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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 927

[Doc. No. AMS–SC–18–0049; SC18–927–2 FR]

Pears Grown in Oregon and Washington; Decreased Assessment Rate for Processed Pears

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This final rule implements a recommendation from the Processed Pear Committee (Committee) to decrease the assessment rate established for ''summer/fall'' varieties of pears for canning for the 2018–2019 and subsequent fiscal periods. The assessment rate will remain in effect indefinitely unless modified, suspended, or terminated.

DATES: Effective January 3, 2019.

FOR FURTHER INFORMATION CONTACT: Dale Novotny, Marketing Specialist, or Gary Olson, Regional Director, Northwest Marketing Field Office, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA; Telephone: (503) 326–2724, Fax: (503) 326–7440, or Email: *DaleJ.Novotny@usda.gov* or *GaryD.Olson@usda.gov.* Small businesses may request information on complying with this regulation by contacting Richard Lower, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, STOP 0237, Washington, DC 20250–0237; Telephone: (202) 720–2491, Fax: (202)720–8938, or Email: *Richard.Lower@usda.gov.*

SUPPLEMENTARY INFORMATION: This action, pursuant to 5 U.S.C. 553, amends regulations issued to carry out a marketing order as defined in 7 CFR 900.2(j). This rule is issued under Marketing Order No. 927, as amended (7 CFR part 927), regulating the handling of pears grown in Oregon and Washington. Part 927, (referred to as the ''Order'') is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the ''Act.'' The Committee locally administers the Order and is comprised of growers, handlers, and processors operating within the area of production, and a public member.

The Department of Agriculture (USDA) is issuing this rule in conformance with Executive Orders 13563 and 13175. This 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).

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under the Order now in effect, Oregon and Washington pear handlers are subject to assessments. Funds to administer the Order are derived from such assessments. The assessment rate established by this rule will be applicable to all ''summer/fall'' varieties of pears specifically used for canning for the 2018–2019 fiscal period, and continue until amended, suspended, or terminated.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with USDA a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. Such handler is afforded the opportunity for a hearing on the petition. After the hearing, USDA would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review USDA's ruling on the petition, provided an action is filed not later than 20 days after the date of the entry of the ruling.

The Order provides authority for the Committee, with the approval of USDA, to formulate an annual budget of expenses and collect assessments from handlers to administer the program. The Committee members are familiar with the Committee's needs and with the costs of goods and services in their local area and can formulate an appropriate budget and assessment rate. The assessment rate is formulated and discussed in a public meeting where all directly affected persons have an opportunity to participate and provide input.

This final rule decreases the assessment rate from $8.00 per ton, the rate that was established for the 2017–2018 and subsequent fiscal periods, to $7.15 per ton of ''summer/fall'' varieties of pears for canning handled for the 2018–2019 and subsequent fiscal periods. The assessment rate for ''winter'' and ''other'' pears for processing will remain unchanged at $0.00. The Committee met on May 30, 2018, and unanimously recommended 2018–2019 fiscal period expenditures of $693,472. In comparison, last year's budgeted expenditures were $800,150. The Committee also unanimously recommended an assessment rate of $7.15 per ton of ''summer/fall'' varieties of pears for canning handled. The new assessment rate of $7.15 per ton is $0.85 lower than the previous $8.00 per ton rate. The Committee recommended the lower assessment rate to balance assessment revenue with its budgeted expenditures and to maintain its monetary reserve at levels authorized by the Order.

The major expenditures recommended by the Committee for the 2018–2019 fiscal period include $495,000 for promotion and paid advertising, $136,172 for research, $15,000 for market access programs, $25,000 for administrative and management services, and $22,300 for Committee expenses. In comparison, these major expense categories for the 2017–2018 fiscal period were budgeted at $591,030, $147,694, $14,576, $25,000, and $21,850; respectively.

The assessment rate recommended by the Committee was derived by considering anticipated expenses, expected shipments, and the amount of

funds available in the authorized reserve. The quantity of assessable ''summer/fall'' pears for canning for the 2018–2019 fiscal period is estimated at 100,000 tons. Thus, the recommended $7.15 per ton assessment rate is expected to provide handler assessments of $715,000. This amount will be adequate to cover budgeted expenses of $693,472, with any excess funds used to make a small contribution to the Committee's monetary reserve. Funds in the reserve (currently $497,565) will be kept within the maximum permitted by § 927.42(a) of approximately one fiscal period's expenses.

The assessment rate established in this rule will continue in effect indefinitely unless modified, suspended, or terminated by USDA upon recommendation and information submitted by the Committee, or other available information.

Although this assessment rate will be in effect for an indefinite period, the Committee will continue to meet prior to or during each fiscal period to recommend a budget of expenses and consider recommendations for modification of the assessment rate. The dates and times of Committee meetings are available from the Committee or USDA. Committee meetings are open to the public and interested persons may express their views at these meetings. USDA will evaluate Committee recommendations and other available information to determine whether modification of the assessment rate is needed. Further rulemaking will be undertaken as necessary. The Committee's budget for subsequent fiscal periods will be reviewed and, as appropriate, approved by USDA.

Final Regulatory Flexibility Analysis

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

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

There are approximately 1,500 growers of pears for processing in the production area and approximately 43 handlers of processed pears subject to regulation under the Order. Small agricultural producers are defined by the Small Business Administration (SBA) as those having annual receipts less than $750,000, and small agricultural service firms are defined as those whose annual receipts are less than $7,500,000 (13 CFR 121.201).

According to data from USDA National Agricultural Statistics Service (NASS), the Committee, and the industry for the 2016–2017 season (the most recent complete season of record) the average f.o.b. price for Oregon-Washington processed Bartlett pears (the only variety used for canning in the production area) was approximately $390.50 per ton. Total shipments for that period were approximately 103,020 tons. Using the number of handlers, and assuming a normal distribution, the majority of handlers may have average annual receipts of less than $7,500,000 ($390.50 per ton times 103,020 tons equals $40,229,310 divided by 43 handlers equals $935,565 per handler).

In addition, based on data from the Committee, the industry produced 103,020 tons of processed pears in the production area during the 2016–2017 season, with an average grower price of $360 per ton. Based on the average grower price, production, and the total number of Oregon-Washington processed pear growers reported by the Committee (1,500), and assuming a normal distribution, the average annual grower revenue is below $750,000 ($360 per ton times 103,020 tons equals $37,087,200 divided by 1,500 growers equals $24,725 per grower). Thus, the majority of Oregon and Washington processed pear handlers and growers may be classified as small entities.

This rule decreases the assessment rate collected from handlers for the 2018–2019 and subsequent fiscal periods from $8.00 per ton to $7.15 per ton of Oregon and Washington ''summer/fall'' pears for canning handled. The Committee unanimously recommended 2018–2019 fiscal period expenditures of $693,472 and the $7.15 per ton assessment rate. The assessment rate of $7.15 per ton is $0.85 lower than the previous rate in effect for the 2017–2018 fiscal period. The quantity of assessable ''summer/fall'' pears for canning for the 2018–2019 fiscal period is estimated at 100,000 tons. Thus, the $7.15 per ton rate should provide $715,000 in assessment income. Income derived from handler assessments should be adequate to cover budgeted expenses, with any excess funds to be carried over in the Committee's monetary reserve to be used in subsequent years.

The major expenditures recommended by the Committee for the 2018–2019 fiscal period include $495,000 for promotion and paid advertising, $136,172 for research, $15,000 for market access programs, $25,000 for administrative and management services, and $22,300 for Committee expenses. In comparison, these major expense categories for the 2017–2018 fiscal period were budgeted at $591,030, $147,694, $14,576, $25,000, and $21,850, respectively.

The new, lower assessment rate is necessary to balance assessment revenue with the Committee's 2018–2019 fiscal period budgeted expenditures and to maintain its monetary reserve at levels authorized in the Order.

Prior to arriving at this budget and assessment rate, the Committee considered the benefits and costs related to maintaining the previous assessment rate of $8.00 per ton and establishing other assessment rates. However, leaving the assessment rate unchanged would have generated more revenue than required to meet the Committee's 2018–2019 fiscal period budgeted expenses of $693,472, and would have added a large amount of excess funds to the Committee's already sufficient monetary reserve. Based on estimated shipments, the assessment rate of $7.15 per ton is expected to provide $715,000 in assessment income. The Committee determined assessment revenue will be adequate to fully cover budgeted expenditures for the 2018–2019 fiscal period, with a small amount of excess funds to be added to the Committee's monetary reserve. Reserve funds will be kept within the amount authorized by the Order.

A review of historical information and preliminary information pertaining to the upcoming fiscal year indicates that the average grower price for the 2018–2019 season should be approximately $296 per ton of pears for processing. Therefore, the estimated assessment revenue for the 2018–2019 fiscal period as a percentage of total grower revenue is about 2.4 percent ($7.15 per ton assessment divided by $296 per ton grower price).

This action decreases the assessment obligation imposed on handlers for the 2018–2019 and subsequent fiscal periods. Assessments are applied uniformly on all handlers, and some of the costs may be passed on to producers. However, decreasing the assessment rate will reduce the burden on handlers, and may reduce the burden on producers.

The Committee's meetings were widely publicized throughout the

Oregon and Washington processed pear industry. All interested persons were invited to attend the meetings and participate in Committee deliberations on all issues. Like all Committee meetings, the May 30, 2018, meeting was a public meeting and all entities, both large and small, were able to express views on this issue.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Order's information collection requirements have been previously approved by OMB and assigned OMB No. 0581–0189, Fruit Crops. No changes in those requirements are necessary because of this action. Should any changes become necessary, they will be submitted to OMB for approval.

This rule does not impose any additional reporting or recordkeeping requirements on either small or large Oregon and Washington processed pear handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies. USDA has not identified any relevant Federal rules that duplicate, overlap, or conflict with this final 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.

A proposed rule concerning this action was published in the **Federal Register** on September 12, 2018 (83 FR 46119). Copies of the proposed rule were also mailed or sent via facsimile to all Oregon and Washington fresh pear handlers. The proposal was made available through the internet by USDA and the Office of the Federal Register. A 30-day comment period ending October 12, 2018, was provided for interested persons to respond to the proposal. Two comments were received during the comment period. The first comment was in support of the action. The second comment was a negative opinion on marketing orders in general and did not address the specific proposed rulemaking action. Accordingly, no changes will be made to the rule as proposed, based on the comments received.

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

After consideration of all relevant material presented, including the information and recommendation submitted by the Committee and other available information, it is hereby found that this rule, will tend to effectuate the declared policy of the Act.

List of Subjects in 7 CFR Part 927

Marketing agreements, Pears, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR part 927 is amended as follows:

PART 927—PEARS GROWN IN OREGON AND WASHINGTON

■ 1. The authority citation for part 927 continues to read as follows:

Authority: 7 U.S.C. 601–674.

■ 2. Section 927.237 is amended by revising the introductory text and paragraph (a) to read as follows:

§ 927.237 Assessment rate.

On and after July 1, 2018, the following base rates of assessment for pears for processing are established for the Processed Pear Committee:

(a) $7.15 per ton for any or all varieties or subvarieties of pears for canning classified as ''summer/fall'' excluding pears for other methods of processing;

* * * * *

Dated: November 29, 2018.

Bruce Summers,

Administrator, Agricultural Marketing Service.

[FR Doc. 2018–26311 Filed 12–3–18; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2018–0034; Airspace Docket No. 17–ANM–34]

RIN 2120–AA66

Establishment of Class E Airspace; Kemmerer, WY

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends Class E surface area airspace at Kemmerer Municipal Airport, Kemmerer, WY, by enlarging the airspace area north of the airport and removing the Notice to Airmen (NOTAM) part-time status for the airspace. Also, this action reduces Class E airspace extending upward from 700 feet above the surface and removes Class E airspace extending upward from 1,200 feet above the surface.

DATES: Effective 0901 UTC, February 28, 2019. The Director of the Federal Register approves this incorporation by reference action under Title 1, Code of Federal Regulations, part 51, subject to the annual revision of FAA Order 7400.11 and publication of conforming amendments.

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

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

FOR FURTHER INFORMATION CONTACT: Bonnie Malgarini, Federal Aviation Administration, Operations Support Group, Western Service Center, 2200 S 216th Street, Des Moines, WA 98198; telephone (206) 231–2329.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it amends Class E airspace at Kemmerer Municipal Airport, Kemmerer, WY, to accommodate airspace redesign in support of IFR operations at the airport.

History

The FAA published a notice of proposed rulemaking in the **Federal Register** (83 FR 21970; May 11, 2018) for Docket No. FAA–2018–0034 to amend Class E airspace at Kemmerer Municipal Airport, Kemmerer, WY, to accommodate airspace redesign in support of IFR operations at the airport. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Class E airspace designations are published in paragraph 6002, and 6005, respectively, of FAA Order 7400.11C, dated August 13, 2018, and effective September 15, 2018, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order 7400.11C, Airspace Designations and Reporting Points, dated August 13, 2018, and effective September 15, 2018. FAA Order 7400.11C is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11C lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

The FAA is amending Title 14 Code of Federal Regulations (14 CFR) part 71 by modifying the north extension of the Class E surface area airspace at Kemmerer Municipal Airport, Kemmerer, WY, to within 1.8 miles (from 1 mile) each side of the 354° bearing (from the 360° bearing) from the airport extending from the 4.3-mile radius of the airport to 7.7 miles (from 7 miles) north of the airport. Also, the NOTAM part-time status for the airspace would be removed to make the airspace effective continuously.

The FAA also amends the Class E airspace extending upward from 700 feet above the surface to within a 4.3-mile radius of Kemmerer Municipal Airport from the airport 035° bearing clockwise to the airport 006° bearing, and within a 9.5 mile radius of the airport from the airport 006° bearing clockwise to the airport 035° bearing, and within 2.2 miles each side of the 354° bearing from the airport extending from the 4.3-mile radius of the airport to 15.9 miles north of the airport, and within 2.2 miles each side of the 172° bearing from the airport extending from the 4.3-mile radius of the airport to 7.4 miles south of the airport (from within the 8-mile radius of Kemmerer Municipal Airport, and within 4 miles each side of the 174° bearing from the airport extending from the airport 11 miles south of the airport, and within 3.6 miles each side of the 354° bearing from the airport extending from the airport to 16.1 miles northwest of the airport). Additionally, the Class E airspace extending upward from 1,200 feet above the surface is removed because sufficient airspace exists (Wasatch and Jackson Class E airspace areas) and duplication is not necessary. This airspace redesign is necessary for the safety and management of IFR operations at the airport.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial and unlikely to result in adverse or negative comments. It, therefore: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

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

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

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

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

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

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11C, Airspace Designations and Reporting Points, dated August 13, 2018, and effective September 15, 2018, is amended as follows:

Paragraph 6002 Class E Airspace Areas Designated as Surface Areas.

* * * * *

ANM WY E2 Kemmerer, WY [Amended]

Kemmerer Municipal Airport, WY
(Lat. 41°49′27″ N, long. 110°33′25″ W)

Within a 4.3-mile radius of Kemmerer Municipal Airport, and within 1.8-miles each side of the 354° bearing from the airport extending from the 4.3-mile radius of the airport to 7.7 miles north of the airport.

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

* * * * *

ANM WY E5 Kemmerer, WY [Amended]

Kemmerer Municipal Airport, WY
(Lat. 41°49′27″ N, long. 110°33′25″ W)

That airspace extending upward from 700 feet above the surface within a 4.3-mile radius of Kemmerer Municipal Airport from the airport 035° bearing clockwise to the airport 006° bearing, and within a 9.5-mile radius of the airport from the airport 006° bearing clockwise to the airport 035° bearing, and within 2.2 miles each side of the 354° bearing from the airport extending from the 4.3-mile radius of the airport to 15.9 miles north of the airport, and within 2.2 miles each side of the 172° bearing from the airport extending from the 4.3-mile radius of the airport to 7.4 miles south of the airport.

Issued in Seattle, Washington, on November 20, 2018.

Shawn M. Kozica,

Group Manager, Operations Support Group, Western Service Center.

[FR Doc. 2018–26195 Filed 12–3–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2017–1147; Airspace Docket No. 17–AWP–29]

RIN 2120–AA66

Revocation of Class E Airspace; Sunol, CA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action removes Class E airspace extending upward from 1,200 feet above the surface at Sunol, CA. This airspace is wholly contained within the Sacramento en route airspace area and duplication is not necessary.

DATES: Effective 0901 UTC, February 28, 2019. The Director of the Federal Register approves this incorporation by reference action under Title 1, Code of Federal Regulations, part 51, subject to the annual revision of FAA Order 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order 7400.11C, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *http://www.faa.gov/air_traffic/publications/*. For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA).

For information on the availability of this material at NARA, call (202) 741–6030, or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

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

FOR FURTHER INFORMATION CONTACT: Bonnie Malgarini, Federal Aviation Administration, Operations Support Group, Western Service Center, 2200 S 216th Street, Des Moines, WA 98198–6547; telephone (206) 231–2329.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it clarifies airspace designations by eliminating the redundancy.

History

The FAA published a notice of proposed rulemaking in the **Federal Register** (83 FR 7432; February 21, 2018) for Docket No. FAA–2017–1147 to remove Class E airspace extending upward from 1,200 feet above the surface at Sunol, CA. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Class E airspace designations are published in paragraph 6005 of FAA Order 7400.11C, dated August 13, 2018, and effective September 15, 2018, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order 7400.11C, Airspace Designations and Reporting Points, dated August 13, 2018, and effective September 15, 2018. FAA Order 7400.11C is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11C lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 removes Class E airspace extending upward from 1,200 feet above the surface at Sunol, CA. This airspace is wholly contained within the Sacramento en route airspace area and duplication is not necessary.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial and unlikely to result in adverse or negative comments. It, therefore: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

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

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

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

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

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

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11C,

Airspace Designations and Reporting Points, dated August 13, 2018, and effective September 15, 2018, is amended as follows:

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

* * * * *

AWP CA E5 Sunol, CA [Removed]

Issued in Seattle, Washington, on November 20, 2018.

Shawn M. Kozica,

Manager, Operations Support Group, Western Service Center.

[FR Doc. 2018–26209 Filed 12–3–18; 8:45 am]

BILLING CODE 4910–13–P

SECURITIES AND EXCHANGE COMMISSION

17 CFR Parts 239 and 274

[Release Nos. 33–10577, IC–33308; File Nos. S7–08–15; S7–04–18]

Form N–1A; Correction

AGENCY: Securities and Exchange Commission.

ACTION: Final rule; technical correction.

SUMMARY: This document makes technical corrections to several amendments to Form N–1A, which the Commission adopted as part of three rulemakings: Investment Company Reporting Modernization, which was published in the **Federal Register** on November 18, 2016; Optional Internet Availability of Investment Company Shareholder Reports, which was published in the **Federal Register** on June 22, 2018; and Investment Company Liquidity Disclosure, which was published in the **Federal Register** on July 10, 2018. This document is being published to correct the paragraph designations that appeared in the amendatory instructions preceding certain of the form amendments that the Commission adopted as part of each of these rulemakings. This document makes technical corrections only to the paragraph designations that appear in the amendatory instructions preceding these form amendments. This document does not make any substantive changes (*i.e.,* changes except corrections to typographical errors) to the text of the form amendments themselves.

DATES: Effective December 4, 2018, except:

- The revisions to Item 27(d)(3) of Form N–1A are effective May 1, 2020;
- Item 27(d)(7) of Form N–1A (referenced in 17 CFR 239.15A and 274.11A) is effective January 1, 2019, through December 31, 2021; and
- Item 27(d)(7) is removed effective January 1, 2022.

FOR FURTHER INFORMATION CONTACT: James Maclean, Senior Counsel, or Amanda Hollander Wagner, Branch Chief, Investment Company Regulation Office, at (202) 551–6792, Division of Investment Management, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–8549.

SUPPLEMENTARY INFORMATION: We are making a technical amendment to Item 27 of Form N–1A under 17 CFR 239.15A and 274.11A.

List of Subjects

17 CFR Part 239

Reporting and recordkeeping requirements, Securities.

17 CFR Part 274

Investment companies, Reporting and recordkeeping requirements, Securities.

Statutory Authority and Text of Amendments

For the reasons set out above, title 17, chapter II of the Code of Federal Regulations is amended as follows:

PART 239—FORMS PRESCRIBED UNDER THE SECURITIES ACT OF 1933

■ 1. The authority citation for part 239 continues to read in part as follows:

Authority: 15 U.S.C. 77c, 77f, 77g, 77h, 77j, 77s, 77z–2, 77z–3, 77sss, 78c, 78*l,* 78m,78n, 78*o*(d), 78*o*–7 note, 78u–5, 78w(a), 78*ll,* 78mm, 80a–2(a), 80a–3, 80a–8, 80a–9, 80a–10, 80a–13, 80a–24, 80a–26, 80a–29, 80a–30, and 80a–37; and sec. 107, Pub. L. 112–106, 126 Stat. 312, unless otherwise noted.

* * * * *

PART 274—FORMS PRESCRIBED UNDER THE INVESTMENT COMPANY ACT OF 1940

■ 2. The authority citation for part 274 continues to read in part as follows:

Authority: 15 U.S.C. 77f, 77g, 77h, 77j, 77s, 78c(b), 78*l,* 78m, 78n, 78*o*(d), 80a–8, 80a–24, 80a–26, 80a–29, and Pub. L. 111–203, sec. 939A, 124 Stat. 1376 (2010), unless otherwise noted.

* * * * *

■ 3. Form N–1A (referenced in §§ 239.15A and 274.11A), Item 27, is amended by:

■ a. Revising paragraph (d)(3);
■ b. Redesignating paragraph (d)(6) as (d)(6)(i);
■ c. Adding new paragraph (d)(6)(ii);
■ d. Adding paragraph (d)(7); and
■ e. Removing paragraph (d)(7).

The revisions and additions read as follows:

Note: The text of Form N–1A does not, and this amendment will not, appear in the Code of Federal Regulations.

Form N–1A

* * * * *

Item 27. Financial Statements

* * * * *

(d) * * *

(3) *Statement Regarding Availability of Quarterly Portfolio Schedule.* A statement that: (i) The Fund files its complete schedule of portfolio holdings with the Commission for the first and third quarters of each fiscal year as an exhibit to its reports on Form N–PORT; (ii) the Fund's Form N–PORT reports are available on the Commission's website at *http://www.sec.gov;* and (iii) if the Fund makes the information on Form N–PORT available to shareholders on its website or upon request, a description of how the information may be obtained from the Fund.

* * * * *

(6) *Board Approvals and Liquidity Reviews.*

(i) *Statement Regarding Basis for Approval of Investment Advisory Contract.* * * *

(ii) *Statement Regarding Liquidity Risk Management Program.* If the board of directors reviewed the Fund's liquidity risk management program pursuant to rule 22e–4(b)(2)(iii) of the Act [17 CFR 270.22e–4(b)(2)(iii)] during the Fund's most recent fiscal half-year, briefly discuss the operation and effectiveness of the Fund's liquidity risk management program over the past year.

Instruction

If the board reviews the liquidity risk management program more frequently than annually, a fund may choose to include the discussion of the program's operation and effectiveness over the past year in one of either the fund's annual or semi-annual reports, but does not need to include it in both reports.

(7) *Front Cover Page or Beginning of Annual and Semi-Annual Report.* Include on the front cover page or at the beginning of the annual or semi-annual report a statement to the following effect, if applicable:

Beginning on [date], as permitted by regulations adopted by the Securities and Exchange Commission, paper copies of the Fund's shareholder reports like this one will no longer be sent by mail, unless you specifically request paper copies of the reports from the Fund [or from your financial intermediary, such as a broker-dealer or bank]. Instead, the reports will be made available on a website, and you will be notified by mail each time a report is posted and provided with a website link to access the report.

If you already elected to receive shareholder reports electronically, you will not be affected by this change and you need not take any action. You may elect to receive shareholder reports and other communications from the Fund [or your financial intermediary] electronically by [insert instructions].

You may elect to receive all future reports in paper free of charge. You can inform the Fund [or your financial intermediary] that you wish to continue receiving paper copies of your shareholder reports by [insert instructions]. Your election to receive reports in paper will apply to all funds held with [the fund complex/your financial intermediary].

* * * * *

Dated: November 29, 2018.

Brent J. Fields,

Secretary.

[FR Doc. 2018–26335 Filed 12–3–18; 8:45 am]

BILLING CODE 8011–01–P

SOCIAL SECURITY ADMINISTRATION

20 CFR Parts 404, 411 and 416

[Docket No. SSA–2017–0071]

RIN 0960–AI24

Removal of Alternate Participant Program

AGENCY: Social Security Administration.

ACTION: Final rule.

SUMMARY: We are removing from the Code of Federal Regulations (CFR) our ''Alternate Participant Program'' rules because they are obsolete. We are removing these rules in accordance with the requirements of Executive Order (E.O.) 13777.

DATES: *Effective Date:* December 4, 2018.

FOR FURTHER INFORMATION CONTACT: Cara Caplan, Social Security Administration, 6401 Security Boulevard, Baltimore, MD 21235–6401, 410–966–0586. For information on eligibility or filing for benefits, call our national toll-free number, 1–800–772–1213 or TTY 1–800–325–0778, or visit our internet site, Social Security Online, at *http://www.socialsecurity.gov.*

SUPPLEMENTARY INFORMATION: We are removing our Alternate Participant Program rules in accordance with E.O. 13777 (''Enforcing the Regulatory Reform Agenda'').[1] The E.O. requires agencies to identify rules that, among other things, are outdated or unnecessary, and repeal, replace, or modify them, consistent with applicable law. These rules, found in 20 CFR Chapter III Part 411, Subpart J, describe how the Alternate Participant Program was affected by the Ticket to Work and Self-Sufficiency Program (Ticket Program),[2] and procedures related to phasing it out.

Under the Social Security Act (Act), the Commissioner of Social Security is authorized to reimburse States for reasonable and necessary costs of vocational rehabilitation (VR) services furnished to certain disabled individuals under a State VR plan that meets specific requirements.[3] If a State is unwilling to participate or does not have a plan meeting the specified requirements, we can enter into agreements or contracts with alternative VR service providers under the same conditions that apply to a State VR agency.[4] In 1994, we created the Alternate Participant Program, which was intended to provide more VR service options to beneficiaries.[5] These alternate VR service providers, referred to as ''alternate participants,'' could be organizations, institutions, individuals, or other public or private agencies.

Our procedures changed when we published final rules implementing the Ticket Program[6] in 2001. The Ticket Program, authorized by the Ticket to Work and Work Incentives Improvement Act of 1999 (TWWIIA),[7] expanded the universe of service providers available to beneficiaries with disabilities who are seeking employment services, VR services, and other support services. Under the Ticket Program, beneficiaries have the option of obtaining services from providers known as employment networks (ENs). As we implemented the Ticket Program and began using ENs, we phased out the use of alternate participants, as authorized by section 101(d)(5) of the TWWIIA.[8]

Under current rules, we cannot pay an alternate participant for services provided after December 31, 2003. There are no outstanding Alternate Participant Program payments and no entity could become eligible for these payments in the future. Because we no longer use the Alternate Participant Program, the rules associated with that program are obsolete and no longer necessary. In alignment with this rule removal, we are also removing references to the program found in Subparts A and E of 20 CFR part 411, sections in Subparts A and V of 20 CFR part 404, and sections in Subpart A and V of 20 CFR part 416.

Regulatory Procedures

Justification for Issuing a Final Rule Without Notice and Comment

We follow the Administrative Procedure Act (APA) rulemaking procedures specified in 5 U.S.C. 553 when we develop regulations. Generally, the APA requires that an agency provide prior notice and opportunity for public comment before issuing a final rule. The APA provides exceptions to its notice and public comment procedures when an agency finds there is good cause for dispensing with such procedures because they are impracticable, unnecessary, or contrary to the public interest.

We find that there is good cause under 5 U.S.C. 553(b)(B) to issue this regulatory change as a final rule without prior notice or public comment. We find that prior notice and public comment are unnecessary because this final rule only removes from the CFR obsolete and unnecessary rules that do not affect any current beneficiaries.

In addition, we find good cause for dispensing with the 30-day delay in the effective date of this rule provided for in 5 U.S.C. 553(d)(3). For the reasons stated above, we find it unnecessary to delay the effective date of the changes we are making in this final rule. Accordingly, we are making them effective upon publication.

Executive Order 12866 as Supplemented by Executive Order 13563

We consulted with the Office of Management and Budget (OMB) and determined that this final rule does not meet the criteria for a significant regulatory action under E.O. 12866, as supplemented by E.O. 13563. Thus, OMB did not review the final rule.

Executive Order 13132 (Federalism)

We analyzed this final rule in accordance with the principles and criteria established by Executive Order 13132 and determined that the rule will not have sufficient Federalism implications to warrant the preparation of a Federalism assessment. We also determined that this rule will not preempt any State law or State regulation or affect the States' abilities to discharge traditional State governmental functions.

E.O. 13771

This regulation codifies legislative changes that already took place. Accordingly, the regulation does not have any financial impact on the public, and as such is an exempt regulatory action under E.O. 13771.

Regulatory Flexibility Act

We certify that this final rule will not have a significant economic impact on a substantial number of small entities because there are no current participants of the Alternate Participant Program. Therefore, the Regulatory Flexibility Act, as amended, does not require us to prepare a regulatory flexibility analysis.

[1] 82 FR 12285 (March 1, 2017).

[2] 66 FR 67369 (December 28, 2001).

[3] Section 222(d)(1) of the Act, 42 U.S.C. 422(d)(1).

[4] Section 222(d)(2) of the Act, 42 U.S.C. 422(d)(2).

[5] 59 FR 11899 (March 15, 1994).

[6] 66 FR 67369 (December 28, 2001).

[7] Public Law 106–170, 113 Stat. 1860.

[8] Section 105(d)(5) of Public Law 106–170, 113 Stat. 1860, 1877.

Paperwork Reduction Act

This rule does not create any new or affect any existing collections and, therefore, does not require Office of Management and Budget approval under the Paperwork Reduction Act.

(Catalog of Federal Domestic Assistance Program Social Security—Retirement Insurance; and 96.004, Social Security—Survivors Insurance)

List of Subjects

20 CFR Part 404

Administrative practice and procedure, Blind, Disability benefits, Old-age, Survivors, and Disability Insurance, Reporting and recordkeeping requirements, Social Security.

20 CFR Part 411

Administrative practice and procedure, Blind, Disability benefits, Public assistance programs, Reporting and recordkeeping requirements, Social Security, Supplemental Security Income (SSI), Vocational rehabilitation.

20 CFR Part 416

Administrative practice and procedure, Alcoholism, Drug abuse, Investigations, Medicaid, Penalties, Reporting and recordkeeping requirements, Social Security, Supplemental Security Income (SSI), Travel and transportation expenses, Vocational rehabilitation.

Nancy A. Berryhill,

Acting Commissioner of Social Security.

For the reasons set out in the preamble, we amend 20 CFR parts 404, 411, and 416 as set forth below:

PART 404—FEDERAL OLD AGE, SURVIVORS AND DISABILITY INSURANCE (1950–)

Subpart A—Introduction, General Provisions and Definitions

■ 1. The authority citation for subpart A of part 404 continues to read as follows:

Authority: Secs. 203, 205(a), 216(j), and 702(a)(5) of the Social Security Act (42 U.S.C. 403, 405(a), 416(j), and 902(a)(5)) and 48 U.S.C. 1801.

■ 2. Amend § 404.1 by revising paragraph (v) to read as follows:

§ 404.1 Introduction

* * * * *

(v) Subpart V relates to payments to State vocational rehabilitative agencies for vocational rehabilitation services.

Subpart V—Payments for Vocational Rehabilitation Services

■ 3. The authority citation for subpart V of part 404 continues to read as follows:

Authority: Secs. 205(a), 222, and 702(a)(5) of the Social Security Act (42 U.S.C. 405(a), 422, and 902(a)(5)).

■ 4. Amend § 404.2102 as follows:
■ a. Remove and reserve paragraphs (c) and (j);
■ b. Revise the introductory text and paragraphs (b), (d), (f), and (k).

The revisions read as follows:

§ 404.2102 Purpose and scope.

This subpart describes the rules under which the Commissioner will pay the State VR agencies for VR services. Payment will be provided for VR services provided on behalf of disabled individuals under one or more of the provisions discussed in § 404.2101.

* * * * *

(b) Section 404.2104 explains how State VR agencies may participate in the payment program under this subpart.

(c) [Reserved]

(d) Sections 404.2108 through 404.2109 describe the requirements and conditions under which we will pay a State VR agency under this subpart.

* * * * *

(f) Section 404.2112 describes when payment will be made to a VR agency because an individual's disability benefits are continued based on his or her participation in a VR program which we have determined will increase the likelihood that he or she will not return to the disability rolls.

* * * * *

(j) [Reserved]

(k) Section 404.2119 describes how we will make payment to State VR agencies for rehabilitation services.

* * * * *

§ 404.2103 [Amended]

■ 5. Amend § 404.2103 by removing the definition of *Alternate participants.*

■ 6. Amend § 404.2104 as follows:
■ a. Remove paragraphs (b)(3) and (f);
■ b. Remove and reserve paragraph (e)(2); and
■ c. Revise the heading of the section and paragraphs (a), (b)(2), (c)(2), and (e)(3).

The revisions read as follows:

§ 404.2104 Participation by State VR agencies.

(a) *General.* In order to participate in the payment program under this subpart through its VR agency(ies), a State must have a plan which meets the requirements of title I of the Rehabilitation Act of 1973, as amended.

(b) * * *

(2) A State with one or more approved VR agencies may choose to limit participation of those agencies to a certain class(es) of disability beneficiaries. For example, a State with separate VR agencies for the blind and disabled may choose to limit participation to the VR agency for the blind. In such a case, we would give the State, through its VR agency for the blind, the opportunity to participate with respect to blind disability beneficiaries in the State in accordance with paragraph (d) of this section. A State that chooses to limit participation of its VR agency(ies) must notify us in advance under paragraph (e)(1) of this section of its decision to limit such participation.

* * * * *

(c) * * *

(2)(i) In order for the State to participate with respect to a disability beneficiary whom we referred to a State VR agency, the State VR agency must notify the appropriate Regional Commissioner (SSA) in writing or through electronic notification of its decision either to accept the beneficiary as a client for VR services or to place the beneficiary into an extended evaluation process. The notice must be received by the appropriate Regional Commissioner (SSA) no later than the close of the fourth month following the month in which we referred the beneficiary to the State VR agency.

(ii) In any case in which a State VR agency notifies the appropriate Regional Commissioner (SSA) in writing within the stated time period under paragraph (c)(2)(i) of this section of its decision to place the beneficiary into an extended evaluation process, the State VR agency also must notify that Regional Commissioner in writing upon completion of the evaluation of its decision whether or not to accept the beneficiary as a client for VR services. If we receive a notice of a decision by the State VR agency to accept the beneficiary as a client for VR services following the completion of the extended evaluation, the State may continue to participate with respect to such beneficiary.

* * * * *

(e) * * *

(2) [Reserved]

(3) A State which has decided not to participate or to limit participation may participate later through its VR agency(ies) in accordance with paragraph (c) of this section. A State which decides to resume participation under paragraph (c) of this section must provide advance written notice of that

decision to the appropriate Regional Commissioner (SSA). A decision of a State to resume participation under paragraph (c) of this section will be effective beginning with the third month following the month in which the notice of the decision is received by the appropriate Regional Commissioner (SSA) or, if later, with a month specified by the State. The notice of the State decision must be submitted by an official authorized to act for the State as explained in paragraph (e)(1) of this section.

* * * * *

§ 404.2106 [Removed and Reserved]

■ 7. Remove and reserve § 404.2106.

■ 8. Amend § 404.2108 by revising paragraphs (a), (d), and (f) to read as follows:

§ 404.2108 Requirements for payment.

(a) The State VR agency must file a claim for payment in each individual case within the time periods specified in § 404.2116;

* * * * *

(d) The VR services for which payment is being requested must have been provided under a State plan for VR services approved under title I of the Rehabilitation Act of 1973, as amended, and must be services that are described in § 404.2114;

* * * * *

(f) The State VR agency must maintain, and provide as we may require, adequate documentation of all services and costs for all disability beneficiaries with respect to whom a State VR agency could potentially request payment for services and costs under this subpart; and

* * * * *

■ 9. Amend § 404.2111 by revising the introductory text and paragraphs (b)(1)(i) and (b)(2) to read as follows:

§ 404.2111 Criteria for determining when VR services will be considered to have contributed to a continuous period of 9 months.

The State VR agency may be paid for VR services if such services contribute to the individual's performance of a continuous 9-month period of SGA. The following criteria apply to individuals who received more than just evaluation services. If a State VR agency claims payment for services to an individual who received only evaluation services, it must establish that the individual's continuous period or medical recovery (if medical recovery occurred before completion of a continuous period) would not have occurred without the services provided. In applying the criteria below, we will consider services described in § 404.2114 that were initiated, coordinated or provided, including services before October 1, 1981.

* * * * *

(b) * * *

(1) * * *

(i) The individualized written rehabilitation program (IWRP) included medical services; and

* * * * *

(2) In some instances, the State VR agency will not have provided, initiated, or coordinated medical services. If this happens, payment for VR services may still be possible under paragraph (a) of this section if:

(i) The medical recovery was not expected by us; and

(ii) The individual's impairment is determined by us to be of such a nature that any medical services provided would not ordinarily have resulted in, or contributed to, the medical cessation.

■ 10. Revise § 404.2112 to read as follows:

§ 404.2112 Payment for VR services in a case where an individual continues to receive disability payments based on participation in an approved VR program.

Sections 404.1586(g), 404.316(c), 404.337(c), and 404.352(c) explain the criteria we will use in determining if an individual whose disability has ceased should continue to receive disability benefits from us because of his or her continued participation in a VR program. A VR agency can be paid for the cost of VR services provided to an individual if the individual was receiving benefits in a month or months, after October 1984, based on § 404.316(c), § 404.337(c), or § 404.352(c). If this requirement is met, a VR agency can be paid for the costs of VR services provided within the period specified in § 404.2115, subject to the other payment and administrative provisions of this subpart.

■ 11. Amend § 404.2114 by revising paragraphs (a) introductory text, (a)(2), and (b)(4) to read as follows:

§ 404.2114 Services for which payment may be made.

(a) *General.* Payment may be made for VR services provided by a State VR agency in accordance with title I of the Rehabilitation Act of 1973, as amended, subject to the limitations and conditions in this subpart. VR services for which payment may be made under this subpart include only those services described in paragraph (b) of this section which are—

* * * * *

(2) Provided by a State VR agency under an IWRP, but only if the services could reasonably be expected to motivate or assist the individual in returning to, or continuing in, SGA.

(b) * * *

(4) Vocational and other training services, including personal and vocational adjustment, books, tools, and other training materials, except that training or training services in institutions of higher education will be covered under this section only if maximum efforts have been made by the State VR agency to secure grant assistance in whole or in part from other sources;

* * * * *

■ 12. Amend § 404.2115 by revising paragraphs (a) introductory text and (b) to read as follows:

§ 404.2115 When services must have been provided.

(a) In order for the VR agency to be paid, the services must have been provided—

* * * * *

(b) If an individual who is entitled to disability benefits under this part also is or has been receiving disability or blindness benefits under part 416 of this chapter, the determination as to when services must have been provided may be made under this section or § 416.2215 of this chapter, whichever is advantageous to the State VR agency that is participating in both VR programs.

■ 13. Amend § 404.2116 by revising the introductory text and paragraphs (b)(1) and (b)(2) to read as follows:

§ 404.2116 When claims for payment for VR services must be made (filing deadlines).

The State VR agency must file a claim for payment in each individual case within the following time periods:

* * * * *

(b) * * *

(1) If a written notice requesting that a claim be filed was sent to the State VR agency, a claim must be filed within 90 days following the month in which VR services end, or if later, within 90 days after receipt of the notice.

(2) If no written notice was sent to the State VR agency, a claim must be filed within 12 months after the month in which VR services end.

■ 14. Amend § 404.2117 by revising the introductory text and paragraphs (a), (b), (c)(1) introductory text, (c)(2), (d), and (e) to read as follows:

§ 404.2117 What costs will be paid.

In accordance with section 222(d) of the Social Security Act, the

Commissioner will pay the State VR agency for the VR services described in § 404.2114 which were provided during the period described in § 404.2115 and which meet the criteria in § 404.2111 or § 404.2112, but subject to the following limitations:

(a) The cost must have been incurred by the State VR agency;

(b) The cost must not have been paid or be payable from some other source. For this purpose, State VR agencies will be required to seek payment or services from other sources in accordance with the ''similar benefit'' provisions under 34 CFR part 361, including making maximum efforts to secure grant assistance in whole or part from other sources for training or training services in institutions of higher education.

(c)(1) The cost must be reasonable and necessary, in that it complies with the written cost-containment policies of the State VR agency. A cost which complies with these policies will be considered necessary only if the cost is for a VR service described in § 404.2114. The State VR agency must maintain and use these cost-containment policies, including any reasonable and appropriate fee schedules, to govern the costs incurred for all VR services, including the rates of payment for all purchased services, for which payment will be requested under this subpart. For the purpose of this subpart, the written cost-containment policies must provide guidelines designed to ensure—

* * * * *

(2) The State VR agency shall submit to us before the end of the first calendar quarter of each year a written statement certifying that cost-containment policies are in effect and are adhered to in procuring and providing goods and services for which the State VR agency requests payment under this subpart. Such certification must be signed by the State's chief financial official or the head of the VR agency. Each certification must specify the basis upon which it is made, *e.g.,* a recent audit by an authorized State, Federal or private auditor (or other independent compliance review) and the date of such audit (or compliance review). We may request the State VR agency to submit to us a copy(ies) of its specific written cost-containment policies and procedures (*e.g.,* any guidelines and fee schedules for a given year) if we determine that such additional information is necessary to ensure compliance with the requirements of this subpart. The State VR agency must provide such information when requested by us.

(d) The total payment in each case, including any prior payments related to earlier continuous 9-month periods of SGA made under this subpart, must not be so high as to preclude a ''net saving'' to the trust funds (a ''net saving'' is the difference between the estimated saving to the trust funds, if disability benefits eventually terminate, and the total amount we pay to the State VR agency);

(e) Any payment to the State VR agency for either direct or indirect VR expenses must be consistent with the cost principles described in OMB Circular No. A–87, as revised;

* * * * *

§ 404.2118 [Removed and Reserved]

■ 15. Remove and reserve § 404.2118.

■ 16. Revise § 404.2119 to read as follows:

§ 404.2119 Method of payment.

Payment to the State VR agencies pursuant to this subpart will be made either by advancement of funds or by payment for services provided (with necessary adjustments for any overpayments and underpayments), as decided by the Commissioner.

■ 17. Revise § 404.2120 to read as follows:

§ 404.2120 Audits.

(a) *General.* The State shall permit us and the Comptroller General of the United States (including duly authorized representatives) access to and the right to examine records relating to the services and costs for which payment was requested or made under these regulations. These records shall be retained by the State for the periods of time specified for retention of records in the Federal Acquisition Regulations (48 CFR part 4, subpart 4.7).

(b) *Audit basis.* Auditing will be based on cost principles and written guidelines in effect at the time services were provided and costs were incurred. The State VR agency will be informed and given a full explanation of any questioned items. It will be given a reasonable time to explain questioned items. Any explanation furnished by the State VR agency will be given full consideration before a final determination is made on questioned items in the audit report.

(c) *Appeal of audit determinations.* The appropriate SSA Regional Commissioner will notify the State VR agency in writing of his or her final determination on the audit report. If the State VR agency disagrees with that determination, it may request reconsideration in writing within 60 days after receiving the Regional Commissioner's notice of the determination. The Commissioner will make a determination and notify the State VR agency of that decision in writing, usually, no later than 45 days from the date of appeal. The decision by the Commissioner will be final and conclusive unless the State VR agency appeals that decision in writing in accordance with 45 CFR part 16 to the Department of Health and Human Services' Departmental Appeals Board within 30 days after receiving it.

■ 18. Amend § 404.2121 by revising paragraphs (a), (b)(3), (c), and (d) to read as follows:

§ 404.2121 Validation reviews.

(a) *General.* We will conduct a validation review of a sample of the claims for payment filed by each State VR agency. We will conduct some of these reviews on a prepayment basis and some on a postpayment basis. We may review a specific claim, a sample of the claims, or all the claims filed by any State VR agency, if we determine that such review is necessary to ensure compliance with the requirements of this subpart. For each claim selected for review, the State VR agency must submit such records of the VR services and costs for which payment has been requested or made under this subpart, or copies of such records, as we may require to ensure that the services and costs meet the requirements for payment. For claims for cases described in § 404.2101(a), a clear explanation or existing documentation which demonstrates how the service contributed to the individual's performance of a continuous 9-month period of SGA must be provided. For claims for cases described in § 404.2101(b) or (c), a clear explanation or existing documentation which demonstrates how the service was reasonably expected to motivate or assist the individual to return to or continue in SGA must be provided. If we find in any prepayment validation review, that the scope or content of the information is inadequate, we will request additional information and will withhold payment until adequate information has been provided. The State VR agency shall permit us (including duly authorized representatives) access to, and the right to examine, any records relating to such services and costs. Any review performed under this section will not be considered an audit for purposes of this subpart.

(b) * * *

(3) To assess the need for additional validation reviews or additional documentation requirements for any State VR agency to ensure compliance

with the requirements under this subpart.

(c) *Determinations.* In any validation review, we will determine whether the VR services and costs meet the requirements for payment and determine the amount of payment. We will notify in writing the State VR agency of our determination. If we find in any postpayment validation review that more or less than the correct amount of payment was made for a claim, we will determine that an overpayment or underpayment has occurred and will notify the State VR agency that we will make the appropriate adjustment.

(d) *Appeals.* If the State VR agency disagrees with our determination under this section, it may appeal that determination in accordance with § 404.2127. For purposes of this section, an appeal must be filed within 60 days after receiving the notice of our determination.

■ 19. Revise § 404.2122 to read as follows:

§ 404.2122 Confidentiality of information and records.

The State shall comply with the provisions for confidentiality of information, including the security of systems, and records requirements described in 20 CFR part 401 and pertinent written guidelines (see § 404.2123).

■ 20. Revise § 404.2123 to read as follows:

§ 404.2123 Other Federal laws and regulations.

Each State VR agency shall comply with the provisions of other Federal laws and regulations that directly affect its responsibilities in carrying out the vocational rehabilitation function.

■ 21. Amend § 404.2127 by revising paragraphs (a) and (c) to read as follows:

§ 404.2127 Resolution of disputes.

(a) *Disputes on the amount to be paid.* The appropriate SSA official will notify the State VR agency in writing of his or her determination concerning the amount to be paid. If the State VR agency disagrees with that determination, the State VR agency may request reconsideration in writing within 60 days after receiving the notice of determination. The Commissioner will make a determination and notify the State VR agency of that decision in writing, usually no later than 45 days from the date of the State VR agency's appeal. The decision by the Commissioner will be final and conclusive upon the State VR agency unless the State VR agency appeals that decision in writing in accordance with 45 CFR part 16 to the Department of Health and Human Services' Departmental Appeals Board within 30 days after receiving the Commissioner's decision.

* * * * *

(c) *Disputes on determinations made by the Commissioner which affect a disability beneficiary's rights to benefits.* Determinations made by the Commissioner which affect an individual's right to benefits (*e.g.,* determinations that disability benefits should be terminated, denied, suspended, continued or begun at a different date than alleged) cannot be appealed by a State VR agency. Because these determinations are an integral part of the disability benefits claims process, they can only be appealed by the beneficiary or applicant whose rights are affected or by his or her authorized representative. However, if an appeal of an unfavorable determination is made by the individual and is successful, the new determination would also apply for purposes of this subpart. While a VR agency cannot appeal a determination made by the Commissioner which affects a beneficiary's or applicant's rights, the VR agency can furnish any evidence it may have which would support a revision of a determination.

PART 411—THE TICKET TO WORK AND SELF-SUFFICIENCY PROGRAM

■ 22. The authority citation for part 411 continues to read as follows:

Authority: Secs. 702(a)(5) and 1148 of the Social Security Act (42 U.S.C. 902(a)(5) and 1320b–19); sec. 101(b)–(e), Public Law 106–170, 113 Stat. 1860, 1873 (42 U.S.C. 1320b–19 note).

Subpart A—Introduction

§ 411.100 [Amended]

■ 23. Amend § 411.100 by removing paragraph (j).

■ 24. Amend § 411.115 by revising paragraph (f) to read as follows:

§ 411.115 Definitions of terms used in this part.

* * * * *

(f) *Employment plan* means an individual work plan described in paragraph (i) of this section, or an individualized plan for employment described in paragraph (j) of this section.

* * * * *

Subpart E—Employment Networks

§ 411.305 [Amended]

■ 25. Amend § 411.305 by removing and reserving paragraph (d).

Subpart J—[Removed]

■ 26. Remove subpart J, consisting of §§ 411.700 through 411.730.

PART 416—SUPPLEMENTAL SECURITY INCOME FOR THE AGED, BLIND, AND DISABLED

Subpart A—Introduction, General Provisions and Definitions

■ 27. The authority citation for subpart A of part 416 is revised to read as follows:

Authority: Secs. 702(a)(5) and 1601–1635 of the Social Security Act (42 U.S.C. 902(a)(5) and 1381–1383d); sec. 212, Pub. L. 93–66, 87 Stat. 155 (42 U.S.C. 1382 note); sec. 502(a), Pub. L. 94–241, 90 Stat. 268 (48 U.S.C. 1681 note).

■ 28. Amend § 416.101 by revising paragraph (v) to read as follows:

§ 416.101 Introduction.

* * * * *

(v) Subpart V of this part explains when payments are made to State vocational rehabilitation agencies for vocational rehabilitation services.

Subpart V—Payments for Vocational Rehabilitation Services

■ 29. The authority citation for subpart V of part 416 continues to read as follows:

Authority: Secs. 702(a)(5), 1615, 1631(d)(1) and (e), and 1633(a) of the Social Security Act (42 U.S.C. 902(a)(5), 1382d, 1383(d)(1) and (e), and 1383b(a)).

■ 30. Amend § 416.2201 introductory text to read as follows:

§ 416.2201 General.

In general, sections 1615(d) and (e) of the Social Security Act (the Act) authorize payment from the general fund for the reasonable and necessary costs of vocational rehabilitation (VR) services provided certain disabled or blind individuals who are eligible for supplemental security income (SSI) benefits, special SSI eligibility status, or federally administered State supplementary payments. In this subpart, such benefits, status, or payments are referred to as disability or blindness benefits (see § 416.2203). Subject to the provisions of this subpart, payment may be made for VR services provided an individual during a month(s) for which the individual is eligible for disability or blindness benefits, including the continuation of such benefits under section 1631(a)(6) of the Act, or for which the individual's disability or blindness benefits are suspended (see § 416.2215). Paragraphs (a) and (b) of this section describe the

cases in which the State VR agencies can be paid for the VR services provided such an individual under this subpart. The purpose of sections 1615(d) and (e) of the Act is to make VR services more readily available to disabled or blind individuals and ensure that savings accrue to the general fund. Payment will be made for VR services provided on behalf of such an individual in cases where—

* * * * *

■ 31. Amend § 416.2202 as follows:

■ a. Remove and reserve paragraphs (c) and (j); and

■ b. Revise the introductory text and paragraphs (b), (d), (f), and (k).

The revisions read as follows:

§ 416.2202 Purpose and scope.

This subpart describes the rules under which the Commissioner will pay the State VR agencies for VR services. Payment will be provided for VR services provided on behalf of disabled or blind individuals under one or more of the provisions discussed in § 416.2201.

* * * * *

(b) Section 416.2204 explains how State VR agencies may participate in the payment program under this subpart.

(c) [Reserved]

(d) Sections 416.2208 through 416.2209 describe the requirements and conditions under which we will pay a State VR agency under this subpart.

* * * * *

(f) Section 416.2212 describes when payment will be made to a VR agency because an individual's disability or blindness benefits are continued based on his or her participation in a VR program which we have determined will increase the likelihood that he or she will not return to the disability rolls.

* * * * *

(j) [Reserved]

(k) Section 416.2219 describes how we will make payment to State VR agencies for rehabilitation services.

* * * * *

§ 416.2203 [Amended]

■ 32. Amend § 416.2203 by removing the definition of *Alternate participants.*

■ 33. Amend § 416.2204 as follows:

■ a. Remove paragraphs (b)(3) and (f);

■ b. Remove and reserve paragraph (e)(2);

■ c. Revise the heading of the section and paragraphs (a), (b)(2), (c)(2), and (e)(3).

The revisions read as follows:

§ 416.2204 Participation by State VR agencies.

(a) *General.* In order to participate in the payment program under this subpart through its VR agency(ies), a State must have a plan which meets the requirements of title I of the Rehabilitation Act of 1973, as amended.

(b) * * *

(2) A State with one or more approved VR agencies may choose to limit participation of those agencies to a certain class(es) of disabled or blind recipients. For example, a State with separate VR agencies for the blind and disabled may choose to limit participation to the VR agency for the blind. In such a case, we would give the State, through its VR agency for the blind, the opportunity to participate with respect to blind recipients in the State in accordance with paragraph (d) of this section. A State that chooses to limit participation of its VR agency(ies) must notify us in advance under paragraph (e)(1) of this section of its decision to limit such participation.

* * * * *

(c) * * *

(2)(i) In order for the State to participate with respect to a disabled or blind recipient whom we referred to a State VR agency, the State VR agency must notify the appropriate Regional Commissioner (SSA) in writing or through electronic notification of its decision either to accept the recipient as a client for VR services or to place the recipient into an extended evaluation process. The notice must be received by the appropriate Regional Commissioner (SSA) no later than the close of the fourth month following the month in which we referred the recipient to the State VR agency.

(ii) In any case in which a State VR agency notifies the appropriate Regional Commissioner (SSA) in writing within the stated time period under paragraph (c)(2)(i) of this section of its decision to place the recipient into an extended evaluation process, the State VR agency also must notify that Regional Commissioner in writing upon completion of the evaluation of its decision whether or not to accept the recipient as a client for VR services. If we receive a notice of a decision by the State VR agency to accept the recipient as a client for VR services following the completion of the extended evaluation, the State may continue to participate with respect to such recipient.

* * * * *

(e) * * *

(2) [Reserved]

(3) A State which has decided not to participate or to limit participation may participate later through its VR agency(ies) in accordance with paragraph (c) of this section. A State that decides to resume participation under paragraph (c) of this section must provide advance written notice of that decision to the appropriate Regional Commissioner (SSA). A decision of a State to resume participation under paragraph (c) of this section will be effective beginning with the third month following the month in which the notice of the decision is received by the appropriate Regional Commissioner (SSA) or, if later, with a month specified by the State. The notice of the State decision must be submitted by an official authorized to act for the State as explained in paragraph (e)(1) of this section.

* * * * *

§ 416.2206 [Removed and Reserved]

■ 34. Remove and reserve § 416.2206.

■ 35. Amend § 416.2208 by revising paragraphs (a), (d), and (f) as follows:

§ 416.2208 Requirements for payment.

(a) The State VR agency must file a claim for payment in each individual case within the time periods specified in § 416.2216;

* * * * *

(d) The VR services for which payment is being requested must have been provided under a State plan for VR services approved under title I of the Rehabilitation Act of 1973, as amended, and must be services that are described in § 416.2214;

* * * * *

(f) The State VR agency must maintain, and provide as we may require, adequate documentation of all services and costs for all disabled or blind recipients with respect to whom a State VR agency could potentially request payment for services and costs under this subpart; and

* * * * *

■ 36. Amend § 416.2211 by revising the introductory text and paragraphs (b)(1)(i), and (b)(2) to read as follows:

§ 416.2211 Criteria for determining when VR services will be considered to have contributed to a continuous period of 9 months.

The State VR agency may be paid for VR services if such services contribute to the individual's performance of a continuous 9-month period of SGA. The following criteria apply to individuals who received more than just evaluation services. If a State VR agency claims payment for services to an individual who received only evaluation services, it must establish that the individual's continuous period or medical recovery (if medical recovery occurred before completion of a continuous period) would not have occurred without the

services provided. In applying the criteria below, we will consider services described in § 416.2214 that were initiated, coordinated or provided, including services before October 1, 1981.

* * * * *

(b) * * *

(1) * * *

(i) The individualized written rehabilitation program (IWRP), included medical services; and

* * * * *

(2) In some instances, the State VR agency will not have provided, initiated, or coordinated medical services. If this happens, payment for VR services may still be possible under paragraph (a) of this section if:

(i) The medical recovery was not expected by us; and

(ii) The individual's impairment is determined by us to be of such a nature that any medical services provided would not ordinarily have resulted in, or contributed to, the medical cessation.

■ 37. Revise § 416.2212 to read as follows:

§ 416.2212 Payment for VR services in a case where an individual continues to receive disability or blindness benefits based on participation in an approved VR program.

Section 1631(a)(6) of the Act contains the criteria we will use in determining if an individual whose disability or blindness has ceased should continue to receive disability or blindness benefits because of his or her continued participation in an approved VR program. A VR agency can be paid for the cost of VR services provided to an individual if the individual was receiving benefits based on this provision in a month(s) after October 1984 or, in the case of a blindness recipient, in a month(s) after March 1988. If this requirement is met, a VR agency can be paid for the costs of VR services provided within the period specified in § 416.2215, subject to the other payment and administrative provisions of this subpart.

■ 38. Amend § 416.2214 by revising paragraph (a) introductory text, (a)(2), and (b)(4) to read as follows:

§ 416.2214 Services for which payment may be made.

(a) *General.* Payment may be made for VR services provided by a State VR agency in accordance with title I of the Rehabilitation Act of 1973, as amended, subject to the limitations and conditions in this subpart. VR services for which payment may be made under this subpart include only those services described in paragraph (b) of this section which are—

* * * * *

(2) Provided by a State VR agency under an IWRP, but only if the services could reasonably be expected to motivate or assist the individual in returning to, or continuing in, SGA.

(b) * * *

(4) Vocational and other training services, including personal and vocational adjustment, books, tools, and other training materials, except that training or training services in institutions of higher education will be covered under this section only if maximum efforts have been made by the State VR agency to secure grant assistance in whole or in part from other sources;

* * * * *

■ 39. Amend § 416.2215 by revising paragraphs (a) introductory text and (b) to read as follows:

§ 416.2215 When services must have been provided.

(a) In order for the VR agency to be paid, the services must have been provided—

* * * * *

(b) If an individual who is receiving disability or blindness benefits under this part, or whose benefits under this part are suspended, also is entitled to disability benefits under part 404 of this chapter, the determination as to when services must have been provided may be made under this section or § 404.2115 of this chapter, whichever is advantageous to the State VR agency that is participating in both VR programs.

■ 40. Amend § 416.2216 by revising the introductory text and paragraphs (b)(1) and (b)(2) to read as follows:

§ 416.2216 When claims for payment for VR services must be made (filing deadlines).

The State VR agency must file a claim for payment in each individual case within the following time periods:

* * * * *

(b) * * *

(1) If a written notice requesting that a claim be filed was sent to the State VR agency, a claim must be filed within 90 days following the month in which VR services end, or if later, within 90 days after receipt of the notice.

(2) If no written notice was sent to the State VR agency, a claim must be filed within 12 months after the month in which VR services end.

■ 41. Amend § 416.2217 by revising the introductory text and paragraphs (a), (b), (c)(1) introductory text, (c)(2), (d), and (e) as follows:

§ 416.2217 What costs will be paid.

In accordance with section 1615(d) and (e) of the Social Security Act, the Commissioner will pay the State VR agency for the VR services described in § 416.2214 which were provided during the period described in § 416.2215 and which meet the criteria in § 416.2211 or § 416.2212, but subject to the following limitations:

(a) The cost must have been incurred by the State VR agency;

(b) The cost must not have been paid or be payable from some other source. For this purpose, State VR agencies will be required to seek payment or services from other sources in accordance with the ''similar benefit'' provisions under 34 CFR part 361, including making maximum efforts to secure grant assistance in whole or part from other sources for training or training services in institutions of higher education.

(c)(1) The cost must be reasonable and necessary, in that it complies with the written cost-containment policies of the State VR agency. A cost which complies with these policies will be considered necessary only if the cost is for a VR service described in § 416.2214. The State VR agency must maintain and use these cost-containment policies, including any reasonable and appropriate fee schedules, to govern the costs incurred for all VR services, including the rates of payment for all purchased services, for which payment will be requested under this subpart. For the purpose of this subpart, the written cost-containment policies must provide guidelines designed to ensure—

* * * * *

(2) The State VR agency shall submit to us before the end of the first calendar quarter of each year a written statement certifying that cost-containment policies are in effect and are adhered to in procuring and providing goods and services for which the State VR agency requests payment under this subpart. Such certification must be signed by the State's chief financial official or the head of the VR agency. Each certification must specify the basis upon which it is made, *e.g.,* a recent audit by an authorized State, Federal or private auditor (or other independent compliance review) and the date of such audit (or compliance review). We may request the State VR agency to submit to us a copy(ies) of its specific written cost-containment policies and procedures (*e.g.,* any guidelines and fee schedules for a given year), if we determine that such additional information is necessary to ensure compliance with the requirements of this subpart. The State VR agency shall

provide such information when requested by us.

(d) The total payment in each case, including any prior payments related to earlier continuous 9-month periods of SGA made under this subpart, must not be so high as to preclude a ''net saving'' to the general funds (a ''net saving'' is the difference between the estimated savings to the general fund, if payments for disability or blindness remain reduced or eventually terminate, and the total amount we pay to the State VR agency);

(e) Any payment to the State VR agency for either direct or indirect VR expenses must be consistent with the cost principles described in OMB Circular No. A–87, as revised;

* * * * *

§ 416.2218 [Removed and Reserved]

■ 42. Remove and reserve § 416.2218.

■ 43. Revise § 416.2219 to read as follows:

§ 416.2219 Method of payment.

Payment to the State VR agencies pursuant to this subpart will be made either by advancement of funds or by payment for services provided (with necessary adjustments for any overpayments and underpayments), as decided by the Commissioner.

■ 44. Revise § 416.2220 to read as follows:

§ 416.2220 Audits.

(a) *General.* The State shall permit us and the Comptroller General of the United States (including duly authorized representatives) access to and the right to examine records relating to the services and costs for which payment was requested or made under these regulations. These records shall be retained by the State for the periods of time specified for retention of records in the Federal Acquisition Regulations (48 CFR part 4, subpart 4.7).

(b) *Audit basis.* Auditing will be based on cost principles and written guidelines in effect at the time services were provided and costs were incurred. The State VR agency will be informed and given a full explanation of any questioned items. They will be given a reasonable time to explain questioned items. Any explanation furnished by the State VR agency will be given full consideration before a final determination is made on questioned items in the audit report.

(c) *Appeal of audit determinations.* The appropriate SSA Regional Commissioner will notify the State VR agency in writing of his or her final determination on the audit report. If the State VR agency disagrees with that determination, it may request reconsideration in writing within 60 days after receiving the Regional Commissioner's notice of the determination. The Commissioner will make a determination and notify the State VR agency of that decision in writing, usually, no later than 45 days from the date of the appeal. The decision by the Commissioner will be final and conclusive unless the State VR agency appeals that decision in writing in accordance with 45 CFR part 16 to the Department of Health and Human Services' Departmental Appeals Board within 30 days after receiving it.

■ 45. Amend § 416.2221 by revising paragraphs (a), (b)(3), (c), and (d) to read as follows:

§ 416.2221 Validation reviews.

(a) *General.* We will conduct a validation review of a sample of the claims for payment filed by each State VR agency. We will conduct some of these reviews on a prepayment basis and some on a postpayment basis. We may review a specific claim, a sample of the claims, or all the claims filed by any State VR agency, if we determine that such review is necessary to ensure compliance with the requirements of this subpart. For each claim selected for review, the State VR agency must submit such records of the VR services and costs for which payment has been requested or made under this subpart, or copies of such records, as we may require to ensure that the services and costs meet the requirements for payment. For claims for cases described in § 416.2201(a), a clear explanation or existing documentation which demonstrates how the service contributed to the individual's performance of a continuous 9-month period of SGA must be provided. For claims for cases described in § 416.2201(b) or (c), a clear explanation or existing documentation which demonstrates how the service was reasonably expected to motivate or assist the individual to return to or continue in SGA must be provided. If we find in any prepayment validation review that the scope or content of the information is inadequate, we will request additional information and will withhold payment until adequate information has been provided. The State VR agency shall permit us (including duly authorized representatives) access to, and the right to examine, any records relating to such services and costs. Any review performed under this section will not be considered an audit for purposes of this subpart.

(b) * * *

(3) To assess the need for additional validation reviews or additional documentation requirements for any State VR agency to ensure compliance with the requirements under this subpart.

(c) *Determinations.* In any validation review, we will determine whether the VR services and costs meet the requirements for payment and determine the amount of payment. We will notify in writing the State VR agency of our determination. If we find in any postpayment validation review that more or less than the correct amount of payment was made for a claim, we will determine that an overpayment or underpayment has occurred and will notify the State VR agency that we will make the appropriate adjustment.

(d) *Appeals.* If the State VR agency disagrees with our determination under this section, it may appeal that determination in accordance with § 416.2227. For purposes of this section, an appeal must be filed within 60 days after receiving the notice of our determination.

■ 46. Revise § 416.2222 to read as follows:

§ 416.2222 Confidentiality of information and records.

The State shall comply with the provisions for confidentiality of information, including the security of systems, and records requirements described in 20 CFR part 401 and pertinent written guidelines (see § 416.2223).

■ 47. Revise § 416.2223 to read as follows:

§ 416.2223 Other Federal laws and regulations.

Each State VR agency shall comply with the provisions of other Federal laws and regulations that directly affect its responsibilities in carrying out the vocational rehabilitation function.

■ 48. Amend § 416.2227 by revising paragraphs (a) and (c) to read as follows:

§ 416.2227 Resolution of disputes.

(a) *Disputes on the amount to be paid.* The appropriate SSA official will notify the State VR agency in writing of his or her determination concerning the amount to be paid. If the State VR agency disagrees with that determination, the State VR agency may request reconsideration in writing within 60 days after receiving the notice of determination. The Commissioner will make a determination and notify the State VR agency of that decision in writing, usually, no later than 45 days

from the date of the State VR agency's appeal. The decision by the Commissioner will be final and conclusive upon the State VR agency unless the State VR agency appeals that decision in writing in accordance with 45 CFR part 16 to the Department of Health and Human Services' Departmental Appeals Board within 30 days after receiving the Commissioner's decision.

* * * * *

(c) *Disputes on determinations made by the Commissioner which affect a disabled or blind beneficiary's rights to benefits.* Determinations made by the Commissioner which affect an individual's right to benefits (*e.g.,* determinations that disability or blindness benefits should be terminated, denied, suspended, continued or begun at a different date than alleged) cannot be appealed by a State VR agency. Because these determinations are an integral part of the disability or blindness benefits claims process, they can only be appealed by the beneficiary or applicant whose rights are affected or by his or her authorized representative. However, if an appeal of an unfavorable determination is made by the individual and is successful, the new determination would also apply for purposes of this subpart. While a VR agency cannot appeal a determination made by the Commissioner which affects a beneficiary's or applicant's rights, the VR agency can furnish any evidence it may have which would support a revision of a determination.

[FR Doc. 2018–26231 Filed 12–3–18; 8:45 am]

BILLING CODE 4191–02–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9 and 721

[EPA–HQ–OPPT–2018–0627; FRL–9986–74]

RIN 2070–AB27

Significant New Use Rules on Certain Chemical Substances; Withdrawal

AGENCY: Environmental Protection Agency (EPA).

ACTION: Withdrawal of direct final rule.

SUMMARY: EPA is withdrawing significant new use rules (SNURs) promulgated under the Toxic Substances Control Act (TSCA) for 26 chemical substances, which were the subject of premanufacture notices (PMNs). EPA published these SNURs using direct final rulemaking procedures, which requires EPA to take certain actions if an adverse comment is received. EPA received adverse comments regarding the SNURs identified in the direct final rule. Therefore, the Agency is withdrawing the direct final rule SNURs identified in this document, as required under the direct final rulemaking procedures.

DATES: The direct final rule published at 83 FR 49806 on October 3, 2018 (FRL–9983–82) is withdrawn effective December 3, 2018.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPPT–2018–0627, is available at *http://www.regulations.gov* or at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT:

For technical information contact: Kenneth Moss, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 564–9232; email address: *moss.kenneth@epa.gov.*

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: *TSCA-Hotline@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Does this action apply to me?

A list of potentially affected entities is provided in the **Federal Register** of October 3, 2018 (83 FR 49806) (FRL–9983–82). If you have questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

II. What direct final SNURs are being withdrawn?

In the **Federal Register** of October 3, 2018 (83 FR 49806) (FRL–9983–82), EPA issued direct final SNURs for 26 chemical substances that are identified in the document. Because the Agency received adverse comments regarding the SNURs identified in the document, EPA is withdrawing the direct final SNURs issued for these 26 chemical substances, which were the subject of PMNs. In addition to the Direct Final SNURs, elsewhere in the same issue of the **Federal Register** of October 3, 2018 (83 FR 49903) (FRL–9983–81), EPA issued proposed SNURs covering these 26 chemical substances. EPA will address all adverse public comments in a subsequent final rule, based on the proposed rule.

III. Good Cause Finding

EPA determined that this document is not subject to the 30-day delay of effective date generally required by the Administrative Procedure Act (APA) (5 U.S.C. 553(d)) because of the time limitations for publication in the **Federal Register**. This document must publish on or before the effective date of the direct final rule containing the direct final SNURs being withdrawn.

IV. Statutory and Executive Order Reviews

This action withdraws regulatory requirements that have not gone into effect and which contain no new or amended requirements and reopens a comment period. As such, the Agency has determined that this action will not have any adverse impacts, economic or otherwise. The statutory and Executive Order review requirements applicable to the direct final rules were discussed in the October 3, 2018 **Federal Register** (83 FR 49806). Those review requirements do not apply to this action because it is a withdrawal and does not contain any new or amended requirements.

V. Congressional Review Act (CRA)

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2). Section 808 of the CRA allows the issuing agency to make a rule effective sooner than otherwise provided by CRA if the agency makes a good cause finding that notice and public procedure is impracticable, unnecessary, or contrary to the public interest. As required by 5 U.S.C. 808(2), this determination is supported by a brief statement in Unit III.

List of Subjects

40 CFR Part 9

Environmental protection, Reporting and recordkeeping requirements.

40 CFR Part 721

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: November 19, 2018.

Lance Wormell,

Acting Director, Chemical Control Division, Office of Pollution Prevention and Toxics.

■ Accordingly, the amendments to 40 CFR parts 9 and 721 published on October 3, 2018 (83 FR 49806), are withdrawn effective December 3, 2018.

[FR Doc. 2018–26358 Filed 12–3–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R01–OAR–2017–0344; FRL–9986–82–Region 1]

Air Plan Approval; New Hampshire; Infrastructure State Implementation Plan Requirements for the 2012 $PM_{2.5}$ NAAQS

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving two State Implementation Plan (SIP) submissions from New Hampshire that address the infrastructure SIP requirements, including the interstate transport requirements, of the Clean Air Act (CAA or Act) for the 2012 fine particle ($PM_{2.5}$) National Ambient Air Quality Standards (NAAQS). The approval does not address CAA section 110(a)(2)(K) (regarding air quality modeling and data), which EPA will address in a later rulemaking. The infrastructure SIP requirements are designed to ensure that the structural components of each state's air quality management program are adequate to meet the state's responsibilities with respect to this NAAQS under the CAA, including the obligations related to transport. The EPA is taking this action under the Clean Air Act.

DATES: This rule is effective on January 3, 2019.

ADDRESSES: EPA has established a docket for this action under Docket Identification No. EPA–R01–OAR–2017–0344. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *i.e.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available at *https://www.regulations.gov* or at the U.S. Environmental Protection Agency, EPA New England Regional Office, Office of Ecosystem Protection, Air Quality Planning Unit, 5 Post Office Square–Suite 100, Boston, MA. EPA requests that if at all possible, you contact the contact listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: Alison C. Simcox, Air Quality Unit, U.S. Environmental Protection Agency, EPA New England Regional Office, 5 Post Office Square–Suite 100, (Mail code OEP05–2), Boston, MA 02109–3912, tel. (617) 918–1684; *simcox.alison@epa.gov.*

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

Table of Contents

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

I. Background and Purpose

On April 10, 2018 (83 FR 15343), EPA published a Notice of Proposed Rulemaking (NPRM) for the State of New Hampshire. The NPRM proposed approval of two SIP submissions from the New Hampshire Department of Environmental Services (NHDES), which included an infrastructure SIP submission for the 2012 fine particle ($PM_{2.5}$[1]) National Ambient Air Quality Standard (NAAQS) submitted by the state on December 22, 2015, and a separate SIP submission addressing the ''Good Neighbor'' (or ''transport'') provisions for the 2012 $PM_{2.5}$ NAAQS (Section 110(a)(2)(D)(i)(I) of the CAA) submitted by the state on June 8, 2016.

This rulemaking does not cover three substantive areas that are not integral to acting on a state's infrastructure SIP submission: (i) Existing provisions related to excess emissions during periods of start-up, shutdown, or malfunction at sources (''SSM'' emissions) that may be contrary to the CAA and EPA's policies addressing such excess emissions; (ii) existing provisions related to ''director's variance'' or ''director's discretion'' that purport to permit revisions to SIP-approved emissions limits with limited public process or without requiring further approval by EPA, that may be contrary to the CAA (''director's discretion''); and, (iii) existing provisions for Prevention of Significant Deterioration (PSD) programs that may be inconsistent with current requirements of EPA's ''Final New Source Review (NSR) Improvement Rule,'' 67 FR 80186 (December 31, 2002), as amended by 72 FR 32526 (June 13, 2007) (''NSR Reform''). Instead, EPA has the authority to address each of these substantive areas separately. A detailed history, interpretation, and rationale for EPA's approach to infrastructure SIP requirements can be found in EPA's May 13, 2014, proposed rule entitled, ''Infrastructure SIP Requirements for the 2008 Lead NAAQS'' in the section, ''What is the scope of this rulemaking?'' *See* 79 FR 27241 at 27242–45.

The rationale for EPA's proposed action is explained in the NPRM and will not be restated here.

II. Response to Comments

EPA received six sets of comments during the comment period. Only one set includes significant, adverse comment, and it relates solely to section 110(a)(2)(K) of the Act (regarding air quality modeling and data). In the NPRM, EPA proposed to approve NHDES' submissions for the 2012 $PM_{2.5}$ NAAQS for the infrastructure requirements of Section 110(a)(2)(A) through (M), including (K). In this rulemaking, EPA is finalizing the approval of New Hampshire's submissions for the infrastructure requirements of section 110(a)(2)(A) through (M), *except* (K). EPA will take separate action at a later date addressing these comments and the section 110(a)(2)(K) requirements for New Hampshire's infrastructure SIP submissions for the 2012 $PM_{2.5}$ NAAQS.

The other five sets of comments we received all discuss subjects outside the scope of an infrastructure SIP action, do not explain (or provide a legal basis for) how the proposed action should differ in any way, and, indeed, make no specific mention of the proposed action. Consequently, those five sets of comments are not germane to this rulemaking and require no further response.

