded file, enter suggested revisions to the data fields appropriate for that information.

2. Fill in the commenter information fields for each suggested revision (*i.e.,* commenter name, commenter organization, commenter email address, commenter phone number, and revision comments).

3. Gather documentation for any suggested emissions revisions (*e.g.,* performance test reports, material balance calculations).

4. Send the entire downloaded file with suggested revisions in Microsoft® Access format and all accompanying documentation to Docket ID No. EPA–HQ–OAR–2018–0417 (through the method described in the **ADDRESSES** section of this preamble).

5. If you are providing comments on a single facility or multiple facilities, you need only submit one file for all facilities. The file should contain all suggested changes for all sources at that facility (or facilities). We request that all data revision comments be submitted in the form of updated Microsoft® Excel files that are generated by the Microsoft® Access file. These files are provided on the RTR website at *https://www3.epa.gov/ttn/atw/rrisk/rtrpg.html.*

[24] Emails from Russell Wozniak to Nathan Topham, dated May 30, 2018, and September 24, 2018. Available in the docket for this action, Docket ID No. EPA–HQ–OAR–2018–0417.

[25] In section IV.D, above, the EPA has proposed to remove the SSM exemptions in the HCl Production NESHAP.

VIII. Statutory and Executive Order Reviews

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

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

This action is not a significant regulatory action and was, therefore, not submitted to OMB for review.

B. Executive Order 13771: Reducing Regulation and Controlling Regulatory Costs

This action is not expected to be 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 proposed rule have been submitted for approval to OMB under the PRA. The Information Collection Request (ICR) document that the EPA prepared has been assigned EPA ICR number 2032.09. You can find a copy of the ICR in the docket for this rule, and it is briefly summarized here.

We are proposing changes to the recordkeeping and reporting requirements associated with 40 CFR part 63, subpart NNNNN, in the form of eliminating the SSM plan and reporting requirements and adding electronic reporting.

Respondents/affected entities: The respondents to the recordkeeping and reporting requirements are owners or operators of facilities that produce HCl subject to 40 CFR part 63, subpart NNNNN.

Respondent's obligation to respond: Mandatory (40 CFR part 63, subpart NNNNN).

Estimated number of respondents: Nineteen (19) facilities.

Frequency of response: Initially and semiannually.

Total estimated burden: The annual recordkeeping and reporting burden for responding facilities to comply with all of the requirements in the NESHAP, averaged over the 3 years of this ICR, is estimated to be 22,000 hours (per year). These proposed amendments reflect 314 hours (per year) in reduced burden to comply with the rule due to the removal of SSM recordkeeping/reporting requirements and the addition of electronic reporting. Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: The annual recordkeeping and reporting cost for responding facilities to comply with all of the requirements in the NESHAP, averaged over the 3 years of this ICR, is estimated to be $2,200,000 (rounded, per year), including $754,000 annualized capital or operation and maintenance costs. This results in a decrease of $17,000 (rounded, per year) to comply with the proposed amendments to the rule.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. 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_submission@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 March 6, 2019. The EPA will respond to any ICR-related comments in the 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 among the 14 ultimate parent companies impacted by this proposed action given the Small Business Administration small business size definition for this industry (1,000 employees or greater for NAICS 325180), and no significant economic impact on any of these entities.

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. No tribal facilities are known to be engaged in HCl production processes that would be affected by this action. Thus, Executive Order 13175 does not apply to this action.

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

This action is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866, and because 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 IV.A and B of this preamble.

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 action involves technical standards. Therefore, the EPA conducted a search to identify potentially applicable voluntary consensus standards. However, the Agency identified no such standards. A thorough summary of the search conducted and results are included in the memorandum titled *Voluntary Consensus Standard Results for Hydrochloric Acid Production Residual Risk and Technology Review,* which is available in the docket for this action.

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 IV.A.6 of this preamble and the technical report, *Hydrochloric Acid Production*

Demographic Analysis, which is available in the docket for this action.