III. Final Action

EPA is approving New Hampshire's December 2015 and June 2016 infrastructure SIP submissions for the 2012 $PM_{2.5}$ NAAQS, except for Section

[1] $PM_{2.5}$ refers to particulate matter of 2.5 microns or less in diameter, often referred to as ''fine'' particles.

110(a)(2)(K) (regarding air quality modeling and data), which EPA will address in a later rulemaking.

IV. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- This action is not an Executive Order 13771 regulatory action because this action is not significant under Executive Order 12866;
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

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

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by February 4, 2019. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

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

Dated: November 28, 2018.

Alexandra Dunn,

Regional Administrator, EPA Region 1.

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

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart EE—New Hampshire

■ 2. Amend § 52.1520 in the table in paragraph (e) by adding an entry for ''Submittals to meet Section 110(a)(2) Infrastructure Requirements for the 2012 $PM_{2.5}$ NAAQS'' at the end of the table to read as follows:

§ 52.1520 Identification of plan.

* * * * *

(e) * * *

NEW HAMPSHIRE NONREGULATORY

Name of nonregulatory SIP provision	Applicable geographic or nonattainment area	State submittal date/ effective date	EPA approved date	Explanations
*	* *	*	* *	*
Submittals to meet Section 110(a)(2) Infrastructure Requirements for the 2012 $PM_{2.5}$ NAAQS.	Statewide	12/22/2015; supplement submitted 6/8/2016.	12/4/2018, [Insert **Federal Register** citation].	These submittals are approved with respect to the following CAA requirements: 110(a)(2)(A), (B), (C), (D), (E), (F), (G), (H), (J), (L), and (M).

[FR Doc. 2018–26284 Filed 12–3–18; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R01–OAR–2018–0099; FRL–9986–97–Region 1]

Air Plan Approval; Connecticut; Volatile Organic Compound Emissions From Consumer Products and Architectural and Industrial Maintenance Coatings; Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; correction.

SUMMARY: This document corrects the preamble in the **DATES** section to a final rule published in the **Federal Register** on November 19, 2018. The Environmental Protection Agency (EPA) published a final rule approving Connecticut's State Implementation Plan (SIP) revision that amended requirements for controlling volatile organic compound (VOC) emissions from consumer products and architectural and industrial maintenance (AIM) coatings by revising Regulations of Connecticut State Agencies (RCSA) sections 22a–174–40, 22a–174–41, and adding section 22a–174–41a.

DATES: This final rule correction is effective on December 4, 2018.

FOR FURTHER INFORMATION CONTACT: Ariel Garcia, Air Quality Planning Unit, U.S. Environmental Protection Agency, EPA Region 1 Regional Office, 5 Post Office Square, Suite 100 (Mail code: OEP05–2), Boston, MA 02109–3912, telephone number: (617) 918–1660, email *garcia.ariel@epa.gov.*

SUPPLEMENTARY INFORMATION: The EPA issued a final rule in the **Federal Register** on November 19, 2018 (83 FR 58188). An error occurred in the **DATES** section where it erroneously stated that ''Written comments must be received on or before December 19, 2018.'' The EPA previously provided an opportunity for written comments, on our proposed approval of Connecticut's SIP revision, in a proposed rule issued in the **Federal Register** on June 4, 2018 (83 FR 25615). Therefore, this corrective action merely designates the Final rule as being effective on December 19, 2018.

Correction

In FR Doc. 2018–24895 appearing on page 58188 in the **Federal Register** of Monday, November 19, 2018, the following correction is made:

On page 58188, in the second column, under the heading entitled **DATES** remove the text ''Written comments must be received on or before December 19, 2018.'' and add in its place the text ''This final rule is effective on December 19, 2018.''.

Dated: November 28, 2018.

Alexandra Dunn,

Regional Administrator, EPA Region 1.

[FR Doc. 2018–26286 Filed 12–3–18; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2018–0116; FRL–9987–12–Region 4]

Air Plan Approval; Georgia; Revisions To VOC Definitions and Ambient Air Quality Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: On November 13, 2017, the State of Georgia through the Georgia Environmental Protection Division (EPD), submitted a revision to the Georgia State Implementation Plan (SIP). The Environmental Protection Agency (EPA) is approving changes to several portions of the revision that modifies the State's air quality regulations as incorporated into the SIP. Specifically, the revision pertains to definition changes, including the modification of the definition of ''volatile organic compounds'' (VOC) and changes to the State's air quality standards for sulfur dioxide, particulate matter, carbon monoxide, ozone, lead and nitrogen dioxide to be consistent with the National Ambient Air Quality Standard (NAAQS). EPA is approving these provisions of the SIP revision because the State has demonstrated that the changes are consistent with the Clean Air Act (CAA or Act).

DATES: This rule will be effective January 3, 2019.

ADDRESSES: EPA has established a docket for this action under Docket Identification No. EPA–R04–OAR–2018–0116. All documents in the docket are listed on the *www.regulations.gov* website. Although listed in the index, some information is not publicly available, *i.e.,* Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy at the Air Regulatory Management Section, Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. EPA requests that if at all possible, you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: Tiereny Bell, Air Regulatory Management Section, Air Planning and Implementation Branch, Pesticides and Toxics Management Division, Region 4, U.S. Environmental Protection Agency, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. The telephone number is (404) 562–9088. Ms. Bell can also be reached via electronic mail at *bell.tiereny@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On July 17, 2018 (83 FR 33168), EPA proposed to approve into the Georgia SIP changes to Georgia's air quality rule 391–3–1–.01, ''Definitions'' and rule 391–3–1–.02(4), ''Ambient Air Standards'' submitted by the State of Georgia through the Georgia EPD on November 13, 2017. EPA's July 17, 2018, rulemaking did not propose action on Georgia's air quality rules 391–3–1–.03(6), ''Exemption'' under permits and rule 391–3–1–.0(7)(a)(1), ''General Requirements'' under Prevention of Significant Deterioration (PSD). EPA will address these changes in a separate notice. Additionally, EPA's July 17, 2018, rulemaking did not propose action on Georgia's air quality rule 391–3–1–.02(7)(a)2(ix), ''Regulated NSR pollutant'' under PSD, and rule 391–3–1–.03(8)(c)(16), ''Additional Provisions for $PM_{2.5}$ Non-attainment Areas'' under permits.[1]

The November 13, 2017, SIP revision changes Rule 391–3–1–.01, ''Definitions'' by adding t-Butyl acetate (also known as tertiary butyl acetate or TBAC) and 1,1,2,2-Tetrafluoro-1-(2,2,2-trifluoroethoxy) ethane to the list of

[1] The State withdrew Rule 391–3–1–.02(7)(a)2(ix), ''Regulated NSR pollutant'' and Rule 391–3–1–.03(8)(c)(16), ''Additional Provisions for $PM_{2.5}$ Non-Attainment Areas'' on December 1, 2016, and July 26, 2017, respectively. The State also acknowledges this in the response to comment of the pre-hearing in the November 13, 2017, submittal. The information is in the Docket.

organic compounds having negligible photochemical reactivity. The definition of VOC is also being updated by removing the recordkeeping requirements for t-Butyl acetate. Additionally, the definition of VOC is being revised to include chemical names to clarify previous exemptions. Lastly, the submission revises Rule 391–3–1–.02(4), ''Ambient Air Standards'' by updating Georgia's air quality standard to be consistent with the NAAQS. The details of the Georgia submission and the rationale for EPA's action are explained in the proposed rulemaking. Comments on the proposed rulemaking were due on or before August 20, 2018. EPA did not receive any adverse comments on the proposed action. EPA is now taking final action to approve the above-referenced revisions.

II. Incorporation by Reference

In this rule, EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is finalizing the incorporation by reference of Georgia Rule 391–3–1–.01 entitled ''Definitions,'' effective July 20, 2017, which revises the VOC definition and removes the recordkeeping requirements for t-Butyl acetate. Rule 391–3–1–.02(4) entitled ''Ambient Air Standards,'' effective July 20, 2017, updates Georgia's air quality standard to be consistent with the NAAQS. EPA has made, and will continue to make, these materials generally available through *www.regulations.gov* and at the EPA Region 4 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information). Therefore, these materials have been approved by EPA for inclusion in the State implementation plan, have been incorporated by reference by EPA into that plan, are fully federally enforceable under sections 110 and 113 of the CAA as of the effective date of the final rulemaking of EPA's approval, and will be incorporated by reference in the next update to the SIP compilation.[2]

III. Final Action

EPA is taking final action to approve Georgia's November 13, 2017, SIP revision which amends the VOC definition in rule 391–3–1–.01, and updates Georgia's air quality standards to be consistent with the NAAQS in rule 391–3–1–.02(4). EPA has evaluated the relevant portions of Georgia's November 13, 2017, SIP revision and has determined that it meets the applicable requirements of the CAA and EPA regulations.

IV. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. *See* 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. This action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because SIP approvals are exempted under Executive Order 12866;
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

The SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it impose substantial direct costs on tribal governments or preempt tribal law.

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

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by February 4, 2019. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. *See* section 307(b)(2).

List of Subjects in 40 CFR Part 52

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

Dated: November 15, 2018.

Onis ''Trey'' Glenn, III,

Regional Administrator, Region 4.

40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

[2] *See* 62 FR 27968 (May 22, 1997).

Subpart L—Georgia

■ 2. In § 52.570, the table in paragraph (c) is amended by revising the entries ''391–3–1–.01'' and ''391–3–1–.02(4)'' to read as follows:

§ 52.570 Identification of plan.

* * * * *

(c)* * *

EPA-APPROVED GEORGIA REGULATIONS

State citation	Title/subject	State effective date	EPA approval date	Explanation
391–3–1–.01	Definitions	7/20/2017	12/4/2018, [insert **Federal Register** citation]	
*	*	*	*	*
Emission Standards				
*	*	*	*	*
391–3–1–.02(4)	Ambient Air Standards	7/20/2017	12/4/2018 [insert **Federal Register** citation]	
*	*	*	*	*

* * * * *

[FR Doc. 2018–26245 Filed 12–3–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R06–OAR–2018–0676; FRL–9986–66–Region 6]

Air Plan Approval; Texas; Emission Statements

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: Pursuant to the Federal Clean Air Act (CAA or the Act), the Environmental Protection Agency (EPA) is approving a portion of a State Implementation Plan (SIP) revision submitted by the State of Texas for the 2008 8-hour ozone national ambient air quality standards (NAAQS). The portion of the SIP revision being approved pertains to CAA 2008 ozone NAAQS requirement for emission statements in the Dallas/Fort Worth ozone nonattainment area (DFW area).

DATES: This rule is effective on March 4, 2019 without further notice, unless the EPA receives relevant adverse comment by January 3, 2019. If the EPA receives such comment, the EPA will publish a timely withdrawal in the **Federal Register** informing the public that this rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket No. EPA–R06–OAR–2018–0676, at *https://www.regulations.gov* or via email to *ruan-lei.karolina@epa.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, please contact Ms. Karolina Ruan Lei, 214–665–7346, *ruan-lei.karolina@epa.gov.* For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.*

Docket: The index to the docket for this action is available electronically at *www.regulations.gov* and in hard copy at EPA Region 6, 1445 Ross Avenue, Suite 700, Dallas, Texas. While all documents in the docket are listed in the index, some information may be publicly available only at the hard copy location (*e.g.,* copyrighted material), and some may not be publicly available at either location (*e.g.,* CBI).

FOR FURTHER INFORMATION CONTACT: Ms. Karolina Ruan Lei, 214–665–7346, *ruan-lei.karolina@epa.gov.* To inspect the hard copy materials, please schedule an appointment with Ms. Karolina Ruan Lei or Mr. Bill Deese at 214–665–7253.

SUPPLEMENTARY INFORMATION: Throughout this document ''we,'' ''us,'' and ''our'' means the EPA.

I. Background

Section 110 of the CAA requires states to develop and submit to the EPA a SIP to ensure that state air quality meets the NAAQS. These ambient standards currently address six criteria pollutants: Carbon monoxide, nitrogen dioxide, ozone, lead, particulate matter, and sulfur dioxide. Each federally-approved SIP protects air quality primarily by addressing air pollution at its point of origin through air pollution regulations and control strategies. The EPA approved SIP regulations and control strategies are federally enforceable.

In 2008, we revised the 8-hour ozone primary and secondary NAAQS to a level of 0.075 parts per million (ppm) to provide increased protection of public health and the environment (73 FR 16436, March 27, 2008). The 2008 8-hour ozone NAAQS revised the 1997 8-hour ozone NAAQS of 0.08 ppm. The DFW area was classified as a ''Moderate'' ozone nonattainment area for the 2008 8-hour ozone NAAQS (77 FR 30088, May 21, 2012). The DFW 2008 ozone nonattainment area consists of Collin, Dallas, Denton, Ellis, Johnson, Kaufman, Parker, Rockwall, Tarrant, and Wise counties.

On August 21, 2018, Texas submitted a SIP revision addressing oxides of nitrogen (NO_x) reasonably available control technology (RACT) for a cement manufacturing plant in Ellis County as a part of its DFW 2008 8-hour ozone NAAQS SIP update. That SIP revision also included a description of how the CAA Section 182(a)(3)(B) requirement for emission statements from stationary point sources are met in the DFW area for the 2008 ozone NAAQS, using already-existing measures previously

approved by EPA.[1] EPA is only evaluating the emission statements portion of the August 21, 2018 SIP submittal in this action.[2] A copy of the SIP revision submittal that includes the emission statement requirement is included in the docket to this rulemaking and is available online at *www.regulations.gov,* Docket number EPA–R06–OAR–2018–0676. In the SIP revision submittal, Texas noted that the SIP revision pertaining to emissions inventory requirements approved by EPA on August 26, 1994 (59 FR 44036) meets the CAA requirement for emission statements. The codification of the Texas SIP approved by EPA can be found at 40 CFR 52.2270(c).

II. The EPA's Evaluation

CAA section 182(a)(3)(B) calls for SIPs for all ozone nonattainment areas to require that the owner or operator of each stationary source of nitrogen oxides or volatile organic compounds (ozone precursors) provide the State with an annual statement of emissions along with a certification that this information is accurate to the best knowledge of the individual certifying the statement.

The Texas SIP includes 30 TAC Section 101.10 (Emissions Inventory Requirements). The certification for emission statements is found at 30 TAC Section 101.10(d) (Certifying statement). We initially approved this certification as meeting the CAA emission statement requirement on August 26, 1994 (59 FR 44036).[3] Most recently we approved revisions to 30 TAC Section 101.10 (Emissions Inventory Requirements) on June 8, 2017 (82 FR 26598). The most recently EPA approved Texas regulation continues to include appropriate provisions so that the owner or operator of each stationary source must provide the State with a statement with each emissions inventory attesting that the information contained in the inventory is true and accurate to the best knowledge of the certifying official (30 TAC Section 101.10(d)(1)). We find that the SIP revision submittal that is the subject of this action continues to be consistent with those requirements. Therefore, since the Texas SIP already includes an approved CAA emission statement requirement, we are approving this portion of the SIP revision as it pertains to the 2008 ozone standard.

III. Final Action

We are approving the revision to the Texas SIP submitted on August 21, 2018, that pertains to the 2008 ozone NAAQS requirement for emission statements for large stationary sources in the DFW area.

The EPA is publishing this rule without prior proposal because we view this as a non-controversial amendment and anticipate no adverse comments. However, in the proposed rules section of this **Federal Register** publication, we are publishing a separate document that will serve as the proposal to approve the SIP revision if relevant adverse comments are received. This rule will be effective on March 4, 2019 without further notice unless we receive relevant adverse comment by January 3, 2019. If we receive relevant adverse comments, we will publish a timely withdrawal in the **Federal Register** informing the public that the rule will not take effect. We will address all public comments in a subsequent final rule based on the proposed rule. We will not institute a second comment period on this action. Any parties interested in commenting must do so now. Please note that if we receive relevant adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, we may adopt as final those provisions of the rule that are not the subject of an adverse comment.

IV. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because SIP approvals are exempted under Executive Order 12866;
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. The EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal**

[1] See page 4–4 of the adopted SIP revision submittal by Texas that is included in the docket to this action.

[2] In a separate action we proposed to approve the remainder of the August 21, 2018 SIP submittal. See Docket number EPA–R06–OAR–2018–0675 online at *www.regulations.gov.*

[3] In that action, we approved revisions to 30 TAC Section 101.10: Emissions Inventory Requirements and the emission statement program for stationary sources within ozone nonattainment areas as the revisions satisfied CAA Section 182(a)(3)(B) requirements and was consistent with EPA's draft Guidance on the Implementation of an Emission Statement Program (July 1992).

Register. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by February 4, 2019. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: November 26, 2018.

Anne Idsal,

Regional Administrator, Region 6.

40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart SS—Texas

■ 2. In § 52.2270(e), the second table titled ''EPA Approved Nonregulatory Provisions and Quasi-Regulatory Measures in the Texas SIP'' is amended by adding an entry at the end for ''Emission Statement Requirements for the 2008 Ozone NAAQS''.

The revision reads as follows:

§ 52.2270 Identification of plan.

* * * * *

(e) * * *

EPA APPROVED NONREGULATORY PROVISIONS AND QUASI-REGULATORY MEASURES IN THE TEXAS SIP

Name of SIP provision	Applicable geographic or non-attainment area	State submittal/ effective date	EPA approval date	Comments
*	*	*	*	*
Emission Statement Requirements for the 2008 Ozone NAAQS.	Dallas-Fort Worth, TX.	8/21/2018	12/4/2018, [Insert **Federal Register** citation].	

[FR Doc. 2018–26294 Filed 12–3–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2017–0633; FRL–9986–89–Region 3]

Approval and Promulgation of Air Quality Implementation Plans; West Virginia; Revisions to Regulation for Control of Ozone Season Nitrogen Oxide Emissions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving two state implementation plan (SIP) revisions submitted by the State of West Virginia. The revisions pertain to a West Virginia regulation that established the nitrogen oxides (NO_X) ozone season trading program under the Clean Air Interstate Rule (CAIR), which implemented requirements for NO_X reductions necessary to reduce interstate transport of pollution. The EPA-administered trading programs under CAIR were discontinued upon the implementation of the Cross-State Air Pollution Rule (CSAPR), which was promulgated by EPA to replace CAIR. CSAPR established Federal implementation plans (FIPs) for 28 states, including West Virginia, and applied to electric generating units (EGUs). The SIP submittals are comprised of revisions to the West Virginia regulation that implemented the CAIR ozone season NO_X trading program that had previously been included in the West Virginia SIP. The revised West Virginia regulation removed the CAIR ozone season NO_X trading program provisions, which also addressed certain large non-electric generating units (non-EGUs), established new requirements for these large non-EGUs, included a state-wide NO_X emissions cap, and recodified certain other provisions that address the NO_X emission reductions required for cement kilns and internal combustion engines. EPA is approving these SIP revisions to West Virginia's ozone season NO_X regulation in accordance with the requirements of the Clean Air Act (CAA).

DATES: This final rule is effective on January 3, 2019.

ADDRESSES: EPA has established a docket for this action under Docket ID Number EPA–R03–OAR–2017–0633. All documents in the docket are listed on the *http://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* confidential business information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through *http://www.regulations.gov,* or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information.

FOR FURTHER INFORMATION CONTACT: Marilyn Powers, (215) 814–2308, or by email at *powers.marilyn@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On August 28, 2018 (82 FR 43836), EPA published a notice of proposed rulemaking (NPRM) which proposed approval of the SIP revisions submitted by the State of West Virginia for revisions to Regulation 45CSR40. The first formal SIP revision was submitted by West Virginia through the West Virginia Department of Environmental Protection (WVDEP) on July 13, 2016. On October 10, 2017, WVDEP provided a supplemental SIP submission comprised of a demonstration showing that NO_X emissions from applicable non-EGUs do not exceed the West

Virginia NO_X budget under EPA's NO_X SIP Call.[1] The NO_X SIP Call, issued pursuant to Section 110 of the CAA and codified at 40 CFR 51.121 and 51.122, was designed to mitigate significant transport of NO_X, one of the precursors of ozone. At the same time, EPA developed the NO_X Budget Trading Program, an EPA-administered allowance trading program that states could adopt to meet their obligations under the NO_X SIP Call. The NO_X Budget Trading Program allowed EGUs greater than 25 megawatts and industrial non-EGUs, such as boilers and turbines, with a rated heat input greater than 250 million British thermal units per hour (MMBtu/hr), referred to as ''large non-EGUs,'' to participate in a regional NO_X cap and trade program. West Virginia complied with the NO_X SIP Call by participation of its large EGUs and large non-EGUs in the NO_X Budget Trading Program. EPA discontinued administration of the NO_X Budget Trading Program in 2009 upon the start of the CAIR trading programs (70 FR 25162, May 12, 2005). The NO_X SIP Call requirements continued to apply, however, and EGUs in most states (including West Virginia) that formerly participated in the NO_X Budget Trading Program continued to meet their NO_X SIP Call requirements under the generally more stringent requirements of the CAIR NO_X Ozone Season Trading Program, either pursuant to CAIR FIPs (71 FR 25328, April 28, 2006) or pursuant to approved CAIR SIP revisions.[2] For the large non-EGUs, states needed to take regulatory action to ensure that their obligations under the NO_X SIP Call continued to be met, either through an option to submit a CAIR SIP revision that allowed the non-EGUs to participate in the CAIR NO_X Ozone Season Trading Program or through adoption of other replacement regulations. West Virginia chose to include the large non-EGUs as CAIR trading sources, and submitted, for inclusion in the SIP, Regulation 40CSR40 which implemented the CAIR NO_X Ozone Season Trading Program and included the non-EGUs as trading sources. EPA approved Regulation 45CSR40 into the West Virginia SIP on August 4, 2009 (74 FR 38536). 45CSR40 also included requirements for stationary internal combustion engines and cement manufacturing kilns that are subject to the NO_X SIP Call.

When CSAPR replaced CAIR starting on January 1, 2015,[3] the CSAPR FIP trading programs for annual NO_X, ozone season NO_X and annual SO_2 were applicable in West Virginia. Thus, since January 1, 2015, the provisions related to implementation of the CAIR Ozone Season Trading Program in West Virginia regulation 45CSR40 were obsolete. Initially, the CSAPR FIP trading programs applied only to EGUs and, unlike CAIR, did not provide for expansion of the ozone season trading program to include the NO_X SIP Call large non-EGUs. States, like West Virginia, whose large non-EGUs had previously traded in the CAIR NO_X Ozone Season Trading Program, were therefore required to address the non-EGU reduction requirements of the NO_X SIP Call outside of a regional trading program.[4]

The CSAPR FIPs which replaced CAIR only applied to EGUs, and, at the time West Virginia developed its SIP submittal, states did not have an option under CSAPR to bring their non-EGUs into the CSAPR NO_X Ozone Season Trading Program. So, while EGU compliance with CSAPR satisfied the EGUs' NO_X SIP Call requirements, West Virginia needed to modify its ozone season NO_X regulation to address the NO_X SIP Call requirements for the non-EGUs that were formerly trading in the CAIR NO_X ozone season trading program. 40 CFR 51.121(f) sets forth alternatives for states to address NO_X SIP Call reduction obligations for large non-EGUs including (1) imposing a NO_X mass emissions cap on each source, (2) imposing a NO_X emissions rate limit on each source and assuming maximum operating capacity for every such source for purposes of estimating NO_X mass emissions, or (3) imposing other regulatory requirements that the state has demonstrated to EPA provide equivalent or greater assurance that the state will comply with its ozone season NO_X budget.

II. Summary of SIP Revision and EPA Analysis

Former Regulation 45CSR40 (effective in West Virginia on July 1, 2016), which was approved into the West Virginia SIP, was originally adopted by WVDEP to implement the ozone season trading program under CAIR and to address NO_X SIP Call requirements. The July 13, 2016 West Virginia SIP submittal is comprised of a revised 45CSR40 which removed the CAIR Ozone Season Trading Program provisions, retained the definitions, applicability, and other provisions responding to the NO_X SIP Call (including monitoring under 40 CFR part 75), added new requirements to address its NO_X SIP Call obligations for sources that were trading under CAIR but are no longer part of a trading program, and retained and recodified the limits on NO_X emissions that applied to stationary internal combustion engines and cement kilns previously in the former version of 45CSR40 (with a State effective date of May 1, 2008) which EPA had approved into the West Virginia SIP. As the CAIR trading program has been replaced by the trading programs under CSAPR, as described previously, these revisions removing references to CAIR are consistent with the requirements for CAA 110(l) as CAIR was replaced by CSAPR and thus no longer yielded reductions in pollutants nor presently applied to any sources.

On February 8, 2018, WVDEP provided a letter clarifying an applicability exclusion specified in section 4 of 45CSR40 of the July 13, 2016 SIP submittal. The letter clarifies that the West Virginia regulation was intended to refer to current provisions of CSAPR, and thus is intended to refer to updated CSAPR provisions. The letter states that West Virginia will work towards revising 45CSR40 as expeditiously as possible to conform the regulation to refer to currently enforceable CSAPR provisions and will submit the revised 45CSR40 as a SIP revision to EPA for approval once the regulation correctly refers to 40 CFR part 97, subpart EEEEE.

Other specific requirements of revised West Virginia regulation 45CSR40 and the rationale for EPA's proposed approval are explained in the NPRM and will not be restated here. However, EPA provides two clarifications on the NPRM—one pertains to an aspect of EPA's summary of the new sections in 45CSR40 that address ozone season NO_X emissions, and the second pertains to the date of West Virginia's supplemental SIP submission.

EPA's summary of section 4 (Applicability) explained that any unit that is already subject to the CSAPR NO_X Ozone Season Trading Program FIP established under 40 CFR part 97, subpart BBBBB is exempt from the ozone season NO_X emission limits,

[1] In October 1998 (63 FR 57356), EPA finalized the ''Finding of Significant Contribution and Rulemaking for Certain States in the Ozone Transport Assessment Group Region for Purposes of Reducing Regional Transport of Ozone''—commonly called the NO_X SIP Call.

[2] EPA approved a CAIR SIP revision replacing the CAIR FIP for West Virginia on August 4, 2009 (74 FR 38536).

[3] *See* NPRM for this action, page 43837, for details on the remand of CAIR.

[4] Subsequent to West Virginia's July 13, 2016 submission, EPA finalized the CSAPR Update Rule to address transport related to the 2008 ozone NAAQS. It is noted that CSAPR Update included flexibility for states to submit SIPs that expand the CSAPR ozone season trading program to include the large non-EGUs. West Virginia has not submitted a SIP that includes the non-EGUs as participants in the CSAPR trading program.

monitoring, recordkeeping, and reporting requirements established in sections 5 and 6 of 45CSR40.[5] Section 4 of 45CSR40 also exempts from applicability any units subject to a CSAPR-equivalent trading program established under regulations approved as a SIP revision pursuant to 40 CFR 52.38(b)(5).[6] Thus, while West Virginia presently does not have a CSAPR-equivalent program in its SIP, if West Virginia submits a SIP revision for a CSAPR-equivalent trading program in the future, and EPA approves the submittal into the State's SIP, sections 5 and 6 of 45CSR40–4 would not apply to such units. EPA's intent, as stated in the NPRM, is to approve the State submission in full, including the entirety of section 4. Thus, our approval of 45CSR40 is not affected; we are providing this clarification to explain the breadth of 45CSR40.

Also, EPA clarifies that the October 10, 2017 SIP submission, which West Virginia submitted to demonstrate compliance with its NO_X SIP Call non-EGU NO_X emissions budget, was the only supplemental submission from West Virginia. The references to an October 11, 2017 and an October 13, 2017 supplemental submission were in error and should have instead referred to the October 10, 2017 submittal, which is included in the docket for this rulemaking action.

III. Public Comments and EPA's Responses

EPA received three anonymous comments on the NPRM, all of which are in the docket for this rulemaking at *www.regulations.gov.* One of the comments did not concern any of the specific issues raised in the NPRM, nor did they address EPA's rationale for the proposed approval of WVDEP's submittal. Therefore, EPA is not responding to this comment. The remaining two comments are addressed as follows:

Comment 1: A commenter noted that the NPRM made reference to an October 11, 2017 and an October 13, 2017 supplemental submission from West Virginia, and asked where these submissions were as the docket only included a supplemental submission dated October 10, 2017.

EPA Response: The references to the October 11, 2017 and October 13, 2017 submittals were in error as EPA intended to refer instead to the October 10, 2017 supplemental submission. There was only one supplemental submission from West Virginia—the October 10, 2017 submittal, which provided the demonstration that West Virginia's NO_X budget was being met. The docket included this submittal, and the preamble to this final rulemaking notice explains that the NPRM inadvertently cited the two incorrect dates that were both intended to refer to the October 10, 2017 submittal.

Comment 2: A commenter made a general comment that, because of the large coal mining industry in West Virginia, air pollution should be taken seriously to ensure good air quality.

EPA Response: As explained in this document and in the NPRM, this action establishes new requirements for large non-EGUs to meet West Virginia's obligations under the NO_X SIP Call. Total NO_X emissions from all affected units may not exceed West Virginia's statewide NO_X budget, or cap, established by EPA under the NO_X SIP Call. Continuous emissions monitoring, recordkeeping, and reporting are required to assure NO_X emissions do not exceed the State cap. Thus, the 45CSR40 in the West Virginia SIP will not interfere with the air quality or CAA requirements, as EPA explained in the NPRM.

IV. Final Action

EPA is approving West Virginia's July 13, 2016 SIP revision submittal as supplemented on October 10, 2017 and clarified on February 8, 2018. Amended regulation 45CSR40 removes the obsolete provisions that implemented the CAIR NO_X Ozone Season Trading Program, establishes new requirements to address the NO_X SIP Call obligations for large non-EGUs in the State that were trading under CAIR but are no longer part of a trading program, establishes an enforceable statewide cap on ozone season NO_X emissions for these non-EGUs in accordance with West Virginia's state budget under the NO_X SIP Call, and recodifies previously SIP-approved provisions that apply to internal combustion engines and cement kilns. The October 10, 2017 supplemental submission demonstrates that the total NO_X emissions from all affected large non-EGUs in West Virginia do not exceed the State cap previously established for West Virginia under the NO_X SIP Call. The February 8, 2018 letter clarified West Virginia's intent to refer specifically to provisions of CSAPR presently enforceable and its intent to address the minor citation cross reference expeditiously with a future SIP revision submittal. The revisions are in accordance with section 110 of the CAA as the SIP submittal meets requirements in the CAA and in 40 CFR 51.121 related to the NO_X SIP Call requirements.

V. Incorporation by Reference

In this document, EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is finalizing the incorporation by reference of West Virginia regulation 45CSR40—Control of Ozone Season Nitrogen Oxides Emissions. EPA has made, and will continue to make, these materials generally available through *www.regulations.gov* and at the EPA Region III Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information). Therefore, these materials have been approved by EPA for inclusion in the SIP, have been incorporated by reference by EPA into that plan, are fully federally enforceable under sections 110 and 113 of the CAA as of the effective date of the final rulemaking of EPA's approval, and will be incorporated by reference in the next update to the SIP compilation.[7]

VI. Statutory and Executive Order Reviews

A. General Requirements

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because

SIP approvals are exempted under Executive Order 12866.

[5] As noted in section I of this document, West Virginia intends to update the existing reference to 40 CFR part 97, subpart BBBBB to cross-reference the currently applicable CFR provisions at 40 CFR part 97, subpart EEEEE, after which West Virginia will submit the updated regulation to EPA for approval into the SIP.

[6] Consistent with the State's clarification that the existing reference to 40 CFR part 97, subpart BBBBB, is intended to cross-reference the currently applicable CFR provisions at 40 CFR part 97, subpart EEEEE, the existing reference to 40 CFR 52.38(b)(5) should be understood as referring to the currently applicable CFR provision at 40 CFR 52.38(b)(9).

[7] 62 FR 27968 (May 22, 1997).

• Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);

• Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);

• Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);

• Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);

• Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);

• Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);

• Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and

• Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

B. Submission to Congress and the Comptroller General

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

C. Petitions for Judicial Review

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by February 4, 2019. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action approving West Virginia revised regulation 45CSR40 into the West Virginia SIP may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2)).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Sulfur oxides.

Dated: November 13, 2018.

Cosmo Servidio,

Regional Administrator, Region III.

40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart XX—West Virginia

■ 2. In § 52.2520, the table in paragraph (c) is amended by:

■ a. Revising the heading ''[45 CSR] Series 40 Control of Ozone Season Nitrogen Oxide Emissions to Mitigate Interstate Transport of Ozone and Nitrogen Oxides'' to read ''[45 CSR] Series 40 Control of Ozone Season Nitrogen Oxides Emissions'';

■ b. Revising ''Section 45–40–1'' through ''Section 45–40–11'';

■ c. Adding ''Section 45–40–9'' in numerical order;

■ d. Removing ''Section 45–40–12'' through ''Section 45–40–110'';

The addition and revisions read as follows:

§ 52.2520 Identification of plan.

* * * * *

(c) * * *

EPA-APPROVED REGULATIONS IN THE WEST VIRGINIA SIP

State citation [chapter 16–20 or 45 CSR]	Title/subject	State effective date	EPA approval date	Additional explanation/ citation at 40 CFR 52.2565
*	*	*	*	*
[45 CSR] Series 40 Control of Ozone Season Nitrogen Oxides Emissions				
Section 45–40–1	General	7/1/16	12/4/2018, [insert **Federal Register** citation].	Revising 1.1.a, 1.1.b, and 1.1.c. Removing 1.2 and 1.3. Recodifying 1.4 and 1.5 to 1.2 and 1.3, respectively. Revising 1.7 and recodifying as 1.5. Prior approval of this section was 74 FR 38536 on 8/4/09.

EPA-APPROVED REGULATIONS IN THE WEST VIRGINIA SIP—Continued

State citation [chapter 16–20 or 45 CSR]	Title/subject	State effective date	EPA approval date	Additional explanation/ citation at 40 CFR 52.2565
Section 45–40–2	Definitions	7/1/16	12/4/2018, [insert **Federal Register** citation].	Removing 2.1, 2.2, 2.3, 2.5–2.8, 2.10–2.28, 2.31–2.34, 2.36–2.39, 2.41, 2.42, 2.46–2.52, 2.54, 2.58, 2.59, 2.62–2.66, 2.68–2.70, 2.72, 2.75, 2.78–2.82, 2.84–2.87, 2.89, 2.90, 2.92, 2.93, 2.95–2.97, and 2.99–2.103. Revising 2.35 and recodifying as 2.5. Revising 2.40 and recodifying as 2.6. Revising 2.43 and recodifying as 2.7. Revising 2.45 and recodifying as 2.8. Revising 2.45 and recodifying as 2.9. Revising 2.60 and recodifying as 2.14. Revising 2.61 and recodifying as 2.15. Revising 2.71 and recodifying as 2.17. Revising 2.88 and recodifying as 2.23. Revising 2.94 and recodifying as 2.25. Revising 2.98 and recodifying as 2.26. Recodifying 2.4 as 2.1, 2.9 as 2.2, 2.29 as 2.3, 2.30 as 2.4, 2.40 as 2.6, 2.44 as 2.8, 2.53 as 2.10, 2.55 as 2.11, 2.56 as 2.12, 2.57 as 2.13, 2.60 as 2.14, 2.67 as 2.16, 2.73 as 2.18, 2.74 as 2.19, 2.76 as 2.20, 2.77 as 2.21, 2.83 as 2.22, 2.91 as 2.24, and 2.104 as 2.27. Prior approval of this section was 74 FR 38536 on 8/4/09.
Section 45–40–3	Measurements, Abbreviations and Acronyms.	7/1/16	12/4/2018, [insert **Federal Register** citation].	Removed definitions for Hg, kW, kWh, MW_w, MWh, O_2, ppm, lb, scfh, SO_2, and H_2O. Prior approval of this section was 74 FR 38536 on 8/4/09.
Section 45–40–4	Applicability	7/1/16	12/4/2018, [insert **Federal Register** citation].	Remove preamble, 4.1, 4.2, 4.3, 4.4, and 4.5. Add new 4.1, 4.2, and 4.3. Prior approval of this section was 74 FR 38536 on 8/4/09.
Section 45–40–5	Ozone Season NO_X Emission Limitations.	7/1/16	12/4/2018, [insert **Federal Register** citation].	Prior approval of this section was 74 FR 38536 on 8/4/09.
Section 45–40–6	Monitoring, Recordkeeping and Reporting Requirements.	7/1/16	12/4/2018, [insert **Federal Register** citation].	Prior approval of this section was 74 FR 38536 on 8/4/09.
Section 45–40–7	Violation	7/1/16	12/4/2018, [insert **Federal Register** citation].	Prior approval of this section was 74 FR 38536 on 8/4/09.
Section 45–40–8	Ozone Season NO_X Budget Demonstration.	7/1/16	12/4/2018, [insert **Federal Register** citation].	Prior approval of this section was 74 FR 38536 on 8/4/09.
Section 45–40–9	Ozone Season NO_X Reduction Requirements for Stationary Internal Combusion Engines.	7/1/16	12/4/2018, [insert **Federal Register** citation].	Prior approval of this section was 74 FR 38536 on 8/4/09.
Section 45–40–10 ..	Ozone Season NO_X Reduction Requirements for Emissions of NO_X from Cement Manufacturing Kilns.	7/1/16	12/4/2018, [insert **Federal Register** citation].	Prior approval of this section was 74 FR 38536 on 8/4/09.
Section 45–40–11 ..	Inconsistency Between Rules	7/1/16	12/4/2018, [insert **Federal Register** citation].	Prior approval of this section was 74 FR 38536 on 8/4/09.
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[FR Doc. 2018–26243 Filed 12–3–18; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2018–0091; FRL–9986–06]

Calcium Formate; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of calcium formate (CAS Reg. No. 544–17–2) when used as an inert ingredient (carrier) in pesticide formulations applied to growing crops only. ADAMA Agan, Ltd. c/o Makhteshim Agan of North America, Inc. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of calcium formate.

DATES: This regulation is effective December 4, 2018. Objections and requests for hearings must be received on or before February 4, 2019, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2018–0091, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Michael L. Goodis, Director, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.* To access the OCSPP test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select ''Test Methods and Guidelines.''

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2018–0091 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before February 4, 2019. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2018–0091, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Petition for Exemption

In the **Federal Register** of April 11, 2018 (83 FR 15528) (FRL–9975–57), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN–11075) by ADAMA Agan, Ltd. c/o Makhteshim Agan of North America, Inc., 3120 Highwoods Blvd., Suite 100, Raleigh, NC 27604. The petition requested that 40 CFR 180.920 be amended by establishing an exemption from the requirement of a tolerance for residues of calcium formate (CAS Reg. No. 544–17–2) when used as an inert ingredient (carrier) in pesticide formulations applied to growing crops only. That document referenced a summary of the petition prepared by ADAMA Agan, LTD, the petitioner, which is available in the docket, *http://www.regulations.gov.*

This is based on the Agency's risk assessment which can be found at *http://www.regulations.gov* in document: Calcium Formate; Human Health Risk Assessment in docket ID number EPA–HQ–OPP–2018–0091. No comments were received in response to the notice published by EPA.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and

diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term ''inert'' is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue . . . .''

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for calcium formate including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with calcium formate follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

The toxicity database on calcium formate is somewhat limited. Consequently, studies on appropriate surrogates were used to supplement the database on calcium formate. Formic acid, sodium formate, potassium formate and ammonium formate were selected as appropriate surrogates since they are either the acid form of calcium formate or other salts of formic acid.

Calcium formate is not expected to be acutely toxic based on acute toxicity data. There are no subchronic or chronic studies on calcium formate, although there are studies on potassium formate. These studies show effects based on reduced body weight gain. A two-year study with potassium formate indicates the compound is not carcinogenic to Wistar rats.

In mutagenicity studies with calcium formate, sodium formate and methyl formate, results of the test were negative for all chemicals. The weight-of-evidence suggests that calcium is not expected to be mutagenic.

There are no available developmental toxicity studies on calcium formate; however, both a rat and rabbit developmental toxicity study have been conducted on sodium formate. In the rat study, the maternal and developmental no-observed-adverse-effect-level (NOAEL) was considered the highest dose tested at 945 milligram/kilogram/day (mg/kg/day). In the rabbit study, the maternal and developmental toxicity NOAEL was also the highest dose tested at 1,000 mg/kg/day. A five-generation rat reproductive toxicity study on calcium formate has been conducted with a NOAEL of >200 mg/kg/day (only dose tested). In a three-generation reproduction study in rats via drinking water, no treatment related effects were observed in the parental animals and off springs at doses up to 200 mg/kg/day.

No studies were submitted for immunotoxicity. However, the toxicity studies available did not show any signs of immunotoxicity up to limit doses. Therefore, immunotoxicity is not of concern.

There are no available studies for neurotoxicity. However, the functional observation battery performed in the 90-day oral toxicity study did not show any signs of neurotoxicity up to limit doses. Therefore, neurotoxicity is not of concern.

A metabolism study is available in the toxicity database. Calcium formate breaks down into calcium and formate ions. Calcium ions are ubiquitous in the natural environment and can be considered as having little toxicity or hazard. Formate ions are readily converted to carbon dioxide in the environment by biodegradation or photooxidation.

Specific information on the studies received and the nature of the adverse effects caused by calcium formate as well as the NOAEL and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in the document Calcium Formate Risk Assessment at page 7 in docket ID number EPA–HQ–OPP–2018–0091.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a

complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm.*

No toxicological endpoints of concern were identified for calcium formate based on available toxicity studies on surrogate chemicals. Formic acid, sodium formate, potassium formate and ammonium formate were selected as appropriate surrogates since they are either the acid form of calcium formate or other salts of formic acid. Most of the available studies on these substances were not conducted up to the limit dose. The highest dose of 200 mg/kg/day in a lifelong study in rats via drinking water did not produce any systemic toxicity (IUCLID, Calcium formate, 2001). Therefore, a conservative risk assessment was conducted using a NOAEL of 200 mg/kg/day for chronic dietary and short- and intermediate-term dermal exposure risk estimates. An uncertainty/safety factor of 100X (10X for interspecies variability and 10X for interspecies extrapolation) was used. The Food Quality Protection Act (FQPA) factor of 10X was reduced to 1X, therefore, the chronic Reference Dose (cRfD) of 2 mg/kg/day is equal to the chronic Population Adjusted Dose (cPAD). A 100% dermal absorption factor is assumed for converting oral to dermal equivalent doses in the absence of dermal toxicity or dermal absorption studies.

For short and intermediate term inhalation exposure, the route specific study was used. The NOAEL of 0.62 mg/l (32 parts per million (ppm)) was observed in a 90-day inhalation toxicity study in rats (IUCLID, Formic acid, 2000). The uncertainty factor is 100X (10X for interspecies variability and IOX for interspecies extrapolation). The FQPA factor of 10 X was reduced to 1X.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to calcium formate, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from calcium formate in food as follows:

Because no endpoint was identified for acute exposure, an acute exposure assessment was not conducted.

In conducting the chronic dietary exposure assessment using the Dietary Exposure Evaluation Model DEEM–FCID™, EPA used food consumption information from the U.S. Department of Agriculture's National Health and Nutrition Examination Survey, what we eat in America, (NHANES/WWEIA). This dietary survey was conducted from 1994–98. As to residue levels in food, no residue data were submitted. In the absence of specific residue data, EPA has developed an approach which uses surrogate information to derive upper bound exposure estimates for the subject inert ingredient. Upper bound exposure estimates are based on the highest tolerance for a given commodity from a list of high-use insecticides, herbicides, and fungicides. A complete description of the general approach taken to assess inert ingredient risks in the absence of residue data is contained in the memorandum entitled ''Alkyl Amines Polyalkoxylates (Cluster 4): Acute and Chronic Aggregate (Food and Drinking Water) Dietary Exposure and Risk Assessments for the Inerts.'' (D361707, S. Piper, 2/25/09) and can be found at *http://www.regulations.gov* in docket ID number EPA–HQ–OPP–2008–0738.

In the dietary exposure assessment, the Agency assumed that the residue level of the inert ingredient would be no higher than the highest tolerance for a given commodity. Implicit in this assumption is that there would be similar rates of degradation (if any) between the active and inert ingredient and that the concentration of inert ingredient in the scenarios leading to these highest of tolerances would be no higher than the concentration of the active ingredient.

The Agency believes the assumptions used to estimate dietary exposures lead to an extremely conservative assessment of dietary risk due to a series of compounded conservatisms. First, assuming that the level of residue for an inert ingredient is equal to the level of residue for the active ingredient will overstate exposure. The concentration of active ingredients in agricultural products is generally at least 50 percent of the product and often can be much higher. Further, pesticide products rarely have a single inert ingredient; rather there is generally a combination of different inert ingredients used which additionally reduces the concentration of any single inert ingredient in the pesticide product in relation to that of the active ingredient.

Second, the conservatism of this methodology is compounded by EPA's decision to assume that, for each commodity, the active ingredient which will serve as a guide to the potential level of inert ingredient residues is the active ingredient with the highest tolerance level. This assumption overstates residue values because it would be highly unlikely, that a single inert ingredient or class of ingredients would be present at the level of the active ingredient in the highest tolerance for every commodity.

Finally, a third compounding conservatism is EPA's assumption that all foods contain the inert ingredient at the highest tolerance level. In other words, EPA assumed 100 percent of all foods are treated with the inert ingredient at the rate and manner necessary to produce the highest residue legally possible for an active ingredient.

In summary, EPA chose a very conservative method for estimating what level of inert residue could be on food, and then used this methodology to choose the highest possible residue that could be found on food and assumed that all food contained this residue. No consideration was given to potential degradation between harvest and consumption even though monitoring data shows that tolerance level residues are typically one to two orders of magnitude higher than actual residues in food when distributed in commerce.

Accordingly, although sufficient information to quantify actual residue levels in food is not available, the compounding of these conservative assumptions will lead to a significant exaggeration of actual exposures. EPA does not believe that this approach underestimates exposure in the absence of residue data.

2. *Dietary exposure from drinking water.* For the purpose of the screening level dietary risk assessment to support this request for an exemption from the requirement of a tolerance for calcium formate, a conservative drinking water concentration value of 100 parts per billion (ppb) based on screening level modeling was used to assess the contribution to drinking water for the chronic dietary risk assessments for parent compound. These values were directly entered into the dietary exposure model.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (*e.g.,* textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables).

There are no known or anticipated residential uses for calcium formate and therefore, residential exposure is not expected.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other

substances that have a common mechanism of toxicity.''

EPA has not found calcium formate to share a common mechanism of toxicity with any other substances, and calcium formate does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that calcium formate does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www.epa.gov/pesticides/cumulative.*

D. Safety Factor for Infants and Children

Section 408(b)(2)(c) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for pre-natal and post-natal toxicity and the completeness of the database on toxicity and exposure unless EPA determines, based on reliable data, that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data is available to EPA to support the choice of a different factor.

EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

1. Toxicological studies were identified for calcium formate in the publicly available databases. However, calcium formate breaks down into calcium and formate ions. Calcium ions are ubiquitous in the natural environment and can be considered as having little toxicity or hazard risk. The toxicological database for calcium formate is limited. There is available data on formic acid and related formate compounds (such as ammonium, sodium and methyl formate), which can serve as suitable surrogates for calcium formate. Studies conducted with methanol are also applicable to formate compounds, since methanol is metabolized into formic acid. Therefore, the database is considered adequate for FQPA assessment.

2. There is no evidence of increased susceptibility of infants and children in the available reproduction and developmental toxicity studies with calcium formate and/or sodium formate. No developmental or maternal systemic toxicity was observed in rats at doses up to 200 mg/kg/day when calcium format was administered via drinking water. No developmental or maternal toxicity was observed in mice at doses up to 750 mg/kg gavage dose of sodium formate on gestation day 8. No evidence of increased susceptibility was observed following pre- and post-natal exposure to calcium formate. In a multigeneration reproduction study (three to five generations), no parental, reproductive or offspring toxicity was observed at doses up to 200 mg/kg/day.

3. No neurotoxicity studies are available in the database. However, there is no evidence of clinical signs of neurotoxicity in the database, nor evidence of susceptibility in the young in the database. Therefore, EPA concluded that the developmental neurotoxicity study is not required. There is no evidence of immunotoxicity in the available database.

4. The dietary food exposure assessment utilizes highly conservative default assumptions that would not under estimate the dietary risk to all populations. For the purpose of the screening level dietary risk assessment to support this request for an exemption from the requirement of a tolerance for ammonium formate, a value of 100 ppb for drinking water based on screening level modeling was used for the chronic dietary risk assessment. The value of 100 ppb is considered to be a high end, conservative assumption that is not likely to underestimate drinking water risks.

Taking into consideration the available information, EPA concludes the additional 10X FQPA safety factor can be reduced to 1X. These assessments will not underestimate the exposure and risks posed by calcium formate.

E. Aggregate Risks and Determination of Safety

Taking into consideration all available information on calcium. EPA has determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to calcium formate under reasonable foreseeable circumstances. Therefore, the establishment of an exemption from tolerance under 40 CFR 180.920 for residues of calcium formate when used as an inert ingredient in pesticide formulations applied is safe under FFDCA section 408.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, calcium formate is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure analysis, EPA has concluded that risk estimates for chronic exposure to calcium formate from food and water are not of concern (<100% cPAD with a risk estimate at 31.2% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. There are no residential uses for calcuim formate.

3. *Short-and intermediate term risk.* Short- and intermediate-term toxicological endpoints were established; however, calcium formate is not registered for any use patterns that would result in short- or intermediate-term residential exposure. Short- and intermediate-term risk is assessed based on short- and intermediate-term residential exposure plus chronic dietary exposure. Because there is no short- or intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-term risk), no further assessment of short- or intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short- and intermediate-term risk for calcium formate.

4. *Aggregate cancer risk U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, calcium formate is not expected to pose a cancer risk to humans.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to calcium formate residues.

V. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.920 for calcium formate (CAS Reg. No. 544–17–2) when used as an inert ingredient (carrier) in pesticide formulations applied to growing crops only.

VII. Statutory and Executive Order Reviews

This action establishes an exemption from the requirement of a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), or Executive Order 13771, entitled ''Reducing Regulations and Controlling Regulatory Costs'' (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VIII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: November 14, 2018.

Donna Davis,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.920, add alphabetically the inert ingredient to the table to read as follows:

§ 180.920 Inert ingredients used pre-harvest; exemptions from the requirement of a tolerance.

* * * * *

Inert ingredients	Limits	Uses
* * * * * * *		
Calcium formate (CAS Reg. No. 544–17–2)		Carrier
* * * * * * *		

[FR Doc. 2018–26353 Filed 12–3–18; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2016–0538; FRL–9982–42]

Bixafen; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of bixafen in or on multiple commodities which are identified and discussed later in this document. FMC Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 4, 2018. Objections and requests for hearings must be received on or before February 4, 2019 and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2016–0538, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP

Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT:

Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2016–0538 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before February 4, 2019. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2016–0538, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.* Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of November 30, 2016 (81 FR 86312) (FRL–9954–06), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 6F8475) by FMC Corporation. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the fungicide bixafen, *N*-(3′,4′-dichloro-5-fluoro[1,1′-biphenyl]-2-yl)-3-(difluoromethyl)-1-methyl-1*H*-pyrazole-4-carboxamide, in or on cattle, fat at 0.5 parts per million (ppm); cattle, kidney at 0.3 ppm; cattle, liver at 1.5 ppm; cattle, muscle at 0.15 ppm; grain, aspirated fractions at 80 ppm; grain, cereal, forage, fodder and straw, group 16 (except rice), forage at 4.0 ppm; grain, cereal, forage, fodder and straw, group 16 (except rice), hay at 5.0 ppm; grain, cereal, forage, fodder and straw, group 16 (except rice), stover at 6.0 ppm; grain, cereal, forage, fodder and straw, group 16 (except rice), straw at 7.0 ppm; grain, cereal, group 15 (except rice and sorghum) at 0.15 ppm; milk at 0.1 ppm; oilseed, rapeseed subgroup 20A at 0.15 ppm; peanut, hay at 10.0 ppm; peanut, nutmeat at 0.02 ppm; peanut, refined oil at 0.04 ppm; poultry, eggs at 0.02 ppm; poultry, fat at 0.02 ppm; poultry, liver at 0.02 ppm; poultry, muscle at 0.02 ppm; sorghum, grain at 3.0 ppm; soybean, hulls at 0.15 ppm; soybean, seed at 0.06 ppm; sugar beet, dried pulp at 1.0 ppm; vegetable, root subgroup 1A at 0.2 ppm and vegetable, tuberous and corm subgroup 1C at 0.02 ppm. That document referenced a summary of the petition prepared by FMC Corporation, the registrant, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA is establishing tolerances that vary from those proposed. The reason for these changes are explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for bixafen including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with bixafen follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable

subgroups of consumers, including infants and children.

Following repeated oral administration of bixafen, the liver was the primary target organ in mice, rats and dogs. Increased liver weights and hepatocellular hypertrophy were observed in all species tested and were considered to reflect hepatic microsomal enzyme induction. Also, in several studies, there was evidence for liver toxicity based on clinical chemistry changes (increased serum alkaline phosphatase and cholesterol, decreased serum albumin) and histopathological changes (hepatocellular pigmentation, degeneration and necrosis). In mice and rats, the thyroid was an additional target in the subchronic and chronic studies, with effects such as increased thyroid weight, follicular cell hypertrophy and follicular cell hyperplasia observed. Thyroid toxicity was seen only in the presence of liver effects, either adverse effects (such as hepatocellular single-cell degeneration/necrosis) or adaptive effects (such as increased liver weights with enzyme changes, hepatocellular hypertrophy). This correlation suggested they thyroid effects are secondary to the liver effects via enhanced hepatic clearance of thyroid hormones. This suggestion was supported by a 14-day mechanistic study in rats in which a marked induction of phase I and II hepatic enzymes, a slight reduction of thyroid hormone (T3, T4) levels and a significant increase of TSH levels were observed at 150 mg/kg bodyweight per day, the only dose tested. Since thyroid toxicity was seen in the absence of adverse liver effects in studies such as the subchronic and chronic rat studies, a primary adverse effect on the thyroid cannot be ruled out. However, no studies are available to address potential susceptibility in the young to potential thyroid toxicity. As a result, the need for a Comparative Thyroid Assay (CTA) was considered. However, given risk estimates are well below the Agency's level of concern (LOC) even when using conservative exposure assumptions, the Agency concluded that a CTA is not required at this time. This conclusion, however, may be revisited should the use pattern change or if updated risk estimates reach a point where the PODs used in the risk assessment are no longer protective of potential life-stage susceptibility.

From the prenatal developmental studies, it is apparent that evidence of increased quantitative susceptibility in offspring was observed in the database. The prenatal developmental study in the rat showed decreased fetal body weights at a dose that produced no adverse effects in the dam. Similarly, the prenatal developmental study in the rabbit showed decreased fetal body weight in the absence of maternal toxicity. In the rat 2-generation reproduction study, however, parental toxicity (decreased body weight and increased liver weight with centrilobular and diffuse hypertrophy) and offspring toxicity (decreased F_1 and F_2 pup body weights) occurred at the same dose level.

An acute neurotoxicity study in the adult rat indicated decreased motor activity in both sexes and decreased rearing counts in females at a high dose level (1,000 mg/kg/day). A subchronic neurotoxicity study was not available, and no evidence of neurotoxicity was observed in other studies in the database.

Bixafen did not produce evidence of mutagenicity or clastogenicity in the required battery of studies. The available mouse carcinogenicity study produced no treatment-related tumors in the presence of other toxicity such as organ weight changes with histopathology in both the liver and thyroid. Thus, bixafen is classified as ''not likely to be carcinogenic to humans.''

Bixafen has low acute oral, dermal, and inhalation toxicity. Bixafen is not an acute eye irritant and is neither a dermal irritant nor a dermal sensitizer. Specific information on the studies received and the nature of the adverse effects caused by bixafen as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in the document Bixafen. Human Health Risk Assessment for Section 3 Registration and Tolerance Requests for a New Active Ingredient Proposed for Use on Cereal Grains, Group 15 (Except Rice); Forage, Fodder and Straw of Cereal Grains, Group 16 (Except Rice); Peanut; Soybean; Root Vegetable Subgroup 1A; and Tuberous and Corm Vegetable Subgroup 1C at pages 14—23 in docket ID number EPA–HQ–OPP–2016–0538.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides.*

A summary of the toxicological endpoints for bixafen used for human risk assessment is shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR BIXAFEN FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (General population including infants and children).	NOAEL = 250 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = 2.5 mg/kg/day. aPAD = 2.5 mg/kg/day	Acute Neurotoxicity Study in rats; MRID 49877279. LOAEL = 1,000 mg/kg/day based on statistically significant decreases in motor activity in both sexes and decreased rearing counts in females approximately 4 hours following a single oral dose.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR BIXAFEN FOR USE IN HUMAN HEALTH RISK ASSESSMENT—Continued

Exposure/scenario	Point of departure and uncertainty/ safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Chronic dietary (All populations)	NOAEL = 2.8 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.03 mg/kg/day. cPAD = 0.03 mg/kg/day	Chronic/Carcinogenicity Studies in Rats; MRIDs 49877272, 49877273. LOAEL = 17.4 mg/kg/day based on thyroid effects (follicular cell hypertrophy, alteration of the thyroid colloid at interim and terminal sacrifice).
Cancer (Oral, dermal, inhalation).	Classification: ''Not likely to be carcinogenic to humans'' based on an absence of tumors in the rat chronic/oncogenicity and mouse carcinogenicity studies.		

FQPA SF = Food Quality Protection Act Safety Factor. mg/kg/day = milligram/kilogram/day. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to bixafen, EPA considered exposure under the petitioned-for tolerances. EPA assessed dietary exposures from bixafen in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

Such effects were identified for bixafen. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) Nationwide Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA) conducted from 2003–2008. As to residue levels in food, the acute dietary analysis was obtained from the Dietary Exposure Evaluation Model using the Food Commodity Intake Database (DEEM–FCID; version 3.16). The assessment is based on tolerance-level residues and 100% crop treated (100 PCT) estimates for all commodities.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA NHANES/WWEIA conducted from 2003–2008. As to residue levels in food, the chronic dietary analysis was obtained from the Dietary Exposure Evaluation Model using the Food Commodity Intake Database (DEEM–FCID; version 3.16). The assessment is based on tolerance-level residues and 100 PCT estimates for all commodities.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that bixafen does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for bixafen. Tolerance-level residues and 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening-level water exposure models in the dietary exposure analysis and risk assessment for bixafen in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of bixafen. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide.*

The Tier II Pesticide in Water Calculator (PWC version 1.52) and Tier I Pesticide Root Zone Model Ground Water (PRZM GW) was used for calculating surface water and ground water EDWCs respectively. The driver for drinking water exposure is from surface water and the EDWC of bixafen for acute exposure is estimated to be 16.3 parts per billion (ppb). For chronic exposure for non-cancer assessment, it is estimated to be 15.2 ppb for surface water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 16.3 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 15.2 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (*e.g.,* for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Bixafen is not proposed nor is it registered for any specific use patterns that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA has not found bixafen to share a common mechanism of toxicity with any other substances, and bixafen does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that bixafen does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the

FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* The prenatal developmental toxicity studies showed effects in the fetus (decreased body weights) at dose levels that were lower than that of the observed maternal toxicity (decreased body weights). However, concerns for potential pre- and postnatal susceptibility from the developmental and reproduction studies are low because clear NOAELs and LOAELs exist for these developmental effects, and the PODs and endpoints selected for risk assessment are protective of potential toxicity in offspring.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for bixafen is considered complete at this time. The following acceptable studies are available to support this determination: A prenatal developmental toxicity study in rabbits, a prenatal developmental toxicity study in rats, a two-generation reproduction study in rats and an acute neurotoxicity study. The following study waivers were accepted, and it was determined that these studies are not required at this time: subchronic inhalation, subchronic neurotoxicity, and an immunotoxicity study. As summarized in Unit III.A., EPA determined that the CTA study is not required at this time.

ii. An acute neurotoxicity study in the adult rat indicated decreased motor activity in both sexes and decreased rearing counts in females at a high dose level (1,000 mg/kg/day). A subchronic neurotoxicity study was not available, and no evidence of neurotoxicity was observed in other studies in the database. Concern for neurotoxicity is low, and thus no developmental neurotoxicity study or FQPA 10X SF is necessary, because (1) signs of neurotoxicity in the database occur only at a high dose level, do not include neuropathology; (2) a clear and well-defined NOAEL has been established; and (3) the PODs used for risk assessment are protective of neurotoxicity seen in the database.

iii. There is evidence of increased prenatal quantitative susceptibility of the developing offspring in the toxicology database for bixafen. Developmental toxicity (reduced fetal body weight) was seen at doses that caused no maternal toxicity in both rats and rabbits. However, clear NOAELs and LOAELs exist for these developmental effects, and the endpoints and PODs selected for risk assessment are protective of these effects. In the 2-generation reproduction toxicity study, toxicity in the offspring (decreased F_1 and F_2 pup body weights) occurred at the same level where parental toxicity (decreased body weight) was observed, and susceptibility was not demonstrated. The subchronic and chronic rat studies in the database indicate thyroid toxicity (epithelial cell hypertrophy) at the LOAELs, and no studies are available to address potential susceptibility in the young to potential thyroid toxicity. As a result, the need for a CTA was considered. However, given risk estimates are well below the Agency's level of concern even when using conservative exposure assumptions and that further refinement of exposure estimates would yield even greater margins of safety, the Agency concluded that a CTA is not required at this time.

iv. There are no residual uncertainties identified in the exposure databases. The unrefined dietary risk assessments are based on high-end assumptions such as tolerance-level residues, 100PCT assumptions, and modeled, high-end estimates of residues in drinking water. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to bixafen in drinking water. These assessments will not underestimate the exposure and risks posed by bixafen.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to bixafen will occupy <1% of the aPAD for children 1–2 years of age, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to bixafen from food and water will utilize 20% of the cPAD for children 1–2 years of age the population group receiving the greatest exposure.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). A short-term adverse effect was identified; however, bixafen is not proposed for any use patterns that would result in short-term residential exposure. Short-term risk is assessed based on short-term residential exposure plus chronic dietary exposure. Because there is no short-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-term risk), no further assessment of short-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short-term risk for bixafen.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

An intermediate-term adverse effect was identified; however, bixafen is not proposed for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for bixafen.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, bixafen is not expected to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to bixafen residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (Analytical Methods 00983 and 01063, high- performance liquid chromatography methods with tandem mass spectrometry detection (LC/MS/MS)) is available as an enforcement method for determination of residues of bixafen and its metabolite bixafen-desmethyl.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has established MRLs for bixafen in or on barley and oats at 0.4 ppm; the U.S. tolerance for grain, cereal, group 15, except rice and grain sorghum at 0.40 ppm is harmonized with those MRLs. Codex has also established MRLs for rye, wheat, and wheat bran at 0.05 ppm, which is not harmonized with the U.S. tolerances for group 15 because use consistent with approved labeling could result in exceedances. Codex has also established MRLs for barley straw and fodder, dry at 20 ppm; oat straw and fodder, dry at 20 ppm; rye straw and fodder, dry at 20 ppm; and wheat straw and fodder, dry at 20 ppm. The U.S. tolerance for grain, cereal, forage, fodder and straw, group 16, except rice at 20 ppm is harmonized with those Codex MRLs.

Additionally, the Codex has established MRLs for bixafen in or on cattle, fat at 2 ppm; cattle, meat byproducts at 4 ppm; cattle, muscle at 2 ppm; goat, fat at 2 ppm; goat, meat byproducts at 4 ppm; goat, muscle at 2 ppm; horse, fat at 2 ppm; horse, meat byproducts at 4 ppm; horse, muscle at 2 ppm; milk at 0.2 ppm; sheep, fat at 2 ppm; sheep, meat byproducts at 4 ppm; and sheep, muscle at 2 ppm. These MRLs are significantly higher than the tolerances being established for bixafen on the same commodities in the United States. The U.S. tolerances are based on calculated dietary burden that supports a lower residue level in fat, muscle, and meat byproducts commodities. Therefore, these tolerances are not harmonized because such high tolerances could mask instances of misuse by U.S. growers. As noted in the next section, the Agency is not establishing tolerances for milk fats and poultry commodities in harmony with Codex MRLs for milk fats, poultry, edible offal, poultry fats, and poultry meat because the Agency has determined that use consistent with the approved pesticide will not result in residues in milk fats and poultry commodities.

C. Revisions to Petitioned-For Tolerances

Several proposed tolerances requested by the petitioner are different from those being established by EPA. For soybean seed; peanut; peanut, hay; vegetable, tuberous and corm (subgroup 1C); and vegetable, root, subgroup 1A, tolerance values were calculated using the Organization for Economic Cooperation and Development (OECD) tolerance calculation procedures and field trial residue data. The combination provided a different tolerance value than the proposed values. EPA is establishing a tolerance for grain, cereal, group 15, except rice and grain sorghum at 0.40 ppm instead of 0.15 ppm and for grain, cereal, forage, fodder and straw, group 16, except rice at 20 ppm, rather than the requested tolerances for forage at 4.0 ppm, hay at 5.0 ppm, stover at 6.0 ppm, straw at 7.0 ppm in order to harmonize with Codex MRLs. Since the tolerance of 20 ppm for group 16 covers the residues on forage, hay, stover, and straw forms of the group 16 commodities, EPA has determined that separate tolerances are unnecessary.

Additionally, while tolerances were proposed on liver and kidney for livestock commodities, EPA is establishing tolerances on meat byproducts, which are inclusive of kidney and liver. EPA is further establishing lower tolerances for residues in fat, muscle and meat byproducts in cattle, based on the calculated dietary burdens paired with low residue transfer rates into ruminant commodities. The tolerance on milk is also established at a lower level (0.04 ppm versus the 0.10 ppm proposed tolerance). This recommendation is also based on the calculated dietary burdens paired with low residue transfer rates into ruminant commodities.

Under EPA's regulations (40 CFR 180.6), EPA assessed whether residues on raw agricultural commodities would result in possible residues entering the diet of man through the ingestion of milk, eggs, meat, and/or poultry produced by animals fed agricultural products bearing such residues. As a result of that assessment, EPA determined that quantifiable residues are expected in commodities from cattle, horses, goats, and sheep and is establishing tolerances for residues in fat, muscle and meat byproducts in horse, goat and sheep. EPA also determined that there is no reasonable expectation of residues in or on milk fats and poultry products; therefore, no tolerances on milk fats and poultry commodities are needed.

Additionally, the proposed use and associated tolerance on Rapeseed subgroup 20A (canola) was subsequently withdrawn by the petitioner; therefore, the Agency is not establishing a tolerance on that subgroup because it is not needed.

The Agency is not establishing a tolerance for peanut, refined oil as requested because the residue data indicate that anticipated residues in the peanut, refined oil are lower than, and will be covered by, the tolerance for peanut.

Finally, the Agency is establishing a tolerance for radish, tops, even though it was not requested by the petitioner. Under EPA's regulations (40 CFR 180.40(f)(1)(i)(B)), EPA will not establish a crop group tolerance unless all necessary tolerances are established, including tolerances for raw commodities not covered by the crop group and derivative of commodities in the group. In this case, EPA is establishing a tolerance for root vegetables, subgroup 1A, which includes radish. Due to the presence of residues on radish tops, EPA is establishing a necessary tolerance on radish tops to facilitate the establishment of the subgroup 1A tolerance.

V. Conclusion

Therefore, tolerances are established for residues of bixafen in or on beet, sugar, dried pulp at 1.0 ppm; cattle, fat at 0.08 ppm; cattle, meat byproducts at 0.40 ppm; cattle, muscle at 0.08 ppm; goat, fat at 0.08 ppm; goat, meat byproducts at 0.40 ppm; goat, muscle at 0.08 ppm; grain, aspirated grain fractions at 80 ppm; grain, cereal, forage, fodder, and straw, group 16, except rice at 20 ppm; grain, cereal, group 15, except rice and grain sorghum at 0.40 ppm; horse, fat at 0.08 ppm; horse, meat byproducts at 0.40 ppm; horse, muscle

at 0.08 ppm; milk at 0.04 ppm; peanut at 0.01 ppm; peanut, hay at 8.0 ppm; radish, tops at 3.0 ppm; sheep, fat at 0.08 ppm; sheep, meat byproducts at 0.40 ppm; sheep, muscle at 0.08 ppm; sorghum, grain, grain at 3.0 ppm; soybean, hulls at 0.15 ppm; soybean, seed at 0.04 ppm; vegetable, root subgroup 1A at 0.30 ppm; and vegetable, tuberous and corm subgroup 1C at 0.01 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), nor is it considered a regulatory action under Executive Order 13771, entitled ''Reducing Regulations and Controlling Regulatory Costs'' (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: November 13, 2018.

Donna Davis,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Add § 180.702 to subpart C to read as follows:

§ 180.702 Bixafen; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the fungicide bixafen, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only bixafen, *N*-(3,4-dichloro-5-fluorobiphenyl-2-yl)-3-(difluoromethyl)-1-methylpyrazole-4-carboxamide, in or on the commodity.

Commodity	Parts per million
Beet, sugar, dried pulp	1.0
Grain, aspirated grain fractions	80
Grain, cereal, forage, fodder, and straw, group 16, except rice	20
Grain, cereal, group 15, except rice and grain sorghum	0.40
Peanut	0.01
Peanut, hay	8.0
Radish, tops	3.0
Sorghum, grain, grain	3.0
Soybean, hulls	0.15
Soybean, seed	0.04
Vegetable, root, subgroup 1A	0.30
Vegetable, tuberous and corm, subgroup 1C	0.01

(2) Tolerances are established for residues of the fungicide bixafen, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of bixafen, *N*-(3,4-dichloro-5-fluorobiphenyl-2-yl)-3-(difluoromethyl)-1-methylpyrazole-4-carboxamide, and its desmethyl metabolite, *N*-(3′,4′-dichloro-5-fluoro[1,1′-biphenyl]-2-yl)-3-(difluoromethyl)-1*H*-pyrazole-4-carboxamide, calculated as the stoichiometric equivalent of bixafen, in or on the commodity.

Commodity	Parts per million
Cattle, fat	0.08
Cattle, meat byproducts	0.40
Cattle, muscle	0.08
Goat, fat	0.08
Goat, meat byproducts	0.40
Goat, muscle	0.08
Horse, fat	0.08
Horse, meat byproducts	0.40
Horse, muscle	0.08
Milk	0.04
Sheep, fat	0.08
Sheep, meat byproducts	0.40
Sheep, muscle	0.08

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 2018–26348 Filed 12–3–18; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2018–0290; FRL–9985–99]

1-Propanesulfonic acid, 2-methyl-2-[(1-oxo-2-propen-1-y1)amino]-, homopolymer, sodium salt and 1-Propanesulfonic acid, 2-methyl-2-[(1-oxo-2-propen-1-y1)amino]-, sodium salt (1:1), homopolymer; Tolerance Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of 1-propanesulfonic acid, 2-methyl-2-[(1-oxo-2-propen-1-y1)amino]-, homopolymer, sodium salt (CAS Reg. No. 55141–01–0), and 1-propanesulfonic acid, 2-methyl-2-[(1-oxo-2-propen-1-y1)amino]-, sodium salt (1:1), homopolymer (CAS Reg. No. 35641–59–9); when used as inert ingredients in a pesticide chemical formulation. BASF Corporation submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of 1-propanesulfonic acid, 2-methyl-2-[(1-oxo-2-propen-1-y1)amino]-, homopolymer, sodium salt) and 1-propanesulfonic acid, 2-methyl-2[(1oxo-2propen-1-y1)amino]-, sodium salt (1:1), homopolymer on food or feed commodities.

DATES: This regulation is effective December 4, 2018. Objections and requests for hearings must be received on or before February 4, 2019, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2018–0290, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. Can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2018–0290 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before February 4, 2019. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2018–0290, by one of the following methods.

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Background and Statutory Findings

In the **Federal Register** of June 14, 2018 (83 FR 27743) (FRL–9978–41), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the receipt of a pesticide petition (PP IN–11148) filed by BASF Corporation, 26 Davis Drive, P.O. Box 13528, Research Triangle Park, NC 277709–3528. The petition requested that 40 CFR 180.960 be amended by establishing an exemption from the requirement of a tolerance for residues of 1-propanesulfonic acid, 2-methyl-2-[(1-oxo-2-propen-1-y1)amino]-, homopolymer, sodium salt (CAS Reg. No. 55141–01–0), and 1-propanesulfonic acid, 2-methyl-2-[(1-oxo-2-propen-1-y1)amino]-, sodium salt (1:1), homopolymer (CAS Reg. Reg. No. 35641–59–9). That document included a summary of the petition prepared by the petitioner and solicited comments on the petitioner's request.

There were no comments received in response to the notice of filling.

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is ''safe.'' Section 408(c)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will

result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and use in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing an exemption from the requirement of a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue . . . '' and specifies factors EPA is to consider in establishing an exemption.

III. Risk Assessment and Statutory Findings

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be shown that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. In the case of certain chemical substances that are defined as polymers, the Agency has established a set of criteria to identify categories of polymers expected to present minimal or no risk. The definition of a polymer is given in 40 CFR 723.250(b) and the exclusion criteria for identifying these low-risk polymers are described in 40 CFR 723.250(d). 1-Propanesulfonic acid, 2-methyl-2-[(1-oxo-2-propen-1-y1)amino]-, homopolymer, sodium salt and 1-propanesulfonic acid, 2-methyl-2-[(1-oxo-2-propen-1-y1)amino]-, sodium salt (1:1), homopolymer both conform to the definition of a polymer given in 40 CFR 723.250(b) and meet the following criteria that are used to identify low-risk polymers.

1. The polymer is not a cationic polymer nor is it reasonably anticipated to become a cationic polymer in a natural aquatic environment.

2. The polymer does contain as an integral part of its composition the atomic elements carbon, hydrogen, and oxygen.

3. The polymer does not contain as an integral part of its composition, except as impurities, any element other than those listed in 40 CFR 723.250(d)(2)(ii).

4. The polymer is neither designed nor can it be reasonably anticipated to substantially degrade, decompose, or depolymerize.

5. The polymer is manufactured or imported from monomers and/or reactants that are already included on the TSCA Chemical Substance Inventory or manufactured under an applicable TSCA section 5 exemption.

6. The polymer is not a water absorbing polymer with a number average molecular weight (MW) greater than or equal to 10,000 daltons.

7. The polymer does not contain certain perfluoroalkyl moieties consisting of a CF_{3-} or longer chain length as listed in 40 CFR 723.250(d)(6).

Additionally, the polymer also meets as required the following exemption criteria specified in 40 CFR 723.250(e).

8. The polymer's number average MW of 14,000 is greater than or equal to 10,000 daltons. The polymer contains less than 2% oligomeric material below MW 500 and less than 5% oligomeric material below MW 1,000.

Thus, 1-propanesulfonic acid, 2-methyl-2-[(1-oxo-2-propen-1-y1)amino]-, homopolymer, sodium salt and 1-propanesulfonic acid, 2-methyl-2-[(1-oxo-2-propen-1-y1)amino]-, sodium salt (1:1), homopolymer meet the criteria for a polymer to be considered low risk under 40 CFR 723.250. Based on their conformance to the criteria in this unit, no mammalian toxicity is anticipated from dietary, inhalation, or dermal exposure to 1-propanesulfonic acid, 2-methyl-2-[(1-oxo-2-propen-1-y1)amino]-, homopolymer, sodium salt and 1-propanesulfonic acid, 2-methyl-2-[(1-oxo-2-propen-1-y1)amino]-, sodium salt (1:1), homopolymer.