List of Subjects in 40 CFR Part 63

Environmental protection, Air pollution control, Hazardous substances, Reporting and recordkeeping requirements.

Dated: December 20, 2018.

Andrew R. Wheeler,

Acting Administrator.

For the reasons stated in the preamble, the EPA proposes to amend title 40, chapter I, part 63 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.*

Subpart NNNNN—National Emission Standards for Hazardous Air Pollutants for Hydrochloric Acid Production

■ 2. Section 63.8985 is amended by revising paragraph (f) to read as follows:

§ 63.8985 Am I subject to this subpart?

* * * * *

(f) An HCl production facility is not subject to this subpart if all of the gaseous streams containing HCl and chlorine (Cl_2) from HCl process vents, HCl storage tanks, and HCl transfer operations are recycled or routed to another process for process purpose, prior to being discharged to the atmosphere.

■ 3. Section 63.9005 is amended by revising paragraphs (a)–(c) and (d)(4)–(6) to read as follows:

§ 63.9005 What are my general requirements for complying with this subpart?

(a) Before [DATE 181 DAYS AFTER PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**], for each existing source, and for each new or reconstructed source for which construction or reconstruction commenced after April 17, 2003, but before February 5, 2019, you must be in compliance with the emission limitations and work practice standards in this subpart at all times, except during periods of startup, shutdown, and malfunction. After [DATE 180 DAYS AFTER PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**], for each such source you must be in compliance with the emission limitations in this subpart at all times. For new and reconstructed sources for which construction or reconstruction commenced after February 4, 2019, you must be in compliance with the emissions limitations in this subpart at all times.

(b) Before [DATE 181 DAYS AFTER PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**], for each existing source, and for each new or reconstructed source for which construction or reconstruction commenced after April 17, 2003, but before February 5, 2019, you must always operate and maintain your affected source, including air pollution control and monitoring equipment, according to the provisions in § 63.6(e)(1)(i). After [DATE 180 DAYS AFTER PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**] for each such source, and after [DATE OF PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**] for new and reconstructed sources for which construction or reconstruction commenced after February 4, 2019, at all times you 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 you 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.

(c) Before [DATE 181 DAYS AFTER PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**], for each existing source, and for each new or reconstructed source for which construction or reconstruction commenced after April 17, 2003, but before February 5, 2019, you must develop a written startup, shutdown, and malfunction plan according to the provisions in § 63.6(e)(3). For each such source, a startup, shutdown, and malfunction plan is not required after [DATE 180 DAYS AFTER PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**]. No startup, shutdown, and malfunction plan is required for any new or reconstructed source for which construction or reconstruction commenced after February 4, 2019.

(d) * * *

(4) Before [DATE 181 DAYS AFTER PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**], for each existing source, and for each new or reconstructed source for which construction or reconstruction commenced after April 17, 2003, but before February 5, 2019, ongoing operation and maintenance (O&M) procedures in accordance with the general requirements of §§ 63.8(c)(1), (3), (4)(ii), (7), and (8), and 63.9025. After [DATE 180 DAYS AFTER PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**] for each such source, and after [DATE OF PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**] for new and reconstructed sources for which construction or reconstruction commenced after February 4, 2019, ongoing operation and maintenance (O&M) procedures in accordance with the general requirements of §§ 63.8(c)(1)(ii), (3), (4)(ii), (7), and (8), and 63.9025.

(5) Before [DATE 181 DAYS AFTER PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**], for each existing source, and for each new or reconstructed source for which construction or reconstruction commenced after April 17, 2003, but before February 5, 2019, ongoing data quality assurance procedures in accordance with the general requirements of § 63.8(d). After [DATE 180 DAYS AFTER PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**] for each such source, and after [DATE OF PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**] for new and reconstructed sources for which construction or reconstruction commenced after [February 4, 2019, ongoing data quality assurance procedures in accordance with the general requirements of § 63.8(d) except for the requirements related to startup, shutdown, and malfunction plans referenced in § 63.8(d)(3). The owner or operator shall 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, to be made available for inspection, upon request, by the Administrator. If the performance evaluation plan is revised, the owner or operator shall 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 to the plan. The program of corrective action should be included in the plan required under § 63.8(d)(2).

(6) Before [DATE 181 DAYS AFTER PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**], for each existing source, and for each new or reconstructed source for which construction or reconstruction commenced after April 17, 2003, but before February 5, 2019, ongoing recordkeeping and reporting procedures in accordance with the general requirements of § 63.10(c) and (e)(1) and (2)(i). After [DATE 180 DAYS AFTER PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**] for each such source, and after [DATE OF PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**] for new and reconstructed sources for which construction or reconstruction commenced after February 4, 2019, ongoing recordkeeping and reporting procedures in accordance with the general requirements of § 63.10(c)(1) through (c)(14), and (e)(1) and (2)(i).

■ 4. Section 63.9020 is amended by revising paragraphs (a)(2) and (a)(3) to read as follows:

§ 63.9020 What performance tests and other procedures must I use?

(a) * * *

(2) Before [DATE 181 DAYS AFTER PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**], for each existing source, and for each new or reconstructed source for which construction or reconstruction commenced after April 17, 2003, but before February 5, 2019, you must conduct each performance test under representative conditions according to the requirements in § 63.7(e)(1) and under the specific conditions that this subpart specifies in Table 3. After [DATE 180 DAYS AFTER PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**] for each such source, and after [DATE OF PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**] for new and reconstructed sources for which construction or reconstruction commenced after February 4, 2019, you must conduct each performance test under conditions representative of normal operations. The owner or operator must record the process information that is necessary to document operating conditions during the test and include in such record an explanation to support that such conditions represent normal operation. Upon request, the owner or operator shall make available to the Administrator such records as may be necessary to determine the conditions of performance tests.

(3) You may not conduct performance tests during periods of startup, shutdown, or malfunction.

* * * * *

■ 5. Section 63.9025 is amended by revising paragraph (a)(3) to read as follows:

§ 63.9025 What are my monitoring installation, operation, and maintenance requirements?

(a) * * *

(3) For at least 75 percent of the operating hours in a 24-hour period, you must have valid data (as defined in your site-specific monitoring plan) for at least 4 equally spaced periods each hour.

* * * * *

■ 6. Section 63.9030 is amended by revising paragraph (c) to read as follows:

§ 63.9030 How do I demonstrate initial compliance with the emission limitations and work practice standards?

* * * * *

(c) For existing sources and for new or reconstructed sources which commenced construction or reconstruction after April 17, 2003, but before February 5, 2019, before [DATE 181 DAYS AFTER PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**], You must submit the Notification of Compliance Status containing the results of the initial compliance demonstration according to the requirements in § 63.9045(f)-(g). After [DATE 180 DAYS AFTER PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**] for such sources, and after [DATE OF PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**] for new or reconstructed sources which commence construction or reconstruction after February 4, 2019, you must submit the Notification of Compliance Status containing the results of the initial compliance demonstration according to the requirements in § 63.9045(f)–(g) and § 63.9050(d).

■ 7. Section 63.9040 is amended by revising paragraph (e) to read as follows:

§ 63.9040 How do I demonstrate continuous compliance with the emission limitations and work practice standards?

* * * * *

(e) For existing sources and for new or reconstructed sources which commenced construction or reconstruction after April 17, 2003, but before February 5, 2019, before [DATE 181 DAYS AFTER PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**], consistent with §§ 63.6(e) and 63.7(e)(1), deviations that occur during a period of startup, shutdown, or malfunction are not violations if you demonstrate to the Administrator's satisfaction that you were operating in accordance with § 63.6(e)(1). The Administrator will determine whether deviations that occur during a period of startup, shutdown, or malfunction are violations, according to the provisions in § 63.6(e). After [DATE 180 DAYS AFTER PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**] for such sources, and after [DATE OF PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**] for new and reconstructed sources which commence construction or reconstruction after February 4, 2019, the exemptions for periods of startup, shutdown, and malfunction in § 63.6(e) no longer apply.