IV. Aggregate Exposures

For the purposes of assessing potential exposure under this exemption, EPA considered that 1-propanesulfonic acid, 2-methyl-2-[(1-oxo-2-propen-1-y1)amino]-, homopolymer, sodium salt and 1-propanesulfonic acid, 2-methyl-2-[(1-oxo-2-propen-1-y1)amino]-, sodium salt (1:1), homopolymer could be present in all raw and processed agricultural commodities and drinking water, and that non-occupational non-dietary exposure was possible. The number average MW of 1-propanesulfonic acid, 2-methyl-2-[(1-oxo-2-propen-1-y1)amino]-, homopolymer, sodium salt and 1-propanesulfonic acid, 2-methyl-2-[(1-oxo-2propen-1-y1)amino]-, sodium salt (1:1), homopolymer are greater than 14,000 daltons. Generally, polymers of this size would be poorly absorbed through the intact gastrointestinal tract or through intact human skin. Since propanesulfonic acid, 2-methyl-2-[(1-oxo-2-propen-1-y1)amino]-, homopolymer, sodium salt and 1-propanesulfonic acid, 2-methyl-2-[(1-oxo-2-propen-1-y1)amino]-, sodium salt (1:1), homopolymer conform to the criteria that identify a low-risk polymer, there are no concerns for risks associated with any potential exposure scenarios that are reasonably foreseeable. The Agency has determined that a tolerance is not necessary to protect the public health.

V. Cumulative Effects From Substances With a Common Mechanism of Toxicity

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA has not found 1-propanesulfonic acid, 2-methyl-2-[(1-oxo-2-propen-1-y1)amino]-, homopolymer, sodium salt and 1-propanesulfonic acid, 2-methyl-2-[(1-oxo-2-propen-1-y1)amino]-, sodium salt (1:1), homopolymer to share a common mechanism of toxicity with any other substances, and 1-propanesulfonic acid, 2-methyl-2-[(1-oxo-2-propen-1-y1)amino]-, homopolymer, sodium salt and 1-propanesulfonic acid, 2-methyl-2-[(1-oxo-2-propen-1-y1)amino]-, sodium salt (1:1), homopolymer do not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that 1-propanesulfonic acid, 2-methyl-2-[(1-oxo-2-propen-1-y1)amino]-, homopolymer, sodium salt and 1-propanesulfonic acid, 2-methyl-2-[(1-oxo-2-propen-1-y1)amino]-, sodium salt (1:1), homopolymer do not have a common mechanism of toxicity with

other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www.epa.gov/pesticides/cumulative.*

VI. Additional Safety Factor for the Protection of Infants and Children

Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base unless EPA concludes that a different margin of safety will be safe for infants and children. Due to the expected low toxicity of 1-propanesulfonic acid, 2-methyl-2-[(1-oxo-2-propen-1-y1)amino]-, homopolymer, sodium salt and 1-propanesulfonic acid, 2-methyl-2-[(1-oxo-2-propen-1-y1)amino]-, sodium salt (1:1), homopolymer, EPA has not used a safety factor analysis to assess the risk. For the same reasons the additional tenfold safety factor is unnecessary.

VII. Determination of Safety

Based on the conformance to the criteria used to identify a low-risk polymer, EPA concludes that there is a reasonable certainty of no harm to the U.S. population, including infants and children, from aggregate exposure to residues of 1-propanesulfonic acid, 2-methyl-2-[(1-oxo-2-propen-1-y1)amino]-, homopolymer, sodium salt and 1-propanesulfonic acid, 2-methyl-2-[(1-oxo-2propen-1-y1)amino]-, sodium salt (1:1), homopolymer.

VIII. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for 1-propanesulfonic acid, 2-methyl-2-[(1-oxo-2-propen-1-y1)amino]-, homopolymer, sodium salt or 1-propanesulfonic acid, 2-methyl-2-[(1-oxo-2propen-1-y1)amino]-, sodium salt (1:1), homopolymer.

IX. Conclusion

Accordingly, EPA finds that exempting residues of 1-propanesulfonic acid, 2-methyl-2-[(1-oxo-2-propen-1-y1)amino]-, homopolymer, sodium salt and 1-propanesulfonic acid, 2-methyl-2-[(1-oxo-2propen-1-y1)amino]-, sodium salt (1:1), homopolymer from the requirement of a tolerance will be safe.

X. Statutory and Executive Order Reviews

This action establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

XI. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: November 14, 2018.

Donna Davis,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.960, alphabetically add the polymers in the table to read as follows:

§ 180.960 Polymers; exemptions from the requirement of a tolerance.

* * * * *

Polymer	CAS No.
* * * * * * *	
Propanesulfonic acid, 2-methyl-2-[(1-oxo-2-propen-1-y1)amino]-, homopolymer, sodium salt, minimum number average molecular weight (in amu) 14,000	55141–01–0
* * * * * * *	
1-Propanesulfonic acid, 2-methyl-2-[(1-oxo-2-propen-1-y1)amino]-, sodium salt (1:1), homopolymer, minimum number average molecular weight (in amu) 14,000	35641–59–9
* * * * * * *	

[FR Doc. 2018–26347 Filed 12–3–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2015–0820; FRL–9986–87]

Oxytetracycline; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of oxytetracycline in or on fruit, citrus, crop group 10–10. Geo Logic Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 4, 2018. Objections and requests for hearings must be received on or before February 4, 2019 and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2015–0820, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2015–0820 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before February 4, 2019. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2015–0820, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of March 16, 2016 (81 FR 14030) (FRL–9942–86), EPA issued a document pursuant to

FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 5F8415) by Geo Logic Corporation, P.O. Box 3091, Tequesta, FL 33469. The petition requested that 40 CFR 180.337 be amended by establishing tolerances for residues of the bactericide oxytetracycline, (4S,4aR,5S,5aR,6S,12aS)-4-(dimethylamino)-1,4,4a,5,5a,6,11,12a-octahydro-3,5,6,10,12,12a-hexahydroxy-6-methyl-1,11-dioxo-2-naphthacenecarboxamide, in or on fruit, citrus, crop group 10–10 at 0.01 parts per million (ppm).

That document referenced a summary of the petition prepared by Geo Logic Corporation, the registrant, which is available in the docket, *http://www.regulations.gov.* One comment was received on the notice of filing. EPA's response to this comment is discussed in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for oxytetracycline including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with oxytetracycline follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

At high doses, the target organ of tetracycline toxicity is the liver. The most common effect in intermediate- or long-term oral exposures in rats and mice was a decrease in body weight. In the prenatal developmental study in rats, clinical signs included increased incidences of respiratory signs and rough hair coat in the dams, in addition to increased mortality and a decreased percentage of dams found pregnant. Also identified was a decrease in fetal body weight. In the mouse prenatal developmental study, there was no toxicity identified in the dams or fetuses. In all of the above animal studies, adverse effects were seen at doses that exceed the limit dose. There is no adequate reproductive toxicity study available in the database, however, the data requirement was waived based on the lack of reproductive effects reported during the history of use as a drug. No evidence of neurotoxicity was observed in any guideline study. A rat immunotoxicity study demonstrated immunosuppression at doses lower than those for systemic toxicity. Tetracyclines are known to inhibit bone growth in developing tissue. When oxytetracycline was administered orally as a single dose to two female infant rhesus monkeys, zygomatic arch bone (lateral surface of temporal bone) growth was inhibited for ~12.5 days with no recovery observed by 21 days. Effects on bone growth are consistent with oxytetracycline's ability to chelate calcium, and so are not unexpected. Bone developmental effects were also observed after administration of chlortetracycline and demethylchlortetracycline in adult rhesus monkeys highlighting the consistency of tetracycline treatment across this class of chemicals.

The Agency has classified oxytetracycline as ''Group D: *Not Classifiable as to Human Carcinogenicity*''. Oxytetracycline has low acute toxicity, being Toxicity Category IV for oral toxicity, the only acute lethality study available in the database.

Specific information on the studies received and the nature of the adverse effects caused by oxytetracycline as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in document ''*Oxytetracycline/Oxytetracycline Hydrochloride/Oxytetracycline Calcium: Draft Human Health Risk Assessment in Support of Registration Review and Tolerance Establishment in/on Citrus Fruit Crop Group 10–10*'' in docket ID number EPA–HQ–OPP–2015–0820.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides.*

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR OXYTETRACYCLINE FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/ safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (All populations) ..	None selected	N/A	No appropriate endpoint for females age 13–49 or for the general population attributable to a single exposure.
Chronic dietary (All populations)	NOAEL= 100 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 10x	Chronic RfD = 1 mg/kg/day. cPAD = 0.10 mg/kg/day	WOE from 3 rats and 2 dogs chronic studies. The NOAEL of 100 mg/kg/day was derived from these studies and no specific LOAEL was established.
Cancer	Classified as a Group D carcinogen—not classifiable as to human carcinogenicity.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. RfD = reference dose. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to oxytetracycline, EPA considered exposure under the petitioned-for tolerances as well as all existing oxytetracycline tolerances in 40 CFR 180.337. EPA assessed dietary exposures from oxytetracycline in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. No such effects were identified in the toxicological studies for oxytetracycline; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA 2003–2008 food consumption data from the USDA's National Health and Nutrition Examination Survey/What We Eat in America. As to residue levels in food, EPA used tolerance-level residues, default processing factors (PFs), and assumed 100 percent crop treated (PCT).

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that oxytetracycline does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and PCT information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for oxytetracycline. Tolerance-level residues and/or 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening-level water exposure models in the dietary exposure analysis and risk assessment for oxytetracycline in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of oxytetracycline. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide.*

Based on the Pesticide Root Zone Model version 5.02/Variable Volume Water Body Model (VVWM V1.02) and Pesticide Root Zone Model Ground Water (PRZM GW), EDWCs of oxytetracycline for chronic exposures for non-cancer assessments are estimated to be 2.85 ppb for surface water and 0.323 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration of value 2.85 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (*e.g.,* for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Oxytetracycline is not registered for any specific use patterns that would result in residential exposure.

Tetracycline hydrochloride (97% chemical similarity to oxytetracycline) is approved by FDA for use as an oral antibiotic to treat certain bacterial and parasitic infections. EPA examined the impact that additional pesticide exposures to oxytetracycline would have on a person who has been prescribed the antibiotic. EPA determined that the additional pesticide exposure would not have more than a minimal impact on the total dose to the pharmaceutical patient, and thus concludes that there is a reasonable certainty that the additional exposure from pesticide uses of oxytetracycline would result in no harm finding to a user being treated therapeutically.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA has assessed the potential for oxytetracycline to share a common mechanism of toxicity with any other substances. Based on its assessment of the available toxicological data, EPA has determined that oxytetracycline does not share a similar toxicological profile with other pesticides, and no further cumulative evaluation is necessary for oxytetracycline.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable

data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* Considering the toxicity database for oxytetracycline, the mouse prenatal development study did not identify adverse effects up to the highest dose tested (HDT), 2,100 mg/kg/day. In addition, the effects seen in the rat prenatal development study occurred only at levels above the limit dose. Although guideline toxicity studies do not suggest an increased lifestage sensitivity/susceptibility (effects above the limit dose or no effects at the highest doses tested), data from the literature suggests that developing infants and children may be more susceptible to oxytetracycline side-effects than adults. When oxytetracycline was administered orally, as a single dose, to two female infant rhesus monkeys, zygomatic arch bone (lateral surface of temporal bone) growth was inhibited for ~12.5 days with no recovery observed by 21 days. The delayed bone growth occurs as a result of chelation of calcium, the mineral needed for bone growth. When the monkeys are treated with a very high dose of oxytetracycline (80 mg/kg), the calcium can be bound up for several days, leading to a delay in bone growth during that short time frame. However, once the oxytetracycline levels diminish, bone growth continues resulting in normal bones at maturity.

3. *Conclusion.* The existing database, together with the extensive literature and study reports available on oxytetracycline, including studies submitted to and reviewed by the EPA, the National Toxicology Program, and World Health Organization, the FDA and open literature studies, is adequate for characterizing toxicity and quantification of risk from the proposed and existing uses of oxytetracycline. EPA is retaining the 10X FQPA SF because of the potential for pre-natal toxicity. The Agency concludes that this safety factor will be protective of potential toxicity to infants and children based on the following findings:

i. The toxicity database for oxytetracycline is complete.

ii. There is no indication that oxytetracycline is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that oxytetracycline results in increased susceptibility in *in utero* rats in the prenatal developmental studies. Within the toxicity database, the mouse prenatal developmental study did not identify adverse effects up to the highest does tested (HDT), 2,100 mg/kg/day. Based on the adverse effects seen in infant rhesus monkeys after oral administration of oxytetracycline, the Food Quality Protection Act (FQPA) Safety Factor (SF) is being retained at 10X.

iv. There are no residual uncertainties identified in the exposure databases. The dietary assessment overestimates actual exposures to oxytetracycline as it incorporated tolerance-level residues, default PFs, assumed that 100% of the proposed and existing crops are treated with oxytetracycline, and included high-end ground and surface drinking water modeling estimates. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to oxytetracycline in drinking water. These assessments will not underestimate the exposure and risks posed by oxytetracycline.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, oxytetracycline is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to oxytetracycline from food and water will utilize 33% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. There are no residential pesticide uses for oxytetracycline.

3. *Short-term risk and Intermediate-term risk.* Short-term and intermediate-term aggregate exposures take into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level) and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level), respectively. Short and intermediate-term adverse effects were identified; however, oxytetracycline is not registered for any residential pesticide uses that would result in short or intermediate-term residential exposures. Short-term risk is assessed based on short-term residential exposure plus chronic dietary exposure and intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there are no short-term or intermediate-term residential exposures and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-term risk), no further assessment of short-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short-term risk for oxytetracycline.

4. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in adequate carcinogenicity studies in two animals, oxytetracycline is not expected to pose a cancer risk to humans and no cancer risk assessment was necessary.

5. *Pharmaceutical aggregate risk for U.S. population.* Section 408 of the FFDCA requires EPA to consider potential sources of exposure to a pesticide and related substances in addition to the dietary sources expected to result from a pesticide use subject to the tolerance and determine that ''there is a reasonable certainty of no harm'' from those exposures. Because the Food and Drug Administration (FDA) may approve pharmaceutical drugs under FFDCA section 505, notwithstanding the possibility that some users may experience adverse side effects. EPA examines the impact that the additional pesticide exposures would have to a pharmaceutical user exposed to a related (or, in some cases, the same) compound in assessing the potential of harm to the pharmaceutical user. Where the additional pesticide exposure has no more than a minimal impact on the pharmaceutical user, EPA has concluded that it can make a reasonable certainty of no harm finding for the pesticide tolerances of that compound under section 408 of the FFDCA.

For oxytetracycline, EPA's pesticide exposure assessment has taken into consideration the appropriate population, exposure route, and exposure duration for comparison with pharmaceutical exposure to oxytetracycline. EPA estimates that the pharmaceutical exposure a person is expected to receive from a typical therapeutic dose (25 mg/kg/day for children) is 750 to 2,800 times greater

than the estimated dietary exposure from the pesticidal sources of oxytetracycline (0.0089334 mg/kg/day). Therefore, because the pesticide exposure has no more than a minimal impact on the total dose to a pharmaceutical user, EPA concludes that there is a reasonable certainty that the potential pesticide exposure will result in no harm to a person being treated therapeutically with oxytetracycline.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to oxytetracycline residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methods are available for determining oxytetracycline residues in/on plant commodities. A high-performance liquid chromatography method with tandem mass spectrometry detection (LC/MS/MS) has been proposed for tolerance enforcement.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: *residuemethods@epa.gov.*

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level. The Codex has not established a MRL for oxytetracycline.

C. Response to Comments

One comment was received generally opposing the use of any pesticides in or on food. The Agency recognizes that some individuals oppose the use of pesticides in or on food, but the FFDCA authorizes the Agency to establish tolerances for residues of pesticides in or on food if the Agency determines that the tolerance is safe. EPA has examined all the available data and determined that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue. The commenter has provided no information to support a finding that the tolerances would not be safe.

V. Conclusion

Therefore, tolerances are established for residues of oxytetracycline, in or on fruit, citrus, group 10–10 at 0.01 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001); Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997); or Executive Order 13771, entitled ''Reducing Regulations and Controlling Regulatory Costs'' (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: November 23, 2018.

Michael Goodis,

Director, Registration Division, Office of Pesticide Program.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.337, add alphabetically the entry for ''Fruit, citrus, group 10–10'' to the table in paragraph (a) to read as follows:

§ 180.337 Oxytetracycline; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Fruit, citrus, group 10–10	0.01
* * * * *	

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[FR Doc. 2018–26343 Filed 12–3–18; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 64

[Docket ID FEMA–2018–0002; Internal Agency Docket No. FEMA–8557]

Suspension of Community Eligibility

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final rule.

SUMMARY: This rule identifies communities where the sale of flood insurance has been authorized under the National Flood Insurance Program (NFIP) that are scheduled for suspension on the effective dates listed within this rule because of noncompliance with the floodplain management requirements of the program. If the Federal Emergency Management Agency (FEMA) receives documentation that the community has adopted the required floodplain management measures prior to the effective suspension date given in this rule, the suspension will not occur and a notice of this will be provided by publication in the **Federal Register** on a subsequent date. Also, information identifying the current participation status of a community can be obtained from FEMA's Community Status Book (CSB). The CSB is available at *https://www.fema.gov/national-flood-insurance-program-community-status-book.*

DATES: The effective date of each community's scheduled suspension is the third date (''Susp.'') listed in the third column of the following tables.

FOR FURTHER INFORMATION CONTACT: If you want to determine whether a particular community was suspended on the suspension date or for further information, contact Adrienne L. Sheldon, PE, CFM, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 400 C Street SW, Washington, DC 20472, (202) 212–3966.

SUPPLEMENTARY INFORMATION: The NFIP enables property owners to purchase Federal flood insurance that is not otherwise generally available from private insurers. In return, communities agree to adopt and administer local floodplain management measures aimed at protecting lives and new construction from future flooding. Section 1315 of the National Flood Insurance Act of 1968, as amended, 42 U.S.C. 4022, prohibits the sale of NFIP flood insurance unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed in this document no longer meet that statutory requirement for compliance with program regulations, 44 CFR part 59. Accordingly, the communities will be suspended on the effective date in the third column. As of that date, flood insurance will no longer be available in the community. We recognize that some of these communities may adopt and submit the required documentation of legally enforceable floodplain management measures after this rule is published but prior to the actual suspension date. These communities will not be suspended and will continue to be eligible for the sale of NFIP flood insurance. A notice withdrawing the suspension of such communities will be published in the **Federal Register**.

In addition, FEMA publishes a Flood Insurance Rate Map (FIRM) that identifies the Special Flood Hazard Areas (SFHAs) in these communities. The date of the FIRM, if one has been published, is indicated in the fourth column of the table. No direct Federal financial assistance (except assistance pursuant to the Robert T. Stafford Disaster Relief and Emergency Assistance Act not in connection with a flood) may be provided for construction or acquisition of buildings in identified SFHAs for communities not participating in the NFIP and identified for more than a year on FEMA's initial FIRM for the community as having flood-prone areas (section 202(a) of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4106(a), as amended). This prohibition against certain types of Federal assistance becomes effective for the communities listed on the date shown in the last column. The Administrator finds that notice and public comment procedures under 5 U.S.C. 553(b), are impracticable and unnecessary because communities listed in this final rule have been adequately notified.

Each community receives 6-month, 90-day, and 30-day notification letters addressed to the Chief Executive Officer stating that the community will be suspended unless the required floodplain management measures are met prior to the effective suspension date. Since these notifications were made, this final rule may take effect within less than 30 days.

National Environmental Policy Act. FEMA has determined that the community suspension(s) included in this rule is a non-discretionary action and therefore the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) does not apply.

Regulatory Flexibility Act. The Administrator has determined that this rule is exempt from the requirements of the Regulatory Flexibility Act because the National Flood Insurance Act of 1968, as amended, Section 1315, 42 U.S.C. 4022, prohibits flood insurance coverage unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed no longer comply with the statutory requirements, and after the effective date, flood insurance will no longer be available in the communities unless remedial action takes place.

Regulatory Classification. This final rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Executive Order 13132, Federalism. This rule involves no policies that have federalism implications under Executive Order 13132.

Executive Order 12988, Civil Justice Reform. This rule meets the applicable standards of Executive Order 12988.

Paperwork Reduction Act. This rule does not involve any collection of information for purposes of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*

List of Subjects in 44 CFR Part 64

Flood insurance, Floodplains.

Accordingly, 44 CFR part 64 is amended as follows:

PART 64—[AMENDED]

■ 1. The authority citation for part 64 continues to read as follows:

Authority: 42 U.S.C. 4001 *et seq.;* Reorganization Plan No. 3 of 1978, 3 CFR,

1978 Comp.; p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp.; p. 376.

§ 64.6 [Amended]

■ 2. The tables published under the authority of § 64.6 are amended as follows:

State and location	Community No.	Effective date authorization/cancellation of sale of flood insurance in community	Current effective map date	Date certain Federal assistance no longer available in SFHAS
Region IV				
Florida: Fort Myers, City of, Lee County	125106	October 30, 1970, Emerg; April 16, 1979, Reg; December 7, 2018, Susp.	Dec. 7, 2018	Dec. 7, 2018.
Georgia:				
Allenhurst, Town of, Liberty County	130350	May 6, 1975, Emerg; June 17, 1986, Reg; December 7, 2018, Susp.	do *	Do.
Flemington, City of, Liberty County	130124	November 27, 1974, Emerg; May 17, 1982, Reg; December 7, 2018, Susp.	do	Do.
Hinesville, City of, Liberty County	130125	June 13, 1975, Emerg; September 16, 1982, Reg; December 7, 2018, Susp.	do	Do.
Liberty County, Unincorporated Areas	130123	January 22, 1975, Emerg; December 1, 1983, Reg; December 7, 2018, Susp.	do	Do.
Midway, City of, Liberty County	130351	July 22, 1975, Emerg; September 30, 1981, Reg; December 7, 2018, Susp.	do	Do.
Riceboro, City of, Liberty County	130126	June 26, 1975, Emerg; November 4, 1981, Reg; December 7, 2018, Susp.	do	Do.
Walthourville, City of, Liberty County	130459	N/A, Emerg; October 29, 2008, Reg; December 7, 2018, Susp.	do	Do.
South Carolina:				
Berkeley County, Unincorporated Areas	450029	October 13, 1978, Emerg; September 30, 1983, Reg; December 7, 2018, Susp.	do	Do.
Goose Creek, City of, Berkeley County	450206	April 18, 1975, Emerg; February 17, 1982, Reg; December 7, 2018, Susp.	do	Do.
Hanahan, City of, Berkeley County	450030	October 25, 1973, Emerg; June 15, 1981, Reg; December 7, 2018, Susp.	do	Do.
Moncks Corner, Town of, Berkeley County	450031	July 1, 1975, Emerg; January 16, 1981, Reg; December 7, 2018, Susp.	do	Do.
Region V				
Minnesota:				
Caledonia, City of, Houston County	270712	May 21, 2001, Emerg; N/A, Reg; December 7, 2018, Susp.	do	Do.
Hokah, City of, Houston County	270192	November 29, 1974, Emerg; March 15, 1982, Reg; December 7, 2018, Susp.	December 7, 2018	December 7, 2018.
Houston, City of, Houston County	270193	November 13, 1974, Emerg; July 16, 1979, Reg; December 7, 2018, Susp.	do	Do.
Houston County, Unincorporated Areas	270190	April 30, 1974, Emerg; January 6, 1982, Reg; December 7, 2018, Susp.	do	Do.
La Crescent, City of, Houston and Winona Counties.	275237	February 11, 1972, Emerg; July 20, 1973, Reg; December 7, 2018, Susp.	do	Do.
Region VII				
Iowa:				
Adel, City of, Dallas County	190103	July 30, 1975, Emerg; August 4, 1987, Reg; December 7, 2018, Susp.	do	Do.
Dallas Center, City of, Dallas County	190564	N/A, Emerg; February 22, 2010, Reg; December 7, 2018, Susp.	do	Do.
Dallas County, Unincorporated Areas	190860	December 14, 1992, Emerg; May 1, 1994, Reg; December 7, 2018, Susp.	do	Do.
Dawson, City of, Dallas County	190358	N/A, Emerg; August 12, 2011, Reg; December 7, 2018, Susp.	do	Do.
De Soto, City of, Dallas County	190359	September 1, 1979, Emerg; September 27, 1985, Reg; December 7, 2018, Susp.	do	Do.
Granger, City of, Dallas County	190104	October 29, 1976, Emerg; June 1, 1987, Reg; December 7, 2018, Susp.	do	Do.
Perry, City of, Dallas County	190105	June 10, 1975, Emerg; September 4, 1985, Reg; December 7, 2018, Susp.	do	Do.
Redfield, City of, Dallas County	190361	October 26, 1976, Emerg; September 18, 1985, Reg; December 7, 2018, Susp.	do	Do.
Van Meter, City of, Dallas County	190362	N/A, Emerg; January 26, 2009, Reg; December 7, 2018, Susp.	do	Do.
Waukee, City of, Dallas County	190678	N/A, Emerg; May 3, 2001, Reg; December 7, 2018, Susp.	do	Do.
Region VIII				
Colorado:				
Colorado Springs, City of, El Paso County	080060	March 30, 1973, Emerg; December 18, 1986, Reg; December 7, 2018, Susp.	do	Do.
El Paso County, Unincorporated Areas	080059	March 9, 1973, Emerg; December 18, 1986, Reg; December 7, 2018, Susp.	do	Do.
Fountain, City of, El Paso County	080061	October 2, 1974, Emerg; June 5, 1985, Reg; December 7, 2018, Susp.	do	Do.
Green Mountain Falls, Town of, El Paso County	080062	March 18, 1975, Emerg; June 5, 1985, Reg; December 7, 2018, Susp.	do	Do.
Manitou Springs, City of, El Paso County	080063	May 29, 1975, Emerg; February 1, 1984, Reg; December 7, 2018, Susp.	do	Do.

State and location	Community No.	Effective date authorization/cancellation of sale of flood insurance in community	Current effective map date	Date certain Federal assistance no longer available in SFHAS
Monument, Town of, El Paso County	080064	June 10, 1975, Emerg; December 18, 1986, Reg; December 7, 2018, Susp.	.....do	Do.
Palmer Lake, Town of, El Paso County	080065	August 16, 1973, Emerg; July 3, 1978, Reg; December 7, 2018, Susp.	.....do	Do.
Region X				
Oregon:				
Bandon, City of, Coos County	410043	October 11, 1974, Emerg; August 15, 1984, Reg; December 7, 2018, Susp.	.....do	Do.
Coos Bay, City of, Coos County	410044	August 23, 1974, Emerg; August 1, 1984, Reg; December 7, 2018, Susp.	.....do	Do.
Coos County, Unincorporated Areas	410042	July 7, 1975, Emerg; November 15, 1984, Reg; December 7, 2018, Susp.	.....do	Do.
Coquille, City of, Coos County	410045	April 29, 1975, Emerg; September 28, 1984, Reg; December 7, 2018, Susp.	.....do	Do.
Lakeside, City of, Coos County	410278	June 2, 1975, Emerg; August 1, 1984, Reg; December 7, 2018, Susp.	.....do	Do.
Myrtle Point, City of, Coos County	410047	January 30, 1975, Emerg; July 16, 1984, Reg; December 7, 2018, Susp.	.....do	Do.
North Bend, City of, Coos County	410048	June 4, 1975, Emerg; August 1, 1984, Reg; December 7, 2018, Susp.	.....do	Do.
Powers, City of, Coos County	410049	August 6, 1975, Emerg; June 30, 1976, Reg; December 7, 2018, Susp.	.....do	Do.

*.....do = Ditto.
Code for reading third column: Emerg.—Emergency; Reg.—Regular; Susp.—Suspension.

Dated: November 16, 2018.

Eric Letvin,

Deputy Assistant Administrator for Mitigation, Federal Insurance and Mitigation Administration—FEMA Resilience, Department of Homeland Security, Federal Emergency Management Agency.

[FR Doc. 2018–26132 Filed 12–3–18; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 156

[CMS–9917–F]

RIN 0938–AT93

Patient Protection and Affordable Care Act; Elimination of Internal Agency Process for Implementation of the Federally-Facilitated User Fee Adjustment

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: The U.S. Department of Health and Human Services (HHS) is issuing this final rule to eliminate references to internal Executive Branch procedures provided for under Office of Management and Budget (OMB) circular A–25R in connection with an adjustment to the Federally-facilitated Exchange (FFE) user fee. HHS is amending these regulations because it has determined that an exception to OMB circular A–25R is not required to effectuate the FFE user fee adjustment. Thus, this final rule removes the language that refers to an exception under OMB circular A–25R as an aspect of reducing a participating issuer's FFE user fee obligation. This rule does not affect the ability of an issuer to obtain an applicable reduction in FFE user fee obligations, amend the calculation of the FFE user fee credit provided to a participating issuer, change the application of the monthly user fee adjustment, or alter any of the other standards that participating issuers must meet to qualify for the user fee adjustment.

DATES: These regulations are effective on January 3, 2019.

FOR FURTHER INFORMATION CONTACT: Jaya Ghildiyal, (301) 492–5149, or Adrianne Patterson, (410) 786–0686.

SUPPLEMENTARY INFORMATION:

I. Background

A. Determination To Issue a Final Rule

The U.S. Department of Health and Human Services (HHS) is publishing this final rule without previously publishing a proposed rule because HHS has determined that the rule qualifies for exemption from notice-and-comment rulemaking under section 553 of the Administrative Procedures Act (Pub. L. 79–404, enacted June 11, 1946) (APA), both because it is a ''matter relating to agency management'' under section 553(a)(2) [1] and a ''rule of agency organization, procedure or practice'' under section 553(b)(3)(A). This rule eliminates an unnecessary reference to an internal inter-agency process, but makes no changes to the policy or operational processes set forth for participating FFE issuers or third parties subject to 45 CFR 156.50(d), and will have no effect on these entities or the other individuals and entities that were subjects of the July 2, 2013 final rule ''Coverage of Certain Preventive Services Under the Affordable Care Act'' (78 FR 39870), namely eligible organizations, self-insured plans of eligible organizations, and participants and beneficiaries of those plans.

B. Legislative and Regulatory Overview

The Patient Protection and Affordable Care Act (Pub. L. 111–148, enacted March 23, 2010) and the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152, enacted March 30, 2010) are collectively referred to as ''PPACA'' in this final rule. Section 1321(a) of the PPACA provides broad authority for the Secretary to establish standards and regulations to implement the statutory requirements related to Exchanges, qualified health plans (QHPs), and other components of title I of the PPACA. When operating an FFE under section 1321(c)(1) of the PPACA, HHS has the authority under sections 1321(c)(1) and 1311(d)(5)(A) of the PPACA to collect and spend user fees. OMB Circular A–25 Revised (OMB Circular A–25R) establishes federal

[1] Although HHS's predecessor agency, the U.S. Department of Health, Education, and Welfare (HEW), waived the APA's exemption to the requirement for notice and comment rulemaking for ''public property, loans, grants, benefits, or contracts'' in section 553(a)(2), *see* ''Public Participation in Rule Making,'' 36 FR 2532 (Feb. 5, 1971), HEW did not waive the exemption in section 553(a)(2) for ''matter[s] relating to agency management or personnel.''

policy regarding user fees and specifies that a user charge will be assessed against each identifiable recipient for special benefits derived from federal activities beyond those received by the general public.

Section 2713(a)(4) of the Public Health Service Act, as added by the PPACA and incorporated into the Employee Retirement Income Security Act of 1974 and the Internal Revenue Code, requires that non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage provide certain women's preventive health services as a benefit without cost sharing, as provided for in comprehensive guidelines supported by the Health Resources and Services Administration. On July 2, 2013, the final rule ''Coverage of Certain Preventive Services Under the Affordable Care Act'' (78 FR 39870) published by HHS, the Department of the Treasury, and the Department of Labor, set forth regulations allowing eligible organizations to receive an accommodation relating to coverage of contraceptive services, so that they are not required to provide, arrange, or pay for these services. Those regulations at 45 CFR 147.131, 26 CFR 54.9815–2713A, and 29 CFR 2590.715–2713A were amended, but largely left in place, by interim final rules with requests for comments published in the **Federal Register** on October 13, 2017, Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act (82 FR 47792) and Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act (82 FR 47838) and final rules published in the **Federal Register** on November 15, 2018,with an effective date of January 14, 2019, Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act (83 FR 57536) and Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act (83 FR 57592). The 2013 final regulation also set forth processes and standards at § 156.50(c) and (d) to take into account the payments for the contraceptive services that are provided for participants and beneficiaries in self-insured plans of eligible organizations under the accommodation described in that final rule through an adjustment in the FFE user fee payable by an issuer participating in an FFE, at no cost to plan participants or beneficiaries, eligible organizations, third party administrators, or issuers.

II. Provisions of the Final Regulations

This final rule amends the regulations for adjustments of FFE user fees set forth at § 156.50, as established in the final rule published in the July 2, 2013 **Federal Register**. HHS is amending § 156.50(d)(3), to remove the current language providing that an authorizing exception under OMB Circular No. A–25R must be in effect in order for HHS to provide a participating issuer a reduction in its obligation to pay the FFE user fee. HHS will calculate the user fee reduction as the sum of the total dollar amount of the payments for contraceptive services submitted by applicable third party administrators, as described in paragraph (d)(2)(iii)(D), and an allowance, specified by HHS, for administrative costs and margin.

HHS is also amending § 156.50(d)(4) to remove a corresponding requirement that an authorizing exception under OMB Circular No. A–25R be in effect. If the amount of the reduction under § 156.50(d)(3) is greater than the amount of the obligation to pay the FFE user fee in a particular month, the participating issuer will be provided a credit in succeeding months in the amount of the excess.

HHS has determined that an exception to OMB Circular No. A–25R is not required to be in effect to effectuate the FFE user fee adjustment for participating issuers. HHS has implemented an adjustment to FFE user fee collections for each benefit year beginning with the 2014 benefit year, and the adjustment has accounted for less than 2 percent of total FFE user fee collections for each benefit year. Therefore, HHS continues to believe that the adjustment to FFE user fee collections will not materially undermine FFE operations. HHS believes that the reduced user fee collections resulting from the adjustment will not necessitate an exception to OMB Circular No. A–25R. Subject to HHS's standing financial management procedures, HHS will continue to monitor user fee collections and expenditures to ensure compliance under OMB Circular No. A–25R going forward. Additionally, HHS notes that it has not raised the FFE user fee finalized in the annual notice of benefit and payment parameters to offset the FFE user fee adjustments for any applicable benefit year. HHS estimates that payments for contraceptive services will continue to represent only a small portion of total FFE user fees in future benefit years, and it does not anticipate that it will need to increase the FFE user fee rate to offset the FFE user fee adjustment available to participating issuers.

III. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping, or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, *et seq.*).

IV. Regulatory Impact Analysis

HHS has examined the impact 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 (Pub. L. 96–354, enacted September 19, 1980) (RFA), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4, enacted March 22, 1995), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs. Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis must be prepared for major rules with economically significant effects ($100 million or more in any one year).

This final rule is not ''economically significant'' within the meaning of section 3(f)(1) of Executive Order 12866 because it is unlikely to have an annual effect of $100 million in any single year. In addition, for the reasons noted in this final rule, HHS does not believe that this final rule is a major rule under the Congressional Review Act.

The RFA requires agencies to analyze options for regulatory relief of small businesses. This rule would not have a significant impact on small businesses.

In addition, section 1102(b) of the Act requires HHS 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 rule would not have a significant impact on small rural hospitals because the amendments

contained in this final rule do not pertain to hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any 1 year by state, local, or tribal governments, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. In 2018, that threshold is approximately $150 million. HHS anticipates this rule would not impact state governments or the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it issues 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. HHS does not anticipate this rule would impose direct requirement costs on state or local governments, preempt state law, or otherwise have federalism implications.

List of Subjects in 45 CFR Part 156

Administrative appeals, Administrative practice and procedure, Advertising, Advisory Committees, American Indian/Alaska Natives, Brokers, Conflict of interest, Consumer protection, Cost-sharing reductions, Grant programs-health, Grants administration, Health care, Health insurance, Health maintenance organization (HMO), Health records, Hospitals, Individuals with disabilities, Loan programs-health, Organization and functions (Government agencies), Medicaid, Payment and collections reports, Public assistance programs, Reporting and recordkeeping requirements, State and local governments, Sunshine Act, Taxes, Technical assistance, Women, and Youth.

For the reasons set forth in the preamble, the Department of Health and Human Services amends 45 CFR part 156 as set forth below:

PART 156—HEALTH INSURANCE ISSUER STANDARDS UNDER THE AFFORDABLE CARE ACT, INCLUDING STANDARDS RELATED TO EXCHANGES

■ 1. The authority citation for part 156 is revised to read as follows:

Authority: 42 U.S.C. 18021–18024, 18031–18032, 18041–18042, 18044, 18054, 18061, 18063, 18071, 18082, 26 U.S.C. 36B, and 31 U.S.C. 9701.

■ 2. Section 156.50 is amended by revising paragraphs (d)(3) and (4) to read as follows:

§ 156.50 Financial support.

* * * * *

(d) * * * * *

(3) If the requirements set forth in paragraph (d)(2) of this section are met, the participating issuer will be provided a reduction in its obligation to pay the Federally-facilitated Exchange user fee specified in paragraph (c) of this section equal in value to the sum of the following:

(i) The total dollar amount of the payments for contraceptive services submitted by the applicable third-party administrators, as described in paragraph (d)(2)(iii)(D) of this section; and

(ii) An allowance for administrative costs and margin. The allowance will be no less than 10 percent of the total dollar amount of the payments for contraceptive services specified in paragraph (d)(3)(i) of this section. HHS will specify the allowance for a particular calendar year in the annual HHS notice of benefit and payment parameters.

(4) If the amount of the adjustment under paragraph (d)(3) of this section is greater than the amount of the participating issuer's obligation to pay the Federally-facilitated Exchange user fee in a particular month, the participating issuer will be provided a credit in succeeding months in the amount of the excess.

* * * * *

Dated: November 16, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: November 20, 2018.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2018–26332 Filed 11–30–18; 4:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 212, 225, and 252

[Docket DARS–2018–0028]

RIN 0750–AJ71

Defense Federal Acquisition Regulation Supplement: Sunset of Provision Relating to the Procurement of Certain Goods (DFARS Case 2018–D007)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: DoD is issuing a final rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to implement a section of the National Defense Authorization Act for Fiscal Year 2018 that repeals the Fiscal Year 2015 restrictions on the source of photovoltaic devices in contracts awarded by DoD that result in DoD ownership of photovoltaic devices by means other than DoD purchase of the photovoltaic devices as end products.

DATES: Effective December 5, 2018.

FOR FURTHER INFORMATION CONTACT: Ms. Amy G. Williams, telephone 571–372–6106.

SUPPLEMENTARY INFORMATION:

I. Background

DoD published a proposed rule in the **Federal Register** at 83 FR 42822 on August 24, 2018, to implement section 813(b) of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2018 (Pub. L. 115–91). Section 813(b) repeals section 858 of the NDAA for FY 2015 (Pub. L. 113–291), but does not repeal section 846 of the NDAA for FY 2011 (Pub. L. 111–383), with regard to sources of photovoltaic devises purchased by contractors that become property of DoD. There were no public comments submitted in response to the proposed rule. There are no changes from the proposed rule in the final rule.

II. Applicability to Contracts at or Below the Simplified Acquisition Threshold and for Commercial Items, Including Commercially Available Off-the-Shelf Items

This rule does not affect the applicability of DFARS clause 252.225–7017, Photovoltaic Devices, and DFARS provision 252.225–7018, Photovoltaic Devices—Certification. A determination was signed by the Director, Defense Procurement and Acquisition Policy, on October 13, 2011, to not apply the requirements of section 846 of the NDAA for FY 2011 to contracts at or below the simplified acquisition threshold, but to apply the rule to contracts for the acquisition of commercial items, including commercially available off-the-shelf items.

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 rule is not an E.O. 13771 regulatory action, because this final rule is not significant under E.O. 12866.

V. Regulatory Flexibility Act

A final regulatory flexibility analysis (FRFA) has been prepared consistent with the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* The FRFA is summarized as follows:

This rule implements section 813(b) of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2018 (Pub. L. 115–91), which repealed of section 858 of the National Defense Authorization Act (NDAA) for FY 2015 (Pub. L. 113–291), while retaining the requirements of section 846 of the NDAA for FY 2011 (Pub. L. 111–383), with regard to sources of photovoltaic devices purchased by contractors that become the property of DoD.

The objective of this rule is to revert to the regulations on photovoltaic devices that were in effect prior to superimposing the additional regulations required by section 858 on November 20, 2015 (80 FR 72599). By restoring the tie to the Buy American statute, this rule reinstates the Buy American exceptions for acquisitions of photovoltaic devices below the micro-purchase threshold, nonavailability, unreasonable cost, and public interest, including the DoD class determinations that exempt U.S.-made and qualifying country photovoltaic devices from the requirements of the Buy American statute, as well as the Governmentwide determination that removes the component test for commercially available off-the-shelf items.

No significant issues were raised by the public comments in response to the initial regulatory flexibility analysis. No public comments were received.

This rule generally applies at the prime contract level to other than small entities. When purchasing renewable power generated via onsite photovoltaic devices, DoD can either purchase the photovoltaic devices and thereby own, operate, and maintain the devices for their full economic life (already covered in DFARS part 225 under standard Buy American statute/Trade Agreements regulations) or, for example, may do some variation of the following:

a. Enter into an energy savings performance contract, which is a contracting method in which the contractor provides capital to facilitate energy conservation measures and maintains them in exchange for a portion of the energy savings generated. Under this arrangement, the Government would take title to the devices during contract performance or at the conclusion of the contract. For example, DoD uses either the master indefinite delivery-indefinite quantity contract of the Department of Energy or the Army Corps of Engineers and awards task orders off one of those contracts. Generally, the same approved contractors are on each contract. Of the approved contractors, all but one are large businesses. There are subcontracting goals that each contractor has to meet, but the ultimate task order award is most often made to a large business.

b. Enter into a power purchase agreement, also referred to as a utility service contract, for the purchase of the power output of photovoltaic devices that are installed on DoD land or buildings, but owned, operated, and maintained by the contractor. At the conclusion of the contract, DoD would either require the contractor to dismantle and remove the photovoltaic equipment or abandon the equipment in place. Prime contractors for this type of contract would generally be large businesses, based on the capital costs involved in these projects. However, many developers tend to subcontract out the majority of the work to smaller companies.

There are approximately 80 manufacturers of photovoltaic devices. We do not currently have data available on whether any of the manufacturers of photovoltaic devices are small entities, because the Federal Procurement Data System does not collect such data on subcontractors.

There are no new reporting burdens under this rule. In fact, there is a *de minimis* reduction in burden, because no certification will be required if the value of the photovoltaic devices does not exceed the micro-purchase threshold, and identification of country of origin will no longer be required if the photovoltaic devices are domestic or U.S.-made. Furthermore, since the prime contractors subject to this rule are other than small businesses, the existing reporting requirements do not impact small entities.

DoD did not identify any significant alternatives that meet the requirements of the statute and would have less impact on small entities. The overall effect of this rule is deregulatory and it does not have significant impact on small entities.

VI. Paperwork Reduction Act

The rule contains information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C chapter 35); however, these changes to the DFARS do not impose additional information collection requirements to the paperwork burden previously approved under OMB Control Number 0704–0229, entitled ''Defense Federal Acquisition Regulation Supplement (DFARS) Part 225, Foreign Acquisition, and related clauses at DFARS 252.225.''

List of Subjects in 48 CFR Parts 212, 225, and 252

Government procurement.

Jennifer Lee Hawes,

Regulatory Control Officer, Defense Acquisition Regulations System.

Therefore, 48 CFR parts 212, 225, and 252 are amended as follows:

■ 1. The authority citation for 48 CFR parts 212, 225, and 252 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 chapter 1.

PART 212—ACQUISITION OF COMMERCIAL ITEMS

■ 2. Amend section 212.301 by revising paragraphs (f)(ix)(J) and (K) to read as follows:

212.301 Solicitation provisions and contract clauses for the acquisition of commercial items.

* * * * *

(f) * * *

(ix) * * *

(J) Use the clause at 252.225–7017, Photovoltaic Devices, as prescribed in 225.7017–4(a), to comply with section 846 of Public Law 111–383.

(K) Use the provision at 252.225–7018, Photovoltaic Devices—Certificate, as prescribed in 225.7017–4(b), to comply with section 846 of Public Law 111–383.

* * * * *

PART 225—FOREIGN ACQUISITION

■ 3. Amend section 225.7017–1 by revising the definitions of ''covered contract'' and ''domestic photovoltaic device'' to read as follows:

225.7017–1 Definitions.

* * * * *

Covered contract means an energy savings performance contract, a utility services contract, or a private housing contract awarded by DoD, to be performed in the United States, if such contract results in DoD ownership of photovoltaic devices, by means other than DoD purchase as end products. DoD is deemed to own a photovoltaic device if the device is—

(1) Installed in the United States on DoD property or in a facility owned by DoD; and

(2) Reserved for the exclusive use of DoD in the United States for the full economic life of the device.

* * * * *

Domestic photovoltaic device means a photovoltaic device that is manufactured in the United States.

* * * * *

■ 4. Revise section 225.7017–2 to read as follows:

225.7017–2 Restriction.

In accordance with section 846 of the National Defense Authorization Act for Fiscal Year 2011 (Pub. L. 111–383), photovoltaic devices provided under any covered contract shall comply with 41 U.S.C. chapter 83, Buy American, subject to the exceptions to that statute provided in the Trade Agreements Act of 1979 (19 U.S.C. 2501 *et seq.*).

■ 5. Revise section 225.7017–3 to read as follows:

225.7017–3 Exceptions.

DoD requires the contractor to utilize domestic photovoltaic devices in covered contracts that exceed the simplified acquisition threshold, with the following exceptions:

(a) *Qualifying country.* Qualifying country photovoltaic devices may be utilized in any covered contract, because 225.103(a)(i)(A) provides an exception to the Buy American statute for products of qualifying countries, as defined in 225.003.

(b) *Buy American—unreasonable cost.* For a covered contract that utilizes photovoltaic devices valued at less than $180,000, the exception for unreasonable cost may apply (see FAR 25.103(c). If the cost of a foreign photovoltaic device plus 50 percent is less than the cost of a domestic photovoltaic device, then the foreign photovoltaic device may be utilized.

(c) *Trade agreements*—(1) *Free Trade Agreements.* For a covered contract that utilizes photovoltaic devices valued at $25,000 or more, photovoltaic devices may be utilized from a country covered under the acquisition by a Free Trade Agreement, depending upon dollar threshold (see FAR subpart 25.4).

(2) *World Trade Organization—Government Procurement Agreement.* For covered contracts that utilize photovoltaic devices that are valued at $180,000 or more, only U.S.-made photovoltaic devices, designated country photovoltaic devices, or qualifying country photovoltaic devices may be utilized.

225.7017–4. [Removed]

■ 6. Remove section 225.7017–4.

225.7017–5 [Redesignated as 225.7017–4]

■ 7. Redesignate section 225.7017–5 as 225.7017–4 and in the newly redesignated section 225.7017–4, revise paragraph (a)(1) to read as follows:

225.7017–4 Solicitation provision and contract clause.

(a)(1) Use the clause at 252.225–7017, Photovoltaic Devices, in solicitations, including solicitations using FAR part 12 procedures for the acquisition of commercial items, for a contract expected to exceed the simplified acquisition threshold that may be a covered contract, *i.e.,* an energy savings performance contract, a utility service contract, or a private housing contract awarded by DoD, if such contract will result in DoD ownership of photovoltaic devices, by means other than DoD purchase as end products.

* * * * *

PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 8. Amend section 252.225–7017 by—

■ a. In the introductory text, removing ''225.7017–5(a)'' and adding ''225.7017–4(a)'' in its place;

■ b. Removing the clause date ''(JAN 2018)'' and adding ''(DEC 2018)'' in its place;

■ c. In paragraph (a)—

■ i. Removing subparagraph designations ''(i)'' and ''(ii)'' and adding ''(1)'' and (2)'' in their places wherever they appear;

■ ii. Removing subparagraph designations ''(iii)'' and ''(iv)'' and adding ''(3)'' and ''(4)'' in their places wherever they appear;

■ iii. Revising the definition of ''domestic photovoltaic device'';

■ d. In paragraph (b), removing ''858 of the National Defense Authorization Act for Fiscal Year 2015 (Pub. L. 113–291)'' and adding ''846 of the National Defense Authorization Act for Fiscal Year 2011 (Pub. L. 111–383)'' in its place; and

■ e. In paragraph (c)—

■ i. Revising paragraph (c)(1);

■ ii. In paragraph (c)(2), removing ''photovoltaic device as specified, or,'' and adding ''photovoltaic device, or,'' in its place; and

■ iii. Revising paragraphs (c)(3), (4), and (5).

The revisions read as follows:

252.225–7017 Photovoltaic Devices.

(a) * * *

Domestic photovoltaic device means a photovoltaic device that is manufactured in the United States.

* * * * *

(c) * * *

(1) More than the micro-purchase threshold but less than $25,000, then the Contractor shall utilize only domestic photovoltaic devices unless, in its offer, it specified utilization of qualifying country or other foreign photovoltaic devices in paragraph (d)(2) of the Photovoltaic Devices—Certificate provision of the solicitation.

* * * * *

(3) $80,317 or more but less than $100,000, then the Contractor shall utilize under this contract only domestic photovoltaic devices, unless, in its offer, it specified utilization of Free Trade Agreement country photovoltaic devices (other than Bahrainian, Korean, Moroccan, Panamanian, or Peruvian photovoltaic devices), qualifying country photovoltaic devices, or other foreign photovoltaic devices in paragraph (d)(4) of the Photovoltaic Devices—Certificate provision of the solicitation. If the Contractor certified in its offer that it will utilize a Free Trade Agreement country photovoltaic device (other than a Bahrainian, Korean, Moroccan, Panamanian, or Peruvian photovoltaic device) or a qualifying country photovoltaic device, then the Contractor shall utilize a Free Trade Agreement country photovoltaic device (other than a Bahrainian, Korean, Moroccan, Panamanian, or Peruvian photovoltaic device) or a qualifying country photovoltaic device; or, at the Contractor's option, a domestic photovoltaic device;

(4) $100,000 or more but less than $180,000, then the Contractor shall utilize under this contract only domestic photovoltaic devices, unless, in its offer it specified utilization of Free Trade Agreement country photovoltaic devices (other than Bahrainian, Moroccan, Panamanian, or Peruvian photovoltaic devices), qualifying country photovoltaic devices, or other foreign photovoltaic devices in paragraph (d)(5) of the Photovoltaic Devices—Certificate provision of the solicitation. If the Contractor certified in

its offer that it will utilize a Free Trade Agreement country photovoltaic device (other than a Bahrainian, Moroccan, Panamanian, or Peruvian photovoltaic device) or a qualifying country photovoltaic device, then the Contractor shall utilize a Free Trade Agreement country photovoltaic device (other than a Bahrainian, Moroccan, Panamanian, or Peruvian photovoltaic device) or a qualifying country photovoltaic device; or, at the Contractor's option, a domestic photovoltaic device; or

(5) $180,000 or more, then the Contractor shall utilize under this contract only U.S.-made, designated country, or qualifying country photovoltaic devices.

* * * * *

■ 9. Amend section 252.225–7018 by—

■ a. In the introductory text, removing ''225.7017–5(b)'' and adding ''225.7017–4(b)'' in its place;

■ b. Removing clause date ''(JAN 2018)'' and adding ''(DEC 2018)'' in its place;

■ c. Revising paragraphs (b)(1) and (2); and

■ d. Revising paragraphs (d)(1), (d)(2) introductory text, and (d)(3) through (6).

The revisions read as follows:

252.225–7018 Photovoltaic Devices—Certificate.

* * * * *

(b) * * *

(1) If more than the micro-purchase threshold but less than $180,000, then the Government will not accept an offer specifying the use of other foreign photovoltaic devices in paragraph (d)(2)(ii), (d)(3)(ii), (d)(4)(ii), or (d)(5)(ii) of this provision, unless the offeror documents to the satisfaction of the Contracting Officer that the price of the foreign photovoltaic device plus 50 percent is less than the price of a comparable domestic photovoltaic device.

(2) If $180,000 or more, then the Government will consider only offers that utilize photovoltaic devices that are U.S.-made, qualifying country, or designated country photovoltaic devices.

* * * * *

(d) * * *

____ (1) No photovoltaic devices will be utilized in performance of the contract, or such photovoltaic devices have an estimated value that does not exceed the micro-purchase threshold.

(2) If more than the micro-purchase threshold but less than $25,000—

* * * * *

(3) If $25,000 or more but less than $80,317—

____ (i) The offeror certifies that each photovoltaic device to be utilized in performance of the contract is a domestic photovoltaic device;

____ (ii) The offeror certifies that each photovoltaic device to be utilized in performance of the contract is a Canadian photovoltaic device or a qualifying country photovoltaic device *[Offeror to specify country of origin_____];* or

____ (iii) The foreign (other than Canadian or qualifying country) photovoltaic devices to be utilized in performance of the contract are the product of _____. *[Offeror to specify country of origin, if known, and provide documentation that the cost of a domestic photovoltaic device would be unreasonable in comparison to the cost of the proposed foreign photovoltaic device, i.e. that the price of the foreign photovoltaic device plus 50 percent is less than the price of a comparable domestic photovoltaic device.]*

(4) If $80,317 or more but less than $100,000—

____ (i) The offeror certifies that each photovoltaic device to be utilized in performance of the contract is a domestic photovoltaic device;

____ (ii) The offeror certifies that each photovoltaic device to be utilized in performance of the contract is a Free Trade Agreement country photovoltaic device (other than a Bahrainian, Korean, Moroccan, Panamanian, or Peruvian photovoltaic device) or a qualifying country photovoltaic device *[Offeror to specify country of origin_____];* or

____ (iii) The offered foreign photovoltaic devices (other than those from countries listed in paragraph (d)(4)(ii) of this provision) are the product of _____. *[Offeror to specify country of origin, if known, and provide documentation that the cost of a domestic photovoltaic device would be unreasonable in comparison to the cost of the proposed foreign photovoltaic device, i.e. that the price of the foreign photovoltaic device plus 50 percent is less than the price of a comparable domestic photovoltaic device.]*

(5) If $100,000 or more but less than $180,000—

____ (i) The offeror certifies that each photovoltaic device to be utilized in performance of the contract is a domestic photovoltaic device;

____ (ii) The offeror certifies that each photovoltaic device to be utilized in performance of the contract is a Free Trade Agreement country photovoltaic device (other than a Bahrainian, Moroccan, Panamanian, or Peruvian photovoltaic device) or a qualifying country photovoltaic device *[Offeror to specify country of origin_____];* or

____ (iii) The offered foreign photovoltaic devices (other than those from countries listed in paragraph (d)(5)(ii) of this provision) are the product of _____. *[Offeror to specify country of origin, if known, and provide documentation that the cost of a domestic photovoltaic device would be unreasonable in comparison to the cost of the proposed foreign photovoltaic device, i.e. that the price of the foreign photovoltaic device plus 50 percent is less than the price of a comparable domestic photovoltaic device.]*

(6) If $180,000 or more, the Offeror certifies that each photovoltaic device to be used in performance of the contract is—

____ (i) A U.S.-made photovoltaic device; or

____ (ii) A designated country photovoltaic device or a qualifying country photovoltaic device. *[Offeror to specify country of origin_____.]*

* * * * *

[FR Doc. 2018–26305 Filed 12–3–18; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Part 217

[Docket DARS–2018–0054]

RIN 0750–AK27

Defense Federal Acquisition Regulation Supplement: Documentation for Interagency Contracts (DFARS Case 2018–D073)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: DoD is issuing a final rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to implement a section of the National Defense Authorization Act for Fiscal Year 2019 that removes the requirement to make a best procurement approach determination to use an interagency acquisition.

DATES: Effective December 4, 2018.

FOR FURTHER INFORMATION CONTACT: Ms. Carrie Moore, telephone 571–372–6093.

SUPPLEMENTARY INFORMATION:

I. Background

DoD is amending the DFARS to implement section 875 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2019 (Pub. L. 115–232). Section 875 amends section 865 of the NDAA for FY 2009 (Pub. L. 110–417) by removing the requirement for agencies,

prior to requesting another agency to conduct an acquisition on its behalf, to make a determination that the use of an interagency acquisition represents the best procurement approach. The requirement for a best procurement approach determination is implemented at Federal Acquisition Regulations (FAR) 17.502–1(a). Removal of the requirement from the FAR, in accordance with section 875, is being accomplished under FAR case 2018–015. This rule removes supplemental text from DFARS 217.502–1 that advises contracting officers, when providing acquisition assistance to deployed DoD units or personnel from another DoD Component, to obtain the determination from the requiring DoD unit or personnel.

II. Applicability to Contracts at or Below the Simplified Acquisition Threshold and for Commercial Items, Including Commercially Available Off-the-Shelf Items

This rule only impacts the internal operating procedures of the agency. As such, the rule does not impose any new requirements on contracts at or below the simplified acquisition threshold or for commercial items, including commercially available off-the-shelf items.

III. Executive Orders 12866 and 13563

Executive Order (E.O.) 12866, Regulatory Planning and Review; and E.O. 13563, Improving Regulation and Regulatory Review, 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. The Office of Management and Budget, Office of Information and Regulatory Affairs (OIRA), has determined that this is not a significant regulatory action as defined under section 3(f) of E.O. 12866 and, therefore, was not subject to review under section 6(b). This rule is not a major rule as defined at 5 U.S.C. 804(2).

IV. Executive Order 13771

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

V. Publication of This Final Rule for Public Comment Is Not Required by Statute

The statute that applies to the publication of the Federal Acquisition Regulation (FAR) is Office of Federal Procurement Policy statute (codified at title 41 of the United States Code). Specifically, 41 U.S.C. 1707(a)(1) requires that a procurement policy, regulation, procedure or form (including an amendment or modification thereof) must be published for public comment if it relates to the expenditure of appropriated funds, and has either a significant effect beyond the internal operating procedures of the agency issuing the policy, regulation, procedure, or form, or has a significant cost or administrative impact on contractors or offerors. This final rule is not required to be published for public comment, because it only impacts determination and documentation processes that are internal to the agency.

VI. Regulatory Flexibility Act

Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule under 41 U.S.C. 1707(a)(1) (see section V. of this preamble), the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are not applicable. Accordingly, no regulatory flexibility analysis is required and none has been prepared.

VII. Paperwork Reduction Act

The rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

List of Subjects in 48 CFR Part 217

Government procurement.

Jennifer Lee Hawes,

Regulatory Control Officer, Defense Acquisition Regulations System.

Therefore, 48 CFR part 217 is amended as follows:

PART 217—SPECIAL CONTRACTING METHODS

■ 1. The authority citation for 48 CFR part 217 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

■ 2. Revise section 217.502–1 to read as follows:

217.502–1 General.

(a) *Written agreement on responsibility for management and administration—*

(1) *Assisted acquisitions.* Follow the procedures at PGI 217.502–1(a)(1), when a contracting activity from a DoD Component provides acquisition assistance to deployed DoD units or personnel from another DoD Component.

[FR Doc. 2018–26309 Filed 12–3–18; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 217 and 252

[Docket DARS–2018–D036]

RIN 0750–AJ87

Defense Federal Acquisition Regulation Supplement: Modification of DFARS Clause "Surge Option" (DFARS Case 2018–D025)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: DoD is issuing a final rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to revise a clause to reflect current terminology and industry practices, pursuant to action taken by the DoD Regulatory Reform Task Force.

DATES: Effective December 4, 2018.

FOR FURTHER INFORMATION CONTACT: Ms. Carrie Moore, telephone 571–372–6093.

SUPPLEMENTARY INFORMATION:

I. Background

DoD published a proposed rule in the **Federal Register** at 83 FR 30659 on June 29, 2018, to modify DFARS clause 252.217–7001, Surge Option, to replace the term ''Production Surge Plan (DI–MGMT–80969)'' with ''Capabilities Analysis Plan (CAP)'' and add text to permit the option increase of supplies or services called for under the clause to be expressed as a specific number. The associated clause prescription at DFARS 217.208–70(b) is amended to reflect that the option increase of supplies or services may also be expressed as a specific number. This rule supports a recommendation from the DoD Regulatory Reform Task Force under Executive Order (E.O.) 13777, Enforcing the Regulatory Reform Agenda.

One respondent submitted a public comment in response to the proposed

rule. The comment is outside the scope of this case and no changes are made in the final rule.

II. Applicability to Contracts at or Below the Simplified Acquisition Threshold and for Commercial Items, Including Commercially Available Off-the-Shelf Items

This rule does not propose to create any new provisions or clauses. The proposed changes to DFARS clause 252.217–7001, Surge Option, are minimal and reflect only updates required to mirror current industry terminology and practice for support that may be required for industrial planning for selected essential military items in the event of an emergency. The rule continues to apply to contracts below the simplified acquisition threshold, however, the rule does not apply to commercial items, including commercially available off-the-shelf items.

III. Executive Orders 12866 and 13563

E.O. 12866, Regulatory Planning and Review; and E.O. 13563, Improving Regulation and Regulatory Review, 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. The Office of Management and Budget, Office of Information and Regulatory Affairs (OIRA), has determined that this is not a significant regulatory action as defined under section 3(f) of E.O. 12866 and, therefore, was not subject to review under section 6(b). This rule is not a major rule as defined at 5 U.S.C. 804(2).

IV. Executive Order 13771

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

V. Regulatory Flexibility Act

A final regulatory flexibility analysis (FRFA) has been prepared consistent with the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* The FRFA is summarized as follows:

The Department of Defense is amending the Defense Federal Acquisition Regulation Supplement (DFARS) to revise a clause to reflect current terminology and industry practices. The objective of this rule is to improve the flexibility offered to contractors submitting pricing for surge options by giving them the option to quote prices by percentage or quantity increases, and to update the terminology used from ''Production Surge Plan'' to ''Capability Analysis Plan'' (CAP), since this is the most current and accurate term for this type of plan. The modification of this DFARS text supports a recommendation from the DoD Regulatory Reform Task Force under E.O. 13777, Enforcing the Regulatory Reform Agenda.

No public comments were received in response to the initial regulatory flexibility analysis.

This rule is not expected 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 the scope of the rule limits the application of the reporting requirement to a small number of service contracts. Based on fiscal year 2017 data from the Federal Procurement Data System, the Government issued approximately 78 contract actions that used mobilization or essential research and development as the reason for other than full and open competition. Of the 78 contract actions, approximately 33 awards were made to 24 unique small entities.

This rule does not include any new reporting, recordkeeping, or other compliance requirements for small businesses.

There are no known significant alternative approaches to the rule that would meet the proposed objectives.

VI. Paperwork Reduction Act

The rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

List of Subjects in 48 CFR Parts 217 and 252

Government procurement.

Jennifer Lee Hawes,

Regulatory Control Officer, Defense Acquisition Regulations System.

Therefore, 48 CFR parts 217 and 252 are amended as follows: 1. The authority citation for parts 217 and 252 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

PART 217—SPECIAL CONTRACTING METHODS

217.208–70 [Amended]

■ 2. In section 217.208–70, amend paragraph (b)(1), by removing ''percentage'' and adding ''percentage or quantity'' in its place.

PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 3. Amend section 252.217–7001 by—
■ a. Removing the clause date of ''(AUG 1992)'' and adding ''(DEC 2018)'' in its place;
■ b. Revising paragraph (a)(1);
■ c. In paragraph (b)(1), removing ''Production Surge Plan (DI–MGMT 80969)'' and adding ''Capabilities Analysis Plan (CAP)'' in its place; and
■ d. In paragraph (b)(2), removing ''Production Surge Plan'' and adding ''CAP'' in its place.

The revision reads as follows:

252.217–7001. Surge option.

* * * * *

(a) * * *

(1) Increase the quantity of supplies or services called for under this contract by no more than ____percent or ____*[insert quantity and description of services or supplies to be increased];* and/or

* * * * *

[FR Doc. 2018–26307 Filed 12–3–18; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

49 CFR Parts 383 and 384

[Docket No. FMCSA–2001–11117]

RIN 2126–AA70

Limitations on the Issuance of Commercial Driver's Licenses With a Hazardous Materials Endorsement

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Interim rules; re-opening of the comment period.

SUMMARY: In May 2003 and April 2005, FMCSA published interim final rules (IFR) regarding the limitations on the issuance of commercial driver's licenses with a hazardous materials endorsement. The comment period for the May 2003 IFR closed on July 7, 2003; there was no comment period for the April 2005 IFR. The Agency received over 50 comments on the 2003

IFR. FMCSA now plans to adopt the provisions of the IFRs that have not previously been made final. To ensure that interested parties have an opportunity to provide comments, the Agency has re-opened the comment period for 15 days.

DATES: The comment periods for the interim final rules published May 5, 2003, at 68 FR 23844, and April 29, 2005, at 70 FR 22268, are reopened. Comments must be received on or before December 19, 2018.

ADDRESSES: You may submit comments identified by Docket Number FMCSA–2001–11117 using any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* West Building, Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays.
- *Fax:* (202) 493–2251.

To avoid duplication, please use only one of these four methods. See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: Mr. Selden Fritschner, CDL Division, Federal Motor Carrier Safety Administration, 1200 New Jersey Avenue SE, Washington, DC 20590–0001; by email at *Selden.Fritschner@dot.gov,* or by telephone at 202–366–0677. If you have questions on viewing or submitting material to the docket, contact Docket Services, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation and Request for Comments

A. Submitting Comments

If you submit a comment, please include the docket number for this IFR (FMCSA–2001–11117), indicate the specific section of the document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that FMCSA can contact you if there are questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov,* put the docket number, FMCSA–2001–11117, in the keyword box, and click ''Search.'' When the new screen appears, click on the ''Comment Now!'' button and type your comment into the text box on the following screen. Choose whether you are submitting your comment as an individual or on behalf of a third party and then submit.

If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope.

FMCSA will consider all comments and material received during the comment period and may change this IFR based on your comments. FMCSA may issue a final rule at any time after the close of the comment period.

B. Viewing Comments and Documents

To view comments, as well as any documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov.* Insert the docket number, FMCSA–2001–11117, in the keyword box, and click ''Search.'' Next, click the ''Open Docket Folder'' button and choose the document to review. If you do not have access to the internet, you may view the docket online by visiting the Docket Management Facility in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays.

C. Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.transportation.gov/privacy.*

II. Background

On May 5, 2003, FMCSA published an IFR titled ''Limitations on the Issuance of Commercial Driver's Licenses with a Hazardous Materials Endorsement'' (68 FR 23844). It revised its regulations to require State licensing agencies to issue or renew a hazardous materials endorsement for a CDL only if the Transportation Security Administration (TSA) has determined that the applicant does not pose a security risk warranting denial of such endorsement. To determine applicability, a CDL renewal, transfer, or upgrade was also considered a new issuance and fell within the scope of these requirements if it involved a hazardous materials endorsement. The IFR implemented FMCSA's part of the requirements of section 1012 of the USA PATRIOT Act, which limited the issuance of hazardous materials licenses. Because FMCSA shares with TSA the responsibility for implementing section 1012, TSA concurrently published an IFR containing regulations governing the security risk determination process in 49 CFR parts 1570 and 1572 (May 5, 2003, 68 FR 23852). No public meeting was requested and none was held. The IFR became effective upon publication on May 5, 2003.

On April 29, 2005, FMCSA published an IFR titled ''Limitations on the Issuance of Commercial Driver's Licenses with a Hazardous Materials Endorsement'' (70 FR 22268). That rule was issued as an IFR because it related to the 2003 IFR. In the preamble, FMCSA wrote that the 2005 IFR would be subsumed into the 2003 IFR when that rulemaking was finalized. FMCSA's 2003 IFR provided a specific date on which States became subject to the new requirement. The 2005 IFR amended the FMCSRs to cross-reference the TSA's compliance date as the date when FMCSA's companion requirements also became applicable (70 FR 22268). Consistent with the TSA regulations, FMCSA also reduced the amount of advance notice that States must provide to drivers that a security threat assessment will be performed when they renew a hazardous materials endorsement.

FMCSA solicited comments to the 2003 IFR. The Agency received over 50 comments. No comment period was included with the 2005 IFR.

On October 5, 2018, Congress enacted the FAA Reauthorization Act of 2018 (Pub. L. 115–254). Under Sec. 1977, a CMV driver who wants to obtain a hazardous materials endorsement on a commercial driver's license is an ''applicable individual who is subject to credentialing or background investigation''. Section 1978 exempted individuals who hold a valid transportation security card (TSC, or TWIC as implemented by TSA) issued under section 70105 of Title 46. FMCSA intends to incorporate this exemption when finalizing the IFRs, subject to TSA

requirements on the issuance of the HME.

Comments Requested

Considering the passage of time since the publication of the IFRs, and because some items may not have been touched on during the initial notice and comment, FMCSA is re-opening the comment period. At the end of the comment period, FMCSA will consider all issues under its authority and may change the IFR based on the comments. FMCSA may issue a final rule at any time after the close of the comment period.

Issued on: November 23, 2018.

Raymond P. Martinez,

Administrator.

[FR Doc. 2018–26250 Filed 12–3–18; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

49 CFR Part 390

[Docket No. FMCSA–2012–0103]

RIN 2126–AC22

Lease and Interchange of Vehicles; Motor Carriers of Passengers; Extension of Compliance Date

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Final rule; extension of compliance date.

SUMMARY: FMCSA extends the compliance date of the May 27, 2015, final rule titled ''*Lease and Interchange of Vehicles; Motor Carriers of Passengers,*'' from January 1, 2019, to January 1, 2021. The final rule received 37 petitions for reconsideration. To address the concerns in the petitions, FMCSA initiated a new notice of proposed rulemaking (NPRM) that also included a proposal to extend the compliance date of the 2015 final rule from January 1, 2019, to January 1, 2021. This extension of the compliance date is necessary to provide time to consider all the issues raised in comments to the NPRM and to publish a final rule, while giving motor carriers sufficient time to comply with the revised requirements.

DATES:

Effective date: December 4, 2018 until January 1, 2021.

Compliance date: As of December 4, 2018, the compliance date for the requirements in subpart F of 49 CFR part 390 (§§ 390.300T, 390.301, 390.303, and 390.305) is extended until January 1, 2021.

FOR FURTHER INFORMATION CONTACT: Ms. Loretta Bitner, (202) 366–2400, *loretta.bitner@dot.gov,* Office of Enforcement and Compliance. FMCSA office hours are from 9 a.m. to 5 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

I. Background

A. History

On May 27, 2015, FMCSA published a final rule titled ''Lease and Interchange of Vehicles; Motor Carriers of Passengers'' (80 FR 30164). The American Bus Association (ABA) and United Motorcoach Association (UMA) filed a joint request for an extension of the June 26, 2015, deadline to submit petitions for reconsideration of the final rule (80 FR 37553). On July 1, 2015, the Agency extended the deadline for such petitions until August 25, 2015 (80 FR 37553).

The Agency received 37 petitions for reconsideration, all of which were filed in the public docket referenced above. After the initial review of the petitions, FMCSA held a meeting on October 28, 2015, with a cross section of the petitioners. Attending were representatives from small and large bus companies, charter and regular-route operations, and diverse geographic areas of the nation. Additionally, two insurance company representatives were invited due to litigation and financial liability concerns. The purpose of the meeting was to have an open discussion and to gather additional details about petitioners' specific operations and concerns.

Based on these discussions, and after further analysis, FMCSA concluded that some aspects of the petitions for reconsideration have merit. The Agency therefore extended the compliance date to January 1, 2018, to allay stakeholder concerns that there would not be sufficient time to adjust passenger carrier operations before compliance with the regulations was required (81 FR 13998, March 16, 2016). After further review of the petitions, the Agency announced on August 31, 2016, that it intended to consider changes to four aspects of the 2015 final rule, but it also denied requests to reconsider other issues raised by petitioners (81 FR 59951). The August 31 document announced that a public roundtable would be held to discuss the four issues. The roundtable was held on October 31, 2016.

On June 16, 2017, FMCSA published a final rule (2017 final rule) and a proposal in the **Federal Register** (82 FR 27766, and 27768). The 2017 final rule extended the compliance date of the 2015 final rule from January 1, 2018, to January 1, 2019. The proposal provided information about FMCSA's planned revisions to the 2015 final rule and requested public comment on those revisions.

B. Related Activity

To address the concerns in the petitions, FMCSA published an NPRM on September 20, 2018 (83 FR 47764). This NPRM (RIN 2126–AC07) proposed to extend the compliance date of the 2015 final rule from January 1, 2019, to January 1, 2021. It also included proposed revisions to the 2015 final rule and requested public comment by November 19, 2018.

In October 2018, several passenger carriers petitioned FMCSA to extend the compliance date immediately in accordance with the Agency's prior commitments and provide sufficient time to finalize the NPRM, to avoid an uncertain operating environment, confusion, and disruption in industry operations. ABA wrote that the outcome of an uncertain business environment is entirely avoidable. The Agency should take the same action it has taken on two prior occasions, and simply publish a final rule to extend the compliance date of the current rule. ABA argued that extending the compliance date would not affect safety, as the current rule has never been in force; nor would an extension interfere with the rulemaking process to finalize revisions to the current rule. Further, the Agency has committed to extending the compliance date on several occasions for the stated purpose of allowing sufficient time to complete revisions to the current rule.

C. Comments Received

FMCSA received 15 comments supporting the extension of the compliance date of the 2015 final rule to January 1, 2021. The extension is necessary to provide time to consider all the issues and to publish a final rule, while giving motor carriers sufficient time to comply with the revised requirements. FMCSA therefore extends the 2019 compliance date until January 1, 2021.

D. Extending the Compliance Date

The Agency is extending the compliance date by 2 years, to January 1, 2021. The temporary section added to subpart F of 49 CFR part 390 when a previous extension of the compliance date was issued, is being updated to include the new compliance date. The temporary section continues to be in

effect only from December 4, 2018 through January 1, 2021.

II. Regulatory Analyses

A. Executive Order (E.O.) 12866 (Regulatory Planning and Review), E.O. 13563 (Improving Regulation and Regulatory Review), and DOT Regulatory Policies and Procedures

FMCSA performed an analysis of the impacts of this final rule and determined it is not a significant regulatory action under section 3(f) of E.O. 12866 (58 FR 51735, October 4, 1993), Regulatory Planning and Review, as supplemented by E.O. 13563 (76 FR 3821, January 21, 2011), Improving Regulation and Regulatory Review. Accordingly, the Office of Management and Budget (OMB) has not reviewed it under that Order. It is also not significant within the meaning of DOT regulatory policies and procedures (DOT Order 2100.5 dated May 22, 1980; 44 FR 11034 (February 26, 1979)). This final rule provides regulatory relief from January 1, 2019, through December 31, 2020, from all compliance costs associated with the 2015 final rule. The Agency's estimates of the cost of the 2015 final rule are thoroughly explained in that rule's Regulatory Evaluation (available in docket FMCSA–2012–0103) and were updated to reflect more recently available data for the NPRM. The analysis of today's final rule utilizes the same data and methodology as the NPRM.