■ 8. Section 63.9045 is amended by revising paragraph (f) to read as follows:

§ 63.9045 What notifications must I submit and when?

* * * * *

(f) You must submit the Notification of Compliance Status, including the performance test results, within 180 calendar days after the applicable compliance dates specified in § 63.8995.

* * * * *

■ 9. Section 63.9050 is amended by revising paragraphs (a), (c)(4), (c)(5), (d) introductory text, (f) introductory text and adding paragraphs (g) through (n).

§ 63.9050 What reports must I submit and when?

(a) You must submit a compliance report that includes the information in § 63.9050(c) through (e), as applicable, as specified in Table 6 to this subpart.

* * * * *

(c) * * *

(4) For existing sources and for new or reconstructed sources for which construction or reconstruction commenced after April 17, 2003, but before February 5, 2019, before [DATE 181 DAYS AFTER PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**], if you had a startup, shutdown, or malfunction during the reporting period and you took actions consistent with your startup, shutdown, and malfunction plan, the compliance report must include the information in § 63.10(d)(5)(i). A startup, shutdown, and malfunction plan and the information in § 63.10(d)(5)(i) is not required after [DATE 180 DAYS AFTER PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**].

(5) For existing sources and for new or reconstructed sources which commenced construction or reconstruction after April 17, 2003, but before February 5, 2019, before [DATE 181 DAYS AFTER PUBLICATION OF

FINAL RULE IN THE **FEDERAL REGISTER**], if there are no deviations from any emission limitations that apply to you, a statement that there were no deviations from the emission limitations during the reporting period.

* * * * *

(d) For each deviation from an emission limitation occurring at an affected source where you are using a CMS to comply with the emission limitation in this subpart, you must include the information in paragraphs (c)(1) through (6) of this section and the following information in paragraphs (d)(1) through (9) of this section and § 63.10(e)(3)(vi). This includes periods of startup, shutdown, and malfunction.

* * * * *

(f) For existing sources and for new or reconstructed sources which commenced construction or reconstruction after April 17, 2003, but before February 5, 2019, before [DATE 181 DAYS AFTER PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**], for each startup, shutdown, or malfunction during the reporting period that is not consistent with your startup, shutdown, and malfunction plan you must submit an immediate startup, shutdown and malfunction report. Unless the Administrator has approved a different schedule for submission of reports under § 63.10(a), you must submit each report according to paragraphs (f)(1) and (2) of this section. An immediate startup, shutdown, and malfunction report is not required after [DATE 180 DAYS AFTER PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**].

* * * * *

(g) Within 60 days after the date of completing each performance test required by this subpart, you must submit the results of the performance test following the procedures specified in paragraphs (g)(1) through (3) of this section.

(1) *Data collected using test methods supported by the EPA's Electronic Reporting Tool (ERT) as listed on the EPA's ERT website (https://www.epa.gov/electronic-reporting-air-emissions/electronic-reporting-tool-ert) at the time of the test.* Submit the results of the performance test to the EPA via the Compliance and Emissions Data Reporting Interface (CEDRI). CEDRI can be accessed through the EPA's Central Data Exchange (CDX) (*https://cdx.epa.gov/*). The data must be submitted in a file format generated through the use of the EPA's ERT. Alternatively, you may submit an electronic file consistent with the extensible markup language (XML) schema listed on the EPA's ERT website.

(2) *Data collected using test methods that are not supported by the EPA's ERT as listed on the EPA's ERT website at the time of the test.* Submit the results of the performance test as an attachment in the ERT.

(3) *Confidential business information (CBI).* If you claim some of the information submitted under paragraph (a)(1) is CBI, you must submit a complete file, including information claimed to be CBI, to the EPA. The file must be 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 website. Submit the file on a compact disc, flash drive or other commonly used electronic storage medium and clearly mark the medium as CBI. Mail the electronic medium 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 must be submitted to the EPA via the EPA's CDX as described in paragraph (a)(1) of this section.

(h) Within 60 days after the date of completing each continuous monitoring system (CMS) performance evaluation (as defined in § 63.2), you must submit the results of the performance evaluation following the procedures specified in paragraphs (h)(1) through (3) of this section.

(1) *Performance evaluations of CMS measuring relative accuracy test audit (RATA) pollutants that are supported by the EPA's ERT as listed on the EPA's ERT website at the time of the evaluation.* Submit the results of the performance evaluation to the EPA via CEDRI, which can be accessed through the EPA's CDX. The data must be submitted in a file format generated through the use of the EPA's ERT. Alternatively, you may submit an electronic file consistent with the XML schema listed on the EPA's ERT website.

(2) *Performance evaluations of CMS measuring RATA pollutants that are not supported by the EPA's ERT as listed on the EPA's ERT website at the time of the evaluation.* Submit the results of the performance evaluation as an attachment in the ERT.

(3) *Confidential business information (CBI).* If you claim some of the information submitted under paragraph (a)(1) is CBI, you must submit a complete file, including information claimed to be CBI, to the EPA. The file must be 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 website. Submit the file on a compact disc, flash drive or other commonly used electronic storage medium and clearly mark the medium as CBI. Mail the electronic medium 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 must be submitted to the EPA via the EPA's CDX as described in paragraph (a)(1) of this section.

(i) You must submit to the Administrator compliance reports. Beginning on [DATE 181 DAYS AFTER PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**], submit all subsequent reports following the procedure specified in paragraph (l) of this section.

(j) You must submit to the Administrator performance evaluations. Beginning on [DATE 181 DAYS AFTER PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**], submit all subsequent reports following the procedure specified in paragraph (l) of this section.

(k) You must submit to the Administrator a Notification of Compliance Status. Beginning on [DATE 181 DAYS AFTER PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**], submit all subsequent reports following the procedure specified in paragraph (l) of this section.

(l) If you are required to submit reports following the procedure specified in this paragraph, you must submit 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 website (*https://www.epa.gov/electronic-reporting-air-emissions/compliance-and-emissions-data-reporting-interface-cedri*) for this subpart. The date report templates become available will be listed on the CEDRI website. The report must be submitted by the deadline specified in this subpart, regardless of the method in which the report is submitted. If you claim some of the information required to be submitted via CEDRI is confidential business information (CBI), submit a complete report, including information claimed to be CBI, to the EPA. The report must be generated using the appropriate form on the CEDRI website. Submit the file on a compact disc, flash drive, or other commonly used electronic storage medium and clearly mark the medium as CBI. Mail the electronic medium 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 must be submitted to the EPA via the EPA's CDX as described earlier in this paragraph.

(m) If you are required to electronically submit a report through CEDRI in the EPA's CDX, you may assert a claim of EPA system outage for failure to timely comply with the reporting requirement. To assert a claim of EPA system outage, you must meet the requirements outlined in paragraphs (m)(1) through (7) of this section.

(1) You must have been or will be precluded from accessing CEDRI and submitting a required report within the time prescribed due to an outage of either the EPA's CEDRI or CDX systems.

(2) The outage must have occurred within the period of time beginning 5 business days prior to the date that the submission is due.

(3) The outage may be planned or unplanned.

(4) 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.

(5) You must provide to the Administrator a written description identifying:

(i) The date, time and length of the outage;

(ii) A rationale for attributing the delay in reporting beyond the regulatory deadline to EPA system outage;

(iii) Measures taken or to be taken to minimize the delay in reporting; and

(iv) The 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.

(6) 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.

(7) In any circumstance, the report must be submitted electronically as soon as possible after the outage is resolved.