To estimate the costs that will result from the final rule, the Agency calculated the total compliance costs from 2019 through 2028, albeit with no costs incurred in years 2019 and 2020. These costs are compared to a baseline in which the compliance costs of the 2015 final rule are incurred beginning in 2019, as shown in Table 1.

TABLE 1—TOTAL COST OF THE FINAL RULE

[In thousands of 2016$]

Year	3% discount rate			7% discount rate		
	No-action baseline costs	Final rule costs	Final rule costs relative to no-action baseline costs	No-action baseline costs	Final rule costs	Final rule costs relative to no-action baseline costs
2019	$33,773	$0	($33,773)	$32,510	$0	($32,510)
2020	6,083	0	(6,083)	5,636	0	(5,636)
2021	5,956	32,376	26,421	5,312	28,879	23,567
2022	5,831	5,831	0	5,007	5,007	0
2023	5,709	5,709	0	4,719	4,719	0
2024	5,590	5,590	0	4,448	4,448	0
2025	5,473	5,473	0	4,192	4,192	0
2026	5,359	5,359	0	3,951	3,951	0
2027	5,247	5,247	0	3,724	3,724	0
2028	5,137	5,137	0	3,510	3,510	0
10-Year Total	84,158	70,723	(13,435)	73,009	58,429	(14,580)
Annualized	9,866	8,291	(1,575)	10,395	8,319	(2,076)

The Agency estimates that the final rule will result in a cost savings of $13.4 million discounted at 3 percent and $14.6 million discounted at 7 percent over the 10-year analysis period. Expressed on an annualized basis, this equates to a cost savings of $1.6 million at a 3 percent discount rate and $2.1 million at a 7 percent discount rate. All values are in 2016 dollars.

B. E.O. 13771 (Reducing Regulation and Controlling Regulatory Costs)

This rule is an E.O. 13771 deregulatory action.[1] The present value of the cost savings of this rule, measured on an infinite horizon at a 7 percent discount rate, is approximately $11.9 million. Expressed on an annualized basis, the cost savings are $0.8 million. These values are expressed in 2016 dollars.

[1] Executive Office of the President. Executive Order 13771 of January 30, 2017. ''Reducing Regulation and Controlling Regulatory Costs.'' 82 FR 9339–9341. February 3, 2017.

C. Regulatory Flexibility Act

Section 603 of the Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121, 110 Stat. 857, March 29, 1996) and the Small Business Jobs Act of 2010 (Pub. L. 111–240, September 27, 2010), requires FMCSA to perform a detailed analysis of the potential impact of the final rule on small entities. Accordingly, DOT policy requires that agencies shall strive to lessen any adverse effects on these businesses and other entities. The Final Regulatory Flexibility Analysis conducted as part of the May 27, 2015, rule continues to be applicable to this final rule.

D. Assistance for Small Entities

In accordance with section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996, FMCSA wants to assist small entities in understanding this rule so that they can better evaluate its effects on themselves. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please consult the FMCSA point of contact, Loretta Bitner, listed in the **FOR FURTHER INFORMATION CONTACT** section of this rule.

Small businesses may send comments on the actions of Federal employees who enforce or otherwise determine compliance with Federal regulations to the SBA's Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of FMCSA, call 1–888–REG–FAIR (1–888–734–3247). DOT has a policy ensuring the rights of small entities to regulatory enforcement fairness and an explicit policy against retaliation for exercising these rights.

E. Federalism (E.O. 13132)

A rule has federalism implications if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on the States. FMCSA analyzed this rule under E.O. 13132 and has determined that it has no federalism implications.

F. Unfunded Mandates Reform Act of 1995

This final rule does not impose an unfunded Federal mandate, as defined by the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1532 *et seq.*), that would result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $161 million (which is the value of $100 million in 2017 after adjusting for inflation) or more in any 1 year.

G. E.O. 12988 (Civil Justice Reform)

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

H. E.O. 13045 (Protection of Children)

FMCSA analyzed this action under E.O. 13045, Protection of Children from Environmental Health Risks and Safety Risks. The Agency has determined that this rule does not create an environmental risk to health or safety that would disproportionately affect children.

I. E.O. 12630 (Taking of Private Property)

FMCSA reviewed this final rule in accordance with E.O. 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights, and has determined it would not effect a taking of private property or otherwise have taking implications.

J. Privacy Impact Assessment

Section 522 of title I of division H of the Consolidated Appropriations Act, 2005, enacted December 8, 2004 (Pub. L. 108–447, 118 Stat. 2809, 3268, 5 U.S.C. 552a note), requires the Agency to conduct a privacy impact assessment (PIA) of a regulation that will affect the privacy of individuals. This final rule does not require the collection of any personally identifiable information.

The Privacy Act (5 U.S.C. 552a) applies only to Federal agencies and any non-Federal agency which receives records contained in a system of records from a Federal agency for use in a matching program. FMCSA has determined this final rule does not result in a new or revised Privacy Act System of Records for FMCSA.

K. E.O. 12372 (Intergovernmental Review)

The regulations implementing E.O. 12372 regarding intergovernmental consultation on Federal programs and activities do not apply to this program.

L. Paperwork Reduction Act

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), Federal agencies must obtain approval from the OMB for each collection of information they conduct, sponsor, or require through regulations. On August 5, 2015, OMB approved the May 27, 2015, final rule's two information collections titled ''Commercial Motor Vehicle Marking Requirements,'' OMB No. 2126–0054, and ''Lease and Interchange of Motor Vehicles,'' OMB No. 2126–0056. OMB renewed these collections of information in October 2018, and they will both expire on October 31, 2021.

M. Environment (NEPA)

FMCSA analyzed this final rule in accordance with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 *et seq.*). The Agency has determined under its environmental procedures Order 5610.1, published March 1, 2004, in the **Federal Register** (69 FR 9680), that this action is categorically excluded from further environmental documentation under Appendix 2, Paragraphs 6.y(2) and 6.y(7) of the Order (69 FR 9702). These categorical exclusions relate to:

- 6.y(2) Regulations implementing motor carrier identification and registration reports; and
- 6.y(7) Regulations implementing prohibitions on motor carriers, agents, officers, representatives, and employees from making fraudulent or intentionally false statements on any application, certificate, report, or record required by FMCSA.

Thus, this final action does not require an environmental assessment or an environmental impact statement.

N. E.O. 13211 (Energy Supply, Distribution, or Use)

FMCSA has analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. The Agency has determined that it is not a ''significant energy action'' under that Executive Order because it is not economically significant and is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

O. E.O. 13175 (Indian Tribal Governments)

This rule does not have tribal implications under E.O. 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

P. National Technology Transfer and Advancement Act (Technical Standards)

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through OMB, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards (*e.g.,* specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) are standards that are developed or adopted by voluntary consensus standards bodies. This rule does not use technical standards. Therefore, FMCSA did not consider the use of voluntary consensus standards.

List of Subjects in 49 CFR Part 390

Highway safety, Intermodal transportation, Motor carriers, Motor vehicle safety, Reporting and recordkeeping requirements.

The Final Rule

For the reasons stated in the preamble, FMCSA amends 49 CFR part 390 in title 49, Code of Federal Regulations, chapter III, subchapter B, as follows:

PART 390—FEDERAL MOTOR CARRIER SAFETY REGULATIONS; GENERAL

■ 1. The authority citation for part 390 continues to read as follows:

Authority: 49 U.S.C. 504, 508, 31132, 31133, 31134, 31136, 31137, 31144, 31149, 31151, 31502; sec. 114, Pub. L. 103–311, 108 Stat. 1673, 1677; secs. 212 and 217, Pub. L. 106–159, 113 Stat. 1748, 1766, 1767; sec. 229, Pub. L. 106–159 (as added and transferred by sec. 4115 and amended by secs. 4130–4132, Pub. L. 109–59, 119 Stat. 1144, 1726, 1743; sec. 4136, Pub. L. 109–59, 119 Stat. 1144, 1745; secs. 32101(d) and 32934, Pub. L. 112–141, 126 Stat. 405, 778, 830; sec. 2, Pub. L. 113–125, 128 Stat. 1388; secs. 5403, 5518, and 5524, Pub. L. 114–94, 129 Stat. 1312,

1548, 1558, 1560; sec. 2, Pub. L. 115–105, 131 Stat. 2263; and 49 CFR 1.81, 1.81a, 1.87.

■ 2. Effective December 4, 2018 until January 1, 2021, revise § 390.300T to read as follows:

§ 390.300T Compliance date.

Motor carriers of passengers operating CMVs under a lease or interchange agreement are subject to §§ 390.301, 390.303, and 390.305 of this subpart on January 1, 2021.

Issued under the authority delegated in 49 CFR 1.87 on: November 23, 2018.

Raymond P. Martinez,

Administrator.

[FR Doc. 2018–26249 Filed 12–3–18; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 180720681–8999–02]

RIN 0648–BI38

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Snapper-Grouper Fishery off the Southern Atlantic Region; Regulatory Amendment 28

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Final rule.

SUMMARY: NMFS issues regulations to implement Regulatory Amendment 28 to the Fishery Management Plan for the Snapper-Grouper Fishery of the South Atlantic Region (FMP) (Regulatory Amendment 28), as prepared and submitted by the South Atlantic Fishery Management Council (Council). This final rule revises the commercial and recreational annual catch limits (ACLs) for golden tilefish in the South Atlantic. The purpose of this final rule is to end overfishing of golden tilefish while minimizing, to the extent practicable, adverse socio-economic effects and achieve optimum yield (OY) on a continuing basis.

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

ADDRESSES: Electronic copies of Regulatory Amendment 28 may be obtained from the Southeast Regional Office website at *http://sero.nmfs.noaa.gov.* Regulatory Amendment 28 includes an environmental assessment (EA), a Regulatory Flexibility Act (RFA) analysis, a regulatory impact review (RIR), and a Fishery Impact Statement.

FOR FURTHER INFORMATION CONTACT: Karla Gore, telephone: 727–824–5305; email: *karla.gore@noaa.gov.*

SUPPLEMENTARY INFORMATION: The snapper-grouper fishery of the South Atlantic is managed under the FMP, and includes golden tilefish along with other snapper-grouper species. The FMP was prepared by the Council and is implemented through regulations at 50 CFR part 622 under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act).

NMFS issued a temporary rule to implement interim measures to reduce the total annual catch limit (ACL), commercial and recreational sector ACLs, and quotas for the hook-and-line and longline components of the commercial sector on January 2, 2018 (83 FR 65). On June 19, 2018, NMFS extended the interim measures for an additional 186 days, through January 3, 2019 (83 FR 28387). On September 27, 2018, NMFS published a proposed rule for Regulatory Amendment 28 and requested public comment (83 FR 48788). Regulatory Amendment 28 and the proposed rule outline the rationale for the actions contained in this final rule. A summary of the actions implemented by Regulatory Amendment 28 and this final rule is provided below.

Background

The Magnuson-Stevens Act requires that NMFS and regional fishery management councils prevent overfishing and achieve, on a continuing basis, the OY from federally managed fish stocks. These mandates are intended to ensure that fishery resources are managed for the greatest overall benefit to the nation, particularly with respect to providing food production and recreational opportunities, and protecting marine ecosystems.

Golden tilefish are harvested by both commercial and recreational fishermen throughout the South Atlantic, although the majority of landings are attributed to the bottom longline component of the commercial sector. Using data through 2010, the golden tilefish stock was assessed in 2011 through the Southeast Data, Assessment, and Review (SEDAR) stock assessment process (SEDAR 25). SEDAR 25 results indicated that the golden tilefish stock was not subject to overfishing and was not overfished. Based upon the results of SEDAR 25, the final rule for Amendment 18B to the FMP specified ACL based upon the acceptable biological catch (ABC) recommendation from the Council's Scientific and Statistical Committee (SSC). The total ACL was distributed among the sectors and commercial gear components (*i.e.,* bottom longline and hook and line) based on allocations specified in Amendment 18B (78 FR 23858; April 23, 2013). For golden tilefish, 97 percent of the combined (commercial and recreational sectors together) ACL is allocated to the commercial sector, with 25 percent of the commercial ACL available for harvest by the hook-and-line component and 75 percent of the commercial ACL available for the longline component. The recreational sector is allocated 3 percent of the combined ACL.

In April 2016, an update to the SEDAR 25 stock assessment was completed for golden tilefish using data through 2014 (SEDAR 25 Update 2016). In May 2016, the Council's SSC reviewed the updated assessment, determined the assessment was based on the best scientific information available, and provided an ABC recommendation. In a letter dated January 4, 2017, NMFS notified the Council of the updated golden tilefish stock status (SEDAR 25 Update 2016) determination that the stock is undergoing overfishing but is not overfished. As mandated by the Magnuson-Stevens Act, NMFS and the Council must prepare and implement a plan amendment and regulations to end overfishing of golden tilefish. Therefore, the Council began development of an amendment to end overfishing of golden tilefish. Because the ABC recommendation from the Council's SSC was not available until late October 2017, there was insufficient time for the Council and NMFS to develop and implement management measures to end overfishing of golden tilefish by the start of the 2018 fishing year on January 1, 2018. Consequently, in a letter to NMFS dated June 27, 2017, the Council requested that NMFS implement interim measures to immediately reduce overfishing of golden tilefish while long-term measures could be developed through Regulatory Amendment 28. A temporary rule, published in the **Federal Register** on January 2, 2018 (83 FR 65), reduced the combined ACL based on a projected yield at 75 percent of the yield produced by the fishing mortality rate at maximum sustainable yield ($F = 75\%F_{MSY}$), which was 362,000 lb (164,654 kg), whole weight. Converting this value to gutted weight using a conversion factor of 1.12 provided a value of 323,000 lb (146,510

kg), gutted weight. On June 19, 2018 (83 FR 28387), the temporary rule was extended for an additional 186 days, through January 3, 2019.

Management Measures Contained in This Final Rule

This final rule revises the combined ACL for golden tilefish to be 342,000 lb (155,129 kg), gutted weight. In May 2016, the Council's SSC reviewed the SEDAR 25 assessment update and provided fishing level recommendations based on a P* (probability of overfishing) value of 30 percent derived from the Council's ABC control rule. However, at their March 2018 meeting, the Council determined that they were willing to accept a risk of overfishing at the level implemented through the temporary interim rule ($F = 75\%F_{MSY}$) when the population is at equilibrium. Thus, the Council requested the SSC recommend an ABC based on $F = 75\%F_{MSY}$, which represented a level closer to a P* value of 40 percent. At their May 2018 meeting, the SSC reviewed the Council's request to revise the ABC recommendation and agreed to change the ABC to the value at $F = 75\%F_{MSY}$. Therefore, the SSC's most recent ABC recommendation was 362,000 lb (164,654 kg), whole weight.

This combined ACL specified in Regulatory Amendment 28 is equal to the Council's SSC ABC recommendation of 362,000 lb (164,654 kg), whole weight, when converted to gutted weight. The SEDAR 25 Update (2016) for golden tilefish used a whole weight to gutted weight conversion factor of 1.059, but the interim rule used a conversion value of 1.12. At their June 2018 meeting, the Council indicated that a conversion factor of 1.059 rather than a 1.12 was more appropriate to convert the ABC recommendation from whole weight to gutted weight. Both SEDAR 25 Update 2016 and the 1.059 conversion factor constitute the best scientific information available for golden tilefish. The SSC's ABC recommendation forms the basis for the actions in Regulatory Amendment 28 and this final rule, which is expected to end overfishing of golden tilefish in the South Atlantic.

This final rule also specifies the commercial and recreational sector ACLs and component commercial quotas using the existing sector allocations of 97 percent commercial and 3 percent recreational, as well as allocating 25 percent of the commercial ACL to the hook-and-line component and 75 percent of the commercial ACL to the longline component. Therefore, through this final rule, the commercial ACL (equivalent to the commercial quota) is 331,740 lb (150,475 kg), gutted weight. The commercial ACL for the hook-and-line component is 82,935 lb (37,619 kg), gutted weight, and the commercial ACL for the longline component is 248,805 lb (112,856 kg), gutted weight. The recreational ACL is 2,316 fish.

The reduction in the ACLs in this final rule is expected to end overfishing of golden tilefish and minimize future adverse socio-economic effects. Adhering to sustainable harvest through an ACL based on information from the most recent stock assessment (Southeast Data Assessment and Review (SEDAR) 25 2016 Update) is expected to be more beneficial to fishers and fishing communities in the long term because catch limits are based on the current conditions. The reduction in the ACLs in this final rule is expected to provide biological benefits (such as protections against recruitment failure) to the golden tilefish stock by reducing the levels of fishing mortality. The revised ACL values in Regulatory Amendment 28 and implemented through this final rule are based on the best scientific information available.

The measures in Regulatory Amendment 28, as described in this final rule, replace the current interim measures outlined in the temporary rule. Failure to implement Regulatory Amendment 28 by the expiration of the temporary rule (January 4, 2019) may risk overfishing of golden tilefish because ACLs will revert to higher levels in place prior to implementation of the temporary rule, and those levels exceed the SSC's most recent ABC recommendation. In addition, implementing Regulatory Amendment 28 by the expiration date of the temporary rule will avoid confusion among fishers and law enforcement with changing catch levels.

Comments and Responses

During the public comment period, NMFS received a total of 10 comments on Regulatory Amendment 28 and the proposed rule from individuals and fishing organizations. Of these, three comments supported the need for protection of golden tilefish, with which NMFS agrees. Two comments generally expressed support for golden tilefish harvest by the recreational sector and complained of increasing costs, but those comments were not directed to the ACL changes contained in the proposed rule; thus, they are considered to be outside the scope of Regulatory Amendment 28. Two additional comments were entirely unrelated to golden tilefish harvest and were, therefore, also outside the scope of Regulatory Amendment 28. Comments that were beyond the scope of Regulatory Amendment 28 and the proposed rule, are not addressed further in this final rule. Comments that specifically relate to the actions contained in the Regulatory Amendment 28 and the proposed rule, as well as NMFS' respective responses, are summarized below.

Comment 1: Regulatory Amendment 28 does not adequately consider the socio-economic impacts that will disproportionately impact the small fishing communities that are affected by the South Atlantic fishing industry.

Response: As described in the EA and the for Regulatory Amendment 28 and the proposed rule, the ACL reductions are necessary to end overfishing of golden tilefish in the South Atlantic. The Council and NMFS have adequately considered the socio-economic impacts through the socio-economic impact analysis developed in Regulatory Amendment 28 for implementing this final rule. NMFS conducted a RIR, an Initial Regulatory Flexibility Analysis (IRFA), and a Final Regulatory Flexibility Analysis (FRFA) that analyze the expected impacts of the actions in the regulatory amendment on the commercial and recreational sectors engaged in fishing for South Atlantic golden tilefish.

NMFS expects the reductions to the ACLs and quotas will result in adverse, short-term economic effects. These effects will apply directly on the participants of the golden tilefish commercial and recreational sectors and indirectly on the supporting industries, such as dealers, tackle and bait shops, and fishing communities. However, Regulatory Amendment 28 and this final rule will likely minimize future adverse socio-economic effects by ending overfishing of South Atlantic golden tilefish and preventing the stock from being overfished.

NMFS has determined that all entities directly affected by the management measures outlined in Regulatory Amendment 28 and this final rule are small entities as this term is defined in the **CLASSIFICATION** section of this rule, so that disproportionate impacts on small versus large entities are not expected to occur. However, effects on affected entities will not be uniform. In general, the larger the sector (*e.g.,* commercial sector) or commercial component's (*e.g.,* longline fishermen) percentage of the allocation, the greater the short-term adverse economic impacts will be. In addition, the more dependent a location or fishing community is on fishing for golden tilefish, the greater the adverse impacts

will be on an area's fishing participants and supporting industries.

Comment 2: Why is the commercial ACL, listed in weight, significantly greater than the recreational ACL, which is given in numbers of fish?

Response: The commercial ACL is greater than the recreational ACL because 97 percent of the total ACL is allocated to the commercial sector and 3 percent to the recreational sector. The sector allocations were specified in 2010 (75 FR 82280; December 30, 2010). Regulatory Amendment 28 and this final rule revise the ACL for golden tilefish based on the ABC recommendation from the Council's SSC, but do not change the allocation of the ACL among the commercial and recreational sectors. This allocation was previously determined by the Council and NMFS to be fair and equitable, based on landings data, and considered the least disruptive to economic and social environments. The commercial ACL is further allocated into commercial quotas with 75 percent to the commercial longline sector and 25 percent to the commercial hook-and-line sector, as established in 2013 through Amendment 18B to the FMP (78 FR 23858; April 23, 2013). These quota allocations were also based on commercial landings data, as more of the commercial harvest is from the commercial longline component than the hook-and-line component.

The commercial allocation is listed in pounds (lb) of gutted weight (gw) and the recreational allocation is in numbers of fish. To convert the recreational ACL into numbers of fish, the recreational landings data collected through the Marine Recreational Information Program and Southeast Region Headboat Survey were used to calculate the average weight of South Atlantic golden tilefish. From 2012–2016, the average weights of recreational golden tilefish have ranged annually from 4.21 lb, gw to 5.11 lb, gw. Using these 5 years of data (2012–2016) provides an average weight of 4.43 lb, gw. Therefore, a conversion factor of 4.43 lb, gw per fish is used for converting the South Atlantic golden tilefish recreational ACL into numbers of fish.

Comment 3: There needs to be better data collected on golden tilefish instead of continuing to use limited existing data applied in inconsistent methods because it is irresponsible with the goal of achieving MSY.

Response: NMFS determined that the data used in Regulatory Amendment 28 represents the best scientific information available and that the data used in SEDAR 25 2016 Update is applied neither inconsistently nor irresponsibly. NMFS notes that Regulatory Amendment 28 and the final rule respond to the latest stock assessment for golden tilefish in the South Atlantic (SEDAR 25 Update 2016). The SEDAR 25 Update 2016 concluded that the stock is undergoing overfishing, but is not overfished.

The SEDAR 25 participants outlined the research needs for the golden tilefish stock assessment and these are contained in the SEDAR 25 Assessment Report. The next golden tilefish stock assessment, which will include a review of all existing data, is scheduled to begin in 2019.

The golden tilefish stock of the South Atlantic was assessed through the SEDAR process, which is a peer-reviewed cooperative effort to assess the status of stocks in the jurisdictions of the South Atlantic, Caribbean, and Gulf of Mexico Fishery Management Councils; as well as NMFS' Southeast Fisheries Science Center and Southeast Regional Office, and the NMFS Highly Migratory Species Division; and the Atlantic and Gulf States Marine Fisheries Commissions. SEDAR also relies on state agencies and universities throughout the region for research, data collection, and stock assessment expertise. Fishery-dependent and independent data were utilized in the stock assessment. All of the data sources used are further described in the SEDAR 25 Update 2016, which is available on the SEDAR website at *http://sedarweb.org.* The SEDAR website also provides supporting documentation that describes data collection programs and research findings.

The Council received the results of the assessment update from their SSC in June 2016, and Council members expressed concern over the large differences in biological benchmarks and fishing level recommendations between SEDAR 25 Update 2016 and SEDAR 25. Subsequently, the Council requested an updated stock assessment for golden tilefish.

To address the Council's concerns, in May 2017, the SEDAR Steering Committee agreed to revise the SEDAR 25 Update 2016, because a new golden tilefish stock assessment could not be completed in 2017. The SSC reviewed the 2017 revision to the SEDAR 25 Update 2016 at their October 2017 meeting and determined that it was unsuitable for management. Therefore, the best scientific information available for golden tilefish remains the SEDAR 25 Update 2016.

Classification

The Regional Administrator for the NMFS Southeast Region has determined that this final rule is consistent with Regulatory Amendment 28, the Magnuson-Stevens Act, and other applicable laws.

This final rule has been determined to be not significant for purposes of Executive Order 12866. This final rule is not an E.O. 13771 regulatory action because this rule is not significant under E.O. 12866.

In compliance with section 604 of the RFA, NMFS prepared a Final Regulatory Flexibility Analysis (FRFA) for this final rule. The FRFA incorporates the IRFA, a summary of the significant economic issues raised by public comments, NMFS' responses to those comments, and a summary of the analyses completed to support the action. The FRFA follows.

A description of this final rule, and its rationale, objectives, and legal basis are contained at the beginning of this section in the preamble and in the **SUMMARY** section of the preamble. The Magnuson-Stevens Act provides the statutory basis for this final rule. No duplicative, overlapping, or conflicting Federal rules have been identified. In addition, no new reporting, record-keeping, or other compliance requirements are introduced by this final rule. Accordingly, this final rule does not implicate the Paperwork Reduction Act.

No comments specific to the IRFA were received from the public or from the Chief Counsel for the Advocacy of the Small Business Administration; however, there are comments that have socio-economic implications, and they are addressed in the *Comments and Responses* section, specifically in *Comment 1.*

No changes to the proposed rule were made in response to public comments. NMFS agrees that the Council's recommendation for the action will best achieve their objectives for this final rule while minimizing, to the extent practicable, the adverse effects on fishermen, support industries, and associated communities.

NMFS expects this final rule will directly affect all commercial vessels that harvest South Atlantic golden tilefish under the FMP. The change in the recreational ACL in this final rule will not directly affect or regulate for-hire businesses. Any impact to the profitability or competitiveness of for-hire fishing businesses will be the result of changes in for-hire angler demand and will therefore be indirect in nature. Under the RFA, recreational anglers who will be directly affected by this final rule, are not considered small entities, so they are outside the scope of this analysis and only the effects on

commercial vessels were analyzed. For RFA purposes only, NMFS has established a small business size standard for businesses, including their affiliates, whose primary industry is commercial fishing (see 50 CFR 200.2). A business primarily engaged in commercial fishing (NAICS code 11411) is classified as a small business if it is independently owned and operated, is not dominant in its field of operation (including affiliates), and has combined annual receipts not in excess of $11 million for all its affiliated operations worldwide.

From 2012 through 2016, an average of 23 longline vessels per year landed golden tilefish from the South Atlantic. The Federal golden tilefish longline endorsement to the snapper-grouper permit started in 2013 upon implementation of the final rule for Amendment 18B to the snapper-grouper FMP (78 FR 23858; April 23, 2013). Endorsed vessels, combined, averaged 255 trips per year in the South Atlantic on which golden tilefish were landed, and 182 other trips that took place either in the South Atlantic (but no golden tilefish were caught) or in other areas (Gulf of Mexico or Mid-Atlantic) that caught any species including golden tilefish. The average annual total dockside revenue (2016 dollars) for these vessels combined was approximately $1.56 million from golden tilefish, approximately $0.10 million from other species co-harvested with golden tilefish (on the same trips), and approximately $0.43 million from other trips by these vessels on trips in the South Atlantic on which no golden tilefish were harvested or on trips which occurred in other areas. Total average annual revenue from all species harvested by longline vessels landing golden tilefish in the South Atlantic was approximately $2.10 million, or approximately $92,000 per vessel. Longline vessels generated approximately 74 percent of their total revenues from golden tilefish. For the same period, an average of 82 vessels per year landed golden tilefish using other gear types (mostly hook-and-line) in the South Atlantic. These vessels, combined, averaged 483 trips per year in the South Atlantic on which golden tilefish were landed and 2,862 trips taken in the South Atlantic on which golden tilefish were not harvested or trips that took place in other areas and caught any species including golden tilefish. The average annual total dockside revenue (2016 dollars) for these 82 vessels was approximately $0.36 million from golden tilefish, approximately $0.66 million from other species co-harvested with golden tilefish (on the same trips in the South Atlantic), and approximately $4.13 million from the other trips taken by these vessels. The total average annual revenue from all species harvested by these 82 vessels was approximately $5.16 million, or approximately $62,000 per vessel. Approximately 7 percent of these vessels' total revenues came from golden tilefish.

Based on the foregoing revenue information, all commercial vessels using longlines or hook-and-line gear affected by this final rule may be considered to be small entities. Because all entities expected to be directly affected by this final rule are assumed to be small entities, NMFS has determined that this final rule will affect a substantial number of small entities. However, since all affected entities are small entities, the issue of disproportionate effects on small versus large entities does not arise in the present case.

This final rule will reduce the combined stock ACL, and consequently the ACLs for the commercial and recreational sectors as well as the longline and hook-and-line component ACLs of the commercial sector. The longline and hook-and-line components of the commercial sector will be expected to lose approximately $592,000 ($25,739 per vessel) and $217,000 ($2,646 per vessel) respectively, in annual ex-vessel revenues. This will very likely translate to profit reductions for both the longline and hook-and-line components, particularly for longline vessels, as they are more dependent on golden tilefish. As noted above, golden tilefish account for about 74 percent of longline vessel revenues and 7 percent of hook-and-line vessel revenues. The ACLs may be changed in the future if this final rule is successful in addressing the overfishing condition for the South Atlantic golden tilefish. Economic benefits would ensue if the ACLs are subsequently increased based on an improved stock status.

The following discussion analyzes the alternatives that were considered by the Council, including those that were not selected as preferred by the Council. Unlike the preferred alternative, six of the other alternatives would provide for varying ACLs over 6 years, at least. For this reason, a 6-year period is considered for comparing alternatives. To carry out a 6-year comparison, the ACL under the preferred alternative is kept constant for 6 years. It is noted that a stock assessment for golden tilefish would be completed in 2019, so the Council may opt to revise the ACL in 2020 or later. Over a 6-year period with constant ACL, the preferred alternative will be expected to reduce revenues by approximately $3.02 million for the longline component and $1.11 million for the hook-and-line component of the commercial sector, using a 7 percent discount rate.

Ten alternatives, including the preferred alternative as described above, were considered for reducing the South Atlantic golden tilefish ACLs. The first alternative, the no action alternative, would maintain the current economic benefits to all participants in the South Atlantic golden tilefish component of the snapper-grouper fishery. This alternative, however, would not address the need to end overfishing of the stock, thereby increasing the likelihood that more stringent measures would need to be implemented in the near future.

With one exception, all the other alternatives would result in larger revenue losses to the longline and hook-and-line vessels than the preferred alternative. Alternatives that would result in larger revenue losses than the preferred alternative would provide for lower ACLs over a 6-year period. Total losses over 6 years from these alternatives would range from $3.17 million to $4.29 million for longline vessels and from $1.16 million to $1.83 million for hook-and-line vessels. The alternative with lower attendant revenue losses than the preferred alternative would be expected to reduce total ex-vessel revenues by approximately $2.65 million for longline vessels and $0.97 million for hook-and-line vessels over 6 years. Relative to the preferred alternative, this alternative would result in larger ex-vessel revenue losses initially but lower revenue losses in subsequent years, because the ACLs in subsequent years would be greater than those of the preferred alternative. Both alternatives would be expected to result in early harvest closures as a result of reaching the ACL during the fishing year, and in the first fishing year, harvest closure under the preferred alternative would occur later than that of the other alternative. The reverse may be expected for the subsequent years. The Council considered the preferred alternative as affording the best means to end overfishing of golden tilefish in the South Atlantic, because it is based on the best scientific information available.

List of Subjects in 50 CFR Part 622

Annual catch limit, Fisheries, Fishing, Golden tilefish, Snapper-grouper, South Atlantic.

Dated: November 29, 2018.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 622 is amended as follows:

PART 622—FISHERIES OF THE CARIBBEAN, GULF OF MEXICO, AND SOUTH ATLANTIC

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

Authority: 16 U.S.C. 1801 *et seq.*

■ 2. In § 622.190, revise paragraphs (a)(2)(i) through (iii) to read as follows:

§ 622.190 Quotas.

* * * * *

(a) * * *

(2) * * *

(i) *Commercial sector (hook-and-line and longline components combined)*—331,740 lb (150,475 kg).

(ii) *Hook-and-line component*—82,935 lb (37,619 kg).

(iii) *Longline component*—248,805 lb (112,856 kg).

* * * * *

■ 3. In § 622.193, revise paragraphs (a)(1)(i) through (iii), and (a)(2), to read as follows:

§ 622.193 Annual catch limits (ACLs), annual catch targets (ACTs), and accountability measures (AMs).

(a) * * *

(1) * * *

(i) *Hook-and-line component.* If commercial hook-and-line landings for golden tilefish, as estimated by the SRD, reach or are projected to reach the commercial ACL (commercial quota) specified in § 622.190(a)(2)(ii), the AA will file a notification with the Office of the Federal Register to close the hook-and-line component of the commercial sector for the remainder of the fishing year. Applicable restrictions after a commercial quota closure are specified in § 622.190(c).

(ii) *Longline component.* If commercial longline landings for golden tilefish, as estimated by the SRD, reach or are projected to reach the longline commercial ACL (commercial quota) specified in § 622.190(a)(2)(iii), the AA will file a notification with the Office of the Federal Register to close the longline component of the commercial sector for the remainder of the fishing year. After the commercial ACL for the longline component is reached or projected to be reached, golden tilefish may not be fished for or possessed by a vessel with a golden tilefish longline endorsement. Applicable restrictions after a commercial quota closure are specified in § 622.190(c).

(iii) If all commercial landings of golden tilefish, as estimated by the SRD, exceed the commercial ACL (including both the hook-and-line and longline component quotas) specified in § 622.190(a)(2)(i), and the combined commercial and recreational ACL of 342,000 lb (155,129 kg) is exceeded during the same fishing year, and golden tilefish are overfished based on the most recent Status of U.S. Fisheries Report to Congress, the AA will file a notification with the Office of the Federal Register to reduce the commercial ACL for that following fishing year by the amount of the commercial ACL overage in the prior fishing year.

(2) *Recreational sector.* (i) If recreational landings of golden tilefish, as estimated by the SRD, reach or are projected to reach the recreational ACL of 2,316 fish, the AA will file a notification with the Office of the Federal Register to close the recreational sector for the remainder of the fishing year regardless if the stock is overfished, unless NMFS determines that no closure is necessary based on the best scientific information available. On and after the effective date of such a notification, the bag and possession limits for golden tilefish in or from the South Atlantic EEZ are zero.

(ii) If recreational landings of golden tilefish, as estimated by the SRD, exceed the recreational ACL specified of 2,316 fish, then during the following fishing year, recreational landings will be monitored for a persistence in increased landings, and if necessary, the AA will file a notification with the Office of the Federal Register to reduce the length of the recreational fishing season and the recreational ACL by the amount of the recreational ACL overage, if the species is overfished based on the most recent Status of U.S. Fisheries Report to Congress, and if the combined commercial and recreational ACL of 342,000 lb (155,129 kg) is exceeded during the same fishing year. The AA will use the best scientific information available to determine if reducing the length of the recreational fishing season and recreational ACL is necessary. When the recreational sector is closed as a result of NMFS reducing the length of the recreational fishing season and ACL, the bag and possession limits for golden tilefish in or from the South Atlantic EEZ are zero.

* * * * *

[FR Doc. 2018–26317 Filed 12–3–18; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 635

[Docket No. 180117042–8884–02]

RIN 0648–XG651

Atlantic Highly Migratory Species; Atlantic Bluefin Tuna Fisheries

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; inseason quota transfer.

SUMMARY: NMFS is transferring 129.2 metric tons (mt) of Atlantic bluefin tuna (BFT) quota from the Reserve category to the General category, and 9.9 mt from the Harpoon category to the General category for the remainder of the 2018 fishing year, to account for accrued overharvests of previous time period subquotas. This action is intended to provide opportunities for General category fishermen to participate in the December General category fishery, which is scheduled to reopen on December 1, 2018, and is based on consideration of the regulatory determination criteria regarding inseason adjustments. This action would affect Atlantic tunas General category (commercial) permitted vessels and Highly Migratory Species (HMS) Charter/Headboat category permitted vessels with a commercial sale endorsement when fishing commercially for BFT.

DATES: The quota transfer is effective November 29, 2018 through December 31, 2018.

FOR FURTHER INFORMATION CONTACT: Uriah Forest-Bulley, 978–675–2154, or Brad McHale, 978–281–9260.

SUPPLEMENTARY INFORMATION: Regulations implemented under the authority of the Atlantic Tunas Convention Act (ATCA; 16 U.S.C. 971 *et seq.*) and the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act; 16 U.S.C. 1801 *et seq.*) governing the harvest of BFT by persons and vessels subject to U.S. jurisdiction are found at 50 CFR part 635. Section 635.27 subdivides the U.S. BFT quota recommended by the International Commission for the Conservation of Atlantic Tunas (ICCAT) and as implemented by the United States among the various domestic fishing categories, per the allocations established in the 2006 Consolidated Highly Migratory Species Fishery

Management Plan (2006 Consolidated HMS FMP) (71 FR 58058, October 2, 2006), as amended by Amendment 7 to the 2006 Consolidated HMS FMP (Amendment 7) (79 FR 71510, December 2, 2014). NMFS is required under ATCA and the Magnuson-Stevens Act to provide U.S. fishing vessels with a reasonable opportunity to harvest the ICCAT-recommended quota.

NMFS published a final rule (*i.e.,* the ''quota rule'' (83 FR 51391, October 11, 2018)) that increased the baseline U.S. BFT quota from 1,058.79 mt to 1,247.86 mt consistent with a 2017 ICCAT recommendation and accordingly increased the category quotas for 2018. Within the General category quota, each time period (January, June through August, September, October through November, and December) is further allocated a subquota or portion of the annual General category quota. Although it is called the ''January'' subquota, the regulations allow the General category fishery under this quota to continue until the subquota is reached or March 31, whichever comes first. The baseline subquotas for each time period are as follows: 29.5 mt for January; 277.9 mt for June through August; 147.3 mt for September; 72.2 mt for October through November; and 28.9 mt for December. Any unused General category quota rolls forward from one time period to the next and is available for use in subsequent time periods within the fishing year, which coincides with the calendar year.

For the January 2018 subquota period, NMFS transferred 14.3 mt of BFT quota from the December 2018 subquota period, and transferred 10 mt from the Reserve category, resulting in an adjusted subquota of 53.8 mt for the January 2018 period and a subquota of 14.6 mt for the December 2018 period (82 FR 60680, December 22, 2017, and 83 FR 9232, March 5, 2018, respectively). For 2018, NMFS also transferred a total of 75 mt from the Reserve and 40 mt from the Harpoon category to the General category through two inseason actions in September and October, resulting in an adjusted 2018 General category quota of 680.8 mt and adjusted 2018 Harpoon category of 36 mt (83 FR 47843, September 21, 2018, and 83 FR 50857, October 10, 2018, respectively). NMFS closed the October through November General category fishery after multiple reopenings when the subquota (127.2 mt) was met, effective November 16, 2018 (83 FR 57340, November 15, 2018). The 2018 General category fishery reopens December 1, 2018, and will remain open until December 31, 2018, or until the General category quota is reached, whichever comes first. Prior to this action, the adjusted Reserve category quota was 142.9 mt, and was most recently adjusted in the October 11, 2018 quota rule, which augmented the 2018 BFT Reserve category quota with available underharvest of the 2017 adjusted U.S. BFT quota. The Harpoon category fishery automatically closed for the year on November 15, 2018.

Quota Transfer

Under § 635.27(a)(9), NMFS has the authority to transfer quota among fishing categories or subcategories, after considering regulatory determination criteria at § 635.27(a)(8). NMFS has considered all of the relevant determination criteria and their applicability to the General category fishery. These considerations include, but are not limited to, the following:

Regarding the usefulness of information obtained from catches in the particular category for biological sampling and monitoring of the status of the stock (§ 635.27(a)(8)(i)), biological samples collected from BFT landed by General category fishermen and provided by BFT dealers continue to provide NMFS with valuable data for ongoing scientific studies of BFT age and growth, migration, and reproductive status. Additional opportunity to land BFT over the longest time-period allowable would support the collection of a broad range of data for these studies and for stock monitoring purposes.

NMFS considered the catches of the General category quota to date (including during the summer/fall and winter fisheries in the last several years), and the likelihood of closure of that segment of the fishery if no adjustment is made (§ 635.27(a)(8)(ii) and (ix)). Preliminary landings data as of November 26, 2018, indicate that the Harpoon category landed 26.1 mt of the 36 mt adjusted Harpoon quota before closing. They also indicate that the General category has landed 770 mt this year, which exceeds the overall General category adjusted quota of 680.8 mt. For all commercial categories, however, approximately 23 percent (267.9 mt) of the total of the BFT category quotas remains available as of November 26, 2018 (*i.e.,* 881 mt of 1148.9 mt has been harvested), and NMFS anticipates that some amount of quota may remain unused by the end of the year even with the transfer. Absent a transfer, the December General category fishery would remain closed, even though quota remains available within the overall quota for the year and NMFS anticipates that commercial-sized BFT will be readily available on the fishing grounds when the fishery is otherwise scheduled to re-open December 1, 2018. Transferring 129.2 mt of BFT quota from the Reserve category, and 9.9 mt from the Harpoon category would allow the General category fishery to resume as scheduled and would result in a total of 50.0 mt being available to the General category in December after accounting for quota exceedances. It would also leave 13.7 mt in the Reserve category to account for any BFT mortalities associated with research and/or any overharvests that may occur in December. In analyzing the criteria for transfer, NMFS also considered the fact that BFT quota management throughout the year had been informed, in part, by anticipated upward adjustments to the overall quota. Such adjustments, while not certain, were anticipated as a result of the 2017 ICCAT recommendation increasing the overall BFT quota and upward adjustments for last year's underharvests, although any such adjustments would only take effect after appropriate rulemaking procedures and actions (*i.e.,* the 2018 quota rule).

Regarding the projected ability of the vessels fishing under the particular category quota (here, the General category) to harvest the additional amount of BFT quota transferred before the end of the fishing year (§ 635.27(a)(8)(iii)), NMFS considered General category landings over the last several years and landings to date this year. Landings are highly variable and depend on access to commercial-sized BFT and fishing conditions, among other factors. A portion of the transferred quota covers overharvests in the category to date, and NMFS anticipates that General category participants will be able to harvest the remaining 50 mt of transferred BFT quota by the end of the fishing year.

NMFS also considered the estimated amounts by which quotas for other gear categories of the fishery might be exceeded (§ 635.27(a)(8)(iv)) and the ability to account for all 2018 landings and dead discards. In the last several years, total U.S. BFT landings have been below the total available U.S. quota such that the United States has carried forward the maximum amount of underharvest allowed by ICCAT from one year to the next. NMFS will need to account for 2018 landings and dead discards within the adjusted U.S. quota, consistent with ICCAT recommendations, and NMFS anticipates having sufficient quota to do that, even with this 139.1 mt transfer to the General category.

This transfer would be consistent with the current U.S. quota, which was established and analyzed in the 2018 BFT quota final rule, and with

objectives of the 2006 Consolidated HMS FMP and amendments. (§ 635.27(a)(8)(v) and (vi)). Another principal consideration is the objective of providing opportunities to harvest the full annual U.S. BFT quota without exceeding it based on the goals of the 2006 Consolidated HMS FMP and amendments, including to achieve optimum yield on a continuing basis and to optimize the ability of all permit categories to harvest their full BFT quota allocations (related to § 635.27(a)(8)(x)).

Based on the considerations above, NMFS is transferring 129.2 mt from the Reserve category to the General category. Therefore, NMFS adjusts the General category December subquota quota to 50.0 mt for the 2018 General category fishing season and adjusts the Reserve category quota to 13.7 mt. The 2018 General category fishery reopens December 1, 2018, and will remain open until December 31, 2018, or until the adjusted General category quota is reached, whichever comes first.

Monitoring and Reporting

NMFS will continue to monitor the BFT fishery closely. Dealers are required to submit landing reports within 24 hours of a dealer receiving BFT. Late reporting by dealers compromises NMFS' ability to timely implement actions such as quota and retention limit adjustment, as well as closures, and may result in enforcement actions. Additionally, and separate from the dealer reporting requirement, General and HMS Charter/Headboat category vessel owners are required to report the catch of all BFT retained or discarded dead within 24 hours of the landing(s) or end of each trip, by accessing *hmspermits.noaa.gov* or by using the HMS Catch Reporting app, or calling (888) 872–8862 (Monday through Friday from 8 a.m. until 4:30 p.m.).

Depending on the level of fishing effort and catch rates of BFT, NMFS may determine that additional action (*e.g.,* quota adjustment or closure) is necessary to ensure available subquotas are not exceeded or to enhance scientific data collection from, and fishing opportunities in, all geographic areas. If needed, subsequent adjustments will be published in the **Federal Register**. In addition, fishermen may call the Atlantic Tunas Information Line at (978) 281–9260, or access *hmspermits.noaa.gov,* for updates on quota monitoring and inseason adjustments.

NMFS reminds General category participants that when the fishery reopens December 1, 2018, the BFT General category daily retention limit will be one large medium or giant BFT (measuring 73'' or greater) per vessel per day/trip.

Classification

The Assistant Administrator for NMFS (AA) finds that it is impracticable and contrary to the public interest to provide prior notice of, and an opportunity for public comment on, this action for the following reasons:

The regulations implementing the 2006 Consolidated HMS FMP and amendments provide for inseason retention limit adjustments to respond to the unpredictable nature of BFT availability on the fishing grounds, the migratory nature of this species, and the regional variations in the BFT fishery. Affording prior notice and opportunity for public comment to implement the quota transfer for the remainder of 2018 is impracticable and contrary to the public interest as such a delay would result in continued closure of the General category fishery (because the available quota has been exceeded) and the need to re-open the fishery later in the December time period, rather than the fishery automatically re-opening on December 1. The delay would preclude the fishery from harvesting BFT that are available on the fishing grounds and that might otherwise become unavailable during a delay. Therefore, the AA finds good cause under 5 U.S.C. 553(b)(B) to waive prior notice and the opportunity for public comment. For these reasons, there also is good cause under 5 U.S.C. 553(d) to waive the 30-day delay in effectiveness.

This action is being taken under § 635.27(a)(9) (Inseason adjustments) and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 971 *et seq.* and 1801 *et seq.*

Dated: November 29, 2018.

Alan D. Risenhoover,

Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2018–26325 Filed 11–29–18; 4:15 pm]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 170816769–8162–02]

RIN 0648–XG470

Fisheries of the Exclusive Economic Zone Off Alaska; Pacific Cod by Catcher Vessels Less Than 50 Feet Length Overall Using Hook-and-Line Gear in the Central Regulatory Area of the Gulf of Alaska

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting directed fishing for Pacific cod by catcher vessels less than 50 feet length overall (LOA) using hook-and-line gear in the Central Regulatory Area of the Gulf of Alaska (GOA). This action is necessary to prevent exceeding the 2018 Pacific cod total allowable catch apportioned to catcher vessels less than 50 feet LOA using hook-and-line gear in the Central Regulatory Area of the GOA.

DATES: Effective 1200 hours, Alaska local time (A.l.t.), December 1, 2018, through 2400 hours, A.l.t., December 31, 2018.

FOR FURTHER INFORMATION CONTACT: Obren Davis, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the GOA exclusive economic zone according to the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679. Regulations governing sideboard protections for GOA groundfish fisheries appear at subpart B of 50 CFR part 680.

The 2018 Pacific cod total allowable catch (TAC) apportioned to catcher vessels less than 50 feet LOA using hook-and-line gear in the Central Regulatory Area of the GOA is 880 metric tons (mt), as established by the final 2018 and 2019 harvest specifications for groundfish of the GOA (83 FR 8768, March 1, 2018).

In accordance with § 679.20(d)(1)(i), the Administrator, Alaska Region, NMFS (Regional Administrator) has

determined that the 2018 Pacific cod TAC apportioned to catcher vessels less than 50 feet LOA using hook-and-line gear in the Central Regulatory Area of the GOA will soon be reached. Therefore, the Regional Administrator is establishing a directed fishing allowance of 870 mt and is setting aside the remaining 10 mt as bycatch to support other anticipated groundfish fisheries. In accordance with § 679.20(d)(1)(iii), the Regional Administrator finds that this directed fishing allowance has been reached. Consequently, NMFS is prohibiting directed fishing for Pacific cod by catcher vessels less than 50 feet LOA using hook-and-line gear in the Central Regulatory Area of the GOA. While this closure is effective the maximum retainable amounts at § 679.20(e) and (f) apply at any time during a trip.

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the directed fishing closure of Pacific cod by catcher vessels less than 50 feet LOA using hook-and-line gear in the Central Regulatory Area of the GOA. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of November 28, 2018.

The AA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

This action is required by § 679.20 and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: November 29, 2018.

Alan D. Risenhoover,

Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2018–26302 Filed 11–29–18; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 83, No. 233
Tuesday, December 4, 2018

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.

SMALL BUSINESS ADMINISTRATION

13 CFR Parts 121, 124, 125, 126, 127, and 129

RIN 3245–AG86

National Defense Authorization Acts of 2016 and 2017, Recovery Improvements for Small Entities After Disaster Act of 2015, and Other Small Business Government Contracting

AGENCY: U.S. Small Business Administration.

ACTION: Proposed rule.

SUMMARY: The U.S. Small Business Administration (SBA or Agency) is proposing to amend its regulations to implement several provisions of the National Defense Authorization Acts (NDAA) of 2016 and 2017 and the Recovery Improvements for Small Entities After Disaster Act of 2015 (RISE Act), as well as implementing other clarifying amendments. The proposed rule would clarify that contracting officers have the authority to request information in connection with a contractor's compliance with applicable limitations on subcontracting clauses; provide exclusions for purposes of compliance with the limitations on subcontracting for certain contracts performed outside of the United States, environmental remediation contracts, and information technology service acquisitions that require substantial cloud computing; require a prime contractor with a commercial subcontracting plan to include indirect costs in its subcontracting goals; establish that failure to provide timely subcontracting reports may constitute a material breach of the contract; clarify the requirements for size and status recertification; and limit the scope of Procurement Center Representative reviews of Department of Defense acquisitions performed outside of the United States and its territories. The proposed rule would also authorize agencies to receive double credit for small business goaling achievements as announced in SBA's scorecard for local area small business set asides in connection with a disaster. Finally, SBA is proposing to remove the kit assembler exception to the non-manufacturer rule.

DATES: Comments must be received on or before February 4, 2019.

ADDRESSES: You may submit comments, identified by RIN 3245–AG86, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *For mail, paper, disk, or CD–ROM submissions:* Brenda Fernandez, U.S. Small Business Administration, Office of Policy, Planning and Liaison, 409 Third Street SW, 8th Floor, Washington, DC 20416.
- *Hand Delivery/Courier:* Brenda Fernandez, U.S. Small Business Administration, Office of Policy, Planning and Liaison, 409 Third Street SW, 8th Floor, Washington, DC 20416.

SBA will post all comments on *www.regulations.gov.* If you wish to submit confidential business information (CBI) as defined in the User Notice at *www.regulations.gov,* please submit the information to Brenda Fernandez, U.S. Small Business Administration, Office of Policy, Planning and Liaison, 409 Third Street SW, 8th Floor, Washington, DC 20416, or send an email to *brenda.fernandez@sba.gov.* Highlight the information that you consider to be CBI and explain why you believe SBA should hold this information as confidential. SBA will review the information and make the final determination on whether it will publish the information.

FOR FURTHER INFORMATION CONTACT: Brenda Fernandez, Office of Policy, Planning and Liaison, 409 Third Street SW, Washington, DC 20416; (202) 205–7337; *brenda.fernandez@sba.gov.*

SUPPLEMENTARY INFORMATION:

I. National Defense Authorization Act for Fiscal Year 2016, Public Law 114–92, 129 Stat. 726, November 25, 2015 (NDAA of 2016)

Posting Notice of Substantial Bundling

Section 863 of the NDAA of 2016 amended section 15(e)(3) of the Small Business Act (15 U.S.C. 644(e)(3)) to provide that if the head of a contracting agency determines that an acquisition plan involves a substantial bundling of contract requirements, the head of the contracting agency shall publish a notice of such determination on a public website within 7 days of making such determination. Section 863 also amended section 44(c)(2) of the Small Business Act (15 U.S.C. 657q(c)(2)) to provide that upon determining that a consolidation of contract requirements is necessary and justified, the Senior Procurement Executive (SPE) or Chief Acquisition Officer (CAO) shall publish a notice on a public website that such determination has been made. An agency may not issue the solicitation any earlier than 7 days after publication of the notice. The SPE or CAO must also publish the justification along with the solicitation. The requirement may be delegated. SBA proposes to amend § 125.2(d) by adding new paragraphs (d)(1)(v) and (d)(7) to implement these changes.

II. National Defense Authorization Act for Fiscal Year 2017, Public Law 114–328, 130 Stat. 2000, December 23, 2016 (NDAA of 2017)

Procurement Center Representative Reviews

Section 1811 of the NDAA of 2017 amended section 15(l) of the Small Business Act (15 U.S.C. 644(l)) to provide that Procurement Center Representatives (PCRs) may review any acquisition, even those where the acquisition is set aside, partially set aside or reserved for small business. SBA's current rules provide that PCRs will review all acquisitions that are not set aside or reserved for small business. These rules were intended to focus limited resources on acquisitions that were not already going to small business, but were not intended to prohibit a PCR from reviewing any acquisition as part of the PCR's role as an advocate for small business. SBA proposes to amend § 125.2(b)(1)(i) to provide that PCRs may review any acquisition regardless of whether it is set aside, partially set aside, or reserved for small business or other socioeconomic categories. SBA believes that this change will enable PCRs to advocate for total set asides, or partial set asides, when appropriate and necessary.

Section 1811 of the NDAA of 2017 also amended section 15(l) of the Small Business Act to limit the scope of PCR review of solicitations for contracts or orders by or for the Department of

Defense if the acquisition is conducted pursuant to the Arms Control Export Act (22 U.S.C. 2762), is a humanitarian operation as defined in 10 U.S.C. 401(e), is for a contingency operation as defined in 10 U.S.C. 101(a)(13), is to be awarded pursuant to an agreement with the government of a foreign country in which Armed Forces of the United States are deployed, or where both the place of award and place of performance are outside of the United States and its territories. SBA is proposing to amend § 125.2(b)(1)(i) to implement these amendments. PCRs may still review acquisitions awarded in the United States and its territories but performed outside of the United States and its territories, or awarded outside of the United States and its territories for performance in the United States or its territories, if the acquisition is not a foreign military sales, or in connection with a contingency operation, humanitarian operation or status of forces agreement. SBA considers performance to be outside of the United States and its territories if the acquisition is awarded and performed or delivered outside of the United States and its territories. If the acquisition is awarded in the United States and its territories or some performance or delivery occurs in the United States and its territories, SBA considers that to be performed in the United States and its territories.

Material Breach of Subcontracting Plan

Section 1821 of the NDAA of 2017 amended section 8(d)(9) of the Small Business Act (15 U.S.C. 637(d)(9)) to provide that it shall be a material breach of a contract or subcontract when the contractor or subcontractor with a subcontracting plan fails to comply in good faith with the requirement to provide assurances that the offeror shall submit such periodic reports or cooperate in any studies or surveys as may be required by the Federal agency or the Administration in order to determine the extent of compliance by the offeror with the subcontracting plan. Such a breach may be considered in any past performance evaluation of the contractor. SBA is proposing to revise § 125.3(d) to implement this provision.

Section 1821 also provides that SBA must provide examples of activities that would be considered a failure to make a good faith effort to comply with a small business subcontracting plan. Good faith effort considers a totality of the contractor's actions to provide the maximum practicable opportunity to small businesses to participate as subcontractors (including those in the socio-economic small business areas), consistent with the information and assurances provided in the subcontracting plan. A failure to exert good faith effort is first predicated upon evidence that an other-than-small-business (OTSB) federal prime contractor, required to have a subcontracting plan with negotiated Small Business Concern (SBC) goals approved by a federal contracting officer, has failed to attain these goals and this failure may be attributable to a lack of good faith effort by the OTSB prime contractor. The term SBC for purposes of this rule includes all categories of small business socio-economic concerns including small business, small disadvantaged businesses, veteran owned small businesses, service disabled veteran owned small businesses, women owned small businesses, small businesses in historically underutilized business zones, Historically Black Colleges and Universities (HBCU/Minority Institutions (MI)) (NASA only) and any successor small business designations. A failure to exert good faith efforts must take into account all actions, or lack thereof, the contractor made to promote subcontracting opportunity to small businesses to the extent agreed upon in the approved subcontracting plan. SBA is reorganizing this section to reflect these new examples in proposed § 125.3(d)(3)(ii). SBA is proposing to renumber current § 125.3(d)(3)(i) through (iii) as § 125.3(d)(3)(i)(A) through (C) to better organize this section for clarity and ease of understanding . This rule does not add a new requirement for supporting documentation for the subcontracting plan.

III. Recovery Improvements for Small Entities After Disaster Act of 2015, Public Law 114–88, 129 Stat. 686, November 25, 2015 (RISE Act)

Section 2108 of the RISE Act authorizes SBA to establish contracting preferences for small business concerns located in disaster areas, and provide agencies with double credit for awards to small business concerns located in disaster areas. In order to implement the changes made by section 2108 of the RISE Act, SBA is proposing to add a new part 129 to title 13 of the Code of Federal Regulations. SBA will implement section 2105 in a separate rulemaking.

Section 2108 of the RISE Act amends section 15 of the Small Business Act (15 U.S.C. 644) by adding a subsection (f), which authorizes procuring agencies to provide contracting preferences for small business concerns located in areas for which the President has declared a major disaster, during the period of the declaration. Section 2108 provides that this contracting preference shall be available for small business concerns located in disaster areas if the small business will perform the work required under the contract in the disaster area. Under § 6.208 of Federal Acquisition Regulation (FAR), title 48 of the Code of Federal Regulations, contracting officers may set aside solicitations to allow only offerors residing or doing business in the area affected by a major disaster. Under existing FAR 26.202–1, such local area set asides may be further set aside for small business concerns. SBA is proposing to use the existing FAR definitions to provide that an agency will receive credit for an ''emergency response contract'' awarded to a ''local firm'' that qualifies as a small business concern under the applicable size standard for a ''Major disaster or emergency area.'' FAR 26.201.

Section 2108 also provides that if an agency awards a contract to a small business located in a disaster area through a contracting preference, the value of the contract shall be doubled for purposes of determining compliance with the small business contracting goals described in section 15(g)(1)(A) of the Small Business Act. Proposed § 129.300 states that agencies shall receive double credit for awarding a contract through the use of a local small business or socioeconomic set aside authorized by proposed § 129.200, *i.e.,* a set-aside restricted to SBCs, 8(a) Business Development (BD) Program Participants, Women-Owned, Service-Disabled Veteran-Owned or HUBZone SBCs located in a disaster area. It is SBA's intent that agencies will enter accurate data into the Federal Procurement Data System (FPDS). SBA will provide the extra credit through the agency scorecard process. Local area set aside and small business contract designations already exist in FPDS, and implementation has already occurred in FY 2017.

IV. Other Small Business Government Contracting Amendments

Clarification That the Non-Manufacturer 500 Employee Size Standard Does Not Apply to Information Technology Value Added Resellers

On September 10, 2014, SBA proposed to eliminate the information technology value added reseller (ITVAR) exception to NAICS 541519, which had a size standard of 150 employees. 79 FR 53646. In the proposed rule, SBA specifically noted that elimination of the exception would

result in these acquisitions, which are primarily for supplies, being subject to the non-manufacturer rule (NMR), which has a size standard of 500 employees. As a result of public comment, SBA altered the language in the ITVAR exception (13 CFR 121.201, footnote 18) to make it clear that the manufacturing performance or limitations on subcontracting requirements and the NMR apply to acquisitions under the ITVAR exception, but retained the 150 employee size standard. 81 FR 4436 (January 26, 2016). By definition, contractors under the ITVAR exception are non-manufacturers, and it would make no sense for SBA to retain a 150 employee size standard if concerns could also qualify under the NMR 500 employee size standard. In a size appeal before the SBA Office of Hearings and Appeals, a firm tried to argue that the size standard under the ITVAR exception was the 500 employee non-manufacturer size standard. *Size Appeal of York Telecom Corporation,* SBA No. SIZ–5742 (May 18, 2016). The appeal was denied, and this rule proposes to clarify in § 121.406(b)(1)(i) that the NMR size standard of 500 employees does not apply to acquisitions that have been assigned the ITVAR NAICS code 541519 exception, footnote 18. The size standard for any acquisition under 541519, footnote 18 is 150 employees for all offerors.

Setting Aside an Order Under a Multiple Award Set Aside Contract

In the final rule implementing 15 U.S.C. 644(r), SBA contemplated the set aside of orders for certain types of SBCs, such as HUBZone SBCs, 8(a) BD Program Participants, SDVO SBCs, or WOSBs. 78 FR 61114, 61124 (October 2, 2013). SBA noted that at the time, the small business programs had major differences with respect to application of the limitations on subcontracting (LOS) and NMR, and therefore it would be difficult for SBCs and agencies to determine the rules that applied to a particular order. SBA was also concerned about the possibility that SBCs could be deprived of an opportunity to compete for orders under a set aside contract if an agency repeatedly set aside orders for other socioeconomic categories. Since that time, SBA has attempted to harmonize the application of the LOS and NMR for each of the various types of small business contracts. The concerns identified in the SBA final rule have since been addressed to enable fair and proper implementation of order set asides. Specifically, the SBA final rule standardized the LOS and NMR across the socioeconomic programs. 81 FR 34243. In addition, some agencies have pursued the strategy of allowing order set asides against set aside multiple award contracts, including notification and incorporation of the clause at FAR 52.219–13, and agencies have reported that they have not encountered any industry concerns. SBA is requesting comment on whether SBA should allow agencies to set aside orders for a socioeconomic small business program (8(a), HUBZone, SDVO, WOSB) under a multiple award contract that was originally conducted as a total small business set-aside. Because SBA believes that a change is appropriate at this time, SBA is proposing to remove the term ''Full and Open'' from § 125.2(e)(6) to specifically afford discretion to an agency to set-aside one or more particular orders for HUBZone SBCs, 8(a) BD SBCs, SDVO SBCs or WOSBs, as appropriate, where the underlying multiple award contract was initially set-aside for small business. Set asides under multiple award set-aside contracts may be implemented by agencies in different ways, including: (1) Establishing set asides to socioeconomic programs at the order solicitation level under multiple award small business set-aside contracts, and (2) establishing socioeconomic set-aside pools at the master contract solicitation level for a multiple award small business set-aside contract. SBA is requesting comments on any burden or adverse impact associated with each of these two approaches. In addition, SBA is specifically interested in whether these two approaches impact the ability for all types of small businesses (*e.g.* 8(a), HUBZone, WOSB, SDVOSB) to compete and receive orders.

Recertification of Size and Status

SBA's rules require recertification of size and status for all long-term (over 5 years) contracts. This includes indefinite delivery contracts under which orders will be placed at a future date and contracts that had not been set-aside for small business, but were awarded to a small business. Thus, SBA is proposing to amend §§ 125.18(e), 126.601(h), and 127.503(h) to clarify that a concern must recertify its status on full and open contracts. In addition, SBA is adding a new paragraph to §§ 124.521 and 124.1015 to reflect the status recertification requirements for 8(a) participants and SDB concerns, which are already present in the SDVO, HUBZone, and WOSB regulations. This change provides greater consistency among the status recertification requirements for small business program contracts. One result of these proposed changes, is that a prime contractor relying on similarly situated entities (an SDVOSB prime with an SDVOSB subcontractor, for example) to meet the applicable performance requirements may not count the subcontractor towards its performance requirements if the subcontractor recertifies as an entity other than that which it had previously certified.

Indirect Costs in Commercial Subcontracting Plans

Other than small business concerns that have a commercial subcontracting plan report on performance through a summary subcontracting report (SSR), and SBA's rules currently require that a contractor using a commercial subcontracting plan must include all indirect costs in its SSR. However, SBA's rules do not require contractors to include indirect costs in their commercial subcontracting plan goals, which leads to inconsistencies when comparing the SSR to the commercial subcontracting plan. SBA is proposing to revise § 125.3(c)(1)(iv) to require that prime contractors with commercial subcontracting plans must include indirect costs in the commercial subcontracting plan goals. This will allow agencies to negotiate more realistic commercial subcontracting plans and monitor performance through the SSR.

Subcontracting Compliance Reviews

SBA is also proposing to change the nomenclature that applies to subcontracting compliance reviews. Instead of rating firms as ''Outstanding,'' ''Highly Successful,'' or ''Acceptable,'' SBA will utilize the terminology ''Exceptional,'' ''Very Good,'' and ''Satisfactory.'' SBA proposes to revise § 125.3(f)(3) to implement these changes to align title 13 of the CFR and the FAR to rectify ambiguity in terminology which causes confusion by Government personnel and industry partners when attempting to ascertain the value and differences of the SBA's rating under § 125.3(f)(3) in an SBA Compliance Review and the ratings in FAR 42.1503 under a Subcontracting Evaluation when FAR 52.219–9 is used and made part of the firm's past performance record.

Independent Contractors—Employees/Subcontractors

SBA's size regulations provide that SBA considers ''all individuals employed on a full-time, part-time, or other basis'' to be employees of the firm whose size is at issue. 13 CFR 121.106(a). ''This includes employees obtained from a temporary employee

agency, professional employee organization or leasing concern.'' Id. Further, ''SBA will consider the totality of the circumstances, including criteria used by the IRS for Federal income tax purposes, in determining whether individuals are employees of a concern.'' Id. In determining what it means to be employed on an ''other'' basis, SBA issued Size Policy Statement No. 1. 51 FR 6099–01 (February 20, 1986). The Size Policy Statement sets forth 11 criteria SBA will consider in determining whether an individual should be treated as an employee. If an individual meets one or more of the criteria they may be treated as an employee. Pursuant to this guidance, an individual contractor paid through a 1099 may be properly treated as an employee for purposes of SBA's regulations (including SBA's regulations governing performance of work or LOS requirements). The reason for such treatment was to prevent a firm that exceeded an applicable employee-based size standard from ''firing'' a specific number of employees in order to get below the size standard, but to then hire them back or ''subcontract'' to them as independent contractors. SBA did not want to encourage firms to attempt to evade SBA's size regulations.

Historically, SBA has said that if an individual qualifies as an ''employee'' under part 121 of SBA's regulations for purposes of determining size, then SBA should consider that individual to be an employee of the firm for the performance of work (or now LOS) requirements of 13 CFR 125.6 (or 124.510). It would not be equitable to say that a given individual counts against a firm in determining size (because he/she is considered an ''employee'' of the firm) and then to say that that same individual also counts against the firm for the LOS requirements (because he/she is not considered an ''employee'' of the firm). Thus, for a contract that is assigned a NAICS code having an employee-based size standard, an independent contractor could be deemed an ''employee'' of the concern for which he/she is doing work. If such an individual is considered an employee for size purposes, he/she would also be considered an employee for LOS purposes.

It appears that SBA's regulation at 13 CFR 125.6(e)(3) has caused some confusion as to how to properly treat independent contractors for purposes of the LOS provisions. That provision provides that ''Work performed by an independent contractor shall be considered a subcontract, and may count toward meeting the applicable LOS where the independent contractor qualifies as a similarly situated entity.'' (Emphasis added). This provision was meant to apply to service or construction contracts. For service contracts, work performed by an independent contractor would always be considered a subcontract, so that a service contractor could not claim that a non-similarly situated entity independent contractor should be considered an employee of the service contractor. For example, for a WOSB service contract, SBA did not want a WOSB prime contractor to pass performance of the contract to one or more independent contractors that would not themselves qualify as WOSBs. The provision identifies that an independent contractor could qualify as a ''similarly situated entity'' and meet the LOS that way, but would not permit a service contractor to effectively avoid meeting the LOS by claiming that independent contractors were in fact employees of the firm.

This proposed rule revises § 125.6(e)(3) to clarify SBA's intent regarding both contracts assigned a NAICS code with an employee-based size standard and those assigned a NAICS code with a receipts-based size standard. Where a contract is assigned a NAICS code with an employee-based size standard, an independent contractor may be deemed an employee of the firm under the terms of the Size Policy Statement. Where a contract is assigned a NAICS code with a receipts-based size standard, an independent contractor could not be considered an employee of the firm for which he or she is performing work, but, rather, would always be deemed a subcontractor. In either case, as a subcontractor, an independent contractor may be considered a ''similarly situated entity'' and work performed by the independent contractor would then count toward meeting the applicable limitation on subcontracting.

Limitation on Subcontracting Compliance

Congress has expressed its strong support for small business government contracting, and has provided agencies with numerous tools to set aside acquisitions for exclusive competition among, or in some cases award contracts on a sole source basis to, SBCs, 8(a) BD Program Participants, HUBZone SBCs, WOSBs, Economically Disadvantaged Women-Owned (EDWOSB) SBCs, and SDVO SBCs. 15 U.S.C. 631(a), 637(a), (m), 644(a), (j), 657a, 657f. As a condition of these preferences, small businesses are limited in their ability to subcontract to other than small business concerns, so that small businesses actually perform a certain percentage of the work. These LOS appear in solicitations and contract clauses for small business set aside and sole source awards. Like with all contract administration, it is the responsibility of the contracting officer to monitor compliance with terms and conditions of a contract. (FAR 1.602–2), including the LOS clause. SBA is proposing language to clarify that contracting officers have the discretion to request information from contractors to demonstrate compliance with LOS clauses. The Government Accountability Office (GAO) has noted in reports that contracting officers have not been monitoring compliance with the limitations on subcontracting. ''Contract Management; Increased Use of Alaska Native Corporations' Special 8(a) Provisions Calls for Tailored Oversight,'' GAO–06–39, April 2006; ''8(a) Subcontracting Limitations, Continued Noncompliance with Monitoring Requirements Signals Need for Regulatory Change,'' GAO–14–706, September 2014; and ''Federal Contracting Monitoring and Oversight of Tribal 8(a) Firms Need Attention,'' GAO–12–84, January 2012. The type of information that small business prime contractors may be requested to provide to demonstrate compliance with the LOS could be copies of subcontracts for a particular procurement or an email that lists the amount that the prime contractor has paid to its subcontractors for a particular procurement and whether those subcontractors are similarly situated entities. In addition, SBA proposed to require information demonstrating compliance with the applicable LOS from all prime contractors performing set-aside and sole-source contracts awarded through SBA's small business programs when the prime contractor intends to rely on similarly situated subcontractors to comply with the LOS. 79 FR 77955 (December 29, 2014). SBA did not adopt such a requirement in the final rule, but indicated that it intended to seek comment on this issue. 81 FR 34243 (May 31, 2016).

SBA is proposing to add new § 125.6(e)(4) to clarify that contracting officers may request information regarding LOS compliance, and to clarify that it is not required for every contract. SBA is requesting comment on whether all small business prime contractors performing set-aside or sole source contracts should be required to demonstrate compliance with LOS to the contracting officer, and if so, how

often should this be required, such as annually or quarterly. What salient data would best provide assurance of compliance? Should demonstrating compliance depend on the length of the contract or the type of contract? Whether it is for commercial products and services? Whether the contract is fixed price? Whether the contract is above the SAT or the TINA threshold? What other considerations should there be when applying the requirement for a contractor to document LOS compliance? We are requesting that industry provide comment on what information can be efficiently requested and provided.

Exclusions From the Limitations on Subcontracting

SBA's LOS regulations provide that for a set aside service contract, the prime contractor must agree that it will not pay more than 50% of the amount paid from the government to firms that are not similarly situated. 13 CFR 125.6(a)(1). Unlike supply and construction contracts, where materials are excluded, no costs are specifically excluded under a service contract, other than for mixed contracts where the non-service portion, such as incidental supplies, are excluded. SBA has received several requests from industry for exclusions related to specific types of contracts, and one related to all industries. Some have advocated that certain direct costs, such as airline tickets and hotel costs, be excluded from the calculation of the amount paid under the contract. In addition, in certain types of contracts or industries, there are factors that may complicate compliance with the LOS, potentially hindering agencies from setting aside acquisitions for small business concerns.

For example, for certain contracts performed outside of the United States, contractors must use non-U.S. local organizations or independent contractors to perform consulting services regarding a particular foreign country. These individuals are not located in the United States, do not reside in the United States, and are not likely to be employees of a United States SBC. SBA is proposing to further clarify how to determine whether an individual is an employee or independent contractor.

In the environmental remediation industry (NAICS 562910), a large part of the cost of the contract is tied to the transportation and disposal of hazardous, toxic and radiological waste. According to some SBCs in this industry that have contacted SBA, given the fact that these services are highly regulated and capital intensive, these particular transportation services can generally be performed only by other than small business concerns. For example, all of the disposal facilities in the United States are large businesses, and most railroads and shipping companies that transport hazardous waste are other than small concerns. This rule proposes to exclude transportation and disposal services from the LOS compliance determination where small business concerns cannot provide the disposal or transportation services. Similarly, where the government acquires media services from small business concerns, the placement of the content in the media may require large payments to the other than small business concerns, even though that is not the principal purpose of the acquisition. SBA is proposing to exclude these media purchases from the LOS determination.

In a prior rulemaking, SBA determined that remote hosting on servers or networks, or cloud computing, should be considered a service and therefore the NMR would not apply. 13 CFR 121.1203(d)(3). Due to the costs and scale involved, cloud computing is generally provided by other than small business concerns. SBA is proposing to exclude cloud computing from the LOS calculation, where the small business concern will perform other services that are the primary purpose of the acquisition. Alternatively, SBA is requesting comment on whether it should treat cloud computing as a supply, and therefore the NMR would apply, which would allow SBA to issue individual or class waivers of the NMR for cloud computing. SBA is also requesting comment on the definition of cloud computing, such as the definition in National Institute of Standards and Technology Special Publication 800–145, so that we can ensure the definition is not used to allow other than small businesses to provide an excessive portion of services on small business set aside contracts.

SBA is requesting comment on whether these types of costs should be excluded from the calculation for purposes of compliance with the LOS. For example, some have suggested that travel costs should be excluded. However, SBA is also concerned about abuse of such exceptions. For example, SBA does not want agencies to receive credit for a small business contract award where the principal purpose of the acquisition is to obtain services from an other than small business concern. If that is the norm for a particular type of contract, perhaps that type of contract should not be set aside for small business concerns. The intent of the LOS is to prevent other than small business concerns from benefitting more than small business concerns on small business set aside contracts. SBA is requesting comment from industry on these issues.

Subcontracting to a Small Business Under a Socioeconomic Program Set Aside

In the context of socioeconomic set aside or sole source service contracts, the ostensible subcontractor rule applies when a small business is unduly reliant on an other than small subcontractor, or when the other than small subcontractor will perform primary and vital parts of the contract. In such cases, assuming that an exception to joint venture affiliation does not apply, SBA will treat the small business prime contractor and its subcontractor as joint venturers, and therefore affiliates. If the subcontractor is other than small, the prime contractor is ineligible for award due to this affiliation. SBA has become aware of service contract set asides for the SDVO, HUBZone, 8(a) or WOSB programs, where the prime contractor subcontracts most or all of the actual performance to a small business that is small for the applicable NAICS code but not eligible to compete for award of the prime contract, and thus not a similarly situated entity as that term is defined at § 125.1.

Under SBA's recently amended joint venture rules (81 FR 34243, May 31, 2016; 13 CFR 121.103(h)(3)(i)), a joint venture can qualify as small as long as each member of the joint venture is small. In the scenario described above, the joint venture regulation prevents SBA from performing an analysis under the ostensible subcontractor rule because both the prime contractor and subcontractor are small for the size standard that applies to the contract and thus subject to the exception from affiliation for joint venture partners that are each small for the size standard. There is no existing regulatory mechanism for an unsuccessful offeror, SBA, or contracting officer to protest a socioeconomic set aside or sole source award to a prime contractor that is unduly reliant on a small, but not similarly situated entity subcontractor. The underlying premise that ostensible subcontractors and their prime contractors should be treated as joint ventures is still SBA's policy. Firms that are performing contracts in a manner more consistent with a joint venture than a prime/sub relationship should follow the requirements of SBA's regulations regarding socioeconomic joint ventures.

The performance of a set-aside or sole source service contract by a small business concern that is not eligible to compete for the prime contract is contrary to the intent and purpose of the statutory authorities for socioeconomic category set-aside and sole source procurements. Thus, SBA is proposing language at §§ 124.507(b)(2), 125.18(f), 125.29(c), 126.601(i), 126.801(a), 127.504(c), and 127.602, which will allow SBA to make a determination concerning a small business program participant's overreliance on a non-similarly situated subcontractor as part of an eligibility or status protest determination. SBA will evaluate these contractor relationships under the established ostensible subcontractor test. If SBA finds that the subcontractor is an ostensible subcontractor, SBA will treat the arrangement between the contractors as a joint venture that does not comply with the formal requirements necessary to receive and perform the socioeconomic program set aside or sole source award as a joint venture.

This rulemaking will not apply to non-service contracts, such as construction contracts or contracts involving non-manufacturers. Due to the nature of the industry, SBA's rules allow small businesses to subcontract large amounts of performance on construction contracts. The Small Business Act, and SBA's regulations generally provide that for set aside supply contracts, a non-manufacturer must supply the product of a small business, unless SBA has issued a waiver. This means that for an SDVO, HUBZone, 8(a), or WOSB set aside or sole source supply contract, the prime contractor that is a non-manufacturer must qualify as an SDVO, HUBZone, 8(a) or WOSB, but the product can be made by a small business that does not qualify as SDVO, HUBZone, 8(a), or WOSB. When the non-manufacturer rule applies to a small business program contract, it is considered an exception to the limitations on subcontracting. Where a waiver of the non-manufacturer rule has been issued that applies to a small business program set-aside or sole source contract, the prime contractor may supply a product manufactured by any size business, also without regard to whether the subcontractor qualifies for the applicable small business program set-aside or sole source contract.

Kit Assemblers

SBA is proposing to remove specific rules related to kit assemblers and the NMR, which are currently contained at 13 CFR 121.406(c). The existing kit assembler rule requires that 50 percent of the total value of the items in the kit must be manufactured by small business concerns, but excludes items manufactured by other than small business concerns if the contracting officer specifies the item for the kit. This rule has led to confusion concerning how to calculate total value, and whether a waiver of the non-manufacturer rule can or must be requested in order to supply items manufactured by other than small concerns. SBA recently amended its rules to address the NMR and multiple item acquisitions. If the majority of items in a kit are made by small business concerns, then the acquisition can be set aside for small business without the need to request a waiver. If the majority of items in a kit are not made by small business concerns, then an individual or class waiver of one or more of the items is necessary for the acquisition to be set aside for small business concerns for acquisitions above the simplified acquisition threshold or for all other socioeconomic set-asides, regardless of value. SBA is proposing to delete the kit assembler exception, and instead apply the multiple item rule in § 121.406(e) to kit assembler acquisitions. Like all other acquisitions, the NMR will not apply to small business set-asides with a value at or below the simplified acquisition threshold.

Clarification on Size Determinations

SBA is also proposing to amend its regulations to remove language that has caused confusion on when size is determined. The general rule is that size is determined at the time of initial offer including price, with the understanding that there are some exceptions such as architecture and engineering procurements, and certain unpriced indefinite delivery indefinite quantity (IDIQ) contracts. However, § 121.404(a) also contains the parenthetical, ''(or other formal response to the solicitation).'' Some parties have misread this to mean formal responses that are after the initial offer, such as final proposal revisions. The clear intent of SBA's general rule is to give both firms and the government certainty as to when size will be determined, the initial response, including price, because in the current government contracting environment a vast amount of time may pass between initial offer and award. Offer covers bids and proposals, and SBA recognizes that in simplified acquisitions the initial response may be acceptance of the government's offer. Thus, SBA is proposing to amend § 121.404(a) to make it clear that size is generally determined at the time of initial offer or response including price. SBA is also proposing to add a paragraph at § 121.404(a)(1)(iv), to articulate an exception to the general rule for when size is determined. When an agency uses an IDIQ multiple award contract that does not require offers for the contract to include price, size will be determined on the date of initial offer for the IDIQ contract, which may not include price. This proposed change reflects the statutory change found at section 825 of the National Defense Authorization Act for Fiscal Year 2017, 114 Public Law 328, (December 23, 2016), and section 876 of the John S. McCain National Defense Authorization Act for Fiscal Year 2019, 115 Public Law 232, (August 13, 2018). SBA is also proposing to remove the last sentence of paragraph § 121.404(g)(5), because it conflicts with recent rules that provide that a firm may rely on similarly situated entities to meet the applicable LOS. The last sentence of (g)(5) is unnecessary, as § 121.103(h) is controlling with respect to the affiliation.

SBA proposes to amend § 121.103(h)(4) to clarify that when two or more small businesses either form a joint venture or are treated as joint venturers due to their relationship as prime and subcontractor, the joint venture exception to affiliation found at § 121.103(h)(3)(i) applies if both firms are considered small for the size standard associated with the procurement. SBA proposes to remove the phrase ''and therefore affiliates'' from the ostensible subcontractor rule at § 121.103(h)(4) to clarify this point. To allow affiliation between firms that are considered joint venturers because of their ostensible subcontracting relationship, even when each firm is individually small for the size standard associated with the procurement, would negate the purpose of § 121.103(h)(3)(i), which explicitly provides an exception to affiliation for such joint ventures.

The purpose of the ostensible subcontractor rule is to treat the relationship between a prime contractor and its subcontractor as a joint venture where the subcontractor performs primary and vital work for the procurement. SBA's current joint venture rules do not aggregate the partners to a joint venture in determining the size of the joint venture, but rather permit a joint venture to qualify as small as long as each partner to the joint venture is individually small. Thus, a rule that equates a prime-sub relationship to that of a joint venture because the subcontractor is performing primary and vital work and then affiliates the two

parties (*i.e.,* requiring them to aggregate their revenues or employees) is inconsistent with the joint venture size rules themselves. The phrase ''and therefore affiliates'' that SBA proposes to delete was a holdover from previous regulations that aggregated the receipts or employees of joint venture partners when determining whether a joint venture qualified as a small business. When SBA changed its size regulations to broaden the exclusion from affiliation for small business to allow two or more small businesses to joint venture for any procurement without being affiliated (*i.e.,* the joint venture would be considered small provided each of the joint venture partners individually qualified as small and SBA would not aggregate the receipts or employees of joint venture partners), SBA amended § 121.103(h)(3), but did not make a correspondingly similar change in § 121.103(h)(4). See 81 FR 34243, 34258 (May 31, 2016). This proposed rule intends to make it clear that if a prime-sub relationship is deemed to be a joint venture because of the ostensible subcontractor rule, then all of the rules pertaining to joint ventures would apply. As already noted, a prime-sub relationship where both parties individually qualified as small would be considered an award to small business. Similarly, if the ostensible subcontractor were a large business that was the SBA-approved mentor of the prime contractor, then the award could qualify as an award to small business if the prime contractor/protégé firm qualifies as small and the relationship (treated as a joint venture) meets the normal requirements for a joint venture. See §§ 124.513(c) and (d); 125.18(b)(2) and (3); 126.616(c) and (d); and 127.506(c) and (d). Although SBA recognizes that it is unlikely that a prime-subcontractor relationship would meet the necessary joint venture requirements of those paragraphs, it is possible, and a prime-sub/joint venture that did in fact meet those requirements could qualify as small.

In addition, the proposed rule further clarifies in § 121.103(h)(4) to provide that the ostensible subcontractor rule does not apply to similarly situated entities, as that term is defined at § 125.1. SBA notes, however, that when both partners to a joint venture are small for the assigned NAICS code but the subcontractor partner is not a similarly situated entity, the prime alone is responsible for compliance with the applicable LOS and cannot rely on its subcontractors to satisfy the LOS requirement.

Clarification Where One Acceptable Offer Is Received on a Set Aside

SBA is proposing to add new § 125.2(e)(5) to clarify that a contracting officer may make an award under a small business or socioeconomic set-aside where only one acceptable offer is received. The decision to conduct a set aside is based on the contracting officer's expectation based on market research that he or she will obtain two or more fair market price offers from capable small business concerns. Pursuant to the FAR, the contracting officer must perform market research before issuing a solicitation to determine whether there are small businesses (including 8(a), HUBZone, SDVO SBCs, WOSBs) that can perform the requirement. 48 CFR 10.001(a)(2); 19.202–2. A contracting officer's ''rule of two'' determination is prospective. Whether there appear to be at least two small businesses that can perform a procurement at a fair price is an analysis that is done during acquisition strategy planning and prior to the issuance of a solicitation. As long as the market research leads a contracting officer to conclude that the agency will receive offers from at least two small business concerns that are technically acceptable and award will be made at a fair market price, the ''rule of two'' is satisfied, no matter how many offers are actually received or how many offers remain after evaluations are conducted, a competitive range is established, or offerors are eliminated in some other fashion.

The FAR currently addresses small business set-asides below $150,000, and provides, ''If the contracting officer receives only one acceptable offer from a responsible small business concern in response to a set-aside, the contracting officer should make an award to that firm.'' FAR 19.502–2(a). There is no reason this policy should not apply to all set-asides above or below $150,000. The contracting officer must determine that an offeror is responsible and price is fair and reasonable before awarding any contract. FAR 9.103(a); 9.104–1; 14.408–2; and 15.304(c)(1). It would be inefficient and detrimental to the Government and offerors to arbitrarily prevent an award where a competition was conducted but only one offer was received. Such a policy would unreasonably prolong the procurement process, requiring a procuring agency to cancel one solicitation and reprocure using another where only one small business offer is received, and could cause contracting officers to limit the use of set-asides.

Compliance With Executive Orders 12866, 13563, 12988, 13132, 13771, the Unfunded Mandates Reform Act of 1995, the Paperwork Reduction Act (44 U.S.C. Ch. 35), and the Regulatory Flexibility Act (5 U.S.C. 601–612) Executive Order 12866

The Office of Management and Budget (OMB) has determined that this proposed rule is a ''significant'' regulatory action for purposes of Executive Order 12866. The benefits to small business from this proposed rule far outweigh any associated costs. The proposed rule makes several other changes needed to clarify ambiguities in or remedy perceived problems with the current regulations. These proposed changes should make SBA's regulations easier for SBCs to use and understand. The proposed change to § 121.404 clarifies when size for a government contract is determined, which will reduce confusion for small business concerns. The proposed change to § 121.406 clarifies that the size standard for information technology value added resellers is 150 employees, again to eliminate confusion among small business concerns. The proposed changes to § 125.2(a) will benefit small business by clarifying that a contracting officer can award a contract to a small business under a set-aside if only one offer is received. The proposed changes to § 125.2(b) implement section 1811 of the NDAA of 2017, and govern what acquisitions PCRs can review and would not impact small business concerns. The proposed changes to § 125.2(d) implement section 863 of the NDAA of 2016 and direct contracting officers on how to notify the public about consolidation and substantial bundling, and will not impact small business concerns. The proposed changes to § 125.2(e) authorize agencies to set aside orders for socioeconomic programs where the contract was set aside for small business, and will benefit firms that qualify for those set asides. The proposed changes to § 125.3 implement section 1821 of the NDAA of 2017 by providing examples of a failure to make a good faith effort to comply with small business subcontracting plans, and will benefit small businesses by providing such examples so that contracting officers can hold other than small prime contractors accountable for failing to make a good faith effort to comply with their small business subcontracting plan. The proposed changes to § 125.3 also implement section 1821 by providing that the contracting officer should evaluate whether an other than small business complied with the requirement to report

on small business subcontracting plan performance. The proposed changes to § 125.6(a) will benefit small business concerns by allowing small businesses to exclude certain costs from the calculation of the limitations on subcontracting. Without these changes, some agencies will not be able to set contracts aside for small business, because certain costs attributable to other than small concerns are too high. The proposed changes to § 125.6 also help small businesses by clarifying the difference between an employee and an independent contractor. The proposed changes to § 125.6 will impose some requirements on small business concerns to demonstrate compliance with the LOS, but only to the extent the information is not already in the possession of the government. Contractors may have this information readily available since it pertains to contract performance and subcontracting of that performance. These information requests are not mandatory, as the contracting officer simply has the discretion to request such information. Contracting officers already have the authority to request information on performance, and this proposed change simply clarifies that the authority exists. Finally, the benefits to small business concerns of this proposed rule substantially outweigh any minor costs imposed by the exercise of existing contracting authority. The proposed addition of part 129 implements section 2108 of the RISE Act and benefits small businesses by providing agencies with an incentive to set aside contracts for small business concerns located in a disaster area. Accordingly, the next section contains SBA's Regulatory Impact Analysis. However, this is not a major rule under the Congressional Review Act, 5 U.S.C. 801, *et seq.*

Regulatory Impact Analysis

1. Is there a need for the regulatory action?

The proposed rule implements section 863 of the National Defense Authorization Act of 2016, Public Law 114–92, 129 Stat. 726 (15 U.S.C. 644(e)(3)); section 2108 of the Recovery Improvements for Small Entities After Disaster Act of 2015 (RISE Act), Public Law 114–88, 129 Stat. 686 (15 U.S.C. 644(f)); and sections 1811 and 1821 of the National Defense Authorization Act of 2017, Public Law 114–328, 130 Stat. 2000 (15 U.S.C. 637(d), 644(l)). In addition, it makes several other changes needed to clarify ambiguities in or remedy perceived problems with the current regulations. These proposed changes should make SBA's regulations easier to use and understand. With respect to contractors demonstrating compliance with the limitations on subcontracting, for decades the general rule has been that on a set aside contract, a small business or socioeconomic small business must generally perform some of the work (services, construction, or manufacturing). This helps ensure that the benefits of a small business set-aside contract flow to the recipients whom Congress intends to help by creating the set aside authority. If performance of a set-aside contract is passed through to other-than-small business concerns, there may not be a need for set-asides in the first place, and the government may be paying more for a good or service without any value added. These limitations on subcontracting appear as a clause in a set aside contract and help to ensure that the intended beneficiaries of set aside contracts are receiving those benefits. The contracting officer is responsible for monitoring compliance with clauses in a contract. FAR 1.602. Nothing in SBA's regulations or the FAR prohibits a contracting officer from requesting documents demonstrating compliance with the limitations on subcontracting clause. It is SBA's view that such authority exists, but that the authority is not clear or express. Without clarifying the authority or process, some contracting officers simply are not monitoring compliance. The result is that there may be increased fraud, waste, and abuse, in the performance of contracts that are set aside for small business concerns, because subcontractors that are not eligible to receive the prime contract may be performing more work than section 46 of the Small Business Act (15 U.S.C. 657s), SBA regulations at 13 CFR 125.6, and FAR clause 52.219–14 permit. This type of fraud frustrates the policy goals associated with awarding contracts set aside for small business concerns.

In this proposed rule, SBA proposes to clarify, by expressly stating, that the contracting officer may request information to demonstrate a contractor's compliance with the limitations on subcontracting clause. SBA proposes to clarify that it is within the contracting officers' discretion to request such a showing of compliance, because in some cases it will not be necessary, such as when a small business performs the contract itself without the use of subcontractors or when information regarding compliance is already available to the Government. Through this proposed rule, SBA intends to deter and reduce potential fraud, waste, and abuse, due to noncompliance with the limitations on subcontracting. Additionally, clarifying a contracting officer's authority to request that a small business concern demonstrate compliance with the limitations on subcontracting is consistent with recommendations made by the U.S. Government Accountability Office (GAO) in several reports: ''Contract Management; Increased Use of Alaska Native Corporations' Special 8(a) Provisions Calls for Tailored Oversight,'' GAO–06–39, April 2006; ''8(a) Subcontracting Limitations, Continued Noncompliance with Monitoring Requirements Signals Need for Regulatory Change,'' GAO–14–706, September 2014; and ''Federal Contracting Monitoring and Oversight of Tribal 8(a) Firms Need Attention,'' GAO–12–84, January 2012.

2. What are the potential benefits and costs of this regulatory action?

The majority of the proposed changes in this rule will have de minimis costs and qualitative benefits that are difficult to quantity: Protecting the integrity of the small business procurement system. The rule proposes to provide exceptions to the LOS in certain service contracts where small businesses must use the services of other than small subcontractors in substantial amounts in order to fully perform a set aside service contract. This will help small business by making acquisitions available for small business set-asides that would not otherwise be available. Many of the other clarifications in this rule will benefit small businesses, by reducing confusion in the marketplace, but this benefit is difficult to quantify. The proposed rule allowing agencies to receive double credit toward its small business procurement goals for awards to local small business concerns in the event of a disaster is intended to benefit local small businesses and provide employment and revenue to concerns located in an area devastated by a disaster. While the authority for contracting preferences for businesses located in a disaster area already exists in FAR subpart 26.2, small businesses located in these areas may receive a greater benefit under this proposed rule due to the incentive for the procuring agency to receive double credit toward its small business procurement goals by utilizing this authority.

SBA is proposing to clarify that the contracting officer may require the prime contractor to demonstrate compliance with the LOS. We believe that contracting officers already possesses the authority to request

information from a contractor concerning compliance with a clause in the contract pursuant to FAR 1.602–2. In addition, on some contracts, compliance can already be reviewed or monitored by reviewing invoices. The proposed rule would clarify that contracting officers have the authority to request information in connection with a contractor's compliance with applicable limitations on subcontracting clauses. Approximately 56,000 firms received approximately 180,000 sole source or set aside awards in FY 2016. SBA is proposing that a contracting officer may request information regarding compliance with prime contractors' limitations on subcontracting. In some cases this information may not be necessary based on the nature of the contract and the invoices submitted. SBA estimates that less than ten percent of small business concerns and contracts would be subject to a request for this information (5,600 small business concerns and 18,000 contracts), and compliance should take on average less than an hour. Small businesses that do not issue subcontracts will not have anything to report. Small businesses may be able to easily report on any subcontracts, as information on subcontracting and paying subcontractors is routinely compiled as part of the normal accounting procedures for any business concern. Accounting or contract management personnel should be able to determine whether the firm issued any subcontracts in connection with the prime contract. SBA estimates that this rule will be finalized in FY 2019. SBA estimates an overall annual cost of approximately $600,120 for small businesses to provide information on compliance with the limitations on subcontracting, as requested by the contracting officer.

This proposed rule will require an other than small prime contractor with a commercial subcontracting plan to include indirect costs in its subcontracting goals. Based on data from the Electronic Subcontracting Reporting System (eSRS), in FY 2017 approximately 700 firms had commercial subcontracting plans. SBA estimates that approximately 95% of those 700 firms include indirect costs in their subcontracting goals. Thus, this proposal would impact approximately 35 firms. The burden would be de minimis, as the accounting or contract manager would know the firm's indirect costs. The benefit of requiring that indirect costs be included in subcontracting goals where a commercial subcontracting plan is utilized, is that it will increase the small business subcontracting goal and thus increase the amount of funds the prime contractor will subcontract to small business concerns. Increasing the value and number of awards to small business concerns provides financial benefits to those firms, who may hire more staff and invest in more resources to support the increased demand. Furthermore, increasing the number and value of awards to small business concerns has macroeconomic and qualitative benefits to the national economy because small businesses are the foundation of the country's economic success.

This proposed rule will establish that failure to provide timely subcontracting reports may constitute a material breach of the contract. These reports are already required by law at 13 CFR 125.3(a). This rule will make failure to provide the report a material breach of the contract, which could subject other than small business concerns to liquidated damages. SBA is not aware of any case where a firm has been subject to liquidated damages for failure to comply with a subcontracting plan. Thus any costs would be de minimis. The benefit of this proposed rule is that it will assist SBA and contracting officers with oversight of prime contractor compliance with subcontracting plans and may result in increased compliance with subcontracting plans.

This proposed rule requires recertification of status on full and open contracts. SBA intended for recertification to occur whenever an agency receives credit for an award towards it goals, and this proposed rule is just a clarification that socioeconomic recertification is required on all contracts, including full and open contracts. We estimate that approximately 150 firms a year recertify on full and open contracts. This will only impact firms that are acquired, merged, or where there is a novation or the firm grows to be other than small on a long term contract. Agencies have goals for the award of prime contractor dollars to small and socioeconomic concerns. The purpose of recertification is to ensure that an agency does not receive small business credit for an award to an other-than-small concern.

This proposed rule will limit the scope of Procurement Center Representative reviews of Department of Defense acquisitions performed outside of the United States and its territories. This applies to the government and will not impose costs or burdens on the public.

This proposed rule will remove the kit assembler exception to the non-manufacturer rule. This clarification requires agencies to request a waiver of the non-manufacturer rule for kits, in accordance with existing regulations. This will reduce confusion, by having only one non-manufacturer rule procedure for purposes of multi-item procurements.

3. What are the alternatives to this rule?

Many of the proposed regulations are required to implement statutory provisions, thus there are no apparent alternatives for these regulations. With respect to the proposal clarifying that contracting officers may request information on compliance with the limitations on subcontracting, SBA considered whether prime contractors should be required to provide this information on compliance with the LOS on all set aside or sole source contracts. However, that may unnecessarily burden small businesses, if compliance is already readily apparent to the contracting officer based on the type of contract, invoicing, or observation. We estimate the alternative considered, having all small businesses provide information on compliance, would have an annual cost of $1,867,040. SBA decided to clarify instead that the contracting officer has the discretion to request such information to the extent such information is not already available. This will enable the contracting officer to request this information as he or she sees fit, in order to ensure that the benefits of the small business programs are flowing to the intended recipients. However, SBA is requesting comment on whether all small businesses should provide information on compliance with the LOS for set aside or sole source contracts.

Executive Order 13563

This executive order directs agencies to, among other things: (a) Afford the public a meaningful opportunity to comment through the internet on proposed regulations, with a comment period that should generally consist of not less than 60 days; (b) provide for an ''open exchange'' of information among government officials, experts, stakeholders, and the public; and (c) seek the views of those who are likely to be affected by the rulemaking, even before issuing a notice of proposed rulemaking. As far as practicable or relevant, SBA considered these requirements in developing this rule, as discussed below.

1. *Did the agency use the best available techniques to quantify anticipated present and future costs when responding to E.O. 12866 (e.g.,*

identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes)?

To the extent possible, the agency utilized the most recent data available in the Federal Procurement Data System—Next Generation, System for Award Management and Electronic Subcontracting Reporting System.

2. *Public participation: Did the agency: (a) Afford the public a meaningful opportunity to comment through the internet on any proposed regulation, with a comment period that should generally consist of not less than 60 days; (b) provide for an ''open exchange'' of information among government officials, experts, stakeholders, and the public; (c) provide timely online access to the rulemaking docket on Regulations.gov; and (d) seek the views of those who are likely to be affected by rulemaking, even before issuing a notice of proposed rulemaking?*

The proposed rule will have a 60 day comment period and will be posted on *www.regulations.gov* to allow the public to comment meaningfully on its provisions. In addition, the proposed rule was discussed with the Small Business Procurement Advisory Council, which consists of the Directors of the Office of Small and Disadvantaged Business Utilization. SBA also submitted the rule to multiple agencies with representatives on the FAR Small Business Subcommittee prior to submitting the rule to the Office of Management and Budget for interagency review.

3. *Flexibility: Did the agency identify and consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public?*

Yes, the proposed rule implements statutory provisions and will provide clarification to rules that were requested by agencies and stakeholders. In addition, SBA is proposing to make clear that contracting officers may request information from their contractors in order to determine whether the contractor is complying with the LOS. This information may already be provided as part of invoicing under certain contracts, and in any event, the information should be readily provided by the contractor, as it simply pertains to what extent the prime contractor is subcontracting work under the contract. Clarifying that the contracting officer has the authority to request this information, instead of requiring all small businesses to submit reports, significantly reduces cost and burden.

Executive Order 12988

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

Unfunded Mandates Reform Act

This rule will not result in an unfunded mandate that will result in expenditures by State governments of $100 million or more (adjusted annually for inflation since 1995).

Executive Order 13132

SBA has determined that this proposed rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

Executive Order 13771

This proposed rule is expected to be an Executive Order 13771 regulatory action. Details on the estimated costs of this proposed rule can be found in the rule's economic analysis.

Paperwork Reduction Act, 44 U.S.C. Ch. 35

Small businesses, such as 8(a) BD Program Participants, HUBZone SBCs, WOSBs, Economically Disadvantaged Women-Owned (EDWOSBCs, and SDVO SBCs, are eligible to receive set-aside or sole source contracts. 15 U.S.C. 631(a), 637(a), (m), 644(a), (j), 657a, 657f. As a condition of these preferences, and to help ensure that small businesses actually perform a certain percentage of the work on a contract, the recipients of set-aside or sole source contracts are limited in their ability to subcontract to other-than-small business concerns by the limitations on subcontracting (LOS) clauses in the particular contract. See, 48 CFR 52.219–3, 52.219–4, 52.219–7, 52.219–14, 52.219–18, 52.219–27, 52.219–29, 52.219–30. Contracting officers are responsible for ensuring contractor compliance with the terms of a contract (FAR 1.602–2). The SBA proposed rule will provide express authority for contracting officers to request information on contractor's compliance with the LOS. Therefore, SBA will seek PRA review and approval from the Office of Management and Budget (OMB) to cover contracting officers' requests for information from small businesses regarding their LOS compliance.

A summary description of the reporting requirement, description of respondents, and estimate of the annual burden is described below. Included in the estimate is the time for reviewing requirements, gathering and maintaining the data needed, and submitting the report to the contracting officer.

Title: Compliance with the Limitations on Subcontracting.

OMB Control Number: (To be determined; new collection).

Summary Description of Compliance Information: In order to show that it is in compliance with the limitations on subcontracting terms that are included in its set-aside or sole source contract, a small business concern may be required to submit certain information to the contracting officer. The specific information relevant to a particular contract will be identified by the contracting officer but could include, where applicable, identification of subcontractor, dollar amount of subcontract, and costs to be excluded from the LOS calculation (*e.g.,* for contracts for supplies, materials).

Description of and Estimated Number of Respondents: Small business concerns that are awarded set-aside or sole source contracts. Based on FPDS data, SBA estimates that approximately 56,000 concerns receive approximately 180,000 small business sole source or set-aside awards in a fiscal year and that no more than ten percent (5,600) of concerns will be asked to provide information on compliance with the limitations on subcontracting for no more than ten percent (18,000) of the awards that have been received.

Estimated Annual Responses: 18,000.

Estimated Response Time per Respondent: 1 hour.

Total Estimated Annual Hour Burden: 18,000.

Estimated costs based on officer's salary: $33.34/hour (based on median pay for accountants and auditors, Bureau of Labor Statistics).

Total estimated hour annual cost burden: 18,000 hours × $33.34/hour = $600,120.

SBA will submit this new information collection (reporting requirement) to the Office of Management and Budget (OMB) for review, and invites the public to comment on: (1) Whether the reporting requirement is necessary for the proper performance of SBA programs, including whether the information will have a practical utility; (2) the accuracy of SBA's estimate of the burden for the reporting requirement; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the

burden imposed as a result of the reporting requirement on the respondents, including the use of automated collection techniques, when appropriate, and other forms of information technology.

Comments must be received by the deadline stated in the **DATES** section of this rule. Refer to the **ADDRESS** section for instructions on how and where to submit comments.

Regulatory Flexibility Act, 5 U.S.C. 601–612

Under the Regulatory Flexibility Act (RFA), this proposed rule may have a significant impact on a substantial number of small businesses. Immediately below, SBA sets forth an initial regulatory flexibility analysis (IRFA) addressing the impact of the proposed rule in accordance with section 603, Title 5, of the United States Code. The IRFA examines the objectives and legal basis for this proposed rule; the kind and number of small entities that may be affected; the projected recordkeeping, reporting, and other requirements; whether there are any Federal rules that may duplicate, overlap, or conflict with this proposed rule; and whether there are any significant alternatives to this proposed rule.

1. What are the need for and objective of the rule?

The proposed rule implements section 863 of the National Defense Authorization Act of 2016, Public Law 114–92, 129 Stat. 726 (15 U.S.C. 644(e)(3)); section 2108 of the Recovery Improvements for Small Entities After Disaster Act of 2015 (RISE Act), Public Law 114–88, 129 Stat. 686 (15 U.S.C. 644(f)); and sections 1811 and 1821 of the National Defense Authorization Act of 2017, Public Law 114–328, 130 Stat. 2000 (15 U.S.C. 637(d), 644(l)). In addition, the proposed rule makes several other changes needed to clarify ambiguities in or remedy perceived problems with the current regulations. These proposed changes should make SBA's regulations easier to use and understand. The proposed rule will make it easier for agencies to award set aside contracts to SBCs. Failure to promulgate this rule could result in a loss of set aside opportunities for SBCs.

The proposed change to § 121.404 clarifies when size for a government contract is determined, which will reduce confusion for small business concerns. The proposed change to § 121.406 clarifies that the size standard for information technology value added resellers is 150 employees, again to eliminate confusion among small business concerns. The proposed changes to § 125.2(a) will benefit small business by clarifying that a contracting officer can award a contract to a small business under a set aside if only one offer is received. The proposed changes to § 125.2(b) implement section 1811 of the NDAA 2017, and govern what acquisitions PCRs can review and would not impact small business concerns. The proposed changes to § 125.2(d) implement section 863 of the NDAA of 2016 and direct contracting officers on how to notify the public about consolidation and substantial bundling, and will not impact small business concerns. The proposed changes to § 125.2(e) authorize agencies to set aside orders for socioeconomic programs where the contract was set aside for small business, and will benefit firms that qualify for those set asides. The proposed changes to § 125.3 implement section 1821 of the NDAA of 2017 by providing examples of a failure to make a good faith effort to comply with small business subcontracting plans, and will benefit small businesses by providing such examples so that contracting officers can hold other than small prime contractors accountable for failing to make a good faith effort to comply with their small business subcontracting plan. The proposed changes to § 125.3 also implement section 1821 by providing that the contracting officer should evaluate whether an other than small business complied with the requirement to report on small business subcontracting plan performance. The proposed changes to § 125.6(a) will benefit small business concerns by allowing small businesses to exclude certain costs from the calculation of the limitations on subcontracting. Without these changes, some agencies will not be able to set contracts aside for small business, because certain costs attributable to other than small concerns are too high. The proposed changes to § 125.6 also help small businesses by clarifying the difference between an employee and an independent contractor. The proposed changes to § 125.6 will impose some information production requirements on small business concerns, but only to the extent the information is not already in the possession of the government. Further, this information is readily available since it pertains to contract performance and subcontracting of that performance. These reports are not mandatory, as the contracting officer simply has the discretion to request such reports. Contracting officers already have the authority to request information demonstrating performance, and this proposed change simply clarifies that the authority exists. Finally, the benefits to small business concerns of this proposed rule substantially outweigh any minor costs imposed by the reporting authority. The proposed addition of part 129 implements section 2108 of the RISE Act and benefits small businesses by providing agencies with an incentive to set aside contracts for small business concerns located in a disaster area.

With respect to the limitation on subcontracting to an ineligible small business under a socioeconomic set aside (proposed 13 CFR 124.507(b)(2)(vi), 125.29(c), 126.601(i), and 127.504(c)), the rule will impact very few firms. The vast majority of small business prime contractors self-perform the required percentage of work, or will subcontract to a similarly situated entity, as is allowed under FAR 52.219–3 (Notice of HUBZone Set-Aside or Sole Source Award), 52–219–27 (Notice of Service-Disabled Veteran-Owned Small Business Set-Aside), and as will be allowed when SBA's rules on similarly situated entities (13 CFR 125.6) are implemented in the FAR. The benefits that will flow to the intended beneficiaries of a socio-economic set-aside far outweigh any impact on firms that have no intention of performing the contract or are not eligible to bid on that contract.

2. What are SBA's description and estimate of the number of small entities to which the rule will apply?

If the proposed rule is adopted in its present form, the rule would be applicable to all small business concerns participating in the Federal procurement market that seek to perform government prime contracts or to perform subcontracts awarded by other than small concerns. SBA estimates that there are approximately 320,000 firms identified as small business concerns in the Dynamic Small Business Search database.

3. What are the projected reporting, recordkeeping, and other compliance requirements of the rule and an estimate of the classes of small entities which will be subject to the requirements?

The proposed rule does not impose new recordkeeping requirements. Contractors already keep records on contract performance and subcontracting. Information may be required, but only to the extent the information is not available through invoices or existing progress reports. The proposed rule would clarify that contracting officers may request access to information in connection with a

contractor's compliance with applicable limitations on subcontracting clauses. Approximately 56,000 firms received sole source or set aside awards in FY 2016. SBA is clarifying that a contracting officer may request information to assure compliance with the LOS clause, and in some cases this information may not be necessary based on the nature of the contract and the invoices submitted. We estimate that less than ten percent of contracts would be subject to a request to provide this information (18,000), and compliance should take less than an hour for each of those contracts. Accounting or contract management personnel should be able to determine whether the firm issued any subcontracts in connection with the prime contract. We estimate the SBA rule will be finalized in FY 2019. We estimate an overall annual cost of approximately $600,120.

4. What are the relevant Federal rules which may duplicate, overlap or conflict with the rule?

We are not aware of any rules that duplicate, overlap or conflict with this rule. The FAR will have to be amended to implement portions of this rule. That will be done through a separate rulemaking.

5. What alternatives will allow the Agency to accomplish its regulatory objectives while minimizing the impact on small entities?

Many of the proposed changes are required to implement statute, and impose requirements on contracting personnel, agencies or other than small concerns, and do not impact small business concerns. Further, many of the proposed changes will benefit small business concerns by clarifying areas where there is confusion and by making it easier for agencies to set aside contracts and orders for small business and small socioeconomic concerns. As an alternative, SBA considered whether prime contractors should be required to provide information on compliance with the LOS on all set aside or sole source contracts. However, that may unnecessarily burden small businesses, if compliance is already readily apparent to the contracting officer based on the type of contract, invoicing, or observation.

List of Subjects

13 CFR Part 121

Government procurement; Government property; Grant programs—business, Individuals with disabilities; Loan programs—business; Small businesses.

13 CFR Part 124

Administrative practice and procedure, Government procurement, Government property, Small businesses.

13 CFR Part 125

Government contracts, Government procurement, Reporting and recordkeeping requirements, Small businesses, Technical assistance.

13 CFR Part 126

Administrative practice and procedure, Government procurement, Reporting and recordkeeping requirements, Small businesses.

13 CFR Part 127

Government contracts, Reporting and recordkeeping requirements, Small businesses.

13 CFR Part 129

Administrative practice and procedure, Government contracts, Government procurement, Small businesses.

Accordingly, for the reasons stated in the preamble, SBA proposes to amend 13 CFR parts 121, 124, 125, 126, and 127 and to add 13 CFR part 129 as follows:

PART 121—SMALL BUSINESS SIZE REGULATIONS

■ 1. The authority citation for part 121 continues to read as follows:

Authority: 15 U.S.C. 632, 634(b)(6), 662, and 694a(9).

■ 2. Amend § 121.103 by revising the first sentence of paragraph (h)(4) to read as follows:

§ 121.103 How does SBA determine affiliation?

* * * * *

(h) * * *

(4) A contractor and its ostensible subcontractor are treated as joint venturers for size determination purposes. * * *

* * * * *

■ 3. Amend § 121.404 by revising paragraph (a) introductory text, adding paragraph (a)(1)(iv), and revising paragraph (g)(5) to read as follows:

§ 121.404 When is the size status of a business concern determined?

(a) SBA determines the size status of a concern, including its affiliates, as of the date the concern submits a written self-certification that it is small to the procuring activity as part of its initial offer or response which includes price.

(1) * * *

(iv) For an indefinite delivery, indefinite quantity (IDIQ), Multiple Award Contract, where concerns are not required to submit price as part of the offer for the IDIQ contract, size will be determined as of the date of initial offer, which may not include price.

* * * * *

(g) * * *

(5) If during contract performance a subcontractor that is not a similarly situated entity performs primary and vital requirements of a contract, the contractor and its ostensible subcontractor will be treated as joint venturers. See § 121.103(h)(4).

* * * * *

■ 4. Amend § 121.406 by:

■ a. Revising paragraph (b)(1)(i);

■ b. Removing paragraph (c); and

■ c. Redesignating paragraphs (d) through (f) as paragraphs (c) through (e) respectively.

The revision to read as follows:

§ 121.406 How does a small business concern qualify to provide manufactured products or other supply items under a small business set-aside, service-disabled veteran-owned small business, HUBZone, WOSB or EDWOSB, or 8(a) contract?

* * * * *

(b) * * *

(1) * * *

(i) Does not exceed 500 employees (or 150 employees for the Information Technology Value Added Reseller exception to NAICS Code 541519, which is found at § 121.201, footnote 18);

* * * * *

PART 124—8(a) BUSINESS DEVELOPMENT/SMALL DISADVANTAGED BUSINESS STATUS DETERMINATIONS

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

Authority: 15 U.S.C. 634(b)(6), 636(j), 637(a), 637(d), 644 and Pub. L. 99–661, Pub. L. 100–656, sec. 1207, Pub. L. 101–37, Pub. L. 101–574, section 8021, Pub. L. 108–87, and 42 U.S.C. 9815.

■ 6. Amend § 124.503 by revising paragraphs (c)(1)(iii) and (iv) and adding paragraph (c)(1)(v) to read as follows:

§ 124.503 How does SBA accept a procurement for award through the 8(a) BD program?

* * * * *

(c) * * *

(1) * * *

(iii) The Participant is small for the size standard corresponding to the NAICS code assigned to the requirement by the procuring activity contracting officer;

(iv) The Participant has submitted required financial statements to SBA; and

(v) The Participant is performing the primary and vital requirements of the service contract, or of an order, and is not unusually reliant on a subcontractor that is not similarly situated, as that term is defined at § 125.1.

■ 7. In § 124.507, add paragraph (b)(2)(vi) to read as follows:

§ 124.507 What procedures apply to competitive 8(a) procurements?

* * * * *

(b) * * *

(2) * * *

(vi) Performing the primary and vital requirements of the service contract, or of an order, or is unusually reliant on a subcontractor that is not a similarly situated entity, as that term is defined at § 125.1.

■ 8. In § 124.521, add paragraph (e) to read as follows:

§ 124.521 What are the requirements for representing 8(a) status, and what are the penalties for misrepresentation?

* * * * *

(e) *Recertification.* (1) Generally, a concern that represents itself and qualifies as an 8(a) Participant at the time of initial offer (or other formal response to a solicitation), which includes price, including a Multiple Award Contract, is considered an 8(a) Participant throughout the life of that contract. For an indefinite delivery, indefinite quantity (IDIQ), Multiple Award Contract, where concerns are not required to submit price as part of the offer for the contract, a concern that represents itself and qualifies as an 8(a) Participant at the time of initial offer, which may not include price, is considered an 8(a) Participant throughout the life of that contract. This means that if an 8(a) Participant is qualified at the time of initial offer for a Multiple Award Contract, then it will be considered an 8(a) Participant for each order issued against the contract, unless a contracting officer requests a new 8(a) certification in connection with a specific order. Where a concern later fails to qualify as an 8(a) Participant, the procuring agency may exercise options and still count the award as an award to an SDB. However, the following exceptions apply:

(i) Where an 8(a) contract is novated to another business concern, or where the concern performing the 8(a) contract is acquired by, acquires, or merges with another concern and contract novation is not required, the concern must comply with the process outlined at §§ 124.105(i) and 124.515.

(ii) Where an 8(a) Participant receives a non-8(a) contract that is novated to another business concern, the concern that will continue performance on the contract must certify its status as an 8(a) Participant to the procuring agency, or inform the procuring agency that it does not qualify as an 8(a) Participant, within 30 days of the novation approval. If the concern is not an 8(a) Participant, the agency can no longer count the options or orders issued pursuant to the contract, from that point forward, towards its SDB goals.

(iii) Where an 8(a) Participant receives a non-8(a) contract, and that Participant acquires, is acquired by, or merges with another concern and contract novation is not required, the concern must, within 30 days of the transaction becoming final, recertify its 8(a) status to the procuring agency, or inform the procuring agency that it no longer qualifies as an 8(a) Participant. If the contractor is not an 8(a) Participant, the agency can no longer count the options or orders issued pursuant to the contract, from that point forward, towards its SDB goals. The agency and the contractor must immediately revise all applicable Federal contract databases to reflect the new status.

(2) For the purposes of contracts (including Multiple Award Contracts) with durations of more than five years (including options), a contracting officer must request that a business concern recertify its 8(a) status no more than 120 days prior to the end of the fifth year of the contract, and no more than 120 days prior to exercising any option. Where a concern fails to recertify its 8(a) status during the 120 days prior to the end of the fifth year of the contract, the option shall not be exercised.

(3) Recertification does not change the terms and conditions of the contract. The limitations on subcontracting, nonmanufacturer and subcontracting plan requirements in effect at the time of contract award remain in effect throughout the life of the contract.

(4) Where the contracting officer explicitly requires concerns to recertify their status in response to a solicitation for an order, SBA will determine eligibility as of the date the concern submits its self-representation as part of its response to the solicitation for the order.

(5) A concern's status may be determined at the time of a response to a solicitation for an basic ordering agreement (BOA), basic agreement (BA), or blanket purchase agreement (BPA) and each order issued pursuant to the BPA, BOA, or BA.

■ 9. In § 124.1015, add paragraph (f) to read as follows:

§ 124.1015 What are the requirements for representing SDB status, and what are the penalties for misrepresentation?

* * * * *

(f) *Recertification.* (1) Generally, a concern that represents itself and qualifies as an SDB at the time of initial offer (or other formal response to a solicitation), which includes price, including a Multiple Award Contract, is considered an SDB throughout the life of that contract. For an indefinite delivery indefinite quantity (IDIQ), Multiple Award Contract, where concerns are not required to submit price as part of their offer for the contract, a concern that represents itself and qualifies as an SDB at the time of initial offer, which may not include price, is considered an SDB throughout the life of that contract. This means that if an SDB is qualified at the time of initial offer for a Multiple Award Contract, then it will be considered an SDB for each order issued against the contract, unless a contracting officer requests a new SDB certification in connection with a specific order. Where a concern later fails to qualify as an SDB, the procuring agency may exercise options and still count the award as an award to an SDB. However, the following exceptions apply:

(i) Where a contract is novated to another business concern, the concern that will continue performance on the contract must certify its status as an SDB to the procuring agency, or inform the procuring agency that it does not qualify as an SDB, within 30 days of the novation approval. If the concern is not an SDB, the agency can no longer count the options or orders issued pursuant to the contract, from that point forward, towards its SDB goals.

(ii) Where a concern that is performing a contract acquires, is acquired by, or merges with another concern and contract novation is not required, the concern must, within 30 days of the transaction becoming final, recertify its SDB status to the procuring agency, or inform the procuring agency that it no longer qualifies as an SDB. If the contractor is not an SDB, the agency can no longer count the options or orders issued pursuant to the contract, from that point forward, towards its SDB goals. The agency and the contractor must immediately revise all applicable Federal contract databases to reflect the new status.

(2) For the purposes of contracts (including Multiple Award Contracts) with durations of more than five years (including options), a contracting officer must request that a business concern recertify its SDB status no more than 120 days prior to the end of the fifth

year of the contract, and no more than 120 days prior to exercising any option.

(3) A business concern that did not certify itself as an SDB, either initially or prior to an option being exercised, may recertify itself as an SDB for a subsequent option period if it meets the eligibility requirements at that time.

(4) Recertification does not change the terms and conditions of the contract. The limitations on subcontracting, nonmanufacturer and subcontracting plan requirements in effect at the time of contract award remain in effect throughout the life of the contract.

(5) Where the contracting officer explicitly requires concerns to recertify their status in response to a solicitation for an order, SBA will determine eligibility as of the date the concern submits its self-representation as part of its response to the solicitation for the order.

(6) A concern's status may be determined at the time of a response to a solicitation for an Agreement and each order issued pursuant to the Agreement.

PART 125—GOVERNMENT CONTRACTING PROGRAMS

■ 9. The authority citation for part 125 is revised to read as follows:

Authority: 15 U.S.C. 632(p), (q); 634(b)(6); 637; 644; 657f; 657r.

■ 10. Amend § 125.2 by:
■ a. Revising paragraph (a);
■ b. In paragraph (b)(1)(i)(A):
■ i. Revising the second sentence; and
■ ii. Adding a sentence at the end of the paragraph;
■ c. Adding paragraph (d)(1)(v);
■ d. Redesignating paragraph (d)(7) as paragraph (d)(8);
■ e. Adding new paragraph (d)(7); and
■ f. Revising paragraph (e)(6).

The revisions and additions to read as follows:

§ 125.2 What are SBA's and the procuring agency's responsibilities when providing contracting assistance to small businesses?

(a)(1) The objective of the SBA's contracting programs is to assist small business concerns, including 8(a) BD Participants, HUBZone small business concerns, Service Disabled Veteran-Owned Small Business Concerns, Women-Owned Small Businesses and Economically Disadvantaged Women-Owned Small Businesses, in obtaining a fair share of Federal Government prime contracts, subcontracts, orders, and property sales. Therefore, these regulations apply to all types of Federal Government contracts, including Multiple Award Contracts, and contracts for architectural and engineering services, research, development, test and evaluation. Small business concerns must receive any award (including orders, and orders placed against Multiple Award Contracts) or contract, part of any such award or contract, any contract for the sale of Government property, or any contract resulting from a reverse auction, regardless of the place of performance, which SBA and the procuring or disposal agency determine to be in the interest of:

(i) Maintaining or mobilizing the Nation's full productive capacity;

(ii) War or national defense programs;

(iii) Assuring that a fair proportion of the total purchases and contracts for property, services and construction for the Government in each industry category are placed with small business concerns; or

(iv) Assuring that a fair proportion of the total sales of Government property is made to small business concerns.

(2) If the contracting officer receives only one acceptable offer from a responsible small business concern in response to any small or socioeconomic set-aside, the contracting officer should make an award to that firm.

(b) * * *

(1) * * *

(i) * * * (A) * * * At the SBA's discretion, PCRs may review any acquisition to determine whether a set aside or sole source award to a small business under one of SBA's programs is appropriate and to identify alternative strategies to maximize the participation of small businesses in the procurement. * * * Unless the contracting agency requests a review, PCRs will not review an acquisition by or on behalf of the Department of Defense if the acquisition is conducted for a foreign government pursuant to section 22 of the Arms Control Export Act (22 U.S.C. 2762), is a humanitarian operation as defined in 10 U.S.C. 401(e), is for a contingency operation as defined in 10 U.S.C. 101(a)(13), is to be awarded pursuant to an agreement with the government of a foreign country in which Armed Forces of the United States are deployed, or where both the place of award and place of performance are entirely outside of the United States and its territories.

* * * * *

(d) * * *

(1) * * *

(v) Not later than 7 days after making a determination that an acquisition strategy involving a consolidation of contract requirements is necessary and justified under subparagraph (d)(1)(i) of this section, the Senior Procurement Executive (SPE) or Chief Acquisition Officer (CAO), or designee, shall publish a notice on the agency's website that such determination has been made. Any solicitation for a procurement related to the acquisition strategy shall not be issued earlier than 7 days after such notice is published. Along with the publication of the solicitation, the SPE or CAO (or designee) must publish in the Government-wide Point of Entry (GPE) the justification for the determination, which shall include the information in paragraphs (d)(1)(i)(A) through (E) of this section.

* * * * *

(7) *Notification to Public of Rationale for Substantial Bundling.* If the head of a contracting agency determines that an acquisition plan for a procurement involves a substantial bundling of contract requirements, the head of a contracting agency shall publish a notice on the agency's website that such determination has been made not later than 7 days after making such determination. Any solicitation for a procurement related to the acquisition plan may not be published earlier than 7 days after such notice is published. Along with the publication of the solicitation, the head of a contracting agency shall publish in the GPE a justification for the determination, which shall include the following information:

(i) The specific benefits anticipated to be derived from the bundling of contract requirements and a determination that such benefits justify the bundling.

(ii) An identification of any alternative contracting approaches that would involve a lesser degree of bundling of contract requirements.

(iii) An assessment of—the specific impediments to participation by small business concerns as prime contractors that result from the bundling of contract requirements; and

(iv) The specific actions designed to maximize participation of small business concerns as subcontractors (including suppliers) at various tiers under the contract or contracts that are awarded to meet the requirements.

* * * * *

(e) * * *

(6) * * *

(i) Notwithstanding the fair opportunity requirements set forth in 10 U.S.C. 2304c and 41 U.S.C. 253j, the contracting officer has the authority to set aside orders against Multiple Award Contracts, including contracts that were set aside for small business. This includes order set asides for 8(a) Participants, HUBZone SBCs, SDVO SBCs and WOSBs.

* * * * *

■ 11. Amend § 125.3 by:
■ a. Revising the last sentence of paragraph (c)(1)(iv);
■ b. Revising paragraph (d)(3);
■ c. Adding paragraph (d)(11); and
■ d. Revising the first sentence of paragraph (f)(3).

The revisions and addition to read as follows:

§ 125.3 What types of subcontracting assistance are available to small businesses?

* * * * *

(c) * * *

(1) * * *

(iv) * * * A contractor authorized to use a commercial subcontracting plan must include all indirect costs in its subcontracting goals and in its SSR;

* * * * *

(d) * * *

(3) Evaluating whether the prime contractor made a good faith effort to comply with its small business subcontracting plan.

(i) Evidence that a large business prime contractor has made a good faith effort to comply with its subcontracting plan or other subcontracting responsibilities includes supporting documentation that:

(A) The contractor performed one or more of the actions described in paragraph (b) of this section, as appropriate for the procurement;

(B) Although the contractor may have failed to achieve its goal in one socioeconomic category, it over-achieved its goal by an equal or greater amount in one or more of the other categories; or

(C) The contractor fulfilled all of the requirements of its subcontracting plan.

(ii) Examples of activities reflective of a failure to make a good faith effort to comply with a subcontracting plan include, but are not limited, to:

(A) Failure to submit the acceptable individual or summary subcontracting reports in eSRS by the report due dates or as provided by other agency regulations within prescribed time frames;

(B) Failure to pay small business concern subcontractors in accordance with the terms of the contract with the prime;

(C) Failure to designate and maintain a company official to administer the subcontracting program and monitor and enforce compliance with the plan;

(D) Failure to maintain records or otherwise demonstrate procedures adopted to comply with the plan including subcontracting flow-down requirements;

(E) Adoption of company policies or documented procedures that have as their objectives the frustration of the objectives of the plan;

(F) Failure to correct substantiated findings from federal subcontracting compliance reviews or participate in subcontracting plan management training offered by the government;

(G) Failure to conduct market research identifying potential small business concern subcontractors through all reasonable means including outreach, industry days, or the use of federal database marketing systems such as SBA's Dynamic Small Business Search (DSBS) or SUBNet Systems or any successor federal systems;

(H) Failure to comply with regulations requiring approval by the contracting officer to change small business concern subcontractors that were used in preparing offers; or

(I) Falsifying records of subcontracting awards to SBCs.

* * * * *

(11) Evaluating whether the contractor or subcontractor complied in good faith with the requirement to provide periodic reports and cooperate in any studies or surveys as may be required by the Federal agency or the Administration in order to determine the extent of compliance by the contractor or subcontractor with the subcontracting plan. Failure to make a good faith effort shall be a material breach of such contract or subcontract and may be considered in any past performance evaluation of the contractor.

* * * * *

(f) * * *

(3) Upon completion of the review and evaluation of a contractor's performance and efforts to achieve the requirements in its subcontracting plans, the contractor's performance will be assigned one of the following ratings: Exceptional, Very Good, Satisfactory, Marginal or Unsatisfactory. * * *

* * * * *

■ 12. Amend § 125.6 by:
■ a. Adding two sentences at the end of paragraph (a)(1);
■ b. Adding a sentence at the end of paragraph (c);
■ c. Revising paragraph (e)(3); and
■ d. Adding paragraph (e)(4).

The revision and additions to read as follows:

§ 125.6 What are the prime contractor's limitations on subcontracting?

(a) * * *

(1) * * * Other direct costs may be excluded to the extent they are not the principal purpose of the acquisition and small business concerns do not provide the service, such as airline travel, work performed by a transportation or disposal entity under a contract assigned the environmental remediation NAICS code (562910), cloud computing services, or mass media purchases. In addition, work performed by an independent contractor under a contract that was awarded pursuant to the Foreign Assistance Act of 1961 may also be excluded.

* * * * *

(c) * * * A prime contractor may no longer count a similarly situated entity towards compliance with the limitations on subcontracting where the subcontractor ceases to qualify as small or under the relevant socioeconomic status.

* * * * *

(e) * * *

(3)(i) For contracts assigned a NAICS code with an employee-based size standard, where an independent contractor is not otherwise treated as an employee of the concern for which he/she is performing work for size purposes under § 121.106(a) of this chapter, work performed by the independent contractor shall be considered a subcontract. Such work will count toward meeting the applicable limitation on subcontracting where the independent contractor qualifies as a similarly situated entity.

(ii) For contracts assigned a NAICS code with a revenue-based size standard, work performed by an independent contractor shall be considered a subcontract, and will count toward meeting the applicable limitation on subcontracting where the independent contractor qualifies as a similarly situated entity. A firm's treatment and reporting of an individual for tax purposes governs whether that individual should be treated as an employee or independent contractor for limitations on subcontracting purposes.

(4) The contracting officer may require the contractor to demonstrate its compliance with the limitations on subcontracting, if the information regarding such compliance is not already available to the contracting officer (*e.g.,* invoices).

* * * * *

■ 13. Amend § 125.18 by:
■ a. In paragraph (e)(1)(i), removing the phrase ''an SDVO contract'' and adding in its place the phrase ''a contract'';
■ b. In paragraph (e)(1)(ii), removing the phrase ''an SDVO SBC contract'' and adding in its place the phrase ''a contract''; and
■ c. Adding paragraph (f).

The addition to read as follows:

§ 125.18 What requirements must an SDVO SBC meet to submit an offer on a contract?

* * * * *

(f) *Ostensible subcontractor.* Where a subcontractor that is not similarly situated performs primary and vital requirements of a set aside or sole source service contract or order, or where a prime contractor is unduly reliant on a small business that is not similarly situated to perform the set aside service or sole source contract or order, the prime contractor is not eligible for award of an SDVO contract. When the subcontractor is small for the size standard assigned to the procurement, this issue may be grounds for an SDVO status protest, as described in subpart D of this part. When the subcontractor is other than small, or alleged to be other than small for the size standard assigned to the procurement, this issue may be grounds for a size protest subject to the ostensible subcontractor rule, as described at § 121.103(h)(4) of this chapter.

■ 14. In § 125.29, add paragraph (c) to read as follows:

§ 125.29 What are the grounds for filing an SDVO SBC protest?

* * * * *

(c) *Ostensible subcontractor.* In cases where the prime contractor appears unduly reliant on a small, non-similarly situated entity subcontractor or where the small non-similarly situated entity is performing the primary and vital requirements of the contract, the Director, Office of Government Contracting will consider a protest only if the protester presents credible evidence of the alleged undue reliance or credible evidence that the primary and vital requirements will be performed by the subcontractor.

PART 126—HUBZONE PROGRAM

■ 15. The authority citation for part 126 is revised to read as follows:

Authority: 15 U.S.C. 632(a), 632(j), 632(p), 644 and 657a; Pub. L. 111–240, 24 Stat. 2504.

■ 16. Amend § 126.601 by:

■ a. In paragraph (h)(1)(i), removing the phrase ''HUBZone contract (or a HUBZone contract awarded through full and open competition based on the HUBZone price evaluation preference'' and adding in its place the word ''contract'';

■ b. In paragraph (h)(1)(ii), removing the phrase ''HUBZone contract'' and adding in its place the word ''contract''; and

■ c. Adding paragraph (i).

The addition to read as follows:

§ 126.601 What additional requirements must a qualified HUBZone SBC meet to bid on a contract?

* * * * *

(i) *Ostensible subcontractor.* Where a subcontractor that is not similarly situated performs primary and vital requirements of a set aside service contract, or where a prime contractor is unduly reliant on a small business that is not similarly situated to perform the set aside service contract, the prime contractor is not eligible for award of a HUBZone contract. When the subcontractor is small for the size standard assigned to the procurement, this issue may be grounds for a HUBZone status protest, as described in subpart H of this part. When the subcontractor is alleged to be other than small for the size standard assigned to the procurement, this issue may be grounds for a size protest under the ostensible subcontractor rule, as described at § 121.103(h)(4) of this chapter.

■ 17. Amend § 126.801 by adding in paragraph (a) a sentence after the third sentence to read as follows:

§ 126.801 How does one file a HUBZone status protest?

(a) * * * SBA will also consider a protest challenging whether a HUBZone prime contractor is unduly reliant on a small, non-similarly situated entity subcontractor or if such subcontractor performs the primary and vital requirements of the contract. * * *

* * * * *

PART 127—WOMEN–OWNED SMALL BUSINESS FEDERAL CONTRACT PROGRAM

■ 18. The authority citation for part 127 continues to read as follows:

Authority: 15 U.S.C. 632, 634(b)(6), 637(m), 644 and 657r.

§ 127.503 [Amended]

■ 19. In § 127.503, amend paragraphs (h)(1)(i) and (ii) by removing the phrase ''WOSB/EDWOSB contract'' wherever it appears and adding in its place the word ''contract''.

■ 20. In § 127.504, add paragraph (c) to read as follows:

§ 127.504 What additional requirements must a concern satisfy to submit an offer on an EDWOSB or WOSB requirement?

* * * * *

(c) Where a subcontractor that is not similarly situated performs primary and vital requirements of a set aside service contract, or where a prime contractor is unduly reliant on a small business that is not similarly situated to perform the set aside service contract, the prime contractor is not eligible for award of a WOSB or EDWOSB contract. When the subcontractor is small for the size standard assigned to the procurement, this issue may be grounds for a WOSB or EDWOSB status protest, as described in subpart F of this part. When the subcontractor is other than small, or alleged to be other than small, for the size standard assigned to the procurement, this issue may be a ground for a size protest, as described at § 121.103(h)(4) of this chapter.

■ 21. Amend § 127.602 by revising the second sentence and adding a new third sentence to read as follows:

§ 127.602 What are the grounds for filing an EDWOSB or WOSB status protest?

* * * SBA will also consider a protest challenging the status of a concern as an EDWOSB or WOSB if the contracting officer has protested because the WOSB or EDWOSB apparent successful offeror has failed to provide all of the required documents, as set forth in § 127.300. In addition, when sufficient credible evidence is presented, SBA will consider a protest challenging whether the prime contractor is unusually reliant on a small, non-similarly situated entity subcontractor, as defined in § 125.1 of this chapter, or a protest alleging that such subcontractor is performing the primary and vital requirements of a set aside or sole source WOSB or EDWOSB contract.

■ 22. Add part 129 to read as follows:

PART 129—CONTRACTS FOR SMALL BUSINESSES LOCATED IN DISASTER AREAS

Sec.

129.100 What definitions are important in this part?
129.200 What contracting preferences are available for small business concerns located in disaster areas?
129.300 What small business goaling credit do agencies receive for awarding a contract to a small business concern under this part?
129.400 What are the applicable performance requirements?
129.500 What are the penalties of misrepresentation of size or status?

Authority: 15 U.S.C. 636(j)(13)(F)(ii), 644(f).

§ 129.100 What definitions are important in this part?

For the purposes of this part:

Concern located in a disaster area is a firm that during the last twelve months—

(1)(i) Had its main operating office in the area; and

(ii) That office generated at least half of the firm's gross revenues and employed at least half of the offeror's permanent employees.

(2) If the firm does not meet the criteria in paragraph (1) of this definition, factors to be considered in determining whether a firm resides or primarily does business in the disaster area include—

(i) Physical location(s) of the firm's permanent office(s) and date any office in the disaster area(s) was established;

(ii) Current state licenses;

(iii) Record of past work in the disaster area(s) (*e.g.,* how much and for how long);

(iv) Contractual history the firm has had with subcontractors and/or suppliers in the disaster area;

(v) Percentage of the firm's gross revenues attributable to work performed in the disaster area;

(vi) Number of permanent employees the firm employs in the disaster area;

(vii) Membership in local and state organizations in the disaster area; and

(viii) Other evidence that establishes the firm resides or primarily does business in the disaster area. For example, sole proprietorships may submit utility bills and bank statements.

Disaster area means the area for which the President has declared a major disaster under section 401 of the Robert T. Stafford Disaster Relief and Assistance Act (42 U.S.C. 5170), during the period of the declaration.

Emergency response contract means a contract with private entities that supports assistance activities in a disaster area, such as debris cleanup, distribution of supplies, or reconstruction.

§ 129.200 What contracting preferences are available for small business concerns located in disaster areas?

Contracting officers may set aside solicitations for emergency response contracts to allow only small businesses located in the disaster area to compete.

§ 129.300 What small business goaling credit do agencies receive for awarding an emergency response contract to a small business concern under this part?

If an agency awards an emergency response contract to a local small business concern through the use of a local area set aside that is also set aside under a small business or socioeconomic set-aside (8(a), HUBZone, SDVO, WOSB, EDWOSB), the value of the contract shall be doubled for purposes of determining compliance with the goals for procurement contracts under section 15(g)(1)(A) of the Small Business Act (15 U.S.C. 644(g)(1)(A)). The procuring agency shall enter the actual contract value, not the doubled contract value in the required contract reporting systems, and appropriately code the contract action to receive the credit. SBA will provide the double credit as part of the Scorecard process.

§ 129.400 What are the applicable performance requirements?

The performance requirements of § 125.6 of this chapter apply to small and socioeconomic set asides under this part. A similarly situated entity as that term is used in § 125.6 of this chapter must qualify as a concern located in a disaster area.

§ 129.500 What are the penalties of misrepresentation of size or status?

The penalties relevant to the particular size or socioeconomic status representation under title 13 §§ 121.108, 125.32, 126.900, and 127.700 of this chapter are applicable to set asides under this part.

Dated: November 8, 2018.

Linda E. McMahon,

Administrator.

[FR Doc. 2018–25705 Filed 12–3–18; 8:45 am]

BILLING CODE 8025–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R06–OAR–2018–0676; FRL–9986–65–Region 6]

Air Plan Approval; Texas; Emission Statements

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: Pursuant to the Federal Clean Air Act (CAA or the Act), the Environmental Protection Agency (EPA) is proposing to approve a portion of a State Implementation Plan (SIP) revision submitted by the State of Texas for the 2008 8-hour ozone national ambient air quality standards (NAAQS). The portion of the SIP revision being approved pertains to CAA 2008 ozone NAAQS requirement for emission statements in the Dallas/Fort Worth ozone nonattainment area (DFW area).

DATES: Written comments should be received on or before January 3, 2019.

ADDRESSES: Submit your comments, identified by EPA–R06–OAR–2018–0676, at *https://www.regulations.gov* or via email to *ruan-lei.karolina@epa.gov.* For additional information on how to submit comments see the detailed instructions in the **ADDRESSES** section of the direct final rule located in the rules section of this **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Ms. Karolina Ruan Lei, 214–665–7346, *ruan-lei.karolina@epa.gov.*

SUPPLEMENTARY INFORMATION: In the final rules section of this **Federal Register**, the EPA is approving the State's SIP submittal as a direct rule without prior proposal because the Agency views this as noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no relevant adverse comments are received in response to this action no further activity is contemplated. If the EPA receives relevant adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. The EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time.

For additional information, see the direct final rule which is located in the rules section of this **Federal Register**.

Dated: November 26, 2018.

Anne Idsal,

Regional Administrator, Region 6.

[FR Doc. 2018–26297 Filed 12–3–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R01–OAR–2018–0771; FRL–9987–00–Region 1]

Air Plan Approval; Massachusetts; Air Emissions Inventory, Emissions Statements, Source Registration, and Emergency Episode Planning Provisions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve State Implementation Plan (SIP) revisions submitted by the Commonwealth of Massachusetts. The revisions establish a 2011 base year emissions inventory, an emissions statement certification, revisions to an existing stationary source registration program, and requirements to be undertaken during air pollution emergencies. This action is being taken under the Clean Air Act.

DATES: Written comments must be received on or before January 3, 2019.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R01–OAR–2018–0771 at *https://www.regulations.gov,* or via email to *mcconnell.robert@epa.gov.* For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* For either manner of submission, the EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.* Publicly available docket materials are available at *https://www.regulations.gov* or at the U.S. Environmental Protection Agency, EPA Region 1 Regional Office, Office of Ecosystem Protection, Air Quality Planning Unit, 5 Post Office Square—Suite 100, Boston, MA. EPA requests that if at all possible, you contact the contact listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: Bob McConnell, Environmental Engineer, Air Quality Planning Unit, Air Programs Branch (Mail Code OEP05–02), U.S. Environmental Protection Agency, Region 1, 5 Post Office Square, Suite 100, Boston, Massachusetts, 02109–3912; (617) 918–1046; *mcconnell.robert@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document whenever ''we,'' ''us,'' or ''our'' is used, we mean EPA. The term ''the Commonwealth'' refers to the State of Massachusetts.

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I. Background

On March 12, 2008, the EPA revised both the primary and secondary NAAQS for ozone to a level of 0.075 parts per million (ppm) (annual fourth-highest daily maximum 8-hour average concentration, averaged over three years) to provide increased protection of public health and the environment (73 FR 16436, March 27, 2008). The 2008 ozone NAAQS retains the same general form and averaging time as the 0.08 ppm NAAQS set in 1997, but is set at a more protective level. Under the EPA's regulations at 40 CFR part 50, the 2008 8-hour ozone NAAQS is attained when the 3-year average of the annual fourth highest daily maximum 8-hour average ambient air quality ozone concentrations is less than or equal to 0.075 ppm. *See* 40 CFR 50.15.

Effective July 20, 2012, the EPA designated as nonattainment any area that was violating the 2008 8-hour ozone NAAQS based on the three most recent years (2008–2010) of air monitoring data (77 FR 30088, May 21, 2012). Within that rulemaking, Dukes County in Massachusetts was designated as a marginal ozone nonattainment area. Pursuant to section 182(a) of the Clean Air Act (CAA), marginal ozone nonattainment areas are required to submit a number of SIP revisions, including, pursuant to section 182(a)(1), an emissions inventory containing actual emission estimates from all sources, and, pursuant to section 182(a)(3)(B), an emissions statement program to collect actual emissions data from certain industrial sources within the state. Massachusetts accomplishes the latter by means of requirements within title 310 of the Code of Massachusetts Regulations (CMR), specifically, within 310 CMR 7.12, Source Registration.

Each time EPA revises a NAAQS, states are required by section 110(a)(2) to submit a certification that their SIP contains the necessary requirements to carry out all the state's obligations under the CAA. These SIPs are referred to as infrastructure SIPs, and EPA conditionally approved several aspects of Massachusetts' infrastructure SIPs for the 1997 ozone, 2008 ozone, and 2010 SO_2 NAAQS. *See* 81 FR 93627 (December 21, 2016). On February 9, 2018, Massachusetts submitted 310 CMR 8.00, *The Prevention and/or Abatement of Air Pollution Episode and Air Pollution Incident Emergencies,* to satisfy one of the conditions within EPA's December 21, 2016, final rule.

II. Description and Evaluation of Commonwealth's Submittals

A. Emissions Statement Certification

EPA's implementation rule for the 2008 ozone NAAQS, herein referred to as the 2008 ozone rule, was published in the **Federal Register** on March 6, 2015. *See* 80 FR 12264. The 2008 ozone rule notes than many areas that were nonattainment for the 2008 ozone NAAQS had previously adopted an emissions statement reporting program due to being nonattainment for a prior ozone NAAQS. For these areas, the 2008 ozone rule indicates that the state should review its existing rule to see whether it still meets the requirements of section 182(a)(3)(B) of the CAA, and if the state determines that it does, the state may submit a SIP revision certification to that effect to meet this obligation for purposes of the 2008 ozone NAAQS.

On February 9, 2018, Massachusetts submitted an emissions statement certification as a SIP revision request. The submittal notes that Massachusetts had previously adopted an emissions statement program pursuant to obligations it had under the one-hour ozone standard, and that EPA approved that program into the Massachusetts SIP on March 24, 1996. *See* 61 FR 11556. Massachusetts reviewed its current set of air pollution reporting requirements and confirmed that pursuant to its authority under 310 CMR 7.12, Source Registration, all stationary sources of volatile organic compounds (VOCs) and/or nitrogen oxides (NO_X) that emit 25 tons or more per year of those pollutants are required to report their emissions to the Commonwealth, along with a certification as to the accuracy of the reported emissions. EPA has approved 310 CMR 7.12 into the Massachusetts SIP, most recently on April 24, 2014. *See* 79 FR 22774. Emissions from smaller stationary sources that emit less than 25 tons per year of VOC and/or NO_X are inventoried as area sources within emissions inventories prepared by the Commonwealth, such as the 2011 emissions inventory that is described in section II.B of this proposal. Given the above, we propose to approve Massachusetts' emissions statement

certification for purposes of the 2008 ozone NAAQS.

B. 2011 Base Year Emissions Inventory

CAA section 172(c)(3) requires that each SIP include a ''comprehensive, accurate, current inventory of actual emissions from all sources of the relevant pollutant or pollutants in [the] area. . . .'' In requiring an accounting of actual emissions from all sources of the relevant pollutants in the area, this section provides for the ''base year'' inventory to include all emissions that contribute to the formation of a particular NAAQS pollutant. Additionally, for the 2008 ozone NAAQS, EPA's March 6, 2015, ozone rule recommended 2011 be used as the base year.

On February 9, 2018, the Commonwealth submitted to EPA an emissions inventory of ozone precursors for 2011 as a SIP revision request. The inventory was submitted to meet the CAA section 182(a)(3)(A) obligation to develop a base year inventory. Massachusetts conducted a public comment process on the inventory which concluded on February 2, 2018. The inventories include emission estimates in tons per summer day and represent emissions estimates from stationary and mobile source categories during a typical summer day when ozone formation is highest. The ozone emissions inventory catalogs NO_X and VOC emissions because these pollutants are precursors to ozone formation. The Commonwealth's 2011 emissions inventory contains emission estimates for each county in the Commonwealth.[1]

The Massachusetts 2011 emission inventory documents the procedures used to estimate emissions from individual stationary sources, referred to as point sources. The inventory describes how individual industrial sources with emissions as low as 1 ton per year submit, by means of the Massachusetts Department of Environmental Protections (MA–DEPs) ''eDEP'' online application, information on fuel use, materials use, air pollution control equipment, and air emissions. The Commonwealth transmitted its 2011 point source air emissions data to EPA's National Emissions Inventory (NEI) database in accordance with the requirements found within 40 CFR part 51, subpart A.

Area source emission estimates are made for small, stationary sources of air pollution that do not emit much individually but do have significant emissions collectively. Examples include gasoline stations, automobile refinishing shops, and architectural and industrial maintenance coatings. The Commonwealth's area source emissions inventory identifies the source categories for which the Commonwealth relied upon EPA's estimates, provides information on any adjustments made to EPA estimates, and notes which categories' emission estimates were prepared by the Commonwealth. The inventory also explains how double counting was avoided between emissions from facilities inventoried as individual point sources and area source emission estimates.

Massachusetts relied upon emission estimates obtained from EPA's Motor Vehicle Emissions Simulator (MOVES) model to calculate emissions for on-road and most non-road mobile source sectors. The Commonwealth provided the model with local activity inputs including vehicle miles traveled (VMT) provided by the Massachusetts Department of Transportation, and data on vehicle type from the Massachusetts Registry of Motor Vehicles. Massachusetts also provided inputs to the model for meteorological parameters and fuel characteristics.

We propose to find that the air emission estimates for these sources were adequately accounted for in the Commonwealth's 2011 emissions inventory. The methodology used to calculate emissions for each source category followed relevant EPA guidance, most notably the July 2017 guidance entitled ''Emissions Inventory Guidance for Implementation of Ozone and Particulate Matter National Ambient Air Quality Standards and Regional Haze Regulations.'' Additionally, the Commonwealth used appropriate, documented emission factors, or relied on emission estimates prepared for EPA's National Emissions Inventory. Furthermore, the inventory submittal is sufficiently documented as to the techniques used to prepare the emission estimates.

Table 1 shows the emissions by source category, in tons per summer day (tpsd), from the 2011 base year emission inventory for Dukes County.

TABLE 1—EMISSIONS INVENTORY SUMMARY FOR DUKES COUNTY

[Tons/summer day]

	Dukes County	
Source	VOC	NO_X
Point	0.09	0.67
Area	1.20	0.06
Nonroad	4.01	6.47
Onroad	0.10	0.21
Biogenic	3.31	0.19
Totals	8.71	7.00

Additional details regarding the Massachusetts emissions inventory are included in the Commonwealth's 2011 Periodic Emissions Inventory document, which is available in the docket for this proposed rulemaking. The inventories are based on the most current and accurate information available to the Commonwealth at the time the inventories were being developed. Additionally, the inventories comprehensively address all source categories in the Commonwealth's nonattainment area and were developed consistent with the relevant EPA inventory guidance. For these reasons, we are proposing to approve the 2011 base year emissions inventory for Dukes county into the Massachusetts SIP as meeting the requirements of CAA section 172(c)(3).

[1] Although the Massachusetts 2011 emissions inventory contains emissions estimates for all counties in the Commonwealth, pursuant to Section 182(a)(3)(A), only an inventory for the Commonwealth's marginal nonattainment area, Dukes county, was required.

C. Stationary Source Registration Requirements

On May 10, 2018, Massachusetts submitted updates to 310 CMR 7.12, Source Registration, which provides the applicability levels and reporting requirements for industrial sources to use to report air emissions data to the Commonwealth. The revisions include an exemption for small combustion sources whose only emissions come from burning oil or gas, a revision to the annual reporting due date for some filers, and a lowered reporting threshold for lead.

The Commonwealth's previous reporting thresholds had been quite low, requiring approximately 2,300 individual facilities to report their air emissions to the Commonwealth, and was considerably lower than required by the federal reporting guidelines found within 40 CFR part 51, subpart A, Air Emissions Reporting Requirements. Subpart A essentially only requires sources considered major for Title V permitting purposes to report their emissions to the state. The Commonwealth's reporting requirements will continue to be more stringent than what is minimally required by 40 CFR part 51, subpart A, after accounting for the exemption. Additionally, emissions from the small, exempted sources will be covered within the area source portion of the emission inventories that the Commonwealth periodically prepares.

Subpart A's air emissions reporting requirements directs states to report their data to EPA by December 31 of the year following that in which the emissions occurred. To accomplish this, states set reporting deadlines generally in the springtime for sources to report their emissions to the state. Massachusetts has moved up some of its reporting deadlines for sources reporting to the Commonwealth in order to provide the Commonwealth with more time to review the submitted information and prepare electronic files for submittal to EPA.