(n) If you are required to electronically submit a report through CEDRI in the EPA's CDX, you may assert a claim of force majeure for failure to timely comply with the reporting requirement. To assert a claim of force majeure, you must meet the requirements outlined in paragraphs (n)(1) through (5) of this section.

(1) You may submit a claim if 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 5 business days prior to the date the submission is due. 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).

(2) 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.

(3) You must provide to the Administrator:

(i) A written description of the force majeure event;

(ii) A rationale for attributing the delay in reporting beyond the regulatory deadline to the force majeure event;

(iii) Measures taken or to be taken to minimize the delay in reporting; and

(iv) The 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.

(4) 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.

(5) In any circumstance, the reporting must occur as soon as possible after the force majeure event occurs.

■ 10. Section 63.9055 is amended by revising paragraph (b)(1) and adding paragraphs (c) and (d).

§ 63.9055 What records must I keep?

* * * * *

(b) * * *

(1) For existing sources and for new or reconstructed sources which commenced construction or reconstruction after April 17, 2003, but before February 5, 2019, before [DATE 180 DAYS AFTER PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**], the records in § 63.6(e)(3)(iii) through (v) related to startup, shutdown, and malfunction. for a period of five years. A startup, shutdown, and malfunction plan is not required after [DATE 180 DAYS AFTER PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**].

* * * * *

(c) After [DATE 180 DAYS AFTER PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**], you must keep records of each deviation specified in paragraphs (c)(1) through (3) of this section.

(1) For each deviation record the date, time and duration of each deviation.

(2) For each deviation, record and retain a list of the affected sources or equipment, an estimate of the quantity 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 63.9005(b), 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 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.

■ 11. Table 1 to subpart NNNNN of part 63 is amended by correcting a typographical error in entry 2.

TABLE 1 TO SUBPART NNNNN OF PART 63—EMISSION LIMITS AND WORK PRACTICE STANDARDS

For each . . .	You must meet the following emission limit and work practice standard
* * * * * * *	
2. Emission stream from an HCl storage tank at an existing source	Reduce HCl emissions by 99 percent or greater or achieve an outlet concentration of 120 ppm by volume or less.
* * * * * * *	

■ 12. Revise table 6 of subpart NNNNN of part 63 to read as follows:

Table 6 to Subpart NNNNN of Part 63—Requirements for Reports

As stated in § 63.9050(a), you must submit a compliance report that includes the information in § 63.9050(c) through (e) as well as the information in the following table. For existing sources and for new or reconstructed sources which commenced construction or reconstruction after April 17, 2003, but before February 5, 2019, before [DATE 181 DAYS AFTER PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**], you must also submit startup, shutdown, and malfunction (SSM) reports according to the requirements in § 63.9050(f) and the following. A startup, shutdown, and malfunction plan is not required after [DATE 180 DAYS AFTER PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**].

If . . .	Then you must submit a report or statement that:
1. There are no deviations from any emission limitations that apply to you.	There were no deviations from any emission limitations that apply to you during the reporting period. Include this statement in the compliance report.
2. There were no periods during which the operating parameter monitoring systems were out-of-control in accordance with the monitoring plan.	There were no periods during which the CMS were out-of-control during the reporting period. Include this statement in the compliance report.
3. There was a deviation from any emission limitation during the reporting period.	Contains the information in § 63.9050(d). Include this statement in the compliance report.
4. There were periods during which the operating parameter monitoring systems were out-of-control in accordance with the monitoring plan.	Contains the information in § 63.9050(d). Include this statement in the compliance report.
5. There was a SSM during the reporting period that is not consistent with your SSM plan.	For existing sources and for new or reconstructed sources which commenced construction or reconstruction after April 17, 2003, but before February 5, 2019, before [DATE 181 DAYS AFTER PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**], contains the information in § 63.9050(f). Include this statement in the compliance report. A startup, shutdown, and malfunction plan is not required after [DATE 180 DAYS AFTER PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**].
6. There were periods when the procedures in the LDAR plan were not followed.	Contains the information in § 63.9050(c)(7). Include this statement in the compliance report.

■ 13. Table 7 to subpart NNNNN of part 63 is amended by:

■ a. Removing the entry ''§ 63.6(e)(1)–(2)'';

■ b. Adding the entries ''§ 63.6(e)(1)(i)'', ''§ 63.6(e)(1)(ii)'', and ''§ 63.6(e)(1)(iii)–(e)(2)'' in numerical order;

■ c. Revising the entry ''§ 63.6(e)(3)'';

■ d. Revising the entry ''§ 63.6(f)(1)'';

■ e. Revising the entry ''§ 63.7(e)(1)'';

■ f. Removing the entry ''§ 63.8(c)(1)–(3)'';

■ g. Adding the entries ''§ 63.8(c)(1)(i)'', ''§ 63.8(c)(1)(ii)'', ''§ 63.8(c)(1)(iii)'', and ''§ 63.8(c)(2)–(3)'' in numerical order;

■ h. Removing the entry ''§ 63.8(d)–(e)'';

■ i. Adding the entries ''§ 63.8(d)(1)–(2)'', ''§ 63.8(d)(3)'', and ''§ 63.8(e)'' in numerical order;

■ j. Removing the entry ''§ 63.10(b)(2)(i)–(xi)'';

■ k. Adding the entries ''§ 63.10(b)(2)(i)–(ii)'', ''§ 63.10(b)(2)(iii)'', ''§ 63.10(b)(2)(iv)'', ''§ 63.10(b)(2)(v)'', ''§ 63.10(b)(2)(vi)'', and ''§ 63.10(b)(2)(vii)–(xi)'' in numerical order;

■ l. Removing the entry ''§ 63.10(c)'';

■ m. Adding the entries ''§ 63.10(c)(1)–(14)'' and ''§ 63.10(c)(15'' in numerical order; and

■ n. Revising the entry ''§ 63.10(d)(5)'';

The revisions and additions read as follows:

TABLE 7 TO SUBPART NNNNN OF PART 63—APPLICABILITY OF GENERAL PROVISIONS TO SUBPART NNNNN

* * * * * * *

Citation	Requirement	Applies to subpart NNNNN	Explanation
*	*	*	*
§ 63.6(e)(1)(i)	General Duty to minimize emissions	No, for new or reconstructed sources which commenced construction or reconstruction after February 4, 2019. Yes, for all other affected sources before [DATE 181 DAYS AFTER PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**], and No thereafter.	Subpart NNNNN requires affected units to meet emissions standards at all times. See § 63.9005(b) for general duty requirement.
§ 63.6(e)(1)(ii)	Requirement to correct malfunctions ASAP.	No, for new or reconstructed sources which commenced construction or reconstruction after February 4, 2019. Yes, for all other affected sources before [DATE 181 DAYS AFTER PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**], and No thereafter.	
§ 63.6(e)(1)(iii)–(e)(2)	Operation and maintenance requirements.	Yes.	