In February of 2015, EPA made a number of changes to the air emissions reporting requirements of 40 CFR part 51, subpart A, including a lowering of the threshold for sources emitting lead from 5 tons per year to 0.5 tons per year. The Commonwealth is, therefore, modifying its lead reporting threshold to match the new federal reporting threshold of 0.5 tons per year.

In addition to the above, Massachusetts made several other minor updates and clarifications to 310 CMR 7.12. These changes, as well as additional details regarding the changes described above, are available within the Commonwealth's SIP submittal which is available in the docket for this action. We are proposing approval of these revisions for the reasons stated above.

D. Emergency Episode Planning Provisions

On February 9, 2018, Massachusetts submitted 310 CMR 8.00, *The Prevention and/or Abatement of Air Pollution Episode and Air Pollution Incident Emergencies,* to EPA as a SIP revision request. The Commonwealth submitted this regulation in response to EPA's December 21, 2016, final rule, which conditionally approved one aspect of the Commonwealth's Infrastructure SIP submissions for CAA section 110(a)(2)(G) for the 1997 ozone, 2008 ozone, and 2010 SO_2 NAAQS. *See* 81 FR 93629. Specifically, EPA conditionally approved the submissions for the contingency plan requirements of section 110(a)(2)(G). Additional details regarding EPA's rationale for requiring that the Commonwealth revise its SIP to address this issue are explained within our July 20, 2016, Notice of Proposed Rulemaking. *See* 81 FR 47133.

We propose that 310 CMR 8.00 satisfies the contingency plan requirements of CAA section 110(a)(2)(G) and implementing regulations at 40 CFR part 51, subpart H. More specifically, 310 CMR 8.00 is modeled on EPA's example regulations for emergency contingency plans at 40 CFR part 51, appendix L, and specifies episode criteria and control actions for air pollution alerts, warnings, and emergencies to prevent ambient pollution concentrations from reaching significant harm levels, thereby satisfying 40 CFR 51.151 and 51.152(a)(1) and (3). *See* 310 CMR 8.03 and 8.07. Section 8.03 also specifically provides for acquisition of forecasts of atmospheric stagnation conditions from the National Weather Service (NWS), thereby satisfying 40 CFR 51.152(b)(1). *See* 310 CMR 8.03(1)(a). Moreover, the Commonwealth, as a matter of practice, posts on the internet daily forecasted ozone and fine particle levels through the EPA AirNow and EPA EnviroFlash systems. Information regarding these two systems is available on EPA's website at *https://www.airnow.gov.* Notices are sent out to EnviroFlash participants when levels are forecast to exceed the current 8-hour ozone and fine particle standards. In addition, when levels are expected to exceed these standards in Massachusetts, the media are alerted via a press release, and the NWS is alerted to issue an Air Quality Advisory through the normal NWS weather alert system. *See also* 310 CMR 8.05(4). These actions are similar to the notification and communication requirements of 40 CFR 51.152(a)(2), (b)(1), and (b)(3). Finally, Massachusetts' emergency contingency plan satisfies 40 CFR 51.152(b)(2) insofar as 310 CMR 8.22 authorizes state and local police, fire department officials, and public health officials to enforce compliance with applicable emergency control action requirements.

For these reasons, EPA proposes that 310 CMR 8.00 satisfies the requirements of CAA § 110(a)(2)(G) and 40 CFR part 51, subpart H. Consequently, we propose to approve 310 CMR 8.00 into the Massachusetts SIP and to convert to full approvals the previous conditional approvals for the contingency plan requirements of CAA § 110(a)(2)(G) for the 1997 ozone, 2008 ozone, and 2010 SO_2 NAAQS infrastructure SIPs.

III. Proposed Action

EPA is proposing to approve SIP revisions submitted by the Commonwealth of Massachusetts representing a 2011 base year emissions inventory, an emissions statement certification, revisions to 310 CMR 7.12, Source Registration, and 310 CMR 8.00, *The Prevention and/or Abatement of Air Pollution Episode and Air Pollution Incident Emergencies.* EPA also proposes to convert to full approvals the previous conditional approvals for the contingency plan requirements of CAA § 110(a)(2)(G) for the 1997 ozone, 2008 ozone, and 2010 SO_2 NAAQS infrastructure SIPs. EPA is soliciting public comments on the issues discussed in this document or on other relevant matters. These comments will be considered before taking final action. Interested parties may participate in the Federal rulemaking procedure by submitting written comments to this proposed rulemaking by following the instructions listed in the **ADDRESSES** section of this **Federal Register**.

IV. Incorporation by Reference

In this rule, the EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is proposing to incorporate by reference 310 CMR 7.12, Source Registration, discussed in section 2.C. of this preamble, and 310 CMR 8.00, *The Prevention and/or Abatement of Air Pollution Episodes and Air Pollution Incident Emergencies,* discussed in section 2. D. of this preamble. The EPA has made, and will continue to make, these documents generally available

through *https://www.regulations.gov* and at the EPA Region 1 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

V. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this proposed action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this proposed action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- This action is not expected to be an Executive Order 13771 regulatory action because this action is not significant under Executive Order 12866;
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

List of Subjects in 40 CFR Part 52

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

Dated: November 28, 2018.

Alexandra Dunn,

Regional Administrator, EPA Region 1.

[FR Doc. 2018–26283 Filed 12–3–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 147

[EPA–HQ–OW–2018–0669; FRL–9987–17–OW]

State of North Dakota Underground Injection Control Program; Class I, III, IV, and V Primacy Revisions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) proposes to approve an application from the State of North Dakota under the Safe Drinking Water Act (SDWA) to revise the State's existing Underground Injection Control (UIC) program for Class I, III, IV, and V injection wells located within the State, except those in Indian country. North Dakota is revising its UIC Class I, III, IV, and V program regulations to transfer primary enforcement authority from the North Dakota Department of Health to the North Dakota Department of Environmental Quality.

DATES: Comments must be received on or before January 8, 2019. A public hearing is scheduled to be held on January 8, 2019 from 2 p.m. to 5 p.m. and 6 p.m. to 8 p.m., central daylight time. The hearing will be held only if requests are received within 30 days of publication. *If no requests are received by* January 3, 2019, *the hearing will be cancelled.* Confirmation or cancellation of the public hearing will be announced on January 3, 2019, on the EPA Region VIII's website at: *https://www.epa.gov/uic/underground-injection-control-epa-region-8-co-mt-nd-sd-ut-and-wy.*

ADDRESSES: *Hearing location:* North Dakota Department of Health's fourth floor Conference Room, 918 East Divide Avenue, Bismarck, North Dakota. Requests for a public hearing may be mailed or emailed to: Omar Sierra-Lopez, U.S. Environmental Protection Agency, Region VIII, Mail Code: 8WP–SUI, 1595 Wynkoop Street, Denver, Colorado 80202–1129, or *sierra-lopez.omar@epa.gov.*

Docket Review and Comments Requested: The application and supplemental docket materials are available electronically on *https://www.regulations.gov,* identified by Docket ID No. EPA–HQ–OW–2018–0669. Submit your comments to the *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or withdrawn. The EPA may publish any comments received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system).

For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Kyle Carey, Drinking Water Protection Division, Office of Ground Water and Drinking Water (4606M), U.S. Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 564–2322; fax number: (202) 564–3754; email address: *carey.kyle@epa.gov,* or Omar Sierra-Lopez, Underground Injection Control Unit, Safe Drinking Water Program, Office of Water Protection (8WP–SUI), U.S. Environmental Protection Agency, Region VIII, 1595 Wynkoop Street,

Denver, Colorado 80202–1129; telephone number: (303) 312–7045; fax number: (303) 312–7517; email address: *sierra-lopez.omar@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

The EPA approved North Dakota's UIC program as meeting the requirements for primary enforcement responsibility (primacy) for Class I, III, IV, and V injection wells, under section 1422 of the Safe Drinking Water Act, on September 21, 1984. The State is revising its UIC Class I, III, IV, and V program statutes and regulations to transfer this authority from the North Dakota Department of Health to the North Dakota Department of Environmental Quality.

II. Legal Authorities

These regulations are being promulgated under authority of sections 1422 and 1450 of the SDWA, 42 U.S.C. 300h–1 and 300j–9.

A. Revision of State UIC Programs

As required by section 1421 of the SDWA, the EPA promulgated minimum requirements in the *Code of Federal Regulations* (CFR) at 40 CFR part 145, for effective State UIC programs, to prevent underground injection activities that endanger underground sources of drinking water (USDWs). Under section 1422 of the SDWA, once the EPA approves a State UIC program, the State has primary enforcement responsibility for underground water sources. A State may revise its UIC program as provided under 40 CFR 145.32(a) and by following the procedures described under 40 CFR 145.32(b), which require the State to submit a modified program description, an Attorney General's statement, a Memorandum of Agreement, or other such documentation as the EPA determines to be necessary under the circumstances (40 CFR 145.32(b)(1)). States with approved programs are required to notify the EPA whenever they propose to transfer all or part of the approved State agency to any other State agency and to identify any new division of responsibilities amongst the agencies involved. Organizational charts required in the State's original primacy approval package must be revised and resubmitted. The new agency is not authorized to administer the program until approval by the Administrator (40 CFR 145.32(c)).

All revisions to the UIC program would be federally enforceable as of the effective date of the EPA's approval of the respective revision and 40 CFR part 147 codification. The State plans to rely on the date when the EPA signs the final notice for purposes of notifying the State legislature that the EPA has approved these revisions, which will provide for the transfer authority from the North Dakota Department of Health to the North Dakota Department of Environmental Quality (NDDEQ) to be effective under State law. Thus, prior to the effective date of this approval, the State intends to take the necessary additional steps as specified in S.L. 2017, ch. 199, Section 1, to ensure that the NDDEQ rules would become federally enforceable on the effective date of the EPA's approval and codification of the approved program in 40 CFR part 147.

Consistent with the EPA Guidance 16, the EPA considers State-initiated program revisions to transfer all or part of any program from the approved authority to another State agency as substantial program revisions. Under the EPA regulations, this means there is an opportunity for public comment and to request a public hearing (40 CFR 145.32(b)(2)).

B. Indian Country

The EPA's approval of North Dakota's application to transfer its SDWA UIC Class I, III, IV, and V primary enforcement authority from the North Dakota Department of Health to the North Dakota Department of Environmental Quality does not extend to Indian lands. Pursuant to the EPA's UIC regulations at 40 CFR 144.3, Indian lands ''means 'Indian country' as defined in 18 U.S.C. 1151.'' As defined in 18 U.S.C. 1151, Indian country generally includes lands within the exterior boundaries of the following Indian reservations located within North Dakota: The Fort Berthold Indian Reservation, The Spirit Lake Reservation, The Standing Rock Sioux Reservation, and The Turtle Mountain Reservation; any land held in trust by the United States for an Indian tribe; and any other areas that are Indian country within the meaning of 18 U.S.C. 1151. The EPA, or eligible Indian tribes, as appropriate, will retain responsibilities under the SDWA UIC program for Class I, III, IV, and V injection wells in Indian country.

III. North Dakota's Application

A. Notice of Completion

On September 18, 2018, the EPA received a complete program revision package from the State of North Dakota, requesting approval of its revised UIC regulations for Class I, III, IV, and V injection wells, to transfer primary enforcement authority from the North Dakota Department of Health to the North Dakota Department of Environmental Quality. The EPA has determined the application contains all the required elements; the application and supplemental materials are available electronically at *https://www.regulations.gov;* and a copy of the application can be accessed for inspection and copying at: The EPA Region VIII, 1595 Wynkoop Street, Denver, Colorado 80202–1129, by contacting Omar Sierra-Lopez at: Telephone number: (303) 312–7045; fax number: (303) 312–7517; email address: *sierra-lopez.omar@epa.gov.* Public comments are requested, and a public hearing will be held if requests are received within 30 days of publication (see **ADDRESSES** for further information on how to request a public hearing).

The UIC program revision package from the State of North Dakota includes revised versions of: (1) The description of the State's UIC program (40 CFR 145.23); (2) copies of all applicable State statutes, regulations, and forms (40 CFR 145.22(a)(5)); (3) the Attorney General's statement that the State has adequate legal authority to carry out the program described and to meet the requirements of 40 CFR part 145; and (4) the Memorandum of Agreement between the State of North Dakota and the EPA's Region VIII Administrator (40 CFR 145.25).

B. Public Participation Activities Conducted by the State of North Dakota

On April 12, 2018, the North Dakota Department of Environmental Quality provided public notice of its intent to amend and adopt North Dakota's 1422 Underground Injection Control Rules. The public notice was published in 52 North Dakota newspapers. Written comments on the proposed rule changes were accepted between April 12, 2018 and May 31, 2018; no comments were received. A public hearing regarding the UIC rules was held on March 21, 2018; the hearing was unattended.

C. Public Participation Activities Conducted by the EPA

On December 4, 2018, a public notice announcing this proposed approval, request for public comment, and notice of a public hearing to be held on January 8, 2019, was published in the Bismarck Tribune and posted to the EPA Region VIII's website at: *https://www.epa.gov/uic/underground-injection-control-epa-region-8-co-mt-nd-sd-ut-and-wy.* Confirmation or cancellation of the public hearing will be announced on January 3, 2019 and on the EPA Region VIII's website at: *https://www.epa.gov/uic/underground-injection-control-epa-*

region-8-co-mt-nd-sd-ut-and-wy. For information regarding the public hearing, including a request to hold a hearing, please contact Omar-Sierra Lopez, U.S. Environmental Protection Agency, Region VIII, Mail Code: 8WP–SUI, 1595 Wynkoop Street, Denver, Colorado 80202–1129, or *sierra-lopez.omar@epa.gov.*

IV. The EPA's Proposed Action

A. What is the EPA proposing?

In this action, the EPA is proposing to approve the State of North Dakota's application to transfer its Class I, III, IV, and V primary enforcement authority from the North Dakota Department of Health to the North Dakota Department of Environmental Quality and to make conforming changes to its regulations to reflect such transfer. Regulations under 40 CFR part 147 set forth the applicable UIC programs for each of the States. This rule would update 40 CFR part 147 subpart JJ to reflect the transfer of authority.

Support of this proposed approval is part of the public record in the EPA's Docket No. EPA–HQ–OW–2018–0669. When finalized, this action will amend 40 CFR part 147 Subpart JJ to incorporate by reference the revised EPA-approved State statutes and regulations. The EPA will continue to administer its UIC program for Class I, III, IV, and V injection wells in Indian country.

The EPA will continue to oversee the State of North Dakota's administration of UIC Class I, III, IV, V and VI programs as authorized under the SDWA. Part of the EPA's oversight responsibility will require State quarterly reports of non-compliance and annual UIC performance reports pursuant to 40 CFR 144.8. The Memorandum of Agreement between the EPA and the State of North Dakota, signed by the Regional Administrator on September 18, 2018, provides the EPA with the opportunity to review and comment on all draft permits.

B. What codification decisions is the EPA proposing in this rule?

In this rule, the EPA is proposing to finalize the federal regulatory text that incorporates by reference the federally authorized North Dakota UIC program for Class I, III, IV, and V injection wells, except those in Indian country. In accordance with the requirements of 1 CFR 51.5, we are proposing to finalize the incorporation by reference of the North Dakota rules described in the amendments to 40 CFR part 147 set forth below. The EPA has made, and will continue to make, these documents generally available through *www.regulations.gov* and at the U.S. Environmental Protection Agency, Region VIII, Library 2nd Floor, 1595 Wynkoop Street, Denver, Colorado 80202–1129.

The EPA will revise the binder at 40 CFR 147.1751 that contains the EPA-approved North Dakota Statutes and Regulations for Well Classes I, III, IV, V, and VI. This binder will be incorporated by reference into 40 CFR 147.1751. The EPA will also revise the table listing the EPA-approved North Dakota Statutes and Regulations for Well Classes I, III, IV, V, and VI in 40 CFR 147.1751. Section 147.1751 also references the Memorandum of Agreement, the statement of legal authority (the Attorney General's Statement), and the Program Description, which are approved as part of the UIC program authorized under the SDWA.

V. Statutory and Executive Order Reviews

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

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

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

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

C. Paperwork Reduction Act (PRA)

This action does not impose any new information collection burden under the PRA. OMB has previously approved the information collection activities contained in the existing regulations and has assigned OMB control number 2040–0042. Reporting or record-keeping requirements will be based on the State of North Dakota UIC Regulations, and the State of North Dakota is not subject to the PRA.

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. In making this determination, the impact of concern is any significant adverse economic impact on small entities. An agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, has no net burden or otherwise has a positive economic effect on the small entities subject to the rule. This rule does not impose any requirements on small entities as this rule approves the State of North Dakota's UIC program revisions. We have therefore concluded that this action will have no net regulatory burden for all directly regulated small entities.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments or the private sector. The EPA's approval of the State of North Dakota's program revisions will not constitute a federal mandate because there is no requirement that a State establish UIC regulatory programs and because the program is a State, rather than a federal program.

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. This action contains no federal mandates for tribal governments and does not impose any enforceable duties on tribal governments. Thus, Executive Order 13175 does not apply to this action.

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

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

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

This rulemaking does not involve technical standards.

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

The EPA has determined that this action is not subject to Executive Order 12898 (59 FR 7629, February 16, 1994) because it does not establish an environmental health or safety standard. This action will simply provide that the State of North Dakota is transferring its primary enforcement authority for its Class I, III, IV, and V wells, pursuant to which the State of North Dakota will be implementing and enforcing a State UIC regulatory program that is as stringent as the existing federal program.

List of Subjects in 40 CFR Part 147

Environmental protection, Indian lands, Incorporation by reference, Intergovernmental relations, Reporting and recordkeeping requirements, Water supply.

Dated: November 20, 2018.

Andrew R. Wheeler,

Acting Administrator.

For the reasons set out in the preamble, the Environmental Protection Agency is proposing to amend 40 CFR part 147 as follows:

PART 147—STATE, TRIBAL, AND EPA-ADMINISTERED UNDERGROUND INJECTION CONTROL PROGRAMS

■ 1. The authority citation for part 147 is revised to read as follows:

Authority: 42 U.S.C. 300f *et seq.;* and 42 U.S.C. 6901 *et seq.*

■ 2. Amend § 147.1751 by:

■ a. Revising the introductory text and paragraph (a);

■ b. Revising paragraph (b)(2) and removing paragraphs (b)(3) and (b)(4);

■ c. Revising paragraphs (c), (d), (e), (f), (g), (h); and

■ e. Adding paragraph (i).

The revisions and addition read as follows:

§ 147.1751 State-administered program—Class I, III, IV, V and VI wells.

The UIC Program for Class I, III, IV, and V wells in the State of North Dakota, except those located on Indian lands, as defined under 40 CFR 144.3, is the program administered by the North Dakota Department of Environmental Quality, approved by the EPA pursuant to section 1422 of the SDWA. Notification of this approval was published in the **Federal Register** on [date of publication of the final rule in the **Federal Register**]; the effective date of this program is (date to be determined at time of final decision but will be no less than 30 days after publication in the **Federal Register**). The UIC Program for Class VI wells in the State of North Dakota, except those located on Indian lands, is the program administered by the North Dakota Industrial Commission (NDIC), approved by the EPA pursuant to section 1422 of the SDWA. Notification of this approval was published in the **Federal Register** on April 24, 2018; the effective date of the NDIC UIC Class VI program is April 24, 2018. The State-administered UIC programs for Classes I, III, IV, V, and VI consist of the following elements, as submitted to the EPA in the State's program applications.

(a) The requirements set forth in the State statutes and regulations cited in the binder entitled ''EPA-Approved North Dakota SDWA § 1422 Underground Injection Control Program Statutes and Regulations for Well Classes I, III, IV, V and VI'', dated December 2018, and Table 1 to paragraph (a) of this section are incorporated by reference and made a part of the applicable UIC program under the SDWA for the State of North Dakota. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of the North Dakota regulations that are incorporated by reference in this paragraph (a) may be inspected at the U.S. Environmental Protection Agency, Region VIII, Library 2nd Floor, 1595 Wynkoop Street, Denver, Colorado 80202–1129; Water Docket, EPA Docket Center (EPA/DC), EPA WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC 20460; and the National Archives and Records Administration (NARA). If you wish to obtain materials from the EPA Regional Office, please call (303) 312–1226; for materials from a docket in the EPA Headquarters Library, please call the Water Docket at (202) 566–2426. For information on the availability of this material at NARA, call (202) 741–6030, or go to *www.archives.gov/federal-register/cfr/ibr-locations.html.*

TABLE 1 TO PARAGRAPH (A) EPA-APPROVED NORTH DAKOTA SDWA § 1422 UNDERGROUND INJECTION CONTROL PROGRAM STATUTES AND REGULATIONS FOR WELL CLASSES I, III, IV, V AND VI

State citation	Title/subject	State effective date	EPA approval date
North Dakota Century Code Sections 38–12–01—38–12–03	Regulation, Development and Production of Subsurface Minerals.	1980	September 21, 1984, 49 FR 37066.
North Dakota Century Code Sections 61–28–02 and 61–28–06.	Control, Prevention and Abatement of Pollution of Surface Waters.	1989	March 6, 1991, 56 FR 9418.
North Dakota Century Code Sections 61–28.1–01—61–28.1–12.	Safe Drinking Water Act	2018	[insert FR citation of final rule].
North Dakota Administrative Code Sections 33.1–25–01–01—33.1–25–01–18.	Underground Injection Control Program.	2018	[insert FR citation of final rule].
North Dakota Administrative Code Sections 43–02–02–01–43–02–02–50.	Subsurface Mineral Exploration and Development.	1986	March 6, 1991, 56 FR 9418.
North Dakota Administrative Code Sections 43–02–02.1–01—43–02–02.2–19.	Underground Injection Control Program.	1984	September 21, 1984, 49 FR 37066.
North Dakota Century Code Sections 38–22–01—38–22–23	Carbon Dioxide Underground Storage.	2009	April 24, 2018, 83 FR 17761.
North Dakota Administrative Code Sections 38–08–16—38–08–17.	Control of Oil and Gas Resources.	2013	April 24, 2018, 83 FR 17761.

TABLE 1 TO PARAGRAPH (A) EPA-APPROVED NORTH DAKOTA SDWA § 1422 UNDERGROUND INJECTION CONTROL PROGRAM STATUTES AND REGULATIONS FOR WELL CLASSES I, III, IV, V AND VI—Continued

State citation	Title/subject	State effective date	EPA approval date
North Dakota Administrative Code Sections 43–05–01–01—43–05–01–20.	Geologic Storage of Carbon Dioxide.	2013	April 24, 2018, 83 FR 17761.

(b) * * *

(2) North Dakota Administrative Code Article 33–22 (Practice and Procedure) (1983).

(c) The Memorandum of Agreement for the Class I, III, IV, and V Underground Injection Control Program between EPA Region VIII and the North Dakota Department of Environmental Quality, signed by the EPA Regional Administrator on September 18, 2018.

(d) The statement of legal authority, ''Class I, III, IV, and V Underground Injection Control Program, Attorney General's Statement,'' signed by the Assistant Attorney General of North Dakota on July 30, 2018, and ''Supplement to the Attorney General Statements Relating to Programs Being Transferred to the North Dakota Department of Environmental Quality'' signed by the Assistant Attorney General of North Dakota on October 23, 2018.

(e) The Class I, III, IV, and V Underground Injection Control Program Description and any other materials submitted as part of the program revision or as supplements thereto.

(f) The Memorandum of Agreement for the Class VI Underground Injection Control Program between EPA Region VIII and the North Dakota Industrial Commission, signed by the EPA Regional Administrator on October 28, 2013.

(g) The Memorandum of Understanding for Class VI between the North Dakota Industrial Commission, Department of Mineral Resources, Oil and Gas Division and the North Dakota Department of Health, Water Quality Division Related to the Underground Injection Control Program, signed on June 19, 2013.

(h) The statement of legal authority, ''Class VI Underground Injection Control Program, Attorney General's Statement,'' signed by the Attorney General of North Dakota on January 22, 2013.

(i) The Class VI Underground Injection Control Program Description and any other materials submitted as part of the program revision or as supplements thereto.

[FR Doc. 2018–25893 Filed 12–3–18; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 19 and 52

[FAR Case 2016–011; Docket No. 2016–0011, Sequence No. 1]

RIN 9000–AN35

Federal Acquisition Regulation: Revision of Limitations on Subcontracting

AGENCY: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Proposed rule.

SUMMARY: DoD, GSA, and NASA are proposing to amend the Federal Acquisition Regulation (FAR) to implement the final rule published by the Small Business Administration implementing section 1651 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2013, which revised and standardized the limitations on subcontracting, including the nonmanufacturer rule, that apply to small business concerns under FAR part 19 procurements.

DATES: Interested parties should submit comments to the Regulatory Secretariat Division at one of the addresses shown below on or before February 4, 2019 to be considered in the formulation of a final rule.

ADDRESSES: Submit comments in response to FAR Case 2016–011 by any of the following methods:

- *Regulations.gov: http://www.regulations.gov.*

Submit comments via the Federal eRulemaking portal by entering ''FAR Case 2016–011'' under the heading ''Enter Keyword or ID'' and selecting ''Search.'' Select the link ''Comment Now'' that corresponds with ''FAR Case 2016–011.'' Follow the instructions provided on the screen. Please include your name, company name (if any), and ''FAR Case 2016–011'' 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 ''FAR case 2016–011'' 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 *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: For clarification of content, contact Ms. Mahruba Uddowla, Procurement Analyst, at 703–605–2868. For information pertaining to status or publication schedules, contact the Regulatory Secretariat Division at 202–501–4755. Please cite ''FAR Case 2016–011.''

SUPPLEMENTARY INFORMATION:

I. Background

DoD, GSA, and NASA are proposing to revise the FAR to implement regulatory changes made by the SBA in its final rule published in the **Federal Register** at 81 FR 34243 on May 31, 2016. SBA's final rule implements the statutory requirements of section 1651 of the NDAA for FY 2013 (15 U.S.C. 657s). Section 1651 revised and standardized the limitations on subcontracting, including the nonmanufacturer rule, that apply to small business concerns under FAR part 19 procurements. SBA's final rule became effective on June 30, 2016.

Prior to passage of section 1651 of the NDAA for FY 2013, the limitations on subcontracting and the nonmanufacturer rule were inconsistent across the small business programs. For example, for awards under some small business programs, the prime contractor was required to perform a certain percentage of work itself, whereas under other programs, the prime contractor could include subcontracts to ''similarly situated entities'' in the percentage of work it performed. The method for

calculating compliance with the limitations on subcontracting also varied across small business programs.

Section 1651 of the NDAA for FY 2013 changed the focus of the limitations on subcontracting rules. Instead of requiring a percentage of work to be performed by a prime contractor, the limitations on subcontracting rules now limit subcontracting to a percentage of the overall award amount to be spent by the prime on subcontractors. As a result, the prime contractor no longer has to track the percentage of costs incurred that it spends performing work itself; it only has to track the percentage of the overall award amount (*i.e.,* contract price) that it spends on subcontractors. For small businesses, this change will reduce a substantial burden associated with tracking and demonstrating compliance with the limitations on subcontracting.

In addition, the percentage of the award amount that the prime contractor spends on subcontractors who are similarly situated entities is not considered subcontracted for purposes of compliance with the limitations on subcontracting. The statute and SBA's implementing regulations define ''similarly situated entity'' as a subcontractor that has the same small business program status as that which qualified the prime contractor for the award and that is considered small for the North American Industry Classification System (NAICS) code the prime contractor assigned to the subcontract the subcontractor will perform. Work performed by similarly situated entities is counted as if it were performed by the prime contractor in determining compliance with the limitations on subcontracting.

These important changes give small businesses greater flexibility on how they choose to comply with the limitations on subcontracting. Under the current FAR clauses, there is only one way for a small business to comply with the limitations: It must spend the required amount on work performed in-house. As proposed in this rule, there will be more than one way to comply with the limitations, and the small business will be able to choose how to comply. For example, a small business that is in compliance with the existing FAR clause will be able to comply with the new limitations on subcontracting. Alternatively, a small business can decide to subcontract more than it did before, and it will be able to comply with the new limitations where it would not have complied before, as long as the amount spent on subcontracts does not exceed 50 percent of the price of the prime contract, for other than construction contracts; different percentages apply for construction contracts. Finally, a small business can decide to subcontract work to a similarly situated entity, in any amount of its choosing, that it previously subcontracted or performed in-house, and it will be in compliance with the new limitations on subcontracting because work performed by a similarly situated entity is counted as if it were performed by the prime contractor. In short, the new rules will make it easier for prime contractors to do business with Federal agencies by giving them more, and less burdensome, options for pursuing and winning larger contracts than before.

SBA's final rule specified that similarly situated entities must also comply with the limitations on subcontracting. Requiring prime contractors and their similarly situated entity subcontractors to comply with the limitations on subcontracting will ensure that the benefits from small business and socioeconomic set-aside and sole-source contracts flow to the intended parties. SBA's final rule also provided updated guidance on the nonmanufacturer rule, including the process for obtaining waivers to the nonmanufacturer rule and the proper application of these waivers to procurements.

The SBA rule also clarified that the limitations on subcontracting and the nonmanufacturer rule do not apply to small business set-aside contracts valued at or below $150,000, but do apply to set-aside and sole-source awards under the other small business programs regardless of dollar value. This proposed rule reflects the same clarification. Thus, this rule provides that the limitations on subcontracting and the nonmanufacturer rule clauses are prescribed for small business set-asides that are expected to exceed $150,000, and for requirements set aside for or awarded on a sole-source basis to 8(a) participants, Historically Underutilized Business Zone (HUBZone) small business, service-disabled veteran-owned small business (SDVOSB), economically disadvantaged women-owned small business (EDWOSB), or Women-Owned Small Business(WOSB) concerns eligible under the WOSB program.

II. Discussion and Analysis

This proposed rule would amend FAR parts 19 and 52. This rule implements the revised and standardized limitations on subcontracting through a single FAR clause applicable to every small business program, instead of continuing to implement through multiple FAR clauses that were specific to particular small business programs. Similarly, this proposed rule creates a new FAR clause implementing the revised and standardized the nonmanufacturer rule across all the small business programs.

These changes are summarized in the following paragraphs:

A. *Nonmanufacturer rule implementation.* Paragraph (f) in section 19.102 is deleted, and 19.502–2 and 19.1303(e) are revised to remove the outdated nonmanufacturer rule guidance. New section 19.103, Nonmanufacturer rule, provides full and updated guidance on the application of the nonmanufacturer rule, including the requirements associated with the nonmanufacturer rule and the circumstances and procedures related to waivers. This section clarifies that the nonmanufacturer rule does not apply to small business set-aside acquisitions at or below $150,000, but does apply to 8(a), HUBZone, SDVOSB, EDWOSB, and WOSB set-aside and sole-source acquisitions regardless of dollar value. Previous references to 19.102(f) at 19.303 and 19.1403 have been updated to refer to the new 19.103 section.

New clause 52.219–XX, Nonmanufacturer Rule, implements the requirements in solicitations and contracts. The prescription for this clause is added at 19.508(g). References to this prescription were added at 19.811–3(f), 19.1309(d), 19.1407(c), and 19.1507(d). The outdated nonmanufacturer rule has been removed from the clauses at 52.219–3, 52.219–6 and its Alternate I, 52.219–7 and its Alternate I, 52.219–18 and its Alternate II, 52.219–27, 52.219–29, and 52.219–30. The prescriptions have been removed from subparts 19.5 and 19.8 for the following clauses: Alternate I of 52.219–6, Alternate I of 52.219–7, and Alternate II of 52.219–18. However, paragraph (f) of the clause at 52.219–4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns, is not revised because the application of the nonmanufacturer rule to acquisitions in which the HUBZone price evaluation preference is used is still under review.

The following provisions and clause are updated to clarify when the size standard for nonmanufacturers applies: 52.204–8, 52.212–1, 52.219–1, and 52.219–28. Additionally, the definition of ''nonmanufacturer rule'' is deleted from 19.001.

B. *Limitations on subcontracting implementation.* The clause at 52.219–14, Limitations on Subcontracting, is revised to implement the updated limitations on subcontracting requirements in solicitations and

contracts. The prescription for this clause at 19.508(e) is revised to apply to all small business programs. References to this prescription were added at 19.1309(c), 19.1407(b), and 19.1507(c), and revised at 19.811–3(e). Additionally, the clause at 52.219–4 is revised to reflect the updated limitations on subcontracting.

The outdated limitations on subcontracting guidance is removed from the following clauses: 52.219–3, 52.219–27, 52.219–29, and 52.219–30. The following clauses have been deleted: Alternate I of 52.219–3 and Alternate I of 52.219–4. In addition, the prescriptions for these clauses at 19.1309 have been deleted. The outdated limitations on subcontracting text at 19.1308 is deleted.

Lastly, the definition of ''similarly situated entity'' is added to 19.001 to support the implementation of the updated limitations on subcontracting.

C. *Conforming changes.* The clause at 52.212–5 is revised to include 52.219–XX, Nonmanufacturer Rule, and to update the dates of clauses revised in this rule.

III. Applicability to Contracts at or Below the Simplified Acquisition Threshold and for Commercial Items, Including Commercially Available Off-the-Shelf Items

The Federal Acquisition Regulatory (FAR) Council has made the following preliminary determinations with respect to the proposed rule's application of section 1651 of the NDAA for FY 2013 to contracts at or below the simplified acquisition threshold (SAT) and for the acquisition of commercial items, including commercially available off-the-shelf (COTS) items. Discussion of these preliminary determinations is set forth below. The FAR Council will consider public feedback before making a final determination on the scope of the final rule.

A. Applicability to Contracts at or Below the SAT.

Pursuant to 41 U.S.C. 1905, a provision of law is not applicable to acquisitions at or below the SAT unless the law (i) contains criminal or civil penalties; (ii) specifically refers to 41 U.S.C. 1905 and states that the law applies to acquisitions at or below the SAT; or (iii) the FAR Council makes a written determination that it is not in the best interest of the Federal Government to exempt contracts or subcontracts at or below the SAT. If none of these conditions are met, the FAR is required to include the statutory requirement(s) on a list of provisions of law that are inapplicable to acquisitions at or below the SAT.

The purpose of this rule is to implement section 1651 of the NDAA for FY 2013. Section 1651 provides revised limitations on subcontracting that apply across all small business programs. It also requires that the limitations on subcontracting be determined based on the percentage of the overall award amount that a prime contractor spends on its subcontractors. In addition, section 1651 provides that the percentage of the award amount that the prime contractor spends on subcontractors who are similarly situated entities is not considered subcontracted for purposes of the limitations on subcontracting in section 1651.

These statutory requirements are reflected in SBA's final rule published in the **Federal Register** at 81 FR 34243, on May 31, 2016, which did not exempt acquisitions at or below the SAT that are set aside for, or awarded on a sole-source basis to, 8(a) program participants, HUBZone, service-disabled veteran-owned, women-owned, or economically disadvantaged women-owned small business concerns. SBA's final rule did exempt acquisitions at or below the SAT that are set aside for small businesses.

The law is silent on the applicability of these requirements to acquisitions at or below the SAT and does not independently provide for criminal or civil penalties; nor does it include terms making express reference to 41 U.S.C. 1905 and its application to acquisitions at or below the SAT. Therefore, it does not apply to acquisitions at or below the SAT unless the FAR Council makes a written determination as provided at 41 U.S.C. 1905.

Application of the law to acquisitions at or below the SAT will maximize the positive impact set-aside and sole-source contracts provide for small businesses in the socioeconomic programs (*e.g.,* HUBZone, 8(a), service-disabled veteran-owned, and women-owned small business programs) by ensuring these benefits extend to the many contracts valued below the SAT. According to fiscal year 2015 data from the Federal Procurement Data System (FPDS), more than 70 percent of the number of acquisitions that were set aside or sole-sourced under the socioeconomic programs were in amounts at or below the SAT. Failure to apply section 1651 to the maximum extent possible would exclude a significant number of acquisitions, which would not advance the interests of small businesses and increase their opportunities in the Federal marketplace. Further, the primary FAR clauses implementing the limitations on subcontracting and the nonmanufacturer rule are currently prescribed for use in solicitations and contracts at or below the SAT that are set aside for, or awarded on a sole-source basis to, 8(a) program participants, HUBZone, service-disabled veteran-owned, women-owned, or economically disadvantaged women-owned small business concerns. This rule merely revises these clauses to implement the requirements of section 1651. Exclusion of these acquisitions would create confusion among contractors and the Federal contracting workforce. Under the FAR clauses amended by this rule, contractors are already required to comply with the limitations on subcontracting and the nonmanufacturer rule. The new requirements will result in substantial savings for contractors.

For these reasons, it is in the best interest of the Federal Government to apply the requirements of the rule to acquisitions at or below the SAT.

B. Applicability to Contracts for the Acquisition of Commercial Items

Pursuant to 41 U.S.C. 1906, acquisitions of commercial items (other than acquisitions of COTS items, which are addressed in 41 U.S.C. 1907) are exempt from a provision of law unless the law (i) contains criminal or civil penalties; (ii) specifically refers to 41 U.S.C. 1906 and states that the law applies to acquisitions of commercial items; or (iii) the FAR Council makes a written determination and finding that it would not be in the best interest of the Federal Government to exempt contracts for the procurement of commercial items from the provision of law. If none of these conditions are met, the FAR is required to include the statutory requirement(s) on a list of provisions of law that are inapplicable to acquisitions of commercial items.

The purpose of this rule is to implement section 1651 of the NDAA for FY 2013. Section 1651 provides revised limitations on subcontracting that apply across all small business programs. It also requires that the limitations on subcontracting be determined based on the percentage of the overall award amount that a prime contractor spends on its subcontractors. In addition, section 1651 provides that the percentage of the award amount that the prime contractor spends on subcontractors who are similarly situated entities is not considered subcontracted for purposes of the limitations on subcontracting in section 1651.

These statutory requirements are reflected in SBA's final rule published in the **Federal Register** at 81 FR 34243, on May 31, 2016, which did not exempt acquisitions of commercial items.

The law is silent on the applicability of these requirements to acquisitions of commercial items and does not independently provide for criminal or civil penalties; nor does it include terms making express reference to 41 U.S.C. 1906 and its application to acquisitions of commercial items. Therefore, it does not apply to acquisitions of commercial items unless the FAR Council makes a written determination as provided at 41 U.S.C. 1906.

The law furthers the Administration's goal of simplifying the acquisition process and facilitating easier access to the Federal marketplace, in this case for small business contractors who make up an important component of the Government's industrial base. It advances the interests of small business prime contractors by making it easier to comply with the limitations on subcontracting, which makes it possible for those contractors to compete for larger contracts than they could in the past. The law also advances the interests of small business subcontractors by encouraging small business prime contractors to award more subcontracts to similarly situated small businesses. Exclusion of a large segment of Federal contracting, such as acquisitions for commercial items, will limit the full implementation of these objectives. Further, the primary FAR clauses implementing the limitations on subcontracting and the nonmanufacturer rule are currently prescribed for use in solicitations and contracts for commercial items. Exclusion of acquisitions for commercial items from these requirements would create confusion among contractors and the Federal contracting workforce. The burden on contractors would not increase significantly if the requirements of section 1651 were applied to acquisitions for commercial items. Under the FAR clauses amended by this rule, contractors are already required to comply with the limitations on subcontracting and the nonmanufacturer rule. The new requirements will result in substantial savings for contractors.

For these reasons, it is in the best interest of the Federal Government to apply the requirements of the rule to the acquisition of commercial items.

C. Applicability to Contracts for the Acquisition of COTS Items

Pursuant to 41 U.S.C. 1907, acquisitions of COTS items will be exempt from a provision of law unless the law (i) contains criminal or civil penalties; (ii) specifically refers to 41 U.S.C. 1907 and states that the law applies to acquisitions of COTS items; (iii) concerns authorities or responsibilities under the Small Business Act (15 U.S.C. 644) or bid protest procedures developed under the authority of 31 U.S.C. 3551 *et seq.,* 10 U.S.C. 2305(e) and (f), or 41 U.S.C. 3706 and 3707; or (iv) the Administrator for Federal Procurement Policy makes a written determination and finding that would not be in the best interest of the Federal Government to exempt contracts for the procurement of COTS items from the provision of law. If none of these conditions are met, the FAR is required to include the statutory requirement(s) on a list of provisions of law that are inapplicable to acquisitions of COTS items.

The purpose of this rule is to implement section 1651 of the NDAA for FY 2013. Section 1651 provides revised limitations on subcontracting that apply across all small business programs. It also requires that the limitations on subcontracting be determined based on the percentage of the overall award amount that a prime contractor spends on its subcontractors. In addition, section 1651 provides that the percentage of the award amount that the prime contractor spends on subcontractors who are similarly situated entities is not considered subcontracted for purposes of the limitations in section 1651.

These statutory requirements are reflected in SBA's final rule published in the **Federal Register** at 81 FR 34243, on May 31, 2016, which did not exempt acquisitions of COTS items.

The law is silent on the applicability of these requirements to acquisitions of COTS items and does not independently provide for criminal or civil penalties; nor does it include terms making express reference to 41 U.S.C. 1907 and its application to acquisitions of COTS items. Therefore, it does not apply to acquisitions of COTS items unless the Administrator for Federal Procurement Policy makes a written determination as provided at 41 U.S.C. 1907.

The law furthers the Administration's goal of simplifying the acquisition process and facilitating easier access to the Federal marketplace, in this case for small business contractors who make up an important component of the Government's industrial base. It advances the interests of small business prime contractors by making it easier to comply with the limitations on subcontracting, which makes it possible for those contractors to compete for larger contracts than they could in the past. The law also advances the interests of small business subcontractors by encouraging small business prime contractors to award more subcontracts to similarly situated small businesses. Exclusion of a large segment of Federal contracting, such as acquisitions for COTS items, will limit the full implementation of these objectives. Further, the primary FAR clauses implementing the limitations on subcontracting and the nonmanufacturer rule are currently prescribed for use in solicitations and contracts for COTS items. Exclusion of acquisitions for COTS items from these requirements would create confusion among contractors and the Federal contracting workforce. The burden on contractors would not increase significantly if the requirements of section 1651 were applied to acquisitions for COTS items. Under the FAR clauses amended by this rule, contractors are already required to comply with the limitations on subcontracting and the nonmanufacturer rule. The new requirements will result in substantial savings for contractors.

For these reasons, it is in the best interest of the Federal Government to apply the requirements of the rule to the acquisition of COTS items.

IV. Expected Cost Savings

The purpose of this rule is to implement statutory authorities and SBA regulations that are designed to make it easier and less burdensome for small business prime contractors to comply with requirements related to how much work they may subcontract under Federal contracts and task and delivery orders (*i.e.,* the ''limitations on subcontracting''). The proposed changes to these requirements would both ease compliance costs and provide more authorized ways to subcontract. Section 1651 of the NDAA for FY 2013 revised and standardized the limitations on subcontracting, including the nonmanufacturer rule. The nonmanufacturer rule is the requirement that the prime contractor provide an end product manufactured by a small business in the United States or its outlying areas. The limitations on subcontracting and the nonmanufacturer rule are meant to ensure that the benefits of contracts and orders awarded to small businesses flow to the intended beneficiaries.

Prior to section 1651, the limitations on subcontracting and the nonmanufacturer rule were inconsistent across the small business programs. For example, under the 8(a) and WOSB Programs, the prime contractor was required to perform a certain percentage of work itself, whereas under the HUBZone and SDVOSB Programs, the prime contractor could include subcontracts to other HUBZone small business or SDVOSB concerns in the percentage of work it performed. Similarly, with regard to the nonmanufacturer rule, a prime contractor for a contract or order set aside or awarded on a sole-source basis under the HUBZone Program was required to provide products manufactured by another HUBZone small business, but for awards under the other small business programs, the prime contractor was required to provide products manufactured by any small business.

In addition, the basis of the limitations on subcontracting has changed. Prior to section 1651, the limitations on subcontracting were calculated as a percentage of work to be performed by a prime contractor; the calculation was based on the contractor's costs to perform the contract (*e.g.,* salaries and other allowable costs under FAR part 31). As a result of section 1651, the limitations on subcontracting will be calculated as a percentage of the overall contract or order amount (*i.e.,* the contract price, including costs and profit or fee) to be spent by the prime contractor on subcontractors. For small businesses, this change will reduce the burden associated with tracking and documenting compliance with the limitations on subcontracting.

Section 1651 also applied the concept of ''similarly situated entities'' to all small business programs. A similarly situated entity is a small business subcontractor that has the same small business program status as that which qualified the prime contractor for the prime contract. The percentage of the contract or order amount that the prime contractor spends on subcontractors who are similarly situated entities is not considered subcontracted for purposes of compliance with the limitations on subcontracting. Prior to section 1651, small businesses that wanted to work together to comply with the limitations on subcontracting were required to form a joint venture or a new legal entity (except in small business programs where the concept of similarly situated entities was already applied). The concept of similarly situated entities eliminates the need for paperwork, coordination, and other costs associated with forming such a joint venture or new legal entity simply to comply with the limitations on subcontracting.

These important changes allow small businesses greater flexibility on how they choose to comply with the limitations on subcontracting. The impact is illustrated in the following example of a non-construction contract:

Limitations on subcontracting	Previous	New
Contract Value	$1,000	$1,000
Small Business' Cost of Contract Performance incurred for personnel.	$800	Not tracked.
LOS Requirement	Must spend $400—*i.e.,* 50 percent of the cost of contract performance incurred for its own personnel.	May pay up to $500 (50 percent of the contract price) to a non-similarly situated entity, *e.g.,* large business, AND/OR subcontract to a similarly situated entity without limitation.

Under the current limitations on subcontracting, the small business only has one way to comply. In the example above, it must spend at least $400 on its own employees and, therefore, must be able to track its contract costs to ensure compliance with the requirement. Under the new limitations on subcontracting, there are multiple and less costly ways to comply, and the small business can choose the most efficient option, as demonstrated below:

- The small business can continue to spend $400 on its own employees and subcontract $400 to any business, as it did to comply with the previous limitations on subcontracting. Because the prime contractor is not subcontracting more than $500 to businesses that are not similarly situated entities, it will meet the new limitations on subcontracting.
- The small business can subcontract to any combination of similarly situated and non-similarly situated entities and remain in compliance with the new limitations on subcontracting as long as the amount spent on non-similarly situated entities does not exceed $500. For example, the small business can subcontract $500 to any business and spend $300 on its own employees, or subcontract $500 to any business, $100 to a similarly situated entity, and spend only $200 on its own employees.

SBA's final rule specified that similarly situated entities must also comply with the limitations on subcontracting. As part of implementing section 1651, the Small Business Administration (SBA) made a few more revisions to their regulations that are reflected in this FAR rule:

- The nonmanufacturer rule does not apply to small business set-asides at or below $150,000. Note that currently, the FAR applies the nonmanufacturer rule to small business set-asides above $25,000.
- Waivers of the nonmanufacturer rule will now be allowed for procurements under the HUBZone Program. Such waivers allow a HUBZone small business to provide the product of any size business.
- In the event SBA grants a nonmanufacturer rule waiver after the issuance of a solicitation, but before award, contracting officers are required to amend that solicitation to notify potential offerors of the waiver and to give them more time to submit proposals.

The above changes drive both costs and savings; however, the rule is expected to result in net savings to small entities, as well as to the Government. Since the rule will only revise regulations under the various small business programs, there will be no costs or savings to large businesses.

The following is a summary of the estimated public cost savings calculated in perpetuity in 2016 dollars at a 7-percent discount rate:

Present Value at 7 percent	−$271,391,140
Annualized 7 percent	−$18,997,380

The full cost analysis narrative can be accessed at *http://www.regulations.gov.*

V. 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 a significant regulatory action and, therefore, was 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.

VI. Executive Order 13771

This rule is considered to be an E.O. 13771 deregulatory action. Details on the estimated cost savings can be found in section IV. of this preamble.

VII. Regulatory Flexibility Act

The change may 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.* The Initial Regulatory Flexibility Analysis (IRFA) has been performed and is summarized as follows:

DoD, GSA, and NASA are proposing to amend the Federal Acquisition Regulation (FAR) to implement regulatory changes made by the Small Business Administration (SBA) in its final rule published in the **Federal Register** at 81 FR 34243 on May 31, 2016. SBA's final rule implements the statutory requirements of section 1651 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2013. Section 1651 revised and standardized the limitations on subcontracting, including the nonmanufacturer rule, that apply to small business concerns under FAR part 19 procurements.

The objectives of this proposed rule are to apply the limitations on subcontracting consistently to the small business concerns identified in FAR 19.000(a)(3) and to change the method of calculation to the percentage of the award amount to be spent on subcontractors. The legal basis for the rule is section 1651 of the NDAA for FY 2013, codified at section 46 of the Small Business Act (15 U.S.C. 657s).

This rule may have a positive economic impact on small businesses, because it will make application of the limitations on subcontracting and the nonmanufacturer rule uniform across all small business programs and make it easier to calculate compliance with the limitations on subcontracting. Through the ability to meet the limitations by means of subcontracts with similarly situated entities, this rule will make it possible for small businesses to compete for larger contracts than they could in the past. The rule will encourage small business prime contractors to award subcontracts to other, similarly situated, small businesses. Analysis of the System for Award Management (SAM) indicates there are over 321,938 small business registrants. Firms looking to be prime contractors of Government contracts are required to register in SAM. However, firms do not need to register in SAM to participate in subcontracting. Thus, the number of small business firms impacted by this rule may be greater than the number of firms registered in SAM.

This proposed rule does not include any new reporting or recordkeeping requirements for small entities. This rule does not include any new compliance requirements. The FAR already required compliance with the limitations on subcontracting and the nonmanufacturer rule for small business prime contractors receiving awards pursuant to set-aside and sole-source acquisitions under part 19. This rule simply revises the limitations on subcontracting and the nonmanufacturer rule to match that required by section 1651 of the NDAA for FY 2013. According to the Federal Procurement Data System (FPDS), in fiscal year 2015 there were 45,963 small business prime contractors performing on acquisitions to which the limitations on subcontracting or the nonmanufacturer rule would apply.

The proposed rule does not duplicate, overlap, or conflict with any other Federal rules.

There are no known significant alternative approaches to the proposed rule that would meet the requirements of the applicable statute.

The Regulatory Secretariat Division has submitted a copy of the IRFA to the Chief Counsel for Advocacy of the Small Business Administration. A copy of the IRFA may be obtained from the Regulatory Secretariat Division. DoD, GSA, and NASA invite comments from small business concerns and other interested parties on the expected impact of this rule on small entities.

DoD, GSA, and NASA will also consider comments from small entities concerning the existing regulations in subparts affected by this rule consistent with 5 U.S.C. 610. Interested parties must submit such comments separately and should cite 5 U.S.C. 610 (FAR Case 2016–011) in correspondence.

VIII. Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C. chapter 35) does apply; however, these changes to the FAR do not impose additional information collection requirements to the paperwork burden previously approved under OMB Control Number 3245–0374, titled: *Certification for the Women-Owned Small Business Federal Contract Program.*

List of Subjects in 48 CFR Parts 19 and 52

Government procurement.

Dated: November 19, 2018.

William F. Clark,

Director, Office of Government-wide Acquisition Policy, Office of Acquisition Policy, Office of Government-wide Policy.

Therefore, DoD, GSA, and NASA are proposing to amend 48 CFR parts 19 and 52 as set forth below:

■ 1. The authority citation for 48 CFR parts 19 and 52 continues to read as follows:

Authority: 40 U.S.C. 121(c); 10 U.S.C. chapter 137; and 51 U.S.C. 20113.

PART 19—SMALL BUSINESS PROGRAMS

■ 2. Amend section 19.001 by removing the definition ''Nonmanufacturer rule'' and adding, in alphabetical order, the definition ''Similarly situated entity'' to read as follows:

19.001 Definitions.

* * * * *

''Similarly situated entity'' means a first-tier subcontractor, including an independent contractor, that has the same small business program status as that which qualified the prime contractor for the award; and is considered small for the NAICS code the prime contractor assigned to the subcontract the subcontractor will perform. An example of a similarly situated entity is a first-tier subcontractor that is a HUBZone small business concern for a HUBZone set-aside or sole-source award under the HUBZone Program.

19.102 [Amended]

■ 3. Amend section 19.102 by removing paragraph (f).

■ 4. Add section 19.103 to read as follows.

19.103 Nonmanufacturer rule.

(a) *Application.* (1) The nonmanufacturer rule applies to small business set-asides above $150,000; it does not apply to small business set-asides at or below $150,000. The nonmanufacturer rule applies to all set-aside and sole-source awards under the 8(a), HUBZone, Service-Disabled Veteran-Owned Small Business, Women-Owned Small Business programs regardless of dollar value.

(2) The nonmanufacturer rule applies to nonmanufacturers in accordance with paragraph (b) and to kit assemblers who are nonmanufacturers in accordance with paragraph (c).

(b) *Nonmanufacturers.* Any concern, including suppliers, that submits an offer for a set-aside or a sole-source award in accordance with part 19, other than on a construction or service

acquisition, but proposes to furnish an end item that it did not itself manufacture, process, or produce (*i.e.,* a ''nonmanufacturer''), is required to—

(1) Provide an end item that a small business has manufactured, processed, or produced in the United States or its outlying areas (see paragraph (d) of this section for determining the manufacturer of an end item);

(2) Not exceed 500 employees;

(3) Be primarily engaged in the retail or wholesale trade and normally sell the type of item being supplied; and

(4) Take ownership or possession of the item(s) with its personnel, equipment, or facilities in a manner consistent with industry practice; for example, providing storage, transportation, or delivery.

(c) *Kit assemblers.* When the end item being acquired is a kit of supplies—

(1) The offeror may not exceed 500 employees; and

(2) At least 50 percent of the total cost of the components of the kit shall be manufactured, processed, or produced in the United States or its outlying areas by business concerns that are small under the size standards for the NAICS codes of the components of the kit.

(d) *Identification of manufacturers.* For the purposes of applying the nonmanufacturer rule, the manufacturer, processor, or producer is the concern that manufactures, processes, or produces an end item with its own facilities (*i.e.,* transforms raw materials, miscellaneous parts, or components into the end item being acquired). See 13 CFR 121.406(b)(2).

(e) *Waiver of nonmanufacturer rule.* (1) SBA may grant an individual or a class waiver to the nonmanufacturer rule to allow a nonmanufacturer to provide the end item of an other than small business without regard to the place of manufacture, processing, or production.

(i) *Class waiver.* An agency may request that SBA waive the requirement at paragraph (b)(1) or (c)(2) of this section for a specific product or class of products. SBA may issue a waiver when SBA has determined that there are no small business manufacturers, processors, or producers in the United States or its outlying areas for a specific product or class of products.

(ii) *Individual waiver.* The contracting officer may request a waiver of the requirements at paragraph (b)(1) or (c)(2) of this section for an individual acquisition once the contracting officer determines through market research that no known small business manufacturers, processors, or producers in the United States or its outlying areas can reasonably be expected to offer an end item meeting the requirements of the solicitation. An individual waiver applies only to a specific acquisition.

(2) *Waiver requests.* Requests for waivers shall include the content specified at 13 CFR 121.1204 and shall be sent via email to *nmrwaivers@sba.gov* or by mail to the—Director, Office of Government Contracting, Small Business Administration, 409 Third Street SW, Washington, DC 20416.

(3) *List of class waivers.* The current listing of class waivers is available at *http://www.sba.gov/content/class-waivers,* or contact the SBA Office of Government Contracting.

(4) *Notification of waiver.* The contracting officer shall provide potential offerors with written notification of any class or individual waiver in the solicitation. If providing the notification after solicitation issuance, the contracting officer shall provide potential offerors a reasonable amount of additional time to respond to the solicitation.

(f) *Multiple-item acquisitions.* (1) If at least 50 percent of the estimated acquisition cost is composed of items that are manufactured, processed, or produced by small business concerns, then a waiver of the nonmanufacturer rule is not required. There is no requirement that each item acquired in a multiple-item acquisition be manufactured, processed, or produced by a small business in the United States or its outlying areas.

(2) If more than 50 percent of the estimated acquisition cost is composed of items manufactured, processed, or produced by other than small business concerns, then a waiver is required. SBA may grant an individual waiver for one or more items in an acquisition in order to ensure that at least 50 percent of the cost of the items to be supplied by the nonmanufacturer comes from small business manufacturers, processors, and producers in the United States or its outlying areas or are subject to a waiver.

(3) If a small business offeror is both a manufacturer of item(s) and a nonmanufacturer of other item(s) for an acquisition, the contracting officer shall apply the manufacturer size standard.

19.303 [Amended]

■ 5. Amend section 19.303 by removing from paragraph (a)(2) ''of 19.102(f)'' and adding ''of 19.103'' in its place.

19.502–2 [Amended]

■ 6. Amend section 19.502–2 by removing paragraph (c).

■ 7. Amend section 19.508 by—

■ a. Revising paragraphs (c), (d) and (e); and

■ b. Adding paragraph (g).

The revisions and addition read as follows:

19.508 Solicitation provisions and contract clauses.

* * * * *

(c) The contracting officer shall insert the clause at 52.219–6, Notice of Total Small Business Set-Aside, in solicitations and contracts involving total small business set-asides or reserves. This includes multiple-award contracts when orders may be set aside for any of the small business concerns identified in 19.000(a)(3), as described in 8.405–5 and 16.505(b)(2)(i)(F). Use the clause at 52.219–6 with its Alternate I when including FPI in the competition in accordance with 19.504.

(d) The contracting officer shall insert the clause at 52.219–7, Notice of Partial Small Business Set-Aside, in solicitations and contracts involving partial small business set-asides. This includes part or parts of multiple-award contracts, including those described in 38.101. Use the clause at 52.219–7 with its Alternate I when including FPI in the competition in accordance with 19.504.

(e) The contracting officer shall insert the clause at 52.219–14, Limitations on Subcontracting, in solicitations and contracts for supplies, services, and construction, if any portion of the requirement is to be set aside or reserved for small business and the contract amount is expected to exceed $150,000, and in any solicitations and contracts that are set aside or awarded on a sole-source basis in accordance with subparts 19.8, 19.13, 19.14, or 19.15, regardless of dollar value. This includes multiple-award contracts when orders may be set aside for small business concerns, as described in 8.405–5 and 16.505(b)(2)(i)(F).

* * * * *

(g)(1) The contracting officer shall insert the clause at 52.219–XX, Nonmanufacturer Rule, in solicitations and contracts when the item being acquired has been assigned a manufacturing or supply NAICS code and—

(i) Any portion of the requirement is set aside for small business and is expected to exceed $150,000; or

(ii) The requirement is set aside or awarded on a sole-source basis in accordance with subparts 19.8, 19.13, 19.14, or 19.15, regardless of dollar value.

(2) The contracting officer shall not insert the clause at 52.219–XX when SBA has waived the nonmanufacturer rule (see 19.103(e)).

■ 8. Amend section 19.811–3 by
■ a. Revising paragraphs (d) and (e); and
■ b. Adding a new paragraph (f).

The revision and addition read as follows:

19.811–3 Contract clauses.

* * * * *

(d) The contracting officer shall insert the clause at 52.219–18, Notification of Competition Limited to Eligible 8(a) Participants, in competitive solicitations and contracts when the acquisition is accomplished using the procedures of 19.805. Use the clause at 52.219–18 with its Alternate I when competition is to be limited to 8(a) concerns within one or more specific SBA districts pursuant to 19.804–2.

(e) The contracting officer shall insert the clause at 52.219–14, Limitations on Subcontracting, in accordance with the prescription at 19.508(e).

(f) The contracting officer shall insert the clause at 52.219–XX, Nonmanufacturer Rule, in accordance with the prescription at 19.508(g).

■ 9. Amend section 19.1303 by revising paragraph (e) to read as follows:

19.1303 Status as a HUBZone small business concern.

* * * * *

(e) A HUBZone small business concern may submit an offer for supplies as a nonmanufacturer if it meets the requirements of the nonmanufacturer rule set forth at 13 CFR 121.406.

19.1308 [Removed and Reserved]

■ 10. Remove and reserve section 19.1308.

■ 11. Revise section 19.1309 to read as follows:

19.1309 Contract clauses.

(a) The contracting officer shall insert the clause at 52.219–3, Notice of HUBZone Set-Aside or Sole-Source Award, in solicitations and contracts for acquisitions that are set aside, or reserved for, or awarded on a sole-source basis to, HUBZone small business concerns under 19.1305 or 19.1306. This includes multiple-award contracts when orders may be set aside for HUBZone small business concerns as described in 8.405–5 and 16.505(b)(2)(i)(F).

(b) The contracting officer shall insert the clause at 52.219–4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns, in solicitations and contracts for acquisitions conducted using full and open competition.

(c) The contracting officer shall insert the clause at 52.219–14, Limitations on Subcontracting, in accordance with the prescription at 19.508(e).

(d) The contracting officer shall insert the clause at 52.219–XX, Nonmanufacturer Rule, in accordance with the prescription at 19.508(g).

19.1403 [Amended]

■ 11. Amend section 19.1403 by removing from paragraph (d) ''19.102(f)'' and adding ''19.103'' in its place.

■ 12. Revise section 19.1407 to read as follows:

19.1407 Contract clauses.

(a) The contracting officer shall insert the clause at 52.219–27, Notice of Service-Disabled Veteran-Owned Small Business Set-Aside, in solicitations and contracts for acquisitions that are set aside or reserved for, or awarded on a sole-source basis to, service-disabled veteran-owned small business concerns under 19.1405 and 19.1406. This includes multiple-award contracts when orders may be set aside for service-disabled veteran-owned small business concerns as described in 8.405–5 and 16.505(b)(2)(i)(F).

(b) The contracting officer shall insert the clause at 52.219–14, Limitations on Subcontracting, in accordance with the prescription at 19.508(e).

(c) The contracting officer shall insert the clause at 52.219–XX, Nonmanufacturer Rule, in accordance with the prescription at 19.508(g).

■ 13. Amend section 19.1507 by—
■ a. Removing from paragraph (a) ''clause 52.219–29'' and adding ''clause at 52.219–29'' in its place;
■ b. Removing from paragraph (b) ''clause 52.219–30'' and adding ''clause at 52.219–30'' in its place; and
■ c. Adding paragraphs (c) and (d) to read as follows:

19.1507 Contract clauses.

* * * * *

(c) The contracting officer shall insert the clause at 52.219–14, Limitations on Subcontracting, in accordance with the prescription at 19.508(e).

(d) The contracting officer shall insert the clause at 52.219–XX, Nonmanufacturer Rule, in accordance with the prescription at 19.508(g).

PART 52—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 14. Amend section 52.204–8 by revising the date of the provision and paragraph (a)(3) to read as follows:

52.204–8 Annual Representations and Certifications.

* * * * *

Annual Representations and Certifications (Date)

* * * * *

(a)(3) If the acquisition is set aside for small business and has a value above $150,000, or is an 8(a), HUBZone, Service-Disabled Veteran-Owned, Economically Disadvantaged Women-Owned, or Women-Owned Small Business set-aside or sole-source award regardless of dollar value, the small business size standard for a concern that submits an offer for a set-aside or sole-source award in accordance with part 19, other than on a construction or service acquisition, but proposes to furnish an end item that it did not itself manufacture, process, or produce is 500 employees.

* * * * *

■ 15. Amend section 52.212–1 by revising the date of the provision and paragraph (a) to read as follows:

52.212–1 Instructions to Offerors—Commercial Items.

* * * * *

Instructions to Offerors—Commercial Items (Date)

(a) *North American Industry Classification System (NAICS) code and small business size standard.* The NAICS code and small business size standard for this acquisition appear in Block 10 of the solicitation cover sheet (SF 1449). However, if the acquisition is set aside for small business and has a value above $150,000, or is an 8(a), HUBZone, Service-Disabled Veteran-Owned, Economically Disadvantaged Women-Owned, or Women-Owned Small Business set-aside or sole-source award regardless of dollar value, the small business size standard for a concern that submits an offer for a set-aside or sole-source award in accordance with part 19, other than on a construction or service acquisition, but proposes to furnish an end item that it did not itself manufacture, process, or produce is 500 employees.

* * * * *

■ 16. Amend section 52.212–5 by—
■ a. Revising the date of the clause and paragraphs (b)(11), (b)(12), (b)(14), (b)(15), (b)(19), (b)(21), (b)(22), (b)(23), and (b)(24);
■ b. Redesignating paragraphs (b)(25) through (b)(60) as paragraphs (b)(26) through (b)(61), respectively; and
■ c. Adding a new paragraph (b)(25).

The revisions and additions read as follows:

52.212–5 Contract Terms and Conditions Required To Implement Statutes or Executive Orders—Commercial Items.

* * * * *

Contract Terms and Conditions Required to Implement Statutes or Executive Orders—Commercial Items (Date)

* * * * *

(b) * * *

____ (11) 52.219–3, Notice of HUBZone Set-Aside or Sole-Source Award (DATE) (15 U.S.C. 657a).

____ (12) 52.219–4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns (DATE) (if the offeror elects to waive the preference, it shall so indicate in its offer) (15 U.S.C. 657a).

* * * * *

____ (14)(i) 52.219–6, Notice of Total Small Business Set-Aside (DATE) (15 U.S.C. 644).

____ (ii) Alternate I (DATE).

____ (15)(i) 52.219–7, Notice of Partial Small Business Set-Aside (DATE) (15 U.S.C. 644).

____ (ii) Alternate I (DATE) of 52.219–7.

* * * * *

____ (19) 52.219–14, Limitations on Subcontracting (DATE) (15 U.S.C. 657s).

* * * * *

____ (21) 52.219–27, Notice of Service-Disabled Veteran-Owned Small Business Set-Aside (DATE) (15 U.S.C. 657f).

____ (22) 52.219–28, Post Award Small Business Program Rerepresentation (DATE) (15 U.S.C. 632(a)(2)).

____ (23) 52.219–29, Notice of Set-Aside for, or Sole-Source Award to, Economically Disadvantaged Women-Owned Small Business Concerns (DATE) (15 U.S.C. 637(m)).

____ (24) 52.219–30, Notice of Set-Aside for, or Sole-Source Award to, Women-Owned Small Business Concerns Eligible Under the Women-Owned Small Business Program (DATE) (15 U.S.C. 637(m)).

____ (25) 52.219–XX, Nonmanufacturer Rule (DATE) (15 U.S.C. 657s).

* * * * *

■ 17. Amend section 52.219–1 by—

■ a. Revising the date of the provision;

■ b. Removing from paragraph (b)(1) ''—'' and adding a space in its place; and

■ c. Revising paragraph (b)(3) to read as follows:

52.219–1 Small Business Program Representations.

* * * * *

Small Business Program Representations (Date)

* * * * *

(b) * * *

(3) If the acquisition is set aside for small business and has a value above $150,000, or is an 8(a), HUBZone, Service-Disabled Veteran-Owned, Economically Disadvantaged Women-Owned, or Women-Owned Small Business set-aside or sole-source award regardless of dollar value, the small business size standard for a concern that submits an offer, other than on a construction or service acquisition, but proposes to furnish an end item that it did not itself manufacture, process, or produce is 500 employees.

* * * * *

■ 18. Amend section 52.219–3 by—

■ a. Revising the date of the clause;

■ b. Revising paragraph (a);

■ c. Removing from paragraph (b)(3) ''set-aside'' and adding ''set aside'' in its place;

■ d. Removing paragraphs (d), (e), and (f);

■ e. Redesignating paragraph (g) as paragraph (d); and

■ f. Removing Alternate I.

The revision reads as follows:

52.219–3 Notice of HUBZone Set-Aside or Sole-Source Award.

As prescribed in 19.1309(a), insert the following clause:

Notice of HUBZone Set-Aside or Sole-Source Award (Date)

(a) *Definition.* ''HUBZone small business concern,'' as used in this clause, means a small business concern, certified by the Small Business Administration (SBA), that appears on the List of Qualified HUBZone Small Business Concerns maintained by the SBA (13 CFR 126.103).

* * * * *

■ 19. Amend section 52.219–4 by—

■ a. Revising the date of the clause and paragraphs (a), (d) and (e) to read as follows; and

■ b. Removing Alternate I.

52.219–4 Notice of Price Evaluation Preference for HUBZone Small Business Concerns.

* * * * *

Notice of Price Evaluation Preference for HUBZone Small Business Concerns (Date)

(a) *Definition.* ''Similarly situated entity,'' as used in this clause, means a first-tier subcontractor, including an independent contractor, that has the same small business program status as that which qualified the prime contractor for the award; and is considered small for the NAICS code the prime contractor assigned to the subcontract the subcontractor will perform. An example of a similarly situated entity is a first-tier subcontractor that is a HUBZone small business concern for a HUBZone set-aside or sole-source award under the HUBZone Program.

* * * * *

(d) *Agreement.* By submission of an offer and execution of a contract, a HUBZone small business concern agrees that, in the case of a contract for—

(1) Services (except construction), it will not pay more than 50 percent of the amount paid by the Government for contract performance to subcontractors that are not similarly situated entities. Any work that a similarly situated entity further subcontracts will count towards the 50 percent subcontract amount that cannot be exceeded;

(2) Supplies (other than procurement from a nonmanufacturer of such supplies), it will not pay more than 50 percent of the amount paid by the Government for contract performance, excluding the cost of materials (see 13 CFR 125.1), to subcontractors that are not similarly situated entities. Any work that a similarly situated entity further subcontracts will count toward the 50 percent subcontract amount that cannot be exceeded;

(3) General construction, it will not pay more than 85 percent of the amount paid by the Government for contract performance, excluding the cost of materials, to subcontractors that are not similarly situated entities. Any work that a similarly situated entity further subcontracts will count towards the 85 percent subcontract amount that cannot be exceeded; or

(4) Construction by special trade contractors, it will not pay more than 75 percent of the amount paid by the Government for contract performance, excluding the cost of materials, to subcontractors that are not similarly situated entities. Any work that a similarly situated entity further subcontracts will count towards the 75 percent subcontract amount that cannot be exceeded.

(e) A HUBZone joint venture agrees that the aggregate of the HUBZone small business concerns to the joint venture, not each concern separately, will perform the applicable requirements specified in paragraph (d) of this clause.

* * * * *

■ 20. Amend section 52.219–6 by—

■ a. Revising the date of the clause;

■ b. Removing paragraph (d);

■ c. Removing Alternate I;

■ d. Redesignating Alternate II as Alternate I; and

■ e. Revising the date of newly redesignated Alternate I.

The revisions read as follows:

52.219–6 Notice of Total Small Business Set-Aside.

* * * * *

Notice of Total Small Business Set-Aside (Date)

* * * * *

Alternate I (DATE). As prescribed in 19.508(c), substitute the following paragraph (c) for paragraph (c) of the basic clause:

* * * * *

■ 21. Amend section 52.219–7 by—
■ a. Revising the date of the clause;
■ b. Removing paragraph (c);
■ c. Removing Alternate I;
■ d. Redesignating Alternate II as Alternate I; and
■ e. Revising the newly redesignated Alternate I.

The revision reads as follows:

52.219–7 Notice of Partial Small Business Set-Aside.

* * * * *

Notice of Partial Small Business Set-Aside (Date)

* * * * *

Alternate I (Date). As prescribed in 19.508(d), add the following paragraph (c) to the basic clause:

(c) Notwithstanding paragraph (b) of this clause, offers from Federal Prison Industries, Inc., will be solicited and considered for both the set-aside and non-set-aside portion of this requirement.

■ 22. Amend section 52.219–14 by—
■ a. Removing from the introductory text of the clause ''or 19.811–3(e)'';
■ b. Revising the date of the clause;
■ c. Redesignating paragraph (c) as paragraph (e) and paragraph (b) as paragraph (c);
■ d. Revising newly designated paragraphs (c) and (e); and
■ e. Adding paragraphs (b), (d), and (f).

The revisions and additions read as follows:

52.219–14 Limitations on Subcontracting.

* * * * *

Limitations on Subcontracting (Date)

* * * * *

(b) *Definition.* ''Similarly situated entity,'' as used in this clause, means a first-tier subcontractor, including an independent contractor, that has the same small business program status as that which qualified the prime contractor for the award; and is considered small for the NAICS code the prime contractor assigned to the subcontract the subcontractor will perform. An example of a similarly situated entity is a first-tier subcontractor that is a HUBZone small business concern for a HUBZone set-aside or sole-source award under the HUBZone Program.

(c) *Applicability.* This clause applies only to—

(1) Contracts that have been set aside or reserved any of the small business concerns identified in 19.000(a)(3);

(2) Part or parts of a multiple-award contract that have been set aside for any of the small business concerns identified in 19.000(a)(3);

(3) Contracts that have been awarded on a sole-source basis in accordance with subparts 19.8, 19.13, 19.14, and 19.15; and

(4) Orders set aside for any of the small business concerns identified in 19.000(a)(3) under multiple-award contracts as described in 8.405–5 and 16.505(b)(2)(i)(F).

(d) *Independent contractors.* An independent contractor shall be considered a subcontractor.

(e) By submission of an offer and execution of a contract, the Offeror/Contractor agrees that, in the case of a contract for—

(1) Services (except construction), it will not pay more than 50 percent of the amount paid by the Government for contract performance to subcontractors that are not similarly situated entities. Any work that a similarly situated entity further subcontracts will count towards the 50 percent subcontract amount that cannot be exceeded;

(2) Supplies (other than procurement from a nonmanufacturer of such supplies), it will not pay more than 50 percent of the amount paid by the Government for contract performance, excluding the cost of materials, to subcontractors that are not similarly situated entities. Any work that a similarly situated entity further subcontracts will count towards the 50 percent subcontract amount that cannot be exceeded;

(3) General construction, it will not pay more than 85 percent of the amount paid by the Government for contract performance, excluding the cost of materials, to subcontractors that are not similarly situated entities. Any work that a similarly situated entity further subcontracts will count towards the 85 percent subcontract amount that cannot be exceeded; or

(4) Construction by special trade contractors, it will not pay more than 75 percent of the amount paid by the Government for contract performance, excluding the cost of materials, to subcontractors that are not similarly situated entities. Any work that a similarly situated entity further subcontracts will count towards the 75 percent subcontract amount that cannot be exceeded.

(f) A joint venture agrees that, in the performance of the contract, the applicable percentage specified in paragraph (e) of this clause will be performed by the aggregate of the joint venture participants.

■ 23. Amend section 52.219–18 by—
■ a. Revising the date of the clause;
■ b. Removing paragraph (d)(1), redesignating paragraph (d)(2) as paragraph (d) and
■ c. Removing Alternate II.

The revision reads as follows:

52.219–18 Notification of Competition Limited to Eligible 8(a) Participants.

* * * * *

Notification of Competition Limited to Eligible 8(a) Participants (Date)

* * * * *

■ 24. Amend section 52.219–27 by—
■ a. Revising the date of the clause;
■ b. Removing paragraph (d);
■ c. Redesignating paragraph (e) as paragraph (d);
■ d. Revising the newly redesignated paragraph (d); and
■ e. Removing paragraph (f).

The revisions read as follows:

52.219–27 Notice of Service-Disabled Veteran-Owned Small Business Set-Aside.

* * * * *

Notice of Service-Disabled Veteran-Owned Small Business Set-Aside (Date)

* * * * *

(d) A joint venture may be considered a service-disabled veteran owned small business concern if—

(1) At least one member of the joint venture is a service-disabled veteran-owned small business concern, and makes the following representations:

(i) That it is a service-disabled veteran-owned small business concern, and

(ii) That it is a small business concern under the North American Industry Classification Systems (NAICS) code assigned to the procurement;

(2) Each other concern is small under the size standard corresponding to the NAICS code assigned to the procurement;

(3) The joint venture meets the requirements of paragraph 7 of the explanation of Affiliates in 19.101 of the Federal Acquisition Regulation; and

(4) The joint venture meets the requirements of 13 CFR 125.15(b).

* * * * *

■ 25. Amend section 52.219–28 by revising the date of the clause and paragraph (d) to read as follows:

52.219–28 Post-Award Small Business Program Rerepresentation.

* * * * *

Post-Award Small Business Program Rerepresentation (Date)

* * * * *

(d) If the acquisition was set aside for small business and has a value above $150,000, or is an 8(a), HUBZone, Service-Disabled Veteran-Owned, Economically Disadvantaged Women-Owned, or Women-Owned Small Business set-aside or sole-source award regardless of dollar value, the small business size standard for a Contractor providing a product which it does not manufacture, process, or produce itself, for a contract other than a construction or service contract, is 500 employees.

* * * * *

■ 26. Amend section 52.219–29 by—

■ a. Revising the date of the clause;

■ b. Removing from the definition ''Economically disadvantaged women-owned small business (EDWOSB)'' ''means- A small'' and adding ''means a small'' in its place;

■ c. Removing from paragraph (c)(3) ''contracting officer'' and adding ''Contracting Officer'' in its place;

■ d. Removing paragraph (d);

■ e. Redesignating paragraph (e) as paragraph (d);

■ f. Removing newly redesignated paragraph (d)(4);

■ g. Redesignating paragraph (d)(5) as (d)(4) and revising newly redesignated paragraph (d)(4); and

■ h. Removing paragraph (f).

The revisions read as follows:

52.219–29 Notice of Set-Aside for, or Sole-Source Award to, Economically Disadvantaged Women-Owned Small Business Concerns.

* * * * *

Notice of Set-Aside for, or Sole-Source Award to, Economically Disadvantaged Women-Owned Small Business Concerns (Date)

* * * * *

(d) * * *

(4) The Contracting Officer executes the contract in the name of the EDWOSB or joint venture.

* * * * *

■ 27. Amend section 52.219–30 by—

■ a. Revising the date of the clause and the introductory text of paragraph (a);

■ b. Removing from the second sentence of paragraph (c)(1) ''WOSB program'' and adding ''WOSB Program'' in its place;

■ c. Removing paragraph (d);

■ d. Redesignating paragraph (e) as paragraph (d);

■ e. Removing newly redesignated paragraph (d)(4);

■ f. Redesignating paragraph (d)(5) as (d)(4) and revising newly redesignated paragraph (d)(4);

■ g. Removing paragraph (f).

The revision reads as follows:

52.219–30 Notice of Set-Aside for, or Sole-Source Award to, Women-Owned Small Business Concerns Eligible Under the Women-Owned Small Business Program.

* * * * *

Notice of Set-Aside for, or Sole-Source Award to, Women-Owned Small Business Concerns Eligible Under the Women-Owned Small Business Program (Date)

(a) *Definitions.* As used in this clause—

* * * * *

(d) * * *

(4) The Contracting Officer executes the contract in the name of the WOSB concern eligible under the WOSB Program or joint venture.

* * * * *

■ 28. Add section 52.219–XX to read as follows:

52.219–XX Nonmanufacturer Rule.

As prescribed in 19.508(g), insert the following clause:

Nonmanufacturer Rule (Date)

(a) *Definitions.* As used in this clause—

''Manufacturer'' means the concern that transforms raw materials, miscellaneous parts, or components into the end item. Concerns that only minimally alter the item being procured do not qualify as manufacturers of the end item. Concerns that add substances, parts, or components to an existing end item to modify its performance will not be considered the end item manufacturer, where those identical modifications can be performed by and are available from the manufacturer of the existing end item.

''Nonmanufacturer'' means a concern, including a supplier, that provides an end item it did not manufacture, process, or produce.

(b) *Applicability.*

(1) This clause does not apply to contracts awarded pursuant to the unrestricted portion of a partial set-aside or to a contractor that is the manufacturer of the product or end item.

(2) This clause applies to—

(i) Contracts that have been awarded pursuant to a set-aside, in total or in part, for any of the small business concerns identified in 19.000(a)(3);

(ii) Contracts that have been awarded on a sole-source basis in accordance with subparts 19.8, 19.13, 19.14, and 19.15; and

(iii) Orders set aside for any of the small business concerns identified in 19.000(a)(3) under multiple-award contracts as described in 8.405–5 and 16.505(b)(2)(i)(F).

(c) *Requirements.*

(1) The Contractor shall—

(i) Provide an end item that a small business has manufactured, processed, or produced in the United States or its outlying areas; for kit assemblers who are nonmanufacturers, see paragraph (c)(2) of this clause instead;

(ii) Be primarily engaged in the retail or wholesale trade and normally sell the type of item being supplied; and

(iii) Take ownership or possession of the item(s) with its personnel, equipment, or facilities in a manner consistent with industry practice; for example, providing storage, transportation, or delivery.

(2) When the end item being acquired is a kit of supplies, at least 50 percent of the total cost of the components of the kit shall be manufactured, processed, or produced in the United States or its outlying areas by small business concerns. Where the Government has specified an item for the kit that is not produced by small business concerns in the United States or its outlying areas, such item is excluded from the calculation of total cost.

(End of clause)

[FR Doc. 2018–25506 Filed 12–3–18; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 208, 212, 213, 215, 216, 217, 234, and 237

[Docket DARS–2018–0055]

RIN 0750–AJ74

Defense Federal Acquisition Regulation Supplement: Restrictions on Use of Lowest Priced Technically Acceptable Source Selection Process (DFARS Case 2018–D010)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Proposed rule.

SUMMARY: DoD proposes to amend the Defense Federal Acquisition Regulation Supplement (DFARS) to implement sections of the National Defense Authorization Acts for Fiscal Years 2017 and 2018 that establish limitations and prohibitions on the use of the lowest price technically source selection process.

DATES: Comments on the proposed rule should be submitted in writing to the address shown below on or before February 4, 2019, to be considered in the formation of a final rule.

ADDRESSES: Submit comments identified by DFARS Case 2018–D010, using any of the following methods:

○ *Federal eRulemaking Portal: http://www.regulations.gov.* Search for ''DFARS Case 2018–D010.'' under the heading ''Enter keyword or ID'' and selecting ''Search.'' Select ''Comment Now and'' follow the instructions provided to submit a comment. Please

include ''DFARS Case 2018–D010'' on your attached documents.

○ *Email: osd.dfars@mail.mil.* Include DFARS Case 2018–D010 in the subject line of the message.

○ *Fax:* 571–372–6093.

○ *Mail:* Defense Acquisition Regulations System, Attn: Ms. Carrie Moore, OUSD (A&S)DPC/DARS, Room 3B941, 3060 Defense Pentagon, Washington, DC 20301–3060.

Comments received generally will be posted without change to *http://www.regulations.gov,* including any personal information provided. To confirm receipt of your comment(s), please check *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. Carrie Moore, telephone 703–372–6093.

SUPPLEMENTARY INFORMATION:

I. Background

DoD is proposing to amend the DFARS to implement the limitations and prohibitions on use of the lowest prices technical acceptable (LPTA) source selection process provided in sections 813, 814, and 892 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2017 (Pub. L. 114–328) and sections 822, 832, 882, and 1002 of the NDAA for FY 2018 (Pub. L. 115–91). The following is a summary of the statutory restrictions:

• Section 813 of the NDAA for FY 2017, as amended by section 822 of the NDAA for FY 2018, establishes that the LPTA source selection process shall only be used when—

○ Minimum requirements can be described clearly and comprehensively and expressed in terms of performance objectives, measures, and standards that will be used to determine the acceptability of offers;

○ No, or minimal, value will be realized from a proposal that exceeds the minimum technical or performance requirements;

○ The proposed technical approaches will require no, or minimal, subjective judgment by the source selection authority as to the desirability of one offeror's proposal versus a competing proposal;

○ The source selection authority has a high degree of confidence that reviewing the technical proposals of all offerors would not result in the identification of characteristics that could provide value or benefit;

○ No, or minimal, additional innovation or future technological advantage will be realized by using a different source selection process;

○ Goods to be procured are predominantly expendable in nature, are nontechnical, or have a short life expectancy or short shelf life;

○ The contract file contains a determination that the lowest price reflects full life-cycle costs of the product(s) or service(s) being acquired; and

○ The contracting officer documents the contract file describing the circumstances justifying the use of the lowest price technically acceptable source selection process.

Section 813, as amended, further provides that use of the LPTA process should be avoided, to the maximum extent practicable, when acquiring information technology, cybersecurity services, systems engineering and technical assistance services, advanced electronic testing, other knowledge-based professional services, personal protective equipment, or certain services in support of contingency or other operations outside the United States.

• Section 814 of the NDAA for FY 2017 prohibits the use of reverse auctions or the LPTA source selection process when purchasing personal protective equipment, if the level of quality or failure of the item could result in combat casualties. Section 882 of the NDAA for FY 2018 amends section 814 to further prohibit the use of reverse auctions or the LPTA source selection process for aviation critical safety items as defined in 10 U.S.C. 2319(g).

• Section 832 of the NDAA for FY 2018 prohibits the use of the LPTA source selection process for engineering and manufacturing development (EMD) of a major defense acquisition program (MDAP) for which budgetary authority is requested beginning in FY 2019.

• Section 892 of the NDAA for FY 2017, as amended by section 1002 of the NDAA for FY 2018, amended 10 U.S.C. 254b to prohibit the use of the LPTA source selection process when acquiring auditing services and requires selection of service providers based on the best value to the Department, as determined by the resource sponsor for an auditing contract.

II. Discussion and Analysis

Use of the LPTA source selection process is implemented in Federal Acquisition Regulation (FAR) section 15.101–2. To supplement the FAR, DoD is proposing to add a new DFARS section 215.101–2–70 that addresses the various limitations and prohibitions on the use of the LPTA source selection process. This new section is broken into two paragraphs: Paragraph (a) addresses the limitations provided in section 813 of the NDAA for FY 2017, as amended by section 822 of the NDAA for FY 2018; paragraph (b) addresses the prohibitions provided in sections 814, 832, and 892 of the NDAA for FY 2017, as amended by sections 882 and 1002 of the NDAA for FY 2018.

Currently, reverse auctions are not addressed in the FAR or DFARS. To implement the specific restriction on the use of reverse auctions to procure personal protective equipment and aviation critical safety items, DoD is proposing to add a new subpart 217.7X under DFARS part 217, Special Contracting Methods, to address the prohibition associated with reverse auctions under a section titled ''Prohibitions.''

The new statutory limitations and prohibitions on the use of the LPTA source selection process and reverse auctions apply to not only acquisitions conducted using FAR part 15 procedures for negotiation, but also—

• Orders placed against Federal Supply Schedules using FAR subpart 8.4 procedures;

• Acquisitions for commercial items using FAR part 12 procedures;

• Acquisitions conducted using FAR part 13 simplified acquisition procedures; and

• Orders placed under multiple award indefinite delivery contracts using FAR 16.505 procedures for fair opportunity.

In order to notify contracting officers of the new limitations and prohibitions when using these other procedures, DoD is proposing to add cross-references to the new limitations and prohibitions outlined at DFARS 215.101–2–70 in DFARS sections 208.405, 212.203, 213.106–1, and 216.505. The new cross-references make clear that the limitations and prohibitions on the use of LPTA at DFARS 215.101–2–70 apply to the type of procurement being conducted. In addition, separate cross-references are added in these sections to highlight the restriction on the use of reverse auctions for the procurement of personal protective equipment and aviation critical safety items at 217.7XXX.

The new list of prohibitions at DFARS 215.101–2–70(b) includes the prohibitions on use of the LPTA source selection process for EMD of certain MDAPs and for audit services. Special requirements associated with the major system acquisitions are addressed in FAR part 234 and special requirements for the acquisition of audit services are addressed at DFARS 237.270. As such, DoD is proposing to add cross-references at DFARS 234.005–2 and

237.270 to the prohibitions associated with these types of procurement at DFARS 215.101–2–70(b).

III. Applicability to Contracts at or Below the Simplified Acquisition Threshold and for Commercial Items, Including Commercially Available Off-the-Shelf Items

This rule does not propose to create any new provisions or clauses or impact any existing provisions or clauses.

IV. 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.

V. Executive Order 13771

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

VI. Regulatory Flexibility Act

DoD does not expect this proposed 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.* The rule primarily affects internal Government requirements determination and acquisition strategy decisions, and contract file documentation requirements. However, an initial regulatory flexibility analysis has been performed and is summarized as follows:

The rule proposes to revise the Defense Federal Acquisition Regulation Supplement (DFARS) to establish a preference for the use of the tradeoff source selection process for certain safety items and auditing services; prohibit the use of reverse auctions or the lowest priced technically acceptable (LPTA) source selection process for specific supplies and services; and specify criteria for use of the LPTA source selection process. The legal basis for the rule is the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2017 (Pub. L. 114–328) and the NDAA for FY 2018 (Pub. L. 115–91).

DoD does not have access to information on the total number of solicitations issued on an annual basis that did or did not specify the use of the lowest price technically acceptable source selection process. However, the Federal Procurement Data System (FPDS) provides the following information for fiscal year 2016:

- *DoD competitive contracts using FAR part 15 procedures.* DoD awarded 18,361 new contracts and orders using negotiated competitive procedures, of which 47% were awarded to 5,221 unique small businesses. It is important to note that FPDS does not collect data for solicitations using the LPTA source selection process; therefore, this data applies to solicitations using both tradeoff and LPTA source selection procedures, which will be subject to future considerations and restrictions provided by section 813 of the NDAA for FY 2017 and section 822 of the NDAA for FY 2018.
- *Personal protective equipment.* Based on information from FPDS for FY 2016, DoD issued 9,130 new competitive contract actions (including task, delivery, and call orders) potentially for combat-related personal protective equipment (PPE) items that could be impacted by restrictions in section 814 of the NDAA for FY 2017. Of those new contract actions, 89% were awarded to 668 unique small businesses.
- *Aviation critical safety items.* As discussed during the rulemaking process for DFARS 252.209–7010 published in the **Federal Register** at 76 FR 14641 on March 17, 2011, the identification of aviation critical safety items occurs entirely outside the procurement process and is not captured in FPDS. Therefore, it is not possible to assess the impact on small businesses.
- *Audit-related services.* DoD issued 46 new competitive contract actions (including task, delivery, and call orders) for audit services which may be impacted by section 1002 of the NDAA for FY 2018. Of those new contract actions, 61% were awarded to 17 unique small businesses. The average award (including all options) to small business was valued over the simplified acquisition threshold.
- *Major defense acquisition programs (MDAPs).* The impact to small businesses resulting from implementation of sections 832 and 882 of the NDAA for FY 2018 cannot be assessed, since FPDS does not collect data for major defense acquisition programs (MDAPs) or for specific acquisition phases (*i.e.,* engineering and manufacturing development (EMD)). Subject matter experts within DoD know of no instances where the LPTA source selection process has been used for procurement of EMD of an MDAP.

The proposed rule does not impose any Paperwork Reduction Act reporting or recordkeeping requirements on any small entities. The rule may impact some small businesses as offerors may need to change the way their quotations or offers are structured to conform to proposal instructions and corresponding evaluation criteria when responding to solicitations that use the tradeoff source selection process for supplies or services where the LPTA source selection process is now prohibited or must now be avoided. This incremental impact, which represents the incremental difference between a noncomplex LPTA proposal and additional information required for a tradeoff proposal, is expected to be minimal.

The rule does not duplicate, overlap, or conflict with any other Federal rules.

There are no known, significant, alternative approaches to the proposed rule that would meet the requirements of the applicable statute.

DoD invites comments from small business concerns and other interested parties on the expected impact of this rule on small entities.

DoD will also consider comments from small entities concerning the existing regulations in subparts affected by this rule in accordance with 5 U.S.C. 610. Interested parties must submit such comments separately and should cite 5 U.S.C. 610 (DFARS Case 2018–D010), in correspondence.

VII. Paperwork Reduction Act

The rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

List of Subjects in 48 CFR Parts 208, 212, 213, 215, 216, 217, 234, and 237

Government procurement.

Jennifer Lee Hawes,

Regulatory Control Officer, Defense Acquisition Regulations System.

Therefore, 48 CFR parts 208, 212, 213, 215, 216, 217, 234, and 237 are proposed to be amended as follows:

■ 1. The authority citation for 48 CFR parts 208, 212, 213, 215, 216, 217, 234, and 237 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

PART 208—REQUIRED SOURCES OF SUPPLIES OR SERVICES

■ 2. Amend section 208.405 by redesignating the text as paragraph (1) and adding paragraphs (2) and (3) to read as follows:

208.405 Ordering procedures for Federal Supply Schedules.

* * * * *

(2) See 215.101–2–70 for the limitations and prohibitions on the use of the lowest price technically acceptable source selection process, which are applicable to orders placed under Federal Supply Schedules.

(3) See 217.7XXX for the prohibition on the use of reverse auctions for personal protective equipment and aviation critical safety items.

PART 212—ACQUISITION OF COMMERCIAL ITEMS

■ 3. Add section 212.203 to read as follows:

212.203 Procedures for solicitation, evaluation, and award.

(1) See 215.101–2–70 for the limitations and prohibitions on the use of the lowest price technically acceptable source selection process, which are applicable to the acquisition of commercial items.

(2) See 217.7XXX for the prohibition on the use of reverse auctions for personal protective equipment and aviation critical safety items.

PART 213—SIMPLIFIED ACQUISITION PROCEDURES

■ 4. Revise section 213.106–1 to read as follows:

213.106–1 Soliciting competition.

(a) *Considerations.* (2)(i) Include an evaluation factor regarding supply chain risk (see subpart 239.73) when acquiring information technology, whether as a service or as a supply, that is a covered system, is a part of a covered system, or is in support of a covered system, as defined in 239.7301.

(ii) See 215.101–2–70 for limitations and prohibitions on the use of the lowest price technically acceptable source selection process, which are applicable to simplified acquisitions.

(iii) See 217.7XXX for the prohibition on the use of reverse auctions for personal protective equipment and aviation critical safety items.

PART 215—CONTRACTING BY NEGOTIATION

■ 5. Add section 215.101–2 heading to read as follows:

215.101–2 Lowest price technically acceptable source selection process.

■ 6. Add section 215.101–2–70 to read as follows:

215.101–2–70 Limitations and prohibitions.

The following limitations and prohibitions apply when considering the use of the lowest price technically acceptable source selection procedures.

(a) *Limitations.* (1) In accordance with section 813 of the National Defense Authorization Act for Fiscal Year 2017 (Pub. L. 114–328) as amended by section 822 of the National Defense Authorization Act for Fiscal Year 2018 (Pub. L. 115–91) (see 10 U.S.C. 2305 note), the lowest price technically acceptable source selection process shall only be used when—

(i) Minimum requirements can be described clearly and comprehensively and expressed in terms of performance objectives, measures, and standards that will be used to determine the acceptability of offers;

(ii) No, or minimal, value will be realized from a proposal that exceeds the minimum technical or performance requirements;

(iii) The proposed technical approaches will require no, or minimal, subjective judgment by the source selection authority as to the desirability of one offeror's proposal versus a competing proposal;

(iv) The source selection authority has a high degree of confidence that reviewing the technical proposals of all offerors would not result in the identification of characteristics that could provide value or benefit;

(v) No, or minimal, additional innovation or future technological advantage will be realized by using a different source selection process;

(vi) Goods to be procured are predominantly expendable in nature, are nontechnical, or have a short life expectancy or short shelf life;

(vii) The contract file contains a determination that the lowest price reflects full life-cycle costs (as defined at FAR 7.101) of the product(s) or service(s) being acquired; and

(viii) The contracting officer documents the contract file describing the circumstances justifying the use of the lowest price technically acceptable source selection process.

(2) In accordance with section 813 of the National Defense Authorization Act for Fiscal Year 2017, as amended by section 822 of the National Defense Authorization Act for Fiscal Year 2018 (see 10 U.S.C. 2305 note), contracting officers shall avoid, to the maximum extent practicable, using the lowest price technically acceptable source selection process in the case of a procurement that is predominately for the acquisition of—

(i) Information technology services, cybersecurity services, systems engineering and technical assistance services, advanced electronic testing, or other knowledge-based professional services;

(ii) Items designated by the requiring activity as personal protective equipment (except see paragraph (b)(1) of this section); or

(iii) Services designated by the requiring activity as knowledge-based training or logistics services in contingency operations or other operations outside the United States, including in Afghanistan or Iraq.

(b) *Prohibitions.* (1) In accordance with section 814 of the National Defense Authorization Act for Fiscal Year 2017 as amended by section 882 of the National Defense Authorization Act for Fiscal Year 2018 (see 10 U.S.C. 2302 note), contracting officers shall not use the lowest price technically acceptable source selection process to procure items designated by the requiring activity as personal protective equipment or an aviation critical safety item, when the requiring activity advises the contracting officer that the level of quality or failure of the equipment or item could result in combat casualties. See 252.209–7010 for the definition and identification of critical safety items.

(2) In accordance with section 832 of the National Defense Authorization Act for Fiscal Year 2018 (see 10 U.S.C. 2442 note), contracting officers shall not use the lowest price technically acceptable source selection process to acquire engineering and manufacturing development for a major defense acquisition program for which budgetary authority is requested beginning in fiscal year 2019.

(3) Contracting officers shall make award decisions based on best value factors and criteria, as determined by the resource sponsor (in accordance with agency procedures), for an auditing contract. The use of the lowest price technically acceptable source selection process is prohibited (10 U.S.C. 254b).

PART 216—TYPES OF CONTRACTS

■ 7. Amend section 216.505 by—

■ a. Adding new paragraph (a) heading;

■ b. Redesignating paragraph (1) as paragraph (a)(S–70);

■ c. Redesignating paragraph (2) as paragraph (a)(6);

■ d. Adding new paragraph (b) heading; and

■ e. Adding new paragraph (b)(1).

The additions read as follows:

216.505 Ordering.

(a) *General.*

* * * * *

(b) *Orders under multiple-award contracts*—(1) *Fair opportunity.*

(A) See 215.101–2–70 for the limitations and prohibitions on the use of the lowest price technically acceptable source selection process, which are applicable to orders placed against multiple award indefinite delivery contracts.

(B) See 217.7XXX for the prohibition on the use of reverse auctions for personal protective equipment and aviation critical safety items.

* * * * *

PART 217—SPECIAL CONTRACTING METHODS

■ 8. Add new subpart 217.7X, to read as follows:

217.7X—REVERSE AUCTIONS

Sec.
7XXX Prohibition.

217.7X—REVERSE AUCTIONS

217.7XXX Prohibition.

In accordance with section 814 of the National Defense Authorization Act for Fiscal Year 2017 (Pub. L. 114–328) as amended by section 882 of the National Defense Authorization Act for Fiscal Year 2018 (Pub. L. 115–91) (see 10 U.S.C. 2302 note), contracting officers shall not use reverse auctions when procuring items designated by the requiring activity as personal protective equipment or an aviation critical safety item, when the requiring activity advises the contracting officer that the level of quality or failure of the equipment or item could result in combat casualties. See 252.209–7010 for the definition and identification of critical safety items.

PART 234—MAJOR SYSTEM ACQUISITION

■ 9. Add section 234.005–2 to read as follows:

234.005–2 Mission-oriented solicitation.

See 215.101–2–70(b)(2) for the prohibition on the use of the lowest price technically acceptable source selection process for engineering and manufacturing development of a major defense acquisition program for which budgetary authority is requested beginning in fiscal year 2019.

PART 237—SERVICE CONTRACTING

■ 10. Amend section 237.270 by—

■ a. Redesignating paragraph (a)(2) as paragraph (a)(3); and

■ b. Adding new paragraph (a)(2) to read as follows:

237.270 Acquisition of audit services.

(a) * * *

(2) See 215.101–2–70(b)(3) for the prohibition on the use of the lowest price technically acceptable source selection process when acquiring audit services.

* * * * *

[FR Doc. 2018–26306 Filed 12–3–18; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Part 219

[Docket DARS–2018–0056]

RIN 0750–AK18

Defense Federal Acquisition Regulation Supplement: Small Business Set-Asides for Architect-Engineer and Construction Design Contracts (DFARS Case 2018–D057)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Proposed rule.

SUMMARY: DoD is proposing to amend the Defense Federal Acquisition Regulation Supplement (DFARS) to implement a section of the National Defense Authorization Act for Fiscal Year 2019 regarding set-asides for architect-engineer and construction design contracts.

DATES: Comments on the proposed rule should be submitted in writing to the address shown below on or before February 4, 2019, to be considered in the formation of a final rule.

ADDRESSES: Submit comments identified by DFARS Case 2018–D057, using any of the following methods:

○ *Federal eRulemaking Portal: http://www.regulations.gov.* Search for ''DFARS Case 2018–D057.'' Select ''Comment Now'' and follow the instructions provided to submit a Comment. Please include ''DFARS Case 2018–D057'' on any attached documents.

○ *Email: osd.dfars@mail.mil.* Include DFARS Case 2018–D057 in the subject line of the message.

○ *Fax:* 571–372–6094.

○ *Mail:* Defense Acquisition Regulations System, Attn: Ms. Jennifer D. Johnson, OUSD(A&S)DPC/DARS, Room 3B941, 3060 Defense Pentagon, Washington, DC 20301–3060.

Comments received generally will be posted without change to *http://www.regulations.gov,* including any personal information provided. To confirm receipt of your comment(s), please check *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. Jennifer D. Johnson, telephone 571–372–6100.

SUPPLEMENTARY INFORMATION:

I. Background

DoD is proposing to revise the DFARS to implement section 2804 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2019 (Pub. L. 115–232), which amends the thresholds at 10 U.S.C. 2855 for small business set-asides of acquisitions for architect-engineer services, including construction design, in connection with military construction projects or military family housing projects. Section 2804 requires these acquisitions to be set aside for small business if valued at less than $1,000,000. Section 2804 also removes the prohibition on setting aside these acquisitions; as a result, these acquisitions may now be set aside for small business, if valued at $1,000,000 or more.

II. Discussion and Analysis

This rule proposes to delete paragraph (2) at DFARS 219.502–1. This paragraph prohibits small business set-asides of acquisitions for architect-engineer services for military construction or family housing projects valued at $400,000 or more. The remaining paragraphs would be combined into a single unnumbered paragraph. In addition, this rule proposes to revise the dollar value at DFARS 219.502–2, paragraph (a)(iii), from $400,000 to $1,000,000. This paragraph requires acquisitions for architect-engineer services for military construction or family housing projects to be set aside for small business below a certain dollar value.

III. Applicability to Contracts at or Below the Simplified Acquisition Threshold and for Commercial Items, Including Commercially Available Off-the-Shelf Items

This rule does not propose to create any new provisions or clauses or impact any existing provisions or clauses.

IV. 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.

V. Executive Order 13771

This proposed rule is not expected to be an E.O. 13771 regulatory action, because this rule is not significant under E.O. 12866.

VI. Regulatory Flexibility Act

DoD does not expect this proposed 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 the rule impacts a small number of small entities. However, an initial regulatory flexibility analysis has been performed and is summarized as follows:

DoD is proposing to revise the DFARS to implement section 2804 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2019 (Pub. L. 115–232), which amends the thresholds at 10 U.S.C. 2855 for small business set-asides of acquisitions for architect-engineer services, including construction design, in connection with military construction projects or military family housing projects.

The objective of this rule is to implement statutory changes to 10 U.S.C. 2855 by removing the restriction on small business set-asides for these acquisitions and increasing the threshold for small business set-aside to $1,000,000. The legal basis for the rule is section 2804 of the NDAA for FY 2019.

The rule applies to contract awards for architect-engineer services, including construction design. Data from the Federal Procurement Data System shows that, during FY 2017, DoD awarded 232 contracts for architect-engineer services to 187 unique small entities. In FY 2017, DoD awarded 41 contracts for architect-engineer services valued at more than the prior threshold of $400,000 and less than the new threshold of $1,000,000. This rule proposes to require future contracts in this range to be awarded pursuant to FAR part 19 set-aside procedures. DoD also awarded 290 contracts for architect-engineer services valued at more than $1,000,000. This rule proposes to make it possible for future contracts at those dollar values to be awarded pursuant to part 19 set-aside procedures. There are more than 33,000 small entities listed in the Small Business Administration's Dynamic Small Business Search that provide architect-engineer services. Of these entities, approximately 300 could benefit from this rule.

This rule does not impose any new reporting, recordkeeping, or other compliance requirements for small entities.

This rule does not duplicate, overlap, or conflict with any other Federal rules.

There are no known alternatives that would meet the requirements of the applicable statute.

DoD invites comments from small business concerns and other interested parties on the expected impact of this rule on small entities. DoD will also consider comments from small entities concerning the existing regulations in subparts affected by this rule in accordance with 5 U.S.C. 610. Interested parties must submit such comments separately and should cite 5 U.S.C 610 (DFARS Case 2018–D057), in correspondence.

VII. Paperwork Reduction Act

The rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

List of Subjects in 48 CFR Part 219

Government procurement.

Jennifer Lee Hawes,

Regulatory Control Officer, Defense Acquisition Regulations System.

Therefore, 48 CFR part 219 is proposed to be amended as follows:

PART 219—SMALL BUSINESS PROGRAMS

■ 1. The authority citation for 48 CFR part 219 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

■ 2. Revise section 219.502–1 to read as follows:

219.502–1 Requirements for setting aside acquisitions.

Do not set aside acquisitions for supplies which were developed and financed, in whole or in part, by Canadian sources under the U.S.-Canadian Defense Development Sharing Program.

219.502–2 [Amended]

■ 3. Amend section 219.502–2, in paragraph (a)(iii), by removing ''of under $400,000'' and adding ''under $1,000,000'' in its place.

[FR Doc. 2018–26308 Filed 12–3–18; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 180724688–8688–01]

RIN 0648–BI39

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Reef Fish Fishery of the Gulf of Mexico; Revisions to Red Snapper and Hogfish Management Measures

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS proposes to implement management measures described in two framework actions to the Fishery Management Plan (FMP) for the Reef Fish Resources of the Gulf of Mexico (Gulf), as prepared by the Gulf of Mexico Fishery Management Council (Council). The framework actions are titled ''Modify the Annual Catch Limit (ACL) for the Gulf Red Snapper and Hogfish Stocks'' (ACL Framework Action) and ''Modify the Red Snapper Recreational Annual Catch Targets (ACT)'' (ACT Framework Action). This proposed rule would modify Gulf red snapper commercial and recreational ACLs (quotas) and ACTs, as well as the Gulf hogfish (West Florida stock) stock ACL, as a result of recent stock assessments for each species. Additionally, this proposed rule would reduce the Federal charter vessel/headboat (for-hire) component's red snapper ACT buffer to a level that would allow a greater harvest in 2019 while continuing to constrain landings to the component and total recreational ACLs. The purposes of this proposed

rule are to respond to updated stock assessment information, maximize socio-economic opportunities for red snapper in the Federal for-hire component, and to continue to achieve optimum yield (OY) for each stock.

DATES: Written comments must be received by January 3, 2019.

ADDRESSES: You may submit comments on the proposed rule identified by ''NOAA–NMFS–2018–0130'' by either of the following methods:

• *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2018-0130,* click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments.

• *Mail:* Submit all written comments to Peter Hood, NMFS Southeast Regional Office, 263 13th Avenue South, St. Petersburg, FL 33701.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

Electronic copies of the two framework actions, which each includes an environmental assessment, a regulatory impact review, and a Regulatory Flexibility Act (RFA) analysis may be obtained from the Southeast Regional Office website at *https://www.fisheries.noaa.gov/action/framework-action-modification-recreational-red-snapper-annual-catch-target-buffers-0.*

FOR FURTHER INFORMATION CONTACT: Peter Hood, NMFS Southeast Regional Office, telephone: 727–824–5305, email: *peter.hood@noaa.gov.*

SUPPLEMENTARY INFORMATION: NMFS and the Council manage the Gulf reef fish fishery under the FMP. The FMP, which includes red snapper and hogfish, was prepared by the Council and is implemented by NMFS through regulations at 50 CFR part 622 under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) (16 U.S.C. 1801 *et seq.*).

The Magnuson-Stevens Act requires NMFS and regional fishery management councils to prevent overfishing and achieve, on a continuing basis, the OY from federally managed fish stocks. These mandates are intended to ensure fishery resources are managed for the greatest overall benefit to the nation, particularly with respect to providing food production and recreational opportunities, and protecting marine ecosystems.

All weights described in this proposed rule are in round (whole) weight.

Background

Red Snapper

The current red snapper stock ACL is equal to the acceptable biological catch (ABC) of 13.74 million lb (6.23 million kg); 51 percent is allocated to the commercial sector and 49 percent to the recreational sector. The recreational sector's ACL is further divided into the private angling component (57.7 percent) and Federal for-hire component (42.3 percent). In addition, recreational ACTs are in place for the recreational sector and its respective components. These component ACLs and ACTs were implemented in 2015 and are currently set to expire in 2022 (81 FR 86971, December 2, 2016).

The regulations require NMFS to project the component fishing seasons based on the respective ACTs, which are set 20 percent below the ACLs. The ACTs were implemented to reduce the likelihood of exceeding the private angling or Federal for-hire component ACLs, as well as the total recreational ACL. The commercial sector does not have an ACT because it is managed under an individual fishing quota program that effectively constrains landings to the commercial ACL.

As set through a framework action in 2017, the current red snapper sector ACLs are 7.007 million lb (3.178 million kg) for the commercial sector and 6.733 million lb (3.054 million kg) for the recreational sector (82 FR 26376, June 7, 2017). The current recreational component ACLs are 2.848 million lb (1.292 million kg) for the for-hire component and 3.885 million lb (1.762 million kg) for the private angling component.

The current red snapper recreational ACT is 5.386 million lb (2.443 million kg). The Federal for-hire component ACT is 2.278 million lb (1.033 million kg) and the private angling component ACT is 3.108 million lb (1.410 million kg). As noted above, the component ACLs and ACTs are effective through 2022, after which sector separation ends and the recreational sector will be managed through a recreational ACL and an ACT, but no component ACLs or ACTs.

The Southeast Data, Assessment, and Review (SEDAR) 52 stock assessment for Gulf red snapper was completed in 2018 and was reviewed by the Council's Scientific and Statistical Committee (SSC) in May 2018. The assessment indicated the Gulf red snapper stock is not overfished or undergoing overfishing, and is still rebuilding consistent with the plan to rebuild the stock by 2032. The SSC determined that the stock assessment represented the best scientific information available, acknowledged the red snapper ABC could be increased, and recommended two different ABC options to the Council: A declining yield stream and a constant catch scenario. The Council decided to use the constant catch recommendation and set the ABC at 15.1 million lb (6.85 million kg).

Because the Federal for-hire component has not exceeded its applicable ACL or ACT, the ACT Framework Action was developed to reduce the buffer between the Federal for-hire component ACT and ACL. The Council did not consider decreasing the private angling component ACT buffer because this component exceeded its ACL in 2 of the past 3 years. Application of the Council's ACL/ACT Control Rule resulted in a suggested buffer of 9 percent for the Federal for-hire component. The ACL/ACT Control Rule is used to determine a buffer based on factors such as recent harvest overages, the percent standard error in Federal for-hire landing estimates, stock status, and whether in-season accountability measures are used. The Council decided to change the Federal for-hire component ACT for the 2019 fishing year to reflect this reduced buffer. The reduction in the Federal for-hire component's ACL/ACT buffer would be effective only for 2019 to coincide with the second year of temporary changes to the management of the private angling component. All five Gulf states received exempted fishing permits (EFPs) from NMFS for the 2018 and 2019 fishing years to allow them to test limited state management of the private angling component. Each state was allocated a percentage of the private angling ACL and each state determined whether to manage a reduced portion of its ACL to account for management uncertainty. Therefore, the Council determined that the reduction in the Federal for-hire component ACT buffer should be limited to 2019. If state management of the private angling component is

extended through an amendment to the FMP, the Council could consider retaining the 9 percent buffer for the Federal for-hire component.

Hogfish

The West Florida stock of hogfish is contained completely within the jurisdiction of the Council and includes hogfish in the Gulf exclusive economic zone (EEZ) except south of 25°09′ N lat. off the west coast of Florida. As implemented through Amendment 43 to the FMP, the West Florida stock ACL is 159,300 lb (72,257 kg) for the 2019 and subsequent fishing years (82 FR 34574, July 25, 2017). There is no ACT designated for West Florida hogfish.

The SEDAR 37 Update assessment for the West Florida hogfish stock was completed in 2018. The assessment indicated the West Florida stock is not overfished or undergoing overfishing. The Council's SSC reviewed the assessment in May 2018, determined that the stock assessment represented the best scientific information available, and provided overfishing limit (OFL) and ABC recommendations based on an increasing yield stream. As a result of uncertainties in the update assessment, the SSC did not provide OFL and ABC recommendations beyond 2021. West Florida hogfish has a stock ACL that is equal to the ABC.

Management Measures Contained in This Proposed Rule

For red snapper, this proposed rule would revise the commercial and recreational sector ACLs and ACTs. For the 2019 fishing year, the for-hire component ACT would be set 9 percent below the component ACL. For hogfish, this proposed rule would revise the stock ACL for the West Florida stock.

Red Snapper ACLs, ACTs, and For-Hire Component ACT Buffer

Through this proposed rule, and as a result of the SEDAR 52 stock assessment and the recommendations of the Council's SSC, the ACL Framework Action would increase the total red snapper ACL from 13.74 million lb (6.23 million kg) to 15.1 million lb (6.85 million kg). Using the current sector allocation ratios the resulting ACLs would be 7.701 million lb (3.493 million kg) for the commercial sector, 7.399 million lb (3.356 million kg) for the recreational sector, 3.130 million lb (1.420 million kg) for the Federal for-hire component, and 4.269 million lb (1.936 million kg) for the private angling component.

As described in the ACT Framework Action, this proposed rule would temporarily reduce the Federal for-hire component ACL/ACT buffer from 20 percent to 9 percent in 2019, which in turn would increase the Federal for-hire component ACT. This would consequently increase the recreational ACT as it is the sum of the Federal for-hire and private angling component's ACTs.

As a result of the increased red snapper ACLs and ACTs through the ACL Framework Action and the increased recreational and Federal for-hire component ACTs through the ACT Framework Action, for the 2019 fishing year, the recreational ACT would be 6.263 million lb (2.841 million kg) and the Federal for-hire component ACT would be 2.848 million lb (1.292 million kg). For 2020 and subsequent fishing years, the recreational ACT would be 5.919 million lb (2.830 million kg) and the Federal for-hire component ACT would be 2.504 million lb (1.136 million kg) for the 2020 through 2022 fishing years. The private angling component ACT would be 3.415 million lb (1.549 million kg) for the 2019 through 2022 fishing years. Therefore, the component ACTs in this proposed rule reflect a 9 percent buffer applied to the Federal for-hire component and a 20 percent buffer applied to the private angling component for 2019, and a 20 percent buffer applied to both for 2020 through 2022.

Hogfish Stock ACL

The ACL Framework Action would set the hogfish stock ACLs equal to the Council's SSC recommended ABCs of 129,500 lb (58,740 kg) for 2019, 141,300 lb (64,093 kg) for 2020, and 150,400 lb (68,220 kg) for 2021. Additionally, the ACL (and ABC) proposed for 2021 would be in effect for the 2021 and subsequent fishing years. Although the proposed ACLs for 2019 through 2021 and beyond are less than the current stock ACL, landings in recent years have not exceeded the current ACL (*e.g.,* less than 50 percent of the stock ACL in 2017). Landings are also expected to be constrained to the stock ACL by an increase in the minimum size limit from 12 to 14 inches (30.5 to 35.6 cm), fork length, implemented in 2017. This measure is expected to reduce the directed harvest of hogfish.

Classification

Pursuant to section 304(b)(1)(A) of the Magnuson-Stevens Act, the NMFS Assistant Administrator has determined that this proposed rule is consistent with the framework actions, the FMP, the Magnuson-Stevens Act, and other applicable law, subject to further consideration after public comment.

This proposed rule has been determined to be not significant for purposes of Executive Order 12866. This proposed rule is not an Executive Order 13771 regulatory action because this rule is not significant under Executive Order 12866.

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration (SBA) that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities. The factual basis for this determination follows.

A description of the proposed rule, why it is being considered, and the objectives of, and legal basis for this proposed rule are contained in the preamble of this rule at the beginning of the **SUPPLEMENTARY INFORMATION** section and in the **SUMMARY** section. The Magnuson-Stevens Act provides the statutory basis for this rule. No duplicative, overlapping, or conflicting Federal rules have been identified. In addition, no new reporting, record-keeping, or other compliance requirements are introduced by this proposed rule. Accordingly, the requirements of the Paperwork Reduction Act do not apply to this proposed rule.

This proposed rule would directly apply to recreational fishers (anglers) and indirectly to for-hire fishing businesses (NAICS code 487210) that harvest red snapper and/or West Florida hogfish in Federal waters of the Gulf. Anglers are not considered small entities as that term is defined in 5 U.S.C. 601(6), whether fishing from for-hire fishing, private or leased vessels. Therefore, estimates of the number of anglers directly affected by the rule and the impacts on them are not provided here. For-hire fishing businesses that harvest red snapper and/or hogfish in Federal waters would be indirectly affected if the rule were to cause changes in angler demand for their services. The RFA does not consider such indirect impacts on small entities.

This proposed rule would directly affect commercial fishing businesses (NAICS code 11411) that harvest red snapper and/or hogfish in the Gulf. First, it would increase the commercial ACL for red snapper, and second, it would decrease the commercial ACL for hogfish.

For RFA purposes, NMFS has established a small business size standard for businesses, including their affiliates, whose primary industry is commercial fishing (see 50 CFR 200.2). A business primarily involved in commercial fishing (NAICS 11411) is

classified as a small business if it is independently owned and operated, is not dominant in its field of operation (including its affiliates), and its combined annual receipts are not in excess of $11 million for all of its affiliated operations worldwide.

The best economic data available related to the commercial harvest of red snapper is available through 2016. From 2012 through 2016, an annual average of 409 vessels landed at least 1 lb (0.45 kg) of red snapper in the Gulf. On average, these vessels combined generated total revenues of approximately $60.37 million, of which $24.96 million were from red snapper and $35.41 million from other species. The average annual revenue per vessel was approximately $148,000. Red snapper accounted for about 41 percent of these vessels' total revenues. Net revenues from fishing operations of these vessels were approximately 36 percent of total revenues.

The best economic data available related to the commercial harvest of hogfish is available through 2017. From 2012 through 2017, an annual average of 61 vessels landed at least 1 lb (0.45 kg) of West Florida hogfish. The average annual total revenue was approximately $0.12 million from hogfish, approximately $0.51 million from other species co-harvested with hogfish (on the same trips), and approximately $1.66 million from trips in the Gulf on which no hogfish were harvested or occurred in the South Atlantic. The average total annual revenue from all species harvested by vessels that harvest hogfish in the Gulf was approximately $2.29 million, or approximately $37,000 per vessel. Hogfish accounted for about 5 percent of these vessels' total revenues.

Based on annual revenue information, all of the commercial fishing businesses with the 409 vessels that annually harvest red snapper and those with the 61 vessels that land West Florida hogfish from the Gulf are small entities.

Because all entities expected to be directly affected by this proposed rule are small entities, NMFS has determined that this proposed rule would affect a substantial number of small entities; however, the issue of disproportionate effects on small versus large entities does not arise in the present case.

Since 2007, the commercial sector's harvest of red snapper has operated under an individual fishing quota (RS–IFQ) program. The RS–IFQ program uses shares and allocations to distribute and account for the commercial fishing quota. The proposed rule would increase the quota, which would increase dockside revenue from red snapper. Total dockside revenue for all vessels combined would increase by $4.462 million in 2019, $4.170 million in 2020, and $3.897 in 2021. For the 409 vessels, total revenue per vessel would increase by $10,909 in 2019, $10,195 in 2020, and $9,528 in 2021. The total value of all IFQ shares and all allocation for 2019 through 2021 would also increase.

The reduction of the West Florida hogfish ACL would reduce dockside revenue by $27,387 (2017 dollars) in 2019, by $16,543 in 2020, and $8,179 annually thereafter. The average annual revenue loss per vessel for the 61 vessels that land hogfish would be $449 in 2019, $271 in 2020 and $134 annually thereafter. Those revenue losses represent 1.12 percent, 0.72 percent and 0.36 percent of average annual revenue of the 61 vessels that land West Florida hogfish. The 61 vessels represent approximately 7 percent of the average 877 vessels permitted to harvest Gulf reef fish annually.

The information provided above supports a determination that this proposed rule would not have a significant economic impact on a substantial number of small entities. Because this proposed rule, if implemented, is not expected to have a significant economic impact on any small entities, an initial regulatory flexibility analysis is not required and none has been prepared.

List of Subjects in 50 CFR Part 622

Commercial, Fisheries, Fishing, Hogfish, Gulf, Recreational, Red snapper.

Dated: November 28, 2018.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 622 is proposed to be amended as follows:

PART 622—FISHERIES OF THE CARIBBEAN, GULF, AND SOUTH ATLANTIC

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

Authority: 16 U.S.C. 1801 *et seq.*

■ 2. In § 622.39, revise paragraphs (a)(1)(i) and (a)(2)(i) to read as follows:

§ 622.39 Quotas.

* * * * *

(a) * * *

(1) * * *

(i) *Commercial quota for red snapper*—7.701 million lb (3.493 million kg), round weight.

* * * * *

(2) * * *

(i) *Recreational quota for red snapper*—(A) *Total recreational.* The total recreational quota, is 7.399 million lb (3.356 million kg), round weight.

(B) *Federal charter vessel/headboat component quota.* The Federal charter vessel/headboat component quota applies to vessels that have been issued a valid Federal charter vessel/headboat permit for Gulf reef fish any time during the fishing year. This component quota is effective through the 2022 fishing year. For the 2023 and subsequent fishing years, the applicable total recreational quota, specified in paragraph (a)(2)(i)(A) of this section, will apply to the recreational sector. The Federal charter vessel/headboat component quota is 3.130 million lb (1.420 million kg), round weight.

(C) *Private angling component quota.* The private angling component quota applies to vessels that fish under the bag limit and have not been issued a Federal charter vessel/headboat permit for Gulf reef fish any time during the fishing year. This component quota is effective through the 2022 fishing year. For the 2023 and subsequent fishing years, the applicable total recreational quota, specified in paragraph (a)(2)(i)(A) of this section, will apply to the recreational sector. The private angling component quota is 4.269 million lb (1.936 million kg), round weight.

* * * * *

■ 3. In § 622.41, revise paragraphs (p) and (q)(2)(iii) to read as follows:

§ 622.41 Annual catch limits (ACLs), annual catch targets (ACTs), and accountability measures (AMs).

* * * * *

(p) *Hogfish in the Gulf EEZ except south of 25°09′ N lat. off the west coast of Florida.* If the sum of the commercial and recreational landings, as estimated by the SRD, exceeds the stock ACL, then during the following fishing year, if the sum of commercial and recreational landings reaches or is projected to reach the stock ACL, the AA will file a notification with the Office of the Federal Register to close the commercial and recreational sectors for the remainder of that fishing year. The stock ACL for hogfish, in round weight, in the Gulf EEZ except south of 25°09′ N lat. off the west coast of Florida, is 129,500 lb (58,740 kg), for the 2019 fishing year, 141,300 lb (64,093 kg), for the 2020 fishing year, and 150,400 lb (68,220 kg) for the 2021 fishing year and subsequent fishing years. See § 622.193(u)(2) for the

ACLs, ACT, and AMs for hogfish in the Gulf EEZ south of 25°09′ N lat. off the west coast of Florida.

(q) * * *

(2) * * *

(iii) *Recreational ACT for red snapper*—(A) *Total recreational ACT.* For the 2019 fishing year, the total recreational ACT is 6.263 million lb (2.841 million kg), round weight. For the 2020 and subsequent fishing years, the total recreational ACT is 5.919 million lb (2.830 million kg), round weight.

(B) *Federal charter vessel/headboat component ACT.* The Federal charter vessel/headboat component ACT applies to vessels that have been issued a valid Federal charter vessel/headboat permit for Gulf reef fish any time during the fishing year. This component ACT is effective through the 2022 fishing year. For the 2019 fishing year, the component ACT is 2.848 million lb (1.292 million kg), round weight. For the 2020, 2021, and 2022 fishing years, the component ACT is 2.504 million lb (1.136 million lb), round weight. For the 2023 and subsequent fishing years, the applicable total recreational ACT, specified in paragraph (q)(2)(iii)(A) of this section, will apply to the recreational sector.

(C) *Private angling component ACT.* The private angling component ACT applies to vessels that fish under the bag limit and have not been issued a Federal charter vessel/headboat permit for Gulf reef fish any time during the fishing year. This component ACT is effective through the 2022 fishing year. The component ACT is 3.415 million lb (1.549 million kg), round weight. For the 2023 and subsequent fishing years, the applicable total recreational ACT, specified in paragraph (q)(2)(iii)(A) of this section, will apply to the recreational sector.

[FR Doc. 2018–26196 Filed 12–3–18; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register

Vol. 83, No. 233

Tuesday, December 4, 2018

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

Census Bureau

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

Agency: Census Bureau.

Title: Construction Progress Reporting Surveys.

OMB Control Number: 0607–0153.

Form Number(s): C–700, C–700(R), C–700(SL), C–700(F).

Type of Request: Extension of a currently approved collection.

Number of Respondents: 25,000.

Average Hours per Response: 11.67 minutes.

Burden Hours: 58,333.

Needs and Uses: The U.S. Census Bureau is requesting an extension of a currently approved collection for forms: C–700, for Private Construction Projects; C–700(R), for Multifamily Residential Projects; C–700(SL), for State and Local Governments Projects; and C–700(F), for Federal Government Projects.

These forms are used to conduct the Construction Progress Reporting Surveys (CPRS) which collect information on the dollar value of construction put in place on non-residential building projects under construction by private companies or individuals, private multifamily residential buildings, and building projects under construction by federal and state and local governments.

The Census Bureau uses the information collected on these forms to publish estimates of the monthly dollar value of construction put in place. These data are a Principal Federal Economic Indicator that is used extensively by the federal government in making policy decisions and is used by the Bureau of Economic Analysis (BEA) to estimate Gross Domestic Product (GDP), with construction spending (nonresidential fixed investment on structures and residential fixed investment) accounting for 6.9 percent of GDP in 2017. The private sector uses the statistics for market analysis and other research.

There are currently no planned content changes to the CPRS questionnaires. However, beginning with the September 2018 statistical period, we mailed redesigned forms, which were previously printed on a single legal page, and are now in booklet form. Additionally, the contact information is now requested on the front page of the booklet rather than on the back page, and the numbering scheme reflects this rearrangement of questions.

Affected Public: Businesses; Not-for-profit institutions; State, local or Tribal governments; Federal Government.

Frequency: Monthly.

Respondent's Obligation: Voluntary.

Legal Authority: Title 13 U.S.C., Sections 131 and 182.

This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_Submission@omb.eop.gov* or fax to (202)395–5806.

Sheleen Dumas,

Departmental Lead PRA Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2018–26300 Filed 12–3–18; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–094]

Refillable Stainless Steel Kegs From the People's Republic of China: Postponement of Preliminary Determination in the Countervailing Duty Investigation

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

DATES: Applicable December 4, 2018.

FOR FURTHER INFORMATION CONTACT: Nicholas Czajkowski or Robert Brown, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone (202) 482–1395 or (202) 482–3702, respectively.

SUPPLEMENTARY INFORMATION:

Background

On October 10, 2018, the Department of Commerce (Commerce) initiated the countervailing duty (CVD) investigation of imports of refillable stainless steel kegs (kegs) from the People's Republic of China.[1] The preliminary determination is currently due no later than December 14, 2018.

Postponement of Preliminary Determination

Section 703(b)(1) of the Tariff Act of 1930, as amended (the Act), requires Commerce to issue the preliminary determination in a CVD investigation within 65 days of the date on which Commerce initiated the investigation. However, if the petitioner makes a request for an extension of the period within which the determination must be made, section 703(c)(1)(A) of the Act allows Commerce to postpone making the preliminary determination until no later than 130 days after the date on which the administering authority initiated the investigation.

On November 27, 2018, the petitioner[2] submitted a request pursuant to section 703(c)(1)(A) of the Act and 19 CFR 351.205(e) to postpone the preliminary determination.[3] The petitioner states that additional time is necessary in light of the number of programs under investigation and the expected complexity of the issues.

For the reasons stated above, Commerce, in accordance with section 703(c)(l)(B) of the Act, is postponing the deadline for the preliminary determination to no later than 130 days after the day on which Commerce initiated this investigation. Therefore,

[1] *See Refillable Stainless Steel Kegs: Initiation of Countervailing Duty Investigation,* 83 FR 52192 (October 16, 2018).

[2] The petitioner is American Keg Company LLC.

[3] *See* the petitioner's Letter dated November 27, 2018, requesting postponement of the preliminary determination.

the new deadline for the preliminary determination is February 19, 2019.[4] Pursuant to section 705(a)(1) of the Act and 19 CFR 351.210(b)(1), the deadline for the final determination will continue to be 75 days after the date of the preliminary determination, unless postponed.

This notice is issued and published in accordance with section 703(c)(2) of the Act and 19 CFR 351.205(f)(1).

Dated: November 28, 2018.

Gary Taverman,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2018–26316 Filed 12–3–18; 8:45 am]

BILLING CODE 3510–DS–P

[4] The actual deadline is February 17, 2019, which is a Sunday. Further, Monday, February 18, 2018 is a Federal holiday. In accordance with Commerce's practice, where a deadline falls on a weekend or federal holiday, the appropriate deadline is the next business day. *See Notice of Clarification: Application of ''Next Business Day'' Rule for Administrative Determination Deadlines Pursuant to the Tariff Act of 1930, As Amended,* 70 FR 24533 (May 10, 2005).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–489–815]

Light-Walled Rectangular Pipe and Tube From Turkey: Rescission of Antidumping Duty Administrative Review; 2017–2018

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) is rescinding the administrative review of the antidumping duty order on light-walled rectangular pipe and tube (LWRPT) from Turkey for the period of review (POR) May 1, 2017, through April 30, 2018.

DATES: Applicable December 4, 2018.

FOR FURTHER INFORMATION CONTACT: Jonathan Hill, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3518.

SUPPLEMENTARY INFORMATION:

Background

On May 1, 2018, Commerce published in the **Federal Register** a notice of opportunity to request an administrative review of the antidumping duty order on LWRPT from Turkey for the POR May 1, 2017, through April 30, 2018.[1] On May 31, 2018, in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.213(b), Noksel Celik Boru Sanayi A.S. (Noksel), requested a review of the order with respect to itself.[2] On July 12, 2018, in accordance with section 751(a) of the Act and 19 CFR 351.221(c)(1)(i), Commerce initiated an administrative review of the antidumping duty order on LWRPT from Turkey with respect to Noksel.[3] On August 7, 2018, Noksel timely withdrew its request for an administrative review of itself.[4] No other party requested a review.

Rescission of Review

Pursuant to 19 CFR 351.213(d)(1), Commerce will rescind an administrative review, in whole or in part, if the party that requested the review withdraws its request within 90 days of the publication date of the notice of initiation of the requested review. Noksel withdrew its request for review within the 90-day deadline. Because Commerce received no other requests for review of Noksel, and no other requests were made for a review of the antidumping duty order on LWRPT from Turkey with respect to other companies, we are rescinding the administrative review covering the POR May 1, 2017, through April 30, 2018, in full, in accordance with 19 CFR 351.213(d)(1).

Assessment

Commerce will instruct U.S. Customs and Border Protection (CBP) to assess antidumping duties on all appropriate entries of LWRPT from Turkey during the May 1, 2017, through April 30, 2018, at rates equal to the cash deposit rate for estimated antidumping duties required at the time of entry, or withdrawal from warehouse, for consumption, in accordance with 19 CFR 351.212(c)(1)(i). Commerce intends to issue appropriate assessment instructions to CBP 15 days after the date of publication of this notice in the **Federal Register**.

Notification to Importers

This notice serves as the only reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the presumption that reimbursement of antidumping duties occurred and the subsequent assessment of doubled antidumping duties.

Notification Regarding Administrative Protective Order

This notice also serves as the only reminder to parties subject to administrative protective orders (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

This notice is issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.213(d)(4).

Dated: November 29, 2018.

James Maeder,

Associate Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations performing the duties of Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2018–26318 Filed 12–3–18; 8:45 am]

BILLING CODE 3510–DS–P

[1] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review,* 83 FR 19047 (May 1, 2018).

[2] *See* Noksel's May 31, 2018 Request for Administrative Review.

[3] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 83 FR 32270 (July 12, 2018).

[4] *See* Noksel's August 7, 2018 Withdrawal of Request for Administrative Review.

CONSUMER PRODUCT SAFETY COMMISSION

[Docket No. CPSC–2011–0074]

Notice of Availability: Table Saw Blade-Contact Injuries Special Study Report, 2017

AGENCY: U.S. Consumer Product Safety Commission.

ACTION: Notice of availability.

SUMMARY: The Consumer Product Safety Commission (CPSC) is announcing the availability of a report titled, ''Table Saw Blade-Contact Injuries Special Study Report, 2017.'' The CPSC requests comments on the report.

DATES: Submit comments by February 4, 2019.

ADDRESSES: You may submit comments, identified by Docket No. CPSC–2011–0074, by any of the following methods:

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: *http://www.regulations.gov*. Follow the instructions for submitting comments. The CPSC does not accept comments submitted by electronic mail (email), except through *www.regulations.gov*. The CPSC encourages you to submit electronic comments by using the Federal eRulemaking Portal, as described above.

Written Submissions: Submit written submissions by mail/hand delivery/courier to: Division of the Secretariat, Consumer Product Safety Commission, Room 820, 4330 East-West Highway, Bethesda, MD 20814; telephone (301) 504–7923.

Instructions: All submissions received must include the agency name and docket number for this notice. All comments received may be posted without change, including any personal identifiers, contact information, or other personal information provided, to: *http://www.regulations.gov*. Do not submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If furnished at all, such information should be submitted in writing.

Docket: For access to the docket to read background documents or comments received, go to: *http://www.regulations.gov,* and insert the docket number CPSC–2011–0074, into the ''Search'' box, and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Caroleene Paul, Directorate for Engineering Sciences, U.S. Consumer Product Safety Commission, 5 Research Place, Rockville, MD 20850; telephone: 301–987–2225; email: *cpaul@cpsc.gov*.

SUPPLEMENTARY INFORMATION: On May 12, 2017, the CPSC published in the **Federal Register** a notice of proposed rulemaking (NPR) on a safety standard for table saw blade-contact injuries. 82 FR 22190. In January 2017, staff began collecting additional information on incident data identified in the National Electronic Injury Surveillance System (NEISS) for table saws to: (1) Obtain information regarding the type of table saws involved in the cases to generate national estimates by saw type and estimated risk of injury associated with each table saw type; (2) gain information regarding the type and usage pattern of the blade guard; and (3) collect additional injury and incident data.

On April 27, 2017, the Commission held a decisional hearing on the NPR. The Commission directed ''staff to analyze and seek public comment on the Table Saw Study started in January 2017, based on the most appropriate time period that will generate information to determine a national estimate from NEISS incidents. Results will be published in the **Federal Register** for notice and comment as part of the docket for this rulemaking.''

CPSC staff has completed the report titled, *Table Saw Blade-Contact Injuries Special Study Report, 2017*. The report is available on the CPSC's website at: *https://www.cpsc.gov/Newsroom/FOIA/ReportList?field_nfr_type_value=commission,* and in *http://www.regulations.gov,* under Supporting and Related Materials, docket number CPSC–2011–0074, and from the CPSC's Division of the Secretariat, at the location listed in the **ADDRESSES** section of this notice.

The CPSC invites comments on the report. Comments should be submitted by February 4, 2019. Information on how to submit comments can be found in the **ADDRESSES** section of this notice.

Abioye Mosheim,

Acting Secretary, Consumer Product Safety Commission.

[FR Doc. 2018–26260 Filed 12–3–18; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

Intent To Prepare a Draft Supplemental Environmental Impact Statement (DSEIS) for the Haile Gold Mine in Lancaster County, South Carolina

AGENCY: U.S. Army Corps of Engineers, DoD.

ACTION: Notice of intent.

SUMMARY: The U.S. Army Corps of Engineers, Charleston District intends to prepare a Draft Supplemental Environmental Impact Statement (DSEIS) to assess the likely social, economic and environmental effects of the proposed expansion of an existing gold mine with the potential to impact Waters of the United States near Kershaw in Lancaster County, South Carolina. The DSEIS will assess potential effects of a range of alternatives.

DATES: *Public Scoping Meeting:* A public scoping meeting has not been scheduled; however, a local public notice will be issued by the Charleston District, and a meeting announcement will be published in local newspapers once the date and location for the scoping meeting has been determined.

ADDRESSES: Mr. Shawn Boone, Project Manager, Charleston District, Regulatory Division, 69–A Hagood Avenue, Charleston, SC 29403.

FOR FURTHER INFORMATION CONTACT: For further information and/or questions about the proposed mine expansion project and DSEIS, please contact Mr. Shawn Boone, Project Manager, by *telephone:* 843–329–8158, or *toll-free* 1–866–329–8187, or by *mail: shawn.a.boone@usace.army.mil.* For inquiries from the media, please contact the Corps, Charleston District Corporate Communications Officer (CCO), Ms. Glenn Jeffries by *telephone:* (843) 329–8123.

SUPPLEMENTARY INFORMATION: The Corps is evaluating a proposal from OceanaGold for the expanded development of the Haile Gold Mine in accordance with Corps regulations and the policies and procedures that are established in the National Environmental Policy Act (NEPA). Based on the available information, the Corps has determined that the expansion of the mine has the potential to significantly affect the quality of the human environment and therefore warrant the preparation of a Supplemental EIS. Additional information about the proposed project and the NEPA process is available on the project website at: *www.hailegoldmineseis.com.*

1. *Description of Proposed Project.* The Haile Gold Mine expansion plan (the proposed Project) includes the ore mining and processing operations that would recover gold and silver by excavating pits and underground deposits, storing excavated soils and overburden, processing the ore, managing surface water and ground water during operations, reclaiming the site at the end of operations, and monitoring site conditions post-mining. The site of the Project is currently an operating mine which was the subject of an Environmental Impact Statement published in 2014.

2. *Alternatives.* A range of alternatives to the proposed action will be identified, and those found to be reasonable alternatives will be fully evaluated in the DSEIS, including: The no-action alternative, the applicant's proposed alternative, alternative site configurations, alternatives that may result in avoidance and minimization of impacts, and mitigation measures not in the proposed action. However, this list is not exclusive and additional alternatives may be considered for inclusion.

3. *Scoping and Public Involvement Process.* A scoping meeting will be conducted to gather information on the scope of the project and alternatives to be addressed in the DSEIS. Individuals and organizations that are interested in the proposed mine expansion or whose interests may be affected by the proposed work are encouraged to attend the scoping meeting to submit oral and/or written comments to the Charleston District. Additional public and agency involvement will be sought through the implementation of a public involvement plan and through an agency coordination team.

4. *Significant Issues.* Issues associated with the proposed project to be given detailed analysis in the DSEIS are likely to include, but are not necessarily limited to, the potential impacts of the proposed development on surface and groundwater quality, aquatic habitat and biota, wetlands and stream habitats, federal and state listed species of concern, indirect and cumulative impacts, threatened and endangered species, environmental justice, mitigation, emergency response and contingency plans, noise, conservation, economics, cultural resources, aesthetics, general environmental concerns, historic properties, fish and wildlife values, flood hazards, land use, recreation, water supply and conservation, water quality, energy needs, safety, the transportation network, and in general, the needs and welfare of the people.

5. *Additional Review and Consultation.* Additional review and consultation, which will be incorporated into the preparation of this DSEIS, will include, but will not necessarily be limited to, Section 401 of Clean Water Act; the National Environmental Policy Act; the Endangered Species Act; and the National Historic Preservation Act.

6. *Availability of the Draft Supplemental Environmental Impact Statement.* The DSEIS is anticipated to be available in early 2020. A Public Hearing will be conducted following the release of the DSEIS.

Jeffrey S. Palazzini,

Lieutenant Colonel, U.S. Army Corps of Engineers, Charleston District.

[FR Doc. 2018–26341 Filed 12–3–18; 8:45 am]

BILLING CODE 3720–58–P

DEPARTMENT OF EDUCATION

2018–2019 Award Year Deadline Dates for Reports and Other Records Associated With the Free Application for Federal Student Aid (FAFSA), the Federal Supplemental Educational Opportunity Grant Program (FSEOG), the Federal Work-Study (FWS) Programs, the Federal Pell Grant (Pell Grant) Program, the William D. Ford Federal Direct Loan (Direct Loan) Program, the Teacher Education Assistance for College and Higher Education (TEACH) Grant Program, and the Iraq and Afghanistan Service Grant Program

AGENCY: Federal Student Aid, Department of Education.

ACTION: Notice.

Catalog of Federal Domestic Assistance (CFDA) Numbers: 84.007 FSEOG Program; 84.033 FWS Program; 84.063 Pell Grant Program; 84.268 Direct Loan Program; 84.379 TEACH Grant Program; 84.408 Iraq and Afghanistan Service Grant Program.

SUMMARY: The Secretary announces deadline dates for the receipt of documents and other information from applicants and institutions participating in certain Federal student aid programs authorized under title IV of the Higher Education Act of 1965, as amended (HEA), for the 2018–2019 award year. These programs, administered by the U.S. Department of Education (Department), provide financial assistance to students attending eligible postsecondary educational institutions to help them pay their educational costs.

The Federal student aid programs (title IV, HEA programs) covered by this deadline date notice are the Pell Grant, Direct Loan, TEACH Grant, Iraq and Afghanistan Service Grant, and campus-based (FSEOG and FWS) programs.

DATES:

Deadline and Submission Dates: See Tables A and B at the end of this notice.

FOR FURTHER INFORMATION CONTACT: Bruce Hughes, U.S. Department of Education, Federal Student Aid, 830 First Street NE, Union Center Plaza, 11th Floor, Washington, DC 20202–5345. Telephone: (202) 377–3882. Email: *Bruce.Hughes@ed.gov.*

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service, toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

Table A—2018–2019 Award Year Deadline Dates by Which a Student Must Submit the FAFSA, by Which the Institution Must Receive the Student's Institutional Student Information Record (ISIR) or Student Aid Report (SAR), and by Which the Institution Must Submit Verification Outcomes for Certain Students.

Table A provides information and deadline dates for receipt of the FAFSA, corrections to and signatures for the FAFSA, ISIRs, and SARs, and verification documents.

The deadline date for the receipt of a FAFSA by the Department's Central Processing System is June 30, 2019, regardless of the method that the applicant uses to submit the FAFSA. The deadline date for the receipt of a signature page for the FAFSA (if required), corrections, notices of change of address or institution, or requests for a duplicate SAR is September 14, 2019.

For all title IV, HEA programs, an ISIR or SAR for the student must be received by the institution no later than the student's last date of enrollment for the 2018–2019 award year or September 21, 2019, whichever is earlier. Note that a FAFSA must be submitted and an ISIR or SAR received for the dependent student for whom a parent is applying for a Direct PLUS Loan.

Except for students selected for Verification Tracking Groups V4 and V5, verification documents must be received by the institution no later than 120 days after the student's last date of enrollment for the 2018–2019 award year or September 21, 2019, whichever is earlier. For students selected for Verification Tracking Groups V4 and V5, institutions must submit identity and high school completion status verification results no later than 60 days following the institution's first request to the student to submit the documentation.

For all title IV, HEA programs except for (1) Direct PLUS Loans that will be made to parent borrowers, and (2) Direct Unsubsidized Loans that will be made to dependent students who have been determined by the institution, pursuant to section 479A(a) of the HEA, to be eligible for such a loan without providing parental information on the FAFSA, the ISIR or SAR must have an official expected family contribution (EFC) and the ISIR or SAR must be received by the institution no later than the earlier of the student's last date of enrollment for the 2018–2019 award year or September 21, 2019. For the two exceptions mentioned above, the ISIR or SAR must be received by the institution by the same dates noted in the paragraph but the ISIR or SAR is not required to have an official EFC.

For a student who is requesting aid through the Pell Grant, FSEOG, or FWS

programs or for a student requesting Direct Subsidized Loans, who does not meet the conditions for a late disbursement under 34 CFR 668.164(j), a valid ISIR or valid SAR must be received by the institution by the student's last date of enrollment for the 2018–2019 award year or September 21, 2019, whichever is earlier.

In accordance with 34 CFR 668.164(j)(4)(i), an institution may not make a late disbursement of title IV, HEA program funds later than 180 days after the date of the institution's determination that the student was no longer enrolled. Table A provides that, to make a late disbursement of title IV, HEA program funds, an institution must receive a valid ISIR or valid SAR no later than 180 days after its determination that the student was no longer enrolled, but not later than September 21, 2019.

Table B—2018–2019 Award Year Pell Grant, Iraq and Afghanistan Service Grant, Direct Loan, and TEACH Grant Programs Deadline Dates for Disbursement by Institutions.

For the Pell Grant, Iraq and Afghanistan Service Grant, Direct Loan, and TEACH Grant programs, Table B provides the earliest disbursement date, the earliest dates for institutions to submit disbursement records to the Department's Common Origination and Disbursement (COD) System, and deadline dates by which institutions must submit disbursement and origination records.

An institution must submit Pell Grant, Iraq and Afghanistan Service Grant, Direct Loan, and TEACH Grant disbursement records to COD, no later than 15 days after making the disbursement or becoming aware of the need to adjust a previously reported disbursement. In accordance with 34 CFR 668.164(a), title IV, HEA program funds are disbursed on the date that the institution: (a) Credits those funds to a student's account in the institution's general ledger or any subledger of the general ledger; or (b) pays those funds to a student directly. Title IV, HEA program funds are disbursed even if an institution uses its own funds in advance of receiving program funds from the Department.

An institution's failure to submit disbursement records within the required timeframe may result in the Department rejecting all or part of the reported disbursement. Such failure may also result in an audit or program review finding or the initiation of an adverse action, such as a fine or other penalty for such failure, in accordance with subpart G of the General Provisions regulations in 34 CFR part 668.

Deadline Dates for Enrollment Reporting by Institutions.

In accordance with 34 CFR 674.19(f), 682.610(c), 685.309(b), and 690.83(b)(2), upon receipt of an enrollment report from the Secretary, institutions must update all information included in the report and return the report to the Secretary in a manner and format prescribed by the Secretary and within the timeframe prescribed by the Secretary. Consistent with the *National Student Loan Data System (NSLDS) Enrollment Reporting Guide,* the Secretary has determined that institutions must report at least every two months. Institutions may find the *NSLDS Enrollment Reporting Guide* on the Information for Financial Aid Professionals website at *https://ifap.ed.gov.*

Other Sources for Detailed Information

We publish a detailed discussion of the Federal student aid application process in the Application and Verification Guide volume of the 2018–2019 *Federal Student Aid Handbook* and in the 2018–2019 *ISIR Guide.*

Information on the institutional reporting requirements for the Pell Grant, Iraq and Afghanistan Service Grant, Direct Loan, and TEACH Grant programs is included in the 2018–2019 *Common Origination and Disbursement (COD) Technical Reference.* Also, see the *NSLDS Enrollment Reporting Guide.*

You may access these publications by selecting the ''iLibrary'' link at the Information for Financial Aid Professionals website at: *https://ifap.ed.gov.*

Additionally, the 2018–2019 award year reporting deadline dates for the Federal Perkins Loan, FWS, and FSEOG programs were published in the **Federal Register** on January 3, 2018 (83 FR 356).

Applicable Regulations: The following regulations apply:

(1) Student Assistance General Provisions, 34 CFR part 668.

(2) Federal Pell Grant Program, 34 CFR part 690.

(3) William D. Ford Direct Loan Program, 34 CFR part 685.

(4) Teacher Education Assistance for College and Higher Education Grant Program, 34 CFR part 686.

Accessible Format: Individuals with disabilities can obtain this document in an accessible format (*e.g.,* braille, large print, audiotape, or compact disc) on request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Program Authority: 20 U.S.C. 1070a, 1070a–1, 1070b–1070b–4, 1070g, 1070h, 1087a–1087j, and 1087aa–1087ii; 42 U.S.C. 2751–2756b.

Dated: November 29, 2018.

James F. Manning,

Acting Chief Operating Officer, Federal Student Aid.

TABLE A—2018–2019 AWARD YEAR DEADLINE DATES BY WHICH A STUDENT MUST SUBMIT THE FAFSA, BY WHICH THE INSTITUTION MUST RECEIVE THE STUDENT'S INSTITUTIONAL STUDENT INFORMATION RECORD (ISIR) OR STUDENT AID REPORT (SAR), AND BY WHICH THE INSTITUTION MUST SUBMIT VERIFICATION OUTCOMES FOR CERTAIN STUDENTS

Who submits?	What is submitted?	Where is it submitted?	What is the deadline date for receipt?
Student	FAFSA—''FAFSA on the Web'' (original or renewal).	Electronically to the Department's Central Processing System (CPS).	[1] June 30, 2019.
	Signature page (if required)	To the address printed on the signature page.	September 14, 2019.

TABLE A—2018–2019 AWARD YEAR DEADLINE DATES BY WHICH A STUDENT MUST SUBMIT THE FAFSA, BY WHICH THE INSTITUTION MUST RECEIVE THE STUDENT'S INSTITUTIONAL STUDENT INFORMATION RECORD (ISIR) OR STUDENT AID REPORT (SAR), AND BY WHICH THE INSTITUTION MUST SUBMIT VERIFICATION OUTCOMES FOR CERTAIN STUDENTS—Continued

Who submits?	What is submitted?	Where is it submitted?	What is the deadline date for receipt?
Student through an Institution.	An electronic FAFSA (original or renewal).	Electronically to the Department's CPS using "Electronic Data Exchange" (EDE) or "FAA Access to CPS Online".	[1] June 30, 2019.
Student	A paper original FAFSA	To the address printed on the FAFSA or envelope provided with the FAFSA.	June 30, 2019.
Student	Electronic corrections to the FAFSA using "Corrections on the Web".	Electronically to the Department's CPS	[1] September 14, 2019.
	Signature page (if required)	To the address printed on the signature page.	September 14, 2019.
Student through an Institution.	Electronic corrections to the FAFSA	Electronically to the Department's CPS using EDE or "FAA Access to CPS Online".	[1] September 14, 2019.
Student	Paper corrections to the FAFSA using a SAR, including change of mailing and email addresses and change of institutions.	To the address printed on the SAR	September 14, 2019.
Student	Change of mailing and email addresses, change of institutions, or requests for a duplicate SAR.	To the Federal Student Aid Information Center by calling 1–800–433–3243.	September 14, 2019.
Student	A SAR with an official EFC calculated by the Department's CPS, except for Parent PLUS Loans and Direct Unsubsidized Loans made to a dependent student under HEA section 479A(a), for which the ISIR does not need to have an official EFC.	To the institution	The earlier of: —The student's last date of enrollment for the 2018–2019 award year; or —[2] September 21, 2019.
Student through CPS.	An ISIR with an official EFC calculated by the Department's CPS, except for Parent PLUS Loans and Direct Unsubsidized Loans made to a dependent student under HEA section 479A(a), for which the ISIR does not need to have an official EFC.	To the institution from the Department's CPS.	
Student	Valid SAR (Pell Grant, FSEOG, FWS, and Direct Subsidized Loans).	To the institution	Except for a student meeting the conditions for a late disbursement under 34 CFR 668.164(j), the earlier of:
Student through CPS.	Valid ISIR (Pell Grant, FSEOG, FWS, and Direct Subsidized Loans).	To the institution from the Department's CPS.	—The student's last date of enrollment for the 2018–2019 award year; or —[2] September 21, 2019.
Student	Valid SAR (Pell Grant, FSEOG, FWS, and Direct Subsidized Loans).	To the institution	For a student receiving a late disbursement under 34 CFR 668.164(j)(4)(i), the earlier of:
Student through CPS.	Valid ISIR (Pell Grant, FSEOG, FWS, and Direct Subsidized Loans).	To the institution from the Department's CPS. —[2] September 21, 2019..	—180 days after the date of the institution's determination that the student withdrew or otherwise became ineligible; or
Student	Verification documents	To the institution —120 days after the student's last date of enrollment for the 2018–2019 award year; or. —[2] September 21, 2019.	[3] The earlier of:
Institution	Identity and high school completion verification results for a student selected for verification by the Department and placed in Verification Tracking Group V4 or V5.	Electronically to the Department's CPS using "FAA Access to CPS Online".	[4] 60 days following the institution's first request to the student to submit the required V4 or V5 identity and high school completion documentation.

[1] The deadline for electronic transactions is 11:59 p.m. (Central Time) on the deadline date. Transmissions must be completed and accepted before 12:00 midnight to meet the deadline. If transmissions are started before 12:00 midnight but are not completed until after 12:00 midnight, those transmissions do not meet the deadline. In addition, any transmission submitted on or just prior to the deadline date that is rejected may not be reprocessed because the deadline will have passed by the time the user gets the information notifying him or her of the rejection.

[2] The date the ISIR/SAR transaction was processed by CPS is considered to be the date the institution received the ISIR or SAR regardless of whether the institution has downloaded the ISIR from its Student Aid Internet Gateway (SAIG) mailbox or when the student submits the SAR to the institution.

[3] Although the Secretary has set this deadline date for the submission of verification documents, if corrections are required, deadline dates for submission of paper or electronic corrections and, for Pell Grant applicants and applicants selected for verification, deadline dates for the submission of a valid SAR or valid ISIR to the institution must still be met. An institution may establish an earlier deadline for the submission of verification documents for purposes of the campus-based programs and the Direct Loan Program, but it cannot be later than this deadline date.

[4] Note that changes to previously submitted Identity Verification Results must be updated within 30 days of the institution becoming aware that a change has occurred.

TABLE B—PELL GRANT, IRAQ AND AFGHANISTAN SERVICE GRANT, DIRECT LOAN, AND TEACH GRANT PROGRAMS DEADLINE DATES FOR DISBURSEMENT INFORMATION BY INSTITUTIONS FOR THE 2018–2019 AWARD YEAR OR PROCESSING YEAR [1]

Which program?	What is submitted?	Under what circumstances is it submitted?	Where is it submitted?	What are the deadlines for disbursement and for submission of records and information?
Pell Grant, Direct Loan, TEACH Grant, and Iraq and Afghanistan Service Grant programs.	An origination or disbursement record.	The institution has made or intends to make a disbursement.	To the Common Origination and Disbursement (COD) System using the Student Aid Internet Gateway (SAIG); or to the COD System using the COD website at: *https://cod.ed.gov*.	The earliest disbursement date is January 31, 2018. The earliest submission date for anticipated disbursement information is March 25, 2018. The earliest submission date for actual disbursement information is March 25, 2018, but no earlier than: (a) 7 calendar days prior to the disbursement date under the advance payment method or the Heightened Cash Monitoring Payment Method 1 (HCM1); or (b) The disbursement date under the reimbursement or the Heightened Cash Monitoring Payment Method 2 (HCM2).
Pell Grant, Iraq and Afghanistan Service Grant, and TEACH Grant programs.	An origination or disbursement record.	The institution has made a disbursement and will submit records on or before the deadline submission date.	To COD using SAIG; or to COD using the COD website at: *https://cod.ed.gov*.	The deadline submission date [2] is the earlier of: (a) 15 calendar days after the institution makes a disbursement or becomes aware of the need to make an adjustment to previously reported disbursement data, except that records for disbursements made between January 31, 2018 and March 25, 2018 must be submitted no later than April 9, 2018; or (b) September 30, 2019.
Direct Loan Program	An origination or disbursement record.	The institution has made a disbursement and will submit records on or before the deadline submission date.	To COD using SAIG; or to COD using the COD website at: *https://cod.ed.gov*.	The deadline submission date [2] is the earlier of: (a) 15 calendar days after the institution makes a disbursement or becomes aware of the need to make an adjustment to previously reported disbursement data, except that records of disbursements made between October 1, 2017 and March 25, 2018, may be submitted no later than April 9, 2018; or (b) July 31, 2020.
Pell Grant and Iraq and Afghanistan Service Grant programs.	A downward adjustment to an origination or disbursement record.	It is after the deadline submission date.	To COD using SAIG; or to COD using the COD website at: *https://cod.ed.gov*.	No later than September 30, 2024.

TABLE B—PELL GRANT, IRAQ AND AFGHANISTAN SERVICE GRANT, DIRECT LOAN, AND TEACH GRANT PROGRAMS DEADLINE DATES FOR DISBURSEMENT INFORMATION BY INSTITUTIONS FOR THE 2018–2019 AWARD YEAR OR PROCESSING YEAR [1]—Continued

Which program?	What is submitted?	Under what circumstances is it submitted?	Where is it submitted?	What are the deadlines for disbursement and for submission of records and information?
Pell Grant and Iraq and Afghanistan Service Grant programs.	An origination or disbursement record.	It is after the deadline submission date and the institution has received approval of its request for an extension to the deadline submission date. Requests for extensions to the established submission deadlines may be made for reasons including, but not limited to:. (a) A program review or initial audit finding under 34 CFR 690.83;. (b) A late disbursement under 34 CFR 668.164(j); or. (c) Disbursements previously blocked as a result of another institution failing to post a downward adjustment.	Via the COD website at: *https://cod.ed.gov*.	The earlier of: (a) When the institution is fully reconciled and is ready to submit all additional data for the program and the award year; or (b) September 30, 2024.
TEACH Grant and Direct Loan programs.				When the institution is fully reconciled and is ready to submit all additional data for the program and the award year.
Pell Grant and Iraq and Afghanistan Service Grant programs.	An origination or disbursement record.	It is after the deadline submission date and the institution has received approval of its request for an extension to the deadline submission date based on a natural disaster, other unusual circumstances, or an administrative error made by the Department.	Via the COD website at: *https://cod.ed.gov*.	The earlier of: (a) A date designated by the Secretary after consultation with the institution; or (b) February 1, 2020.
Pell Grant and Iraq and Afghanistan Service Grant programs.	An origination or disbursement record.	It is after the deadline submission date and the institution has received approval of its request for administrative relief to extend the deadline submission date based on a student's reentry to the institution within 180 days after initially withdrawing [3].	Via the COD website at: *https://cod.ed.gov*.	The earlier of: (a) 15 days after the student reenrolls; or (b) May 1, 2020.

[1] A COD Processing Year is a period of time in which institutions are permitted to submit Direct Loan records to the COD System that are related to a given award year. For a Direct Loan, the period of time includes loans that have a loan period covering any day in the 2018–2019 award year.

[2] Transmissions must be completed and accepted before the designated processing time on the deadline submission date. The designated processing time is published annually via an electronic announcement posted to the Information for Financial Aid Professionals website (*https://ifap.ed.gov*). If transmissions are started at the designated time, but are not completed until after the designated time, those transmissions will not meet the deadline. In addition, any transmission submitted on or just prior to the deadline date that is rejected may not be reprocessed because the deadline will have passed by the time the user gets the information notifying him or her of the rejection.

[3] Applies only to students enrolled in clock-hour and nonterm credit-hour educational programs.

Note: The COD System must accept origination data for a student from an institution before it accepts disbursement information from the institution for that student. Institutions may submit origination and disbursement data for a student in the same transmission. However, if the origination data is rejected, the disbursement data is rejected.

[FR Doc. 2018–26313 Filed 12–3–18; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket ID ED–2018–FSA–0080]

Privacy Act of 1974; Matching Program

AGENCY: Department of Education.

ACTION: Notice of a new matching program.

SUMMARY: This provides notice of the re-establishment of the matching program between the U.S. Department of Education (Department or ED) (recipient agency) and the U.S. Department of Veterans Affairs (VA) (source agency). The purpose of the matching program is to assist the Department with verification of a veteran's status during the processing of applications for financial assistance under title IV of the Higher Education Act of 1965, as amended (HEA).

DATES: Submit your comments on the proposed matching program on or before January 3, 2019.

The matching program will go into effect at the later of the following two dates: (1) January 2, 2019, or (2) 30 days after the publication of this notice, December 4, 2018, unless comments have been received from interested members of the public requiring modification and replication of the notice. The matching program will continue for 18 months after the effective date and may be extended for an additional 12 months, if the respective Data Integrity Boards (DIBs) of the Department and VA determine that the conditions specified in 5 U.S.C. 552a(o)(2)(D) have been met.

ADDRESSES: Submit your comments through the Federal eRulemaking Portal or via postal mail, commercial delivery, or hand delivery. We will not accept comments submitted by fax or by email or those submitted after the comment period. To ensure that we do not receive duplicate copies, please submit your comments only once. In addition, please include the Docket ID at the top of your comments.

- *Federal eRulemaking Portal:* Go to *www.regulations.gov* to submit your comments electronically. Information on using *Regulations.gov*, including instructions for accessing agency documents, submitting comments, and viewing the docket, is available on the site under the ''help'' tab.
- *Postal Mail, Commercial Delivery, or Hand Delivery:* If you mail or deliver your comments about these proposed regulations, address them to Marya Dennis, Management and Program Analyst, U.S. Department of Education, Federal Student Aid, Union Center Plaza, 830 First Street NE, Washington, DC 20002–5345.

Privacy Note: The Department's policy is to make all comments received from members of the public available for public viewing in their entirety on the Federal eRulemaking Portal at *www.regulations.gov.* Therefore, commenters should be careful to include in their comments only information that they wish to make publicly available.

Assistance to Individuals with Disabilities in Reviewing the Rulemaking Record: On request we will provide an appropriate accommodation or auxiliary aid to an individual with a disability who needs assistance to review the comments or other documents in the public rulemaking record for this notice. If you want to schedule an appointment for this type of accommodation or auxiliary aid, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

FOR FURTHER INFORMATION CONTACT: Ms. Marya Dennis, Management and Program Analyst, U.S. Department of Education, Federal Student Aid, Union Center Plaza, 830 First Street NE, Washington, DC 20002–5345. Telephone: (202) 377–3385.

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free at 1–800–877–8339.

SUPPLEMENTARY INFORMATION: We provide this notice in accordance with the Privacy Act of 1974, as amended (5 U.S.C. 552a); Office of Management and Budget (OMB) Final Guidance Interpreting the Provisions of Public Law 100–503, the Computer Matching and Privacy Protection Act of 1988, 54 FR 25818 (June 19, 1989); and OMB Circular No. A–108, 81 FR 94424 (December 23, 2016).

The prior Computer Matching Agreement (CMA) was published in the **Federal Register** on June 1, 2016 (81 FR 35003). Under the provisions of the Computer Matching and Privacy Protection Act of 1988, Public Law 100–503, the CMA was renewed for an additional 12 months through January 1, 2019, because: (1) The program was conducted without change; and (2) each Data Integrity Board Chairperson certified in writing that the program was conducted in compliance with the CMA. ED and VA are now re-establishing the matching program through this notice.

Participating Agencies

ED and VA.

Authority for Conducting the Matching Program

ED is authorized to participate in the matching program under sections 480(c)(1) and 480(d)(1)(D) of the HEA (20 U.S.C. 1087vv(c)(1) and (d)(1)(D)). VA is authorized to participate in the matching program under 38 U.S.C. 523.

Purpose(s)

The purpose of this matching program is to assist the Secretary of Education with verification of a veteran's status during the processing and review of applications for financial assistance under title IV of the Higher Education Act of 1965, as amended (HEA).

The Secretary of Education is authorized by the HEA to administer the title IV programs and to enforce the terms and conditions of the HEA.

Section 480(c)(1) of the HEA defines the term ''veteran'' to mean ''any individual who (A) has engaged in the active duty in the United States Army, Navy, Air Force, Marines, or Coast Guard; and (B) was released under a condition other than dishonorable.'' (20 U.S.C. 1087vv(c)(1)). Under section 480(d)(1)(D) of the HEA, an applicant who is a veteran (as defined in section 480(c)(1)) is considered an independent student for purposes of title IV, HEA program assistance eligibility, and, therefore, does not have to provide parental income and asset information to apply for title IV, HEA program assistance. (20 U.S.C. 1087vv(d)(1)(D)).

Categories of Individuals

Individuals who have completed the Free Application for Federal Student Aid (FAFSA) and have indicated that they are a veteran.

Categories of Records

ED will provide to the VA the Social Security number, first and last name, and date of birth of each applicant for financial assistance under title IV of the HEA who indicates veteran status in his or her application for financial assistance under title IV of the HEA.

System(s) of Records

ED system of records: Federal Student Aid Application File (18–11–01) (76 FR 46774, August 3, 2011).

VA system of records: Veterans and Beneficiaries Identification and Records Location Subsystem—VA (38VA21) last published in full at 47 FR 367 (January 5, 1982) and most recently amended at 66 FR 30049 (June 4, 2001).

Accessible Format: Individuals with disabilities can obtain this document in an accessible format (such as, Braille, large print, audiotape, or compact disc) on request to the contact person listed under **FOR FURTHER INFORMATION CONTACT**.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: November 29, 2018.

James F. Manning,

Acting Chief Operating Officer, Federal Student Aid.

[FR Doc. 2018–26312 Filed 12–3–18; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Extension of the Public Comment Period for the U.S. Department of Energy Interpretation of High-Level Radioactive Waste

AGENCY: Office of Environmental Management, U.S. Department of Energy.

ACTION: Extension of public comment period.

SUMMARY: The U.S. Department of Energy (DOE) is extending the public comment period for the request for public comments on its proposed interpretation of the statutory term high-level radioactive waste (HLW). DOE published a notice in the **Federal Register** on October 10, 2018, establishing a 60-day public comment period ending on December 10, 2018. DOE is extending the public comment period for 30 days, ending on January 9, 2019.

DATES: The comment period for the Notice published on October 10, 2018 (83 FR 50909) is extended. DOE will consider all comments submitted or postmarked by January 9, 2019.

ADDRESSES: Please direct comments to:

(a) *Email:* Send comments to *HLWnotice@em.doe.gov.* Please submit comments in Microsoft™ Word, or PDF file format, and avoid the use of encryption.

(b) *Mail:* Send to the following address: Theresa Kliczewski, U.S. Department of Energy, Office of Environmental Management, Office of Waste and Materials Management (EM–4.2), 1000 Independence Avenue SW, Washington, DC 20585.

FOR FURTHER INFORMATION CONTACT: Ms. Theresa Kliczewski at *HLWnotice@em.doe.gov* or at U.S. Department of Energy, Office of Environmental Management, Office of Waste and Materials Management (EM–4.2), 1000 Independence Avenue SW, Washington, DC 20585. Telephone: (202) 586–3301.

SUPPLEMENTARY INFORMATION: On October 10, 2018, DOE published a notice in the **Federal Register** [83 FR 50909] soliciting public comment on its interpretation of the statutory term high-level radioactive waste (HLW) as set forth in the Atomic Energy Act of 1954 and the Nuclear Waste Policy Act of 1982. This statutory term indicates that not all wastes from reprocessing of spent nuclear fuel are HLW, and DOE interprets the statutory term such that some reprocessing wastes may be classified as not HLW (non-HLW) and may be disposed of in accordance with their radiological characteristics. DOE established a 60-day public comment period ending on December 10, 2018. DOE has received public comments in response to the Notice, including requests from several entities requesting extensions of the public comment period. Commenters noted the significance of this matter, the overlap in comment periods with another DOE radioactive waste proceeding at DOE's Hanford site, etc. DOE has reviewed the requests for an extension of the public comment period and considered the benefit to DOE and stakeholders in providing additional time to the public to review the Notice and provide comments to DOE on its HLW interpretation. Accordingly, DOE has determined that an extension of the comment period is appropriate, and is hereby extending the comment period an additional 30 days, with the public comment period ending on January 9, 2019.

Issued at Washington, DC, on November 28, 2018.

Anne Marie White,

Assistant Secretary, Office of Environmental Management.

[FR Doc. 2018–26319 Filed 12–3–18; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP19–311–000.
Applicants: NEXUS Gas Transmission, LLC.
Description: § 4(d) Rate Filing: Negotiated Rate—CNX Gas to DTE Energy to be effective 12/1/2018.
Filed Date: 11/27/18.
Accession Number: 20181127–5023.
Comments Due: 5 p.m. ET 12/10/18.

Docket Numbers: RP19–312–000.
Applicants: Guardian Pipeline, L.L.C.
Description: § 4(d) Rate Filing: Non-Conforming and Negotiated Rate Agreement Wisconsin Gas & Wisconsin Electric to be effective 12/1/2018.
Filed Date: 11/27/18.
Accession Number: 20181127–5060.
Comments Due: 5 p.m. ET 12/10/18.

Docket Numbers: RP19–313–000.
Applicants: Guardian Pipeline, L.L.C.
Description: § 4(d) Rate Filing: Non-Conforming and Negotiated Rate Agreement Wisconsin Gas & Wisconsin Electric to be effective 12/1/2018.
Filed Date: 11/27/18.
Accession Number: 20181127–5077.
Comments Due: 5 p.m. ET 12/10/18.

Docket Numbers: RP19–314–000.
Applicants: Gas Transmission Northwest LLC.
Description: § 4(d) Rate Filing: Annual Fuel Filing 2018 to be effective 1/1/2019.
Filed Date: 11/27/18.
Accession Number: 20181127–5094.
Comments Due: 5 p.m. ET 12/10/18.

Docket Numbers: RP19–315–000.
Applicants: Florida Gas Transmission Company, LLC.
Description: § 4(d) Rate Filing: New Service Agreement (PowerSouth) Filing on 11–27–18 to be effective 12/1/2018.
Filed Date: 11/27/18.

Accession Number: 20181127–5101.
Comments Due: 5 p.m. ET 12/10/18.

Docket Numbers: RP19–316–000.
Applicants: Florida Gas Transmission Company, LLC.
Description: § 4(d) Rate Filing: Update Non-Conforming List (PowerSouth) Filing on 11–27–18 to be effective 12/1/2018.
Filed Date: 11/27/18.
Accession Number: 20181127–5102.
Comments Due: 5 p.m. ET 12/10/18.

Docket Numbers: RP19–317–000.
Applicants: Northern Natural Gas Company.
Description: § 4(d) Rate Filing: 20181127 Negotiated Rate to be effective 11/28/2018.
Filed Date: 11/27/18.
Accession Number: 20181127–5137.
Comments Due: 5 p.m. ET 12/10/18.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 28, 2018.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2018–26331 Filed 12–3–18; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG19–26–000.
Applicants: Solomon Forks Wind Project, LLC.
Description: Notice of Self-Certification of Exempt Wholesale Generator Status of Solomon Forks Wind Project, LLC.
Filed Date: 11/28/18.
Accession Number: 20181128–5033.
Comments Due: 5 p.m. ET 12/19/18.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–3079–014.
Applicants: Tyr Energy, LLC.
Description: Amendment to December 12, 2017 Updated Market Power Analysis for the Southeast Region of Tyr Energy, LLC.
Filed Date: 11/27/18.
Accession Number: 20181127–5159.
Comments Due: 5 p.m. ET 12/18/18.

Docket Numbers: ER19–66–001.
Applicants: Conemaugh Power Pass-Through Holders LLC.
Description: Tariff Amendment: Modify Market-Based Rate Application to be effective 11/29/2018.
Filed Date: 11/28/18.
Accession Number: 20181128–5128.
Comments Due: 5 p.m. ET 12/19/18.

Docket Numbers: ER19–70–001.
Applicants: Keystone Power Pass-Through Holders LLC.
Description: Tariff Amendment: Modify Market-Based Rate Tariff Application to be effective 11/29/2018.
Filed Date: 11/28/18.
Accession Number: 20181128–5134.
Comments Due: 5 p.m. ET 12/19/18.

Docket Numbers: ER19–406–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Original ISA, SA No. 5236; Queue No. AA2–070 to be effective 10/26/2018.
Filed Date: 11/27/18.
Accession Number: 20181127–5113.
Comments Due: 5 p.m. ET 12/18/18.

Docket Numbers: ER19–407–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: § 205(d) Rate Filing: 2018–11–27_SA 3155 Termination of ATC–ACEC PCA (Springwater) to be effective 11/28/2018.
Filed Date: 11/27/18.
Accession Number: 20181127–5158.
Comments Due: 5 p.m. ET 12/18/18.

Docket Numbers: ER19–408–000.
Applicants: Wisconsin Power and Light Company.
Description: § 205(d) Rate Filing: WPL—Pioneer Power Wholesale Service Agreement to be effective 1/28/2019.
Filed Date: 11/28/18.
Accession Number: 20181128–5000.
Comments Due: 5 p.m. ET 12/19/18.

Docket Numbers: ER19–409–000
Applicants: NSTAR Electric Company.
Description: Initial rate filing: NSTAR–HQUS Transfer Agreement (MMWEC Use Rights) to be effective 12/20/2018.
Filed Date: 11/28/18.
Accession Number: 20181128–5016.
Comments Due: 5 p.m. ET 12/19/18.

Docket Numbers: ER19–410–000.
Applicants: Midcontinent Independent System Operator, Inc., ALLETE, Inc.
Description: § 205(d) Rate Filing: 2018–11–28_SA 3215 MP–GRE ICA (Bear Creek) to be effective 11/29/2018.
Filed Date: 11/28/18.
Accession Number: 20181128–5020.
Comments Due: 5 p.m. ET 12/19/18.

Docket Numbers: ER19–411–000.
Applicants: Midcontinent Independent System Operator, Inc., ALLETE, Inc.
Description: § 205(d) Rate Filing: 2018–11–28_SA 3216 MP–GRE IA (Long Lake) to be effective 11/29/2018.
Filed Date: 11/28/18.
Accession Number: 20181128–5024.
Comments Due: 5 p.m. ET 12/19/18.

Docket Numbers: ER19–412–000.
Applicants: P.H. Glatfelter Company.
Description: Notice of Cancellation of Market-Based Rate Tariff of P.H. Glatfelter Company.
Filed Date: 11/28/18.
Accession Number: 20181128–5103.
Comments Due: 5 p.m. ET 12/19/18.

Docket Numbers: ER19–413–000.
Applicants: Southern California Edison Company.
Description: § 205(d) Rate Filing: LGIA Willy 9 Project SA No. 216 to be effective 11/29/2018.
Filed Date: 11/28/18.
Accession Number: 20181128–5113.
Comments Due: 5 p.m. ET 12/19/18.

Docket Numbers: ER19–414–000.
Applicants: Southern California Edison Company.
Description: § 205(d) Rate Filing: LGIA Willow Springs 4 Project SA No. 215 to be effective 11/29/2018.
Filed Date: 11/28/18.
Accession Number: 20181128–5115.
Comments Due: 5 p.m. ET 12/19/18.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings

can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf*. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 28, 2018.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2018–26330 Filed 12–3–18; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2017–0750; FRL–9985–62]

Registration Review Proposed Interim Decisions for Several Pesticides; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the availability of EPA's proposed interim registration review decisions and opens a 60-day public comment period on the proposed interim decisions for the following pesticides: 2,4-xylenol, Abamectin, Ametryn, *Bacteriophage active against Xanthomonas campestris pv. vesicatoria, Bacteriophage active against Pseudomonas syringae pv. tomato,* Barium metaborate, Bicarbonates, Biobor, Butralin, *Chondrostereum Purpureum,* Corn glutens, Cyhalofop-butyl, Diphenylamine, Indole-3-acetic acid, L-glutamic acid and gamma aminobutyric acid, Lysophosphatidylethanolamine, Meta-cresol, Methiocarb, Methyl anthranilate, Oil of black pepper, Oryzalin, Phosphoric acid and its salts, Potato leaf roll virus resistance gene, Predator urines, Prodiamine, Pyrithiobac-sodium, Sodium cyanide, Sodium fluoroacetate, Straight chain lepidopteran pheromones, *Verticillium isolate* WCS850, Yeast extract hydrolysate, and Zinc borate.

DATES: Comments must be received on or before February 4, 2019.

ADDRESSES: Submit your comments, identified by the docket identification (ID) number for the specific pesticide of interest provided in the Table in Unit IV, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html*.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: *For pesticide specific information, contact:* The Chemical Review Manager for the pesticide of interest identified in the Table in Unit IV.

For general information on the registration review program, contact: Dana Friedman, Pesticide Re-Evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (703) 347–8827; email address: *friedman.dana@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general, and may be of interest to a wide range of stakeholders including environmental, human health, farm worker, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the Chemical Review Manager for the pesticide of interest identified in the Table in Unit IV.

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

1. *Submitting CBI.* Do not submit this information to EPA through *regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information on a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *http://www.epa.gov/dockets/comments.html*.

II. Background

Registration review is EPA's periodic review of pesticide registrations to ensure that each pesticide continues to satisfy the statutory standard for registration, that is, the pesticide can perform its intended function without unreasonable adverse effects on human health or the environment. As part of the registration review process, the Agency has completed proposed interim decisions for all pesticides listed in the Table in Unit IV. Through this program, EPA is ensuring that each pesticide's registration is based on current scientific and other knowledge, including its effects on human health and the environment.

III. Authority

EPA is conducting its registration review of the chemicals listed in the Table in Unit IV pursuant to section 3(g) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Procedural Regulations for Registration Review at 40 CFR part 155, subpart C. Section 3(g) of FIFRA provides, among other things, that the registrations of pesticides are to be reviewed every 15 years. Under FIFRA, a pesticide product may be registered or remain registered only if it meets the statutory standard for registration given in FIFRA section 3(c)(5) (7 U.S.C. 136a(c)(5)). When used in accordance with widespread and commonly recognized practice, the pesticide product must perform its intended function without unreasonable adverse effects on the environment; that is, without any unreasonable risk to man or the environment, or a human dietary risk from residues that result from the use of a pesticide in or on food.

IV. What action is the Agency taking?

Pursuant to 40 CFR 155.58, this notice announces the availability of EPA's proposed interim registration review decisions for the pesticides shown in the following table, and opens a 60-day public comment period on the proposed interim decisions. For barium metaborate, cyhalofop-butyl, prodiamine, sodium cyanide, and sodium fluoroacetate this notice also opens a comment period on the ecological and human health risk assessments. For diphenylamine, this notice also opens a comment period on the human health risk assessment.

Registration review case name and No.	Docket ID number	Chemical review manager and contact information
2,4-Xylenol, Case 4098	EPA–HQ–OPP–2010–0240	Jonathan Williams, *williams.jonathanr@epa.gov*, (703) 347–0670.
Abamectin, Case 7430	EPA–HQ–OPP–2013–0360	Julie Javier, *javier.julie@epa.gov*, (703) 347–0790.
Ametryn, Case 2010	EPA–HQ–OPP–2013–0249	Christian Bongard, *bongard.christian@epa.gov*, (703) 347–0337.
Bacteriophage active against Xanthomonas campestris pv. vesicatoria, Case 6509 and, Bacteriophage active against Pseudomonas syringae pv. Tomato, Case 6510.	EPA–HQ–OPP–2015–0702	Susanne Cerrelli *cerrelli.susanne@epa.gov*, (703) 308–8077.
Barium Metaborate, Case 0632	EPA–HQ–OPP–2008–0047	Daniel Halpert, *halpert.daniel@epa.gov*, (703) 347–0133.
Bicarbonates, Case 4048	EPA–HQ–OPP–2012–0407	Maggie Rudick, *rudick.maggie@epa.gov*, (703) 347–0257.
Biobor, Case 3029	EPA–HQ–OPP–2008–0453	Megan Snyderman, *snyderman.megan@epa.gov*, (703) 347–0671.
Butralin, Case 2075	EPA–HQ–OPP–2011–0720	Lauren Bailey, *bailey.lauren@epa.gov*, (703) 347–0374.
Chondrostereum Purpureum, Case 6091	EPA–HQ–OPP–2015–0051	Daniel Schoeff, *schoeff.daniel@epa.gov*, (703–347–0143.
Corn Glutens, Case 6040	EPA–HQ–OPP–2016–0253	Maggie Rudick, *rudick.maggie@epa.gov*, (703) 347–0257.
Cyhalofop-butyl, Case 7255	EPA–HQ–OPP–2014–0115	Rachel Fletcher, *fletcher.rachel@epa.gov*, (703 347–0512.
Diphenylamine, Case 2210	EPA–HQ–OPP–2015–0749	Samantha Thomas, *thomas.samantha@epa.gov*, (703) 347–0514.
Indole-3-Acetic acid, Case 6205	EPA–HQ–OPP–2016–0665	Maggie Rudick, *rudick.maggie@epa.gov*, (703) 347–0257.
L-Glutamic Acid (LGA) and Gamma Aminobutyric Acid (GABA), Case 6025.	EPA–HQ–OPP–2014–0109	Cody Kendrick *kendrick.cody@epa.gov*, (703) 347–0468.
Lysophosphatidylethanolamine (LPE), Case 6043	EPA–HQ–OPP–2017–0059	Maggie Rudick, *rudick.maggie@epa.gov*, (703) 347–0257.
meta-Cresol, Case 4027	EPA–HQ–OPP–2010–0244	Jonathan Williams, *williams.jonathanr@epa.gov*, (703) 347–0670.
Methiocarb, Case 0577	EPA–HQ–OPP–2010–0278	Veronica Dutch, *dutch.veronica@epa.gov*, (703) 308–8585.
Methyl Anthranilate, Case 6056	EPA–HQ–OPP–2011–0678	Susanne Cerrelli *cerrelli.susanne@epa.gov*, (703) 308–8077.
Oil of Black Pepper, Case 6004	EPA–HQ–OPP–2017–0262	Cody Kendrick *kendrick.cody@epa.gov*, 703) 347–0468.
Oryzalin, Case 0186	EPA–HQ–OPP–2010–0940	Christina Scheltema, *scheltema.christina@epa.gov*, (703) 308–2201.
Phosphoric Acid and Its Salts Case 6072	EPA–HQ–OPP–2012–0672	Cody Kendrick *kendrick.cody@epa.gov*, (703) 347–0468.
Potato Leaf Roll Virus Resistance Gene, Case 6505	EPA–HQ–OPP–2012–0416	Michael Glikes, *glikes.michael@epa.gov*, (703) 305–6231.
Predator Urines: Coyote Urine and Fox Urine, Case 6202.	EPA–HQ–OPP–2016–0086	Alexandra Boukedes, *boukedes.alexandra@epa.gov*, (703) 347–0305.
Prodiamine, Case 7201	EPA–HQ–OPP–2010–0920	Jordan Page, *page.jordan@epa.gov*, (703 347–0467.
Pyrithiobac-sodium, Case 7239	EPA–HQ–OPP–2011–0661	Linsey Walsh, *walsh.linsey@epa.gov*, (703) 347–8030.
Sodium Cyanide, Case 3086	EPA–HQ–OPP–2010–0752	Leigh Rimmer, *rimmer.leigh@epa.gov*, (703) 347–0553.
Sodium Fluoroacetate, Case 3073	EPA–HQ–OPP–2010–0753	Leigh Rimmer, *rimmer.leigh@epa.gov*, (703) 347–0553.
Straight Chain Lepidopteran Pheromones (SCLP), Case 8200.	EPA–HQ–OPP–2012–0127	Maggie Rudick, *rudick.maggie@epa.gov*, (703) 347–0257.
Verticillium isolate WCS850 Case 6508	EPA–HQ–OPP–2016–0306	Maggie Rudick, *rudick.maggie@epa.gov*, (703) 347–0257.
Yeast Extract Hydrolysate, Case 6081	EPA–HQ–OPP–2017–0282	Daniel Schoeff, *schoeff.daniel@epa.gov*, (703) 347–0143.
Zinc Borate, Case 5025	EPA–HQ–OPP–2007–0675	Stephen Savage, *savage.stephen@epa.gov*, (703) 347–0345.

The registration review docket for a pesticide includes earlier documents related to the registration review case. For example, the review opened with a Preliminary Work Plan, for public comment. A Final Work Plan was placed in the docket following public comment on the Preliminary Work Plan.

The documents in the dockets describe EPA's rationales for conducting additional risk assessments for the registration review of the pesticides included in the table in Unit IV, as well as the Agency's subsequent risk findings and consideration of possible risk mitigation measures. These proposed interim registration review decisions are supported by the rationales included in those documents. Following public comment, the Agency will issue interim or final registration review decisions for the pesticides listed in the table in Unit IV.

The registration review final rule at 40 CFR 155.58(a) provides for a minimum 60-day public comment period on all proposed interim registration review decisions. This comment period is intended to provide an opportunity for public input and a mechanism for initiating any necessary amendments to the proposed interim decision. All

comments should be submitted using the methods in **ADDRESSES**, and must be received by EPA on or before the closing date. These comments will become part of the docket for the pesticides included in the Table in Unit IV. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments.

The Agency will carefully consider all comments received by the closing date and may provide a ''Response to Comments Memorandum'' in the docket. The interim registration review decision will explain the effect that any comments had on the interim decision and provide the Agency's response to significant comments.

Background on the registration review program is provided at: *http://www.epa.gov/pesticide-reevaluation.*

Authority: 7 U.S.C. 136 *et seq.*

Dated: October 25, 2018.

Yu-Ting Guilaran,

Director, Pesticide Re-Evaluation Division, Office of Pesticide Programs.

[FR Doc. 2018–26344 Filed 12–3–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2017–0751; FRL–9985–61]

Interim Registration Review Decisions and Case Closures for Several Pesticides; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the availability of EPA's interim registration review decision for the following chemicals: Acibenzolar-s-methyl, *Aspergillus flavus,* Asulam, *Bacillus licheniformis* strain SB3086, Chloroxylenol, Copper compounds, Dried Fermentation Solids and Solubles of *Myrothecium verrucaria,* EPTC, Ethylene, Fludioxonil, Formic Acid, Methyl Nonyl Ketone, Niclosamide, N^6-Benzyladenine, Potassium Silicate, Propamocarb hydrochloride, Putrescent Whole Egg Solids, Sodium carbonate and TFM. It also announces the case closure for Bis (bromoacetoxy)-2-butene (BBAB) (Case 3030, Docket ID Number EPA–HQ–OPP–2014–0799) because the last U.S. registrations for these pesticides have been canceled.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general, and may be of interest to a wide range of stakeholders including environmental, human health, farm worker, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the pesticide specific contact person listed under **FOR FURTHER INFORMATION CONTACT**: *For pesticide specific information, contact:* The Chemical Review Manager for the pesticide of interest identified in the Table in Unit IV.

For general information on the registration review program, contact: Dana Friedman, Pesticide Re-Evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (703) 347–8827; email address: *friedman.dana@epa.gov.*

II. Background

Registration review is EPA's periodic review of pesticide registrations to ensure that each pesticide continues to satisfy the statutory standard for registration, that is, the pesticide can perform its intended function without unreasonable adverse effects on human health or the environment. As part of the registration review process, the Agency has completed interim decisions for all pesticides listed in the Table in Unit IV. Through this program, EPA is ensuring that each pesticide's registration is based on current scientific and other knowledge, including its effects on human health and the environment.

III. Authority

EPA is conducting its registration review of the chemicals listed in the Table in Unit IV pursuant to section 3(g) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Procedural Regulations for Registration Review at 40 CFR part 155, subpart C. Section 3(g) of FIFRA provides, among other things, that the registrations of pesticides are to be reviewed every 15 years. Under FIFRA, a pesticide product may be registered or remain registered only if it meets the statutory standard for registration given in FIFRA section 3(c)(5) (7 U.S.C. 136a(c)(5)). When used in accordance with widespread and commonly recognized practice, the pesticide product must perform its intended function without unreasonable adverse effects on the environment; that is, without any unreasonable risk to man or the environment, or a human dietary risk from residues that result from the use of a pesticide in or on food.

IV. What action is the Agency taking?

Pursuant to 40 CFR 155.58, this notice announces the availability of EPA's interim registration review decisions for the pesticides shown in the following table. The interim registration review decisions are supported by rationales included in the docket established for each chemical.

TABLE 1—REGISTRATION REVIEW INTERIM DECISIONS BEING ISSUED

Registration review case name and number	Docket ID number	Chemical review manager and contact information
Acibenzolar-S-methyl, Case 7031	EPA–HQ–OPP–2013–0755.	Leigh Rimmer, *rimmer.leigh@epa.gov*, (703) 347–0553
Aspergillus flavus, Case 6008	EPA–HQ–OPP–2015–0281.	Alexandra Boukedes, *boukedes.alexandra@epa.gov*, (703) 347–0305
Asulam, Case 0265	EPA–HQ–OPP–2010–0783.	Caitlin Newcamp, *newcamp.caitlin@epa.gov*, (703) 347–0325
Bacillus licheniformis strain SB3086, Case 6014	EPA–HQ–OPP–2014–0184.	Daniel Schoeff, *schoeff.daniel@epa.gov*, (703) 347–0143
Chloroxylenol, Case 3045	EPA–HQ–OPP–2009–0010.	Rachel Ricciardi, *ricciardi.rachel@epa.gov*, (703) 347–0465
Copper Compounds, Cases 0636, 0649, 4025, 4026	EPA–HQ–OPP–2010–0212.	Jordan Page, *page.jordan@epa.gov*, (703) 347–0467, Kimberly Wilson, *wilson.kimberly@epa.gov*, (703) 347–0495

TABLE 1—REGISTRATION REVIEW INTERIM DECISIONS BEING ISSUED—Continued

Registration review case name and number	Docket ID number	Chemical review manager and contact information
Dried Fermentation Solids and Solubles of *Myrothecium verrucaria*, Case 6051.	EPA–HQ–OPP–2013–0539.	Cody Kendrick, *kendrick.cody@epa.gov*, (703) 347–0468
EPTC, Case 0064	EPA–HQ–OPP–2012–0720.	Patricia Biggio, *biggio.patricia@epa.gov*, (703) 347–0547
Ethylene, Case 3071	EPA–HQ–OPP–2009–0877.	Susanne Cerrelli, *cerrelli.susanne@epa.gov*, (703) 308–8077
Fludioxonil, Case 7017	EPA–HQ–OPP–2010–1067.	Patricia Biggio, *biggio.patricia@epa.gov*, (703) 347–0547
Formic Acid, Case 6073	EPA–HQ–OPP–2014–0105.	Cody Kendrick, *kendrick.cody@epa.gov*, (703) 347–0468
Methyl Nonyl Ketone, Case 3094	EPA–HQ–OPP–2012–0125.	Daniel Schoeff, *schoeff.daniel@epa.gov*, (703) 347–0143
Niclosamide, Case 2455	EPA–HQ–OPP–2013–0137.	R. David Jones, *jones.rdavid@epa.gov*, (703) 305–6725
N^6-Benzyladenine, Case 2040	EPA–HQ–OPP–2011–0190.	Alexandra Boukedes, *boukedes.alexandra@epa.gov*, (703) 347–0305
Potassium Silicate, Case 6204	EPA–HQ–OPP–2017–0329.	Donna Kamarei, *kamarei.donna@epa.gov*, (703) 347–0443
Propamocarb hydrochloride, Case 3124	EPA–HQ–OPP–2011–0662.	Christina Scheltema, *scheltema.christina@epa.gov*, (703) 308–2201
Putrescent Whole Egg Solids, Case 4079	EPA–HQ–OPP–2010–0726.	Susanne Cerrelli, *cerrelli.susanne@epa.gov*, (703) 308–8077
Sodium carbonate, Case 4066	EPA–HQ–OPP–2012–0809.	SanYvette Williams, *williams.sanyvette@epa.gov*, (703) 305–7702
TFM, Case 3082	EPA–HQ–OPP–2013–0137.	R. David Jones, *jones.rdavid@epa.gov*, (703) 305–6725

The proposed interim registration review decisions for the chemicals in the table above were posted to the docket and the public was invited to submit any comments or new information. EPA addressed the comments or information received during the 60-day comment period for the proposed interim decisions in the discussion for each pesticide listed in the table. Comments from the 60-day comment period that were received may or may not have affected the Agency's interim decision. Pursuant to 40 CFR 155.58(c), the registration review case docket for the chemicals listed in the Table will remain open until all actions required in the interim decision have been completed.

This document also announces the closure of the registration review case for Bis (bromoacetoxy)-2-butene (BBAB) (Case 3030, Docket ID Number EPA–HQ–OPP–2014–0799), because the last U.S. registrations for these pesticides have been canceled. Background on the registration review program is provided at: *http://www.epa.gov/pesticide-reevaluation.*

Authority: 7 U.S.C. 136 *et seq.*

Dated: October 25, 2018.

Yu-Ting Guilaran,

Director, Pesticide Re-Evaluation Division, Office of Pesticide Programs.

[FR Doc. 2018–26354 Filed 12–3–18; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than December 31, 2018.

A. Federal Reserve Bank of Atlanta (Kathryn Haney, Assistant Vice President) 1000 Peachtree Street NE, Atlanta, Georgia 30309. Comments can also be sent electronically to *Applications.Comments@atl.frb.org:*

1. *B.P.C. Corporation, Cookeville, Tennessee;* to merge with CFB Bancshares, Inc., and thereby indirectly acquire Citizens First Bank, both of Wartburg, Tennessee.

Board of Governors of the Federal Reserve System, November 29, 2018.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2018–26328 Filed 12–3–18; 8:45 am]

BILLING CODE P

GENERAL SERVICES ADMINISTRATION

[Notice–MA–2018–10; Docket No. 2018–0002; Sequence No. 28]

Relocation Allowances: Taxes on Travel, Transportation, and Relocation Expenses

AGENCY: Office of Government-wide Policy (OGP), General Services Administration (GSA).

ACTION: Notice of Federal Travel Regulation (FTR) Bulletin 19–02, Relocation Allowances—Taxes on Travel, Transportation, and Relocation Expenses.

SUMMARY: The purpose of this notice is to inform Federal agencies that FTR Bulletin 19–02, pertaining to travel, transportation, and relocation allowances impacted by recent changes to Federal tax law, has been published and is now available online at *www.gsa.gov/ftrbulletin*.

DATES: *Applicability:* This notice applies to travel, transportation, and relocation expenses paid on or after January 1, 2018.

FOR FURTHER INFORMATION CONTACT: For clarification of content, please contact Mr. Rick Miller, Office of Government-wide Policy, Office of Asset and Transportation Management, at 202–501–3822, or by email at *travelpolicy@gsa.gov*. Please cite Notice of FTR Bulletin 19–02.

Dated: November 27, 2018.

Jessica Salmoiraghi,

Associate Administrator, Office of Government-wide Policy.

[FR Doc. 2018–26342 Filed 12–3–18; 8:45 am]

BILLING CODE 6820–14–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Interventions for Substance Use Disorders in Adolescents: A Systematic Review

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for supplemental evidence and data submissions.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from the public. Scientific information is being solicited to inform our review of *Interventions for Substance Use Disorders in Adolescents: A Systematic Review,* which is currently being conducted by the AHRQ's Evidence-based Practice Centers (EPC) Program. Access to published and unpublished pertinent scientific information will improve the quality of this review.

DATES: *Submission Deadline* on or before January 3, 2019.

ADDRESSES: *Email submissions: epc@ahrq.hhs.gov.*

Print submissions:

Mailing Address: Center for Evidence and Practice Improvement, Agency for Healthcare Research and Quality, ATTN: EPC SEADs Coordinator, 5600 Fishers Lane, Mail Stop 06E53A, Rockville, MD 20857.

Shipping Address (FedEx, UPS, etc.): Center for Evidence and Practice Improvement, Agency for Healthcare Research and Quality, ATTN: EPC SEADs Coordinator, 5600 Fishers Lane, Mail Stop 06E77D, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Jenae Benns, Telephone: 301–427–1496 or Email: *epc@ahrq.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Centers (EPC) Program to complete a review of the evidence for *Interventions for Substance Use Disorders in Adolescents: A Systematic Review.* AHRQ is conducting this systematic review pursuant to Section 902(a) of the Public Health Service Act, 42 U.S.C. 299a(a).

The EPC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by requesting information from the public (*e.g.,* details of studies conducted). We are looking for studies that report on *Interventions for Substance Use Disorders in Adolescents: A Systematic Review,* including those that describe adverse events. The entire research protocol, including the key questions, is also available online at: *https://effectivehealthcare.ahrq.gov/topics/substance-use-disorders-adolescents/protocol.*

This is to notify the public that the EPC Program would find the following information on *Interventions for Substance Use Disorders in Adolescents: A Systematic Review* helpful:

- A list of completed studies that your organization has sponsored for this indication. In the list, please *indicate whether results are available on ClinicalTrials.gov along with the ClinicalTrials.gov trial number.*
- *For completed studies that do not have results on ClinicalTrials.gov,* please provide a summary, including the following elements: study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened/eligible/enrolled/lost to follow-up/withdrawn/analyzed, effectiveness/efficacy, and safety results.
- *A list of ongoing studies that your organization has sponsored for this indication.* In the list, please provide the *ClinicalTrials.gov* trial number or, if the trial is not registered, the protocol for the study including a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.
- Description of whether the above studies constitute ALL Phase II and above clinical trials sponsored by your organization for this indication and an index outlining the relevant information in each submitted file.

Your contribution will be very beneficial to the EPC Program. Materials submitted must be publicly available or able to be made public. Materials that are considered confidential; marketing materials; study types not included in the review; or information on indications not included in the review cannot be used by the EPC Program. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EPC Program website and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the email list at: *https://www.effectivehealthcare.ahrq.gov/email-updates.*

The systematic review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions.

The Key Questions

KQ 1: What are the effects of behavioral, pharmacologic, and combined interventions compared with placebo or no active treatment for substance use disorders and problematic substance use [1] in adolescents to achieve abstinence, reduce quantity and frequency of use, improve functional outcomes, and reduce substance-related harms?

a. How do benefits and adverse outcomes of interventions vary by subpopulations? [2]

[1] Substances considered: Alcohol, cannabis, opioids, sedatives/hypnotics/anxiolytics, stimulants, inhalants and hallucinogens. Tobacco is excluded.

[2] Subpopulations considered: Psychiatric co-morbidities, age (early, middle and late

Continued

b. How do benefits and adverse outcomes of interventions vary by intervention characteristics? [3]

KQ 2: What are the comparative effects of active interventions for substance use disorders and problematic substance use [1] in adolescents to achieve abstinence, reduce quantity and frequency of use, improve functional outcomes, and reduce harms?

a. How do comparative benefits and adverse outcomes of interventions vary by subpopulations? [2]

b. How do comparative benefits and adverse outcomes of interventions vary by intervention characteristics? [3]

PICOTS (Populations, Interventions, Comparators, Outcomes, Timing, Settings)

Population (all KQs)

- *Age:* Adolescents (12–20 years inclusive)
  - ○ *Exclude* if >20 percent of study sample (or identifiable subgroup) is <12 or >20 years, combined
- SUD or problematic use of:
  - ○ Alcohol
    - ▪ *Exclude* primary studies of treatment of alcohol use disorder/problematic alcohol use in the college setting (we will include existing systematic reviews)
  - ○ Cannabis
  - ○ Opioids
    - ▪ Nonmedical prescription drug use (codeine, hydrocodone, oxycodone)
    - ▪ Illicit (*e.g.,* heroin, illicit synthetics)
  - ○ Sedatives, hypnotics, or anxiolytics (*e.g.,* benzodiazepines, carbamates, barbiturates, methaqualone)
  - ○ Stimulants
    - ▪ Nonmedical prescription drug use (*e.g.,* methylphenidate)
    - ▪ Illicit (*e.g.,* cocaine, methamphetamine)
  - ○ Inhalants
  - ○ Hallucinogens (*e.g.,* phencyclidine, ketamine, MDMA, LSD)
  - ○ Unspecified or polysubstance use
    - ▪ *Exclude* if predominately tobacco/nicotine use
  - ○ *Exclude* tobacco/nicotine use disorder or problematic tobacco/nicotine use
  - ○ *Exclude* limited (or experimental) substance use that has not been deemed to be at least ''problematic''
- Subpopulations of interest (not necessary for eligibility)
  - ○ Psychiatric comorbidities
    - ▪ Attention deficit hyperactivity disorder (ADHD), depression, other internalizing and externalizing disorders.
  - ○ *Age*
    - ▪ Early adolescence (12–14 years)
    - ▪ Middle adolescence (15–17 years)
    - ▪ Late adolescence (18–20 years)
  - ○ *Sex and gender*
    - ▪ Male vs. female
    - ▪ Gender identity (cis vs. transgender)
    - ▪ Sexual orientation
  - ○ *Racial/ethnic minority*
  - ○ Socioeconomic status and related characteristics (*e.g.,* homelessness, poverty)
  - ○ Pregnant, postpartum, and parenting adolescents
  - ○ Demographic/family characteristics
    - ▪ Demographics
    - ▪ Family and community dynamics (*i.e.* substance using family member)
    - ▪ Involvement with child protection services.

Interventions

- Behavioral health treatments (major intervention models are indicated by arrowhead bullets, in bold)

➢ **Family Therapies**

- ○ Family behavioral therapy (FBT)
- ○ Family systems therapy (FST)
- ▪ Brief strategic family therapy (BSFT)
- ○ Functional family therapy (FFT)
- ○ Ecological family therapy
- ○ Multidimensional family therapy (MDFT)
- ○ Ecologically based family therapy (EBFT)
- ○ Family systems network (FSN)
- ○ Educational family therapy
- ○ Multi-systemic therapy (MST)

➢ **Cognitive Behavioral Therapy (CBT)**

- ○ Adolescent community reinforcement approach (ACRA)
- ○ Dialectical behavior therapy
- ○ Cognitive therapy

➢ **Contingency Management**

➢ **Motivational Interviewing/ Motivation Enhancement Therapy**

➢ **Multi-Component Interventions** consisting of two or more models (*e.g.,* MST + CBT; FFT + CBT)

➢ **Psychoeducation**

➢ **Treatment as Usual** (does not meet criteria for any of the above categories)

➢ **Integrated Interventions** for substance use and a co-occurring disorder

➢ **Other**

- ○ Culturally sensitive interventions

➢ **Recovery Support**

- ○ 12-step programs
- ○ Peer-based and/or peer supports
- ○ Assertive continuing care (ACC)

Exclude primary (universal) and secondary preventive interventions.

Exclude interventions used in population that do not aim to reduce substance use (*e.g.,* needle exchange).

- **Pharmacologic Interventions**
  - ▪ *Exclude* medications being used to treat overdose (*e.g.,* naloxone)
  - ▪ *Exclude* pharmacologic management of acute withdrawal symptoms
  - ○ Medications to reduce and/or eliminate substance use and to prevent relapse (See Appendix B for details of FDA approvals)
    - ▪ Alcohol
    - • Gabapentin
    - • Naltrexone
    - • Acamprosate
    - • Disulfiram
    - • Topiramate
    - • Ondansetron
    - ▪ Cannabis
    - • N-acetylcysteine (NAC)
    - ▪ Opioids
    - • Methadone
    - • Buprenorphine
    - • Buprenorphine/Naloxone
    - • Naltrexone
  - ○ Medications to treat co-occurring psychiatric disorders in patients in patients with concurrent problematic substance use or SUD.

Comparators

KQ 1

- No active treatment
  - ○ Wait list
  - ○ Placebo (for medications)
- Usual care (if not a clearly defined behavioral intervention)

KQ 2

- Active interventions (we will evaluate other comparisons if the evidence allows)
  - ○ Pharmacologic plus behavioral vs. behavioral or pharmacologic alone
  - ○ Between major behavioral intervention models (*e.g.* family therapy, cognitive behavioral therapy)
  - ○ Multicomponent interventions vs. single behavioral intervention model

Outcomes

➢ **Abstinence**

- ○ Urine drug test results (from substance identified on admission to treatment, abstinence from all substances, duration of abstinence)

➢ **Quantity, Frequency, or Severity of Use** (of primary substance identified on entry to treatment and other substances)

- ○ Days of use/abstinence over

adolescence), sex and gender, race/ethnicity, socioeconomic status and related characteristics (*e.g.,* homelessness, poverty), pregnant, postpartum, and parenting adolescents, demographic/family characteristics. Factors in bold will be prioritized if necessary.

[3] Intervention characteristics: Target (*e.g.* teen, family or group of teens), duration and setting.

specified time period
- ○ Quantity of use over specified time period
- ○ Substance-related problems/symptom count scales

➢ **Functional Outcomes**

- ○ School performance and educational attainment
- ▪ Attendance
- ▪ Grades/academic performance
- ▪ Graduation rates
- ▪ Entering higher education (including trade schools)
- ○ Social relationships
- ▪ Family functioning
- ▪ Peer relationships

➢ **Harmful Consequences Associated With SUD**

- ○ Mental health outcomes
- ▪ Suicidal ideation and behavior
- ○ Physical health outcomes
- • Mortality
- ▪ All-cause
- ▪ Drug-related, including fatal overdose
- ▪ Morbidity
- ▪ Injuries (non-fatal)
- • Infections
- ▪ HIV
- ▪ Hepatitis C
- ▪ Other sexually transmitted infections
- ○ Legal outcomes
- • Arrests
- • Drunk or impaired driving
- • Contact with juvenile justice system

➢ **Adverse Effects of Intervention(s)**

- ○ Side effects of pharmacologic interventions
- ○ Loss of privacy/confidentiality
- ○ Stigmatization/discrimination
- ○ Iatrogenic effects of group therapy due to peer deviance
- ○ Other reported adverse effects ascribed to interventions

Study Designs and Information Sources

- • Published, peer reviewed articles and data from *clinicaltrials.gov*
  - ○ Randomized controlled trials (including cross-over trials)
  - ▪ N ≥ 10 participants per study group
  - ○ Large nonrandomized comparative studies with longitudinal follow-up
  - ▪ N ≥ 100 participants per study group
  - ▪ Must report multiple regression, other adjustment, matching, propensity scoring, or other method to account for confounding.
  - ○ Single arm pharmacologic studies with at least 200 participants and longitudinal follow-up (to identify side-effects of medications)
  - ○ We will summarize information from existing systematic reviews specific to treatment of alcohol SUD on college campuses
  - ▪ SR eligible if inclusion criteria for individual studies consistent with our PICOTS criteria for individual studies.

Exclusions

- ○ Case-control studies
- ○ Cross-sectional studies
- ○ Single-arm studies of behavioral interventions
- ○ Conference abstracts letters, and other non-peer reviewed reports

Timing

- • Any duration of treatment
- • Duration of follow-up of at least a month (but must be longitudinal with separation in time between intervention and outcomes)

Setting

- • Any setting, including (but not limited to) primary care, school, outpatient, emergency department, in-patient, intensive outpatient, partial hospitalization, intensive inpatient/residential, juvenile justice

Exclude: laboratory-based assessments.

Francis D. Chesley, Jr.,

Acting Deputy Director.

[FR Doc. 2018–26304 Filed 12–3–18; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[CDC–2018–0065; Docket Number NIOSH–317]

Final National Occupational Research Agenda for Oil and Gas Extraction

AGENCY: National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of availability.

SUMMARY: NIOSH announces the availability of the final *National Occupational Research Agenda for Oil and Gas Extraction*

DATES: The final document was published on November 27, 2018 on the CDC website.

ADDRESSES: The document may be obtained at the following link: *https://www.cdc.gov/nora/councils/oilgas/agenda.html*

FOR FURTHER INFORMATION CONTACT: Emily Novicki, M.A., M.P.H, (*NORACoordinator@cdc.gov*), National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, Mailstop E–20, 1600 Clifton Road NE, Atlanta, GA 30329, phone (404) 498–2581 (not a toll free number).

SUPPLEMENTARY INFORMATION: On July 26, 2018, NIOSH published a request for public review in the **Federal Register** [83 FR 35485] of the draft version of the *National Occupational Research Agenda for Oil and Gas Extraction.* The single comment received expressed support.

Dated: November 29, 2018.

Frank J. Hearl,

Chief of Staff, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

[FR Doc. 2018–26315 Filed 12–3–18; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–6063–N4]

Medicare Program; Extension of Prior Authorization for Repetitive Scheduled Non-Emergent Ambulance Transports

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces a 1-year extension of the Medicare Prior Authorization Model for Repetitive Scheduled Non-Emergent Ambulance Transport. The extension of this model is applicable to the following states and the District of Columbia: Delaware, Maryland, New Jersey, North Carolina, Pennsylvania, South Carolina, Virginia, and West Virginia.

DATES: This extension begins on December 2, 2018 and ends on December 1, 2019.

FOR FURTHER INFORMATION CONTACT: Angela Gaston, (410) 786–7409. Questions regarding the Medicare Prior Authorization Model Extension for Repetitive Scheduled Non-Emergent Ambulance Transport should be sent to *AmbulancePA@cms.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Medicare may cover ambulance services, including air ambulance (fixed-wing and rotary-wing) services, if the ambulance service is furnished to a beneficiary whose medical condition is

such that other means of transportation are contraindicated. The beneficiary's condition must require both the ambulance transportation itself and the level of service provided in order for the billed service to be considered medically necessary.

Non-emergent transportation by ambulance is appropriate if either the—(1) beneficiary is bed-confined and it is documented that the beneficiary's condition is such that other methods of transportation are contraindicated; or (2) beneficiary's medical condition, regardless of bed confinement, is such that transportation by ambulance is medically required. Thus, bed confinement is not the sole criterion in determining the medical necessity of non-emergent ambulance transportation; rather, it is one factor that is considered in medical necessity determinations.[1]

A repetitive ambulance service is defined as medically necessary ambulance transportation that is furnished in 3 or more round trips during a 10-day period, or at least 1 round trip per week for at least 3 weeks.[2] Repetitive ambulance services are often needed by beneficiaries receiving dialysis or cancer treatment.

Medicare may cover repetitive, scheduled non-emergent transportation by ambulance if the—(1) medical necessity requirements described previously are met; and (2) ambulance provider/supplier, before furnishing the service to the beneficiary, obtains a written order from the beneficiary's attending physician certifying that the medical necessity requirements are met (see 42 CFR 410.40(d)(1) and (2)).[3]

In addition to the medical necessity requirements, the service must meet all other Medicare coverage and payment requirements, including requirements relating to the origin and destination of the transportation, vehicle and staff, and billing and reporting. Additional information about Medicare coverage of ambulance services can be found in 42 CFR 410.40, 410.41, and in the Medicare Benefit Policy Manual (Pub. 100–02), Chapter 10, at *http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c10.pdf*.

According to a study published by the Government Accountability Office in October 2012, entitled ''Costs and Medicare Margins Varied Widely; Transports of Beneficiaries Have Increased,''[4] the number of basic life support (BLS) non-emergent transports for Medicare Fee-For-Service beneficiaries increased by 59 percent from 2004 to 2010. A similar finding published by the Department of Health and Human Services' Office of Inspector General in a 2006 study, entitled ''Medicare Payments for Ambulance Transports,''[5] indicated a 20 percent nationwide improper payment rate for non-emergent ambulance transport. Likewise, in June 2013, the Medicare Payment Advisory Commission published a report[6] that included an analysis of non-emergent ambulance transports to dialysis facilities and found that, during the 5-year period between 2007 and 2011, the volume of transports to and from a dialysis facility increased 20 percent, more than twice the rate of all other ambulance transports combined.

Section 1115A of the Social Security Act (the Act) authorizes the Secretary to test innovative payment and service delivery models to reduce program expenditures, while preserving or enhancing the quality of care furnished to Medicare, Medicaid, and Children's Health Insurance Program beneficiaries. Section 1115A(d)(1) of the Act authorizes the Secretary to waive such requirements of Titles XI and XVIII, as well as sections 1902(a)(1), 1902(a)(13), 1903(m)(2)(A)(iii), and 1934 (other than subsections (b)(1)(A) and (c)(5)) of the Act as may be necessary solely for purposes of carrying out section 1115A of the Act with respect to testing models described in section 1115A(b) of the Act. Consistent with this standard, we will continue to waive the same provisions for the extension of this model as have been waived for the prior 4 years of the model. Additionally, we have determined that the implementation of this model does not require the waiver of any fraud and abuse law, including sections 1128A, 1128B, and 1877 of the Act. Thus providers and suppliers affected by this model must comply with all applicable fraud and abuse laws.

In the November 14, 2014 **Federal Register** (79 FR 68271), we published a notice entitled ''Medicare Program; Prior Authorization of Repetitive Scheduled Non-emergent Ambulance Transports,'' which announced the implementation of a 3-year Medicare Prior Authorization model that established a process for requesting prior authorization for repetitive, scheduled non-emergent ambulance transport rendered by ambulance providers/suppliers garaged in three states (New Jersey, Pennsylvania, and South Carolina). These states were selected as the initial states for the model because of their high utilization and improper payment rates for these services. The model began on December 1, 2014, and was originally scheduled to end in all three states on December 1, 2017.

In the October 23, 2015 **Federal Register** (80 FR 64418), we published a notice titled ''Medicare Program; Expansion of Prior Authorization of Repetitive Scheduled Non-emergent Ambulance Transports,'' which announced the inclusion of six additional states (Delaware, the District of Columbia, Maryland, North Carolina, West Virginia, and Virginia) in the Repetitive Scheduled Non-Emergent Ambulance Transport Prior Authorization model in accordance with section 515(a) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10). These six states began participation on January 1, 2016, and the model was originally scheduled to end in all nine model states on December 1, 2017.

In the December 12, 2017 **Federal Register** (82 FR 58400), we published a notice titled ''Medicare Program; Extension of Prior Authorization for Repetitive Scheduled Non-Emergent Ambulance Transports,'' which announced a 1-year extension of the prior authorization model in all states through December 1, 2018.

II. Provisions of the Notice

This notice announces that the Medicare Prior Authorization Model for Repetitive Scheduled Non-Emergent Ambulance Transport is again being extended in the current model states of Delaware, the District of Columbia, Maryland, New Jersey, North Carolina, Pennsylvania, South Carolina, Virginia, and West Virginia for an additional year while we continue to evaluate the model and determine if the model meets the statutory requirements for nationwide expansion under section 1834(l)(16) of the the Act, as added by section 515(b) of MACRA (Pub. L. 114–10). The model is currently scheduled to end in all states on December 1, 2019. Prior authorization will not be available for repetitive scheduled non-emergent ambulance transportation services furnished after that date.

We will continue to test whether prior authorization helps reduce expenditures, while maintaining or

[1] 42 CFR 410.40(d)(1).

[2] Program Memorandum Intermediaries/Carriers, Transmittal AB–03–106.

[3] Per 42 CFR 410.40(d)(2), the physician's order must be dated no earlier than 60 days before the date the service is furnished.

[4] Government Accountability Office Cost and Medicare Margins Varied Widely; Transports of Beneficiaries Have Increased (October 2012).

[5] Office of Inspector General Medicare Payment for Ambulance Transport (January 2006).

[6] Medicare Payment Advisory Commission, June 2013, pages 167–193.

improving quality of care, using the established prior authorization process for repetitive, scheduled non-emergent ambulance transport to reduce utilization of services that do not comply with Medicare policy.

We will continue to use this prior authorization process to help ensure that all relevant clinical or medical documentation requirements are met before services are furnished to beneficiaries and before claims are submitted for payment. This prior authorization process further helps to ensure that payment complies with Medicare documentation, coverage, payment, and coding rules.

The use of prior authorization does not create new clinical documentation requirements. Instead, it requires the same information that is already required to support Medicare payment, just earlier in the process. Prior authorization allows providers and suppliers to address coverage issues prior to furnishing services.

The prior authorization process under this model will continue to apply in the nine states listed previously for the following codes for Medicare payment:

- A0426 Ambulance service, advanced life support, non-emergency transport, Level 1 (ALS1).
- A0428 Ambulance service, BLS, non-emergency transport.

While prior authorization is not needed for the mileage code, A0425, a prior authorization decision for an A0426 or A0428 code will automatically include the associated mileage code.

We have conducted and will continue to conduct outreach and education to ambulance providers/suppliers, as well as beneficiaries, through such methods as updating the operational guide, frequently asked questions (FAQs) on our website, a physician letter explaining the ambulance providers/suppliers' need for the proper documentation, and educational events and materials issued by the Medicare Administrative Contractors (MACs). We will also continue our recent initiative to help find alternative resources for beneficiaries who do not meet the requirements of the Medicare repetitive scheduled non-emergent ambulance transport benefit. Additional information about the implementation of the prior authorization model is available on the CMS website at *http://go.cms.gov/PAAmbulance.*

Under this model, submitting a prior authorization request is voluntary. However, an ambulance provider/supplier or beneficiary is encouraged to submit to the MAC a request for prior authorization along with all relevant documentation to support Medicare coverage of a repetitive, scheduled non-emergent ambulance transport. If prior authorization has not been requested by the fourth round trip in a 30-day period, the subsequent claims will be stopped for prepayment review.

In order for a prior authorization request to be provisionally affirmed, the request for prior authorization must meet all applicable rules and policies, including any local coverage determination (LCD) requirements for ambulance transport claims. A provisional affirmation is a preliminary finding that a future claim submitted to Medicare for the service likely meets Medicare's coverage, coding, and payment requirements. After receipt of all relevant documentation, the MACs will make every effort to conduct a review and postmark the notification of their decision on a prior authorization request within 10 business days for an initial submission. Notification will be provided to the ambulance provider/supplier and to the beneficiary. If a subsequent prior authorization request is submitted after a non-affirmative decision on an initial prior authorization request, the MACs will make every effort to conduct a review and postmark the notification of their decision on the resubmitted request within 20 business days.

An ambulance provider/supplier or beneficiary may request an expedited review when the standard timeframe for making a prior authorization decision could jeopardize the life or health of the beneficiary. If the MAC agrees that the standard review timeframe would put the beneficiary at risk, the MAC will make reasonable efforts to communicate a decision within 2 business days of receipt of all applicable Medicare-required documentation. As this model is for non-emergent services only, we expect requests for expedited reviews to be extremely rare.

A provisional affirmative prior authorization decision may affirm a specified number of trips within a specific amount of time. The prior authorization decision, justified by the beneficiary's condition, may affirm up to 40 round trips (which equates to 80 one-way trips) per prior authorization request in a 60-day period. Alternatively, a provisional affirmative decision may affirm less than 40 round trips in a 60-day period, or may affirm a request that seeks to provide a specified number of transports (40 round trips or less) in less than a 60-day period. A provisional affirmative decision can be for all or part of the requested number of trips. Transports exceeding 40 round trips (or 80 one-way trips) in a 60-day period require an additional prior authorization request.

The following describes examples of various prior authorization scenarios:

- *Scenario 1:* When an ambulance provider/supplier or beneficiary submits a prior authorization request to the MAC with appropriate documentation and all relevant Medicare coverage and documentation requirements are met for the ambulance transport, the MAC will send a provisional affirmative prior authorization decision to the ambulance provider/supplier and the beneficiary. When the subsequent claim is submitted to the MAC by the ambulance provider/supplier, it is linked to the prior authorization decision via the claims processing system, and the claim will be paid so long as all Medicare coding, billing, and coverage requirements are met. However, the claim could be denied for technical reasons, such as the claim was a duplicate claim or the claim was for a deceased beneficiary. In addition, a claim denial could occur because certain documentation, such as the trip record, needed in support of the claim cannot be submitted with a prior authorization request because it is not available until after the service is provided.
- *Scenario 2:* When an ambulance provider/supplier or beneficiary submits a prior authorization request, but all relevant Medicare coverage requirements are not met, the MAC will send a non-affirmative prior authorization decision to the ambulance provider/supplier and to the beneficiary advising them that Medicare will not pay for the service. The provider/supplier or beneficiary may then resubmit the request with additional documentation showing that Medicare requirements have been met. Alternatively, an ambulance provider/supplier could furnish the service and submit a claim with a non-affirmative prior authorization tracking number, at which point the MAC would deny the claim. The ambulance provider/supplier and the beneficiary would then have the Medicare denial for secondary insurance purposes and would have the opportunity to submit an appeal of the claim denial if they believe Medicare coverage was denied inappropriately.
- *Scenario 3:* When an ambulance provider/supplier or beneficiary submits a prior authorization request with incomplete documentation, a detailed decision letter will be sent to the ambulance provider/supplier and to the beneficiary, with an explanation of what information is missing. The ambulance provider/supplier or beneficiary can rectify the error(s) and resubmit the

prior authorization request with appropriate documentation.

• *Scenario 4:* If an ambulance provider or supplier renders a service to a beneficiary and does not request prior authorization by the fourth round trip in a 30-day period, and the claim is submitted to the MAC for payment, then the claim will be stopped for prepayment review and documentation will be requested.

++ If the claim is determined to be for services that were not medically necessary or for which there was insufficient documentation, the claim will be denied, and all current policies and procedures regarding liability for payment will apply. The ambulance provider/supplier or the beneficiary, or both, can appeal the claim denial if they believe the denial was inappropriate.

++ If the claim is determined to be payable, it will be paid.

Only one prior authorization request per beneficiary per designated time period can be provisionally affirmed. If the initial ambulance provider/supplier cannot complete the total number of prior authorized transports (for example, the initial ambulance company closes or no longer services that area), the initial request is cancelled. In this situation, a subsequent prior authorization request may be submitted for the same beneficiary and must include the required documentation in the submission. If multiple ambulance providers/suppliers are providing transports to the beneficiary during the same or overlapping time period, the prior authorization decision will only cover the ambulance provider/supplier indicated in the provisionally affirmed prior authorization request. Any ambulance provider/supplier submitting claims for repetitive, scheduled non-emergent ambulance transports for which no prior authorization request is submitted by the fourth round trip in a 30-day period will be subject to 100 percent prepayment medical review of those claims.

Under the model, we will work to limit any adverse impact on beneficiaries and to educate beneficiaries about the process. If a prior authorization request is non-affirmed, and the claim is still submitted by the ambulance provider/supplier, the claim will be denied, but beneficiaries will continue to have all applicable administrative appeal rights. We have also recently implemented a process to help find alternative resources for beneficiaries who do not meet the requirements of the Medicare repetitive scheduled non-emergent ambulance transport benefit.

Additional information is available on the CMS website at *http://go.cms.gov/PAAmbulance.*

III. Collection of Information Requirements

Section 1115A(d)(3) of the Act states that chapter 35 of title 44, United States Code (the Paperwork Reduction Act of 1995), shall not apply to the testing and evaluation of models or expansion of such models under this section. Consequently, this document need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

IV. Regulatory Impact Statement

This document announces a 1-year extension of the Medicare Prior Authorization Model for Repetitive Scheduled Non-Emergent Ambulance Transport. Therefore, there are no regulatory impact implications associated with this notice.

Authority: Section 1115A of the Act.

Dated: November 27, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2018–26334 Filed 11–30–18; 11:15 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–E–2801]

Determination of Regulatory Review Period for Purposes of Patent Extension; ASPIRE ASSIST

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for ASPIRE ASSIST and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that medical device.

DATES: Anyone with knowledge that any of the dates as published (see the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by February 4, 2019. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by June 3, 2019. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before February 4, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 3, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and

identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2017–E–2801 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; ASPIRE ASSIST.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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 § 10.20 (21 CFR 10.20) and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA has approved for marketing the medical device ASPIRE ASSIST. ASPIRE ASSIST is indicated for use in adults aged 22 or older with a body mass index (BMI) of 35.0–55.0 kg/m2 who have failed to achieve and maintain weight loss with non-surgical weight loss therapy. The ASPIRE ASSIST is intended for a long-term duration of use in conjunction with lifestyle therapy and continuous medical monitoring. Subsequent to this approval, the USPTO received a patent term restoration application for ASPIRE ASSIST (U.S. Patent No. 9,039,677) from Aspire Bariatrics, Inc., and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated October 16, 2017, FDA advised the USPTO that this medical device had undergone a regulatory review period and that the approval of ASPIRE ASSIST represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for ASPIRE ASSIST is 2,785 days. Of this time, 2,444 days occurred during the testing phase of the regulatory review period, while 341 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360j(g)) involving this device became effective:* October 31, 2008. The applicant claims that the investigational device exemption (IDE) required under section 520(g) of the FD&C Act for human tests to begin became effective on May 16, 2012. However, FDA records indicate that the IDE was determined substantially complete for clinical studies to have begun on October 31, 2008, which represents the IDE effective date.

2. *The date an application was initially submitted with respect to the device under section 515 of the FD&C Act (21 U.S.C. 360e):* July 10, 2015. The applicant claims July 7, 2015, as the date the premarket approval application (PMA) for ASPIRE ASSIST (PMA P150024) was initially submitted. However, FDA records indicate that PMA P150024 was submitted on July 10, 2015.

3. *The date the application was approved:* June 14, 2016. FDA has verified the applicant's claim that PMA P150024 was approved on June 14, 2016.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 385 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of

§ 60.30, including but not limited to: Must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: November 28, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–26290 Filed 12–3–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–3632]

Noncirrhotic Nonalcoholic Steatohepatitis With Liver Fibrosis: Developing Drugs for Treatment; Draft 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 draft guidance for industry entitled ''Noncirrhotic Nonalcoholic Steatohepatitis With Liver Fibrosis: Developing Drugs for Treatment.'' This draft guidance is intended to assist sponsors in the clinical development of drugs for the treatment of noncirrhotic nonalcoholic steatohepatitis (NASH) with liver fibrosis.

DATES: Submit either electronic or written comments on the draft guidance by February 4, 2019 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance 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–2018–D–3632 for ''Noncirrhotic Nonalcoholic Steatohepatitis With Liver Fibrosis: Developing Drugs for Treatment.'' 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 the draft 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. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Evangela Covert, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5234, Silver Spring, MD 20993–0002, 301–796–4075.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Noncirrhotic Nonalcoholic Steatohepatitis With Liver Fibrosis: Developing Drugs for Treatment.'' This draft guidance is intended to assist sponsors in the clinical development of drugs for the treatment of noncirrhotic NASH with liver fibrosis. The draft guidance also identifies knowledge gaps that represent important challenges in

the development of drugs for this indication. This draft guidance does not address the clinical development of drugs for the treatment of cirrhosis caused by NASH.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Non-Cirrhotic Nonalcoholic Steatohepatitis with Liver Fibrosis: Developing Drugs for Treatment.'' 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. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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 21 CFR part 312 addressing investigational new drug applications and 21 CFR part 314 addressing new drug applications have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively. The collections of information in 21 CFR parts 50 and 56 (Protection of Human Subjects: Informed Consent; Institutional