TABLE 7 TO SUBPART NNNNN OF PART 63—APPLICABILITY OF GENERAL PROVISIONS TO SUBPART NNNNN—Continued

Citation	Requirement	Applies to subpart NNNNN	Explanation
*	*	*	*
§ 63.6(e)(3)	SSM plans	No, for new or reconstructed sources which commenced construction or reconstruction after February 4, 2019. Yes, for all other affected sources before [DATE 181 DAYS AFTER PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**], and No thereafter.	
§ 63.6(f)(1)	Compliance except during SSM	No, for new or reconstructed sources which commenced construction or reconstruction after February 4, 2019. Yes, for all other affected sources before [DATE 181 DAYS AFTER PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**], and No thereafter.	
*	*	*	*
§ 63.7(e)(1)	Conditions for conducting performance tests.	No, for new or reconstructed sources which commenced construction or reconstruction after February 4, 2019. Yes, for all other affected sources before [DATE 181 DAYS AFTER PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**], and No thereafter.	See § 63.9020(a) for performance testing requirements.
*	*	*	*
§ 63.8(c)(1)(i)	General duty to minimize emissions and CMS operation.	No, for new or reconstructed sources which commenced construction or reconstruction after February 4, 2019. Yes, for all other affected sources before [DATE 181 DAYS AFTER PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**], and No thereafter.	
§ 63.8(c)(1)(ii)	Continuous monitoring system O&M	Yes	Applies as modified by § 63.9005(d).
§ 63.8(c)(1)(iii)	Requirement to develop SSM Plan for CMS.	No, for new or reconstructed sources which commenced construction or reconstruction after February 4, 2019. Yes, for all other affected sources before [DATE 181 DAYS AFTER PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**], and No thereafter.	
§ 63.8(c)(2)–(3)	Continuous monitoring system O&M	Yes	Applies as modified by § 63.9005(d).
*	*	*	*
§ 63.8(d)(1)–(2)	Quality control program and CMS performance evaluation.	Yes	Applies as modified by § 63.9005(d).
§ 63.8(d)(3)	Written procedures for CMS	No, for new or reconstructed sources which commenced construction or reconstruction after February 4, 2019. Yes, for all other affected sources before [DATE 181 DAYS AFTER PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**], and No thereafter.	See § 63.9005(d)(5) for written procedures for CMS.
§ 63.8(e)	Performance evaluation of CMS	Yes	Applies as modified by § 63.9005(d).
*	*	*	*
§ 63.10(b)(2)(i)–(ii)	Records related to SSM periods	No, for new or reconstructed sources which commenced construction or reconstruction after February 4, 2019. Yes, for all other affected sources before [DATE 181 DAYS AFTER PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**], and No thereafter.	See 63.9055 for recordkeeping of (1) date, time and duration; (2) listing of affected source or equipment, and an estimate of the quantity of each regulated pollutant emitted over the standard; and (3) actions to minimize emissions and correct the failure.
§ 63.10(b)(2)(iii)	Maintenance Records	Yes.	

TABLE 7 TO SUBPART NNNNN OF PART 63—APPLICABILITY OF GENERAL PROVISIONS TO SUBPART NNNNN—Continued

Citation	Requirement	Applies to subpart NNNNN	Explanation
*	*	*	*
§ 63.10(b)(2)(iv)	Actions taken to minimize emissions during SSM.	No, for new or reconstructed sources which commenced construction or reconstruction after February 4, 2019. Yes, for all other affected sources before [DATE 181 DAYS AFTER PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**], and No thereafter.	
§ 63.10(b)(2)(v)	Actions taken to minimize emissions during SSM.	No, for new or reconstructed sources which commenced construction or reconstruction after February 4, 2019. Yes, for all other affected sources before [DATE 181 DAYS AFTER PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**], and No thereafter.	
§ 63.10(b)(2)(vi)	Recordkeeping for CMS malfunctions	Yes.	
§ 63.10(b)(2)(vii)–(xi)	Records for performance tests and CMS.	Yes.	
*	*	*	*
§ 63.10(c)(1)–(14)	Additional recordkeeping requirements for sources with CMS.	Yes	Applies as modified by § 63.9005 (d).
§ 63.10(c)(15)	Use of SSM Plan	No, for new or reconstructed sources which commenced construction or reconstruction after February 4, 2019. Yes, for all other affected sources before [DATE 181 DAYS AFTER PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**], and No thereafter.	
*	*	*	*
§ 63.10(d)(5)	SSM reports	No, for new or reconstructed sources which commenced construction or reconstruction after February 4, 2019. Yes, for all other affected sources before [DATE 181 DAYS AFTER PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**], and No thereafter.	See § 63.9050(c)(5) for malfunction reporting requirements.
*	*	*	*

[FR Doc. 2018–28322 Filed 2–1–19; 8:45 am]

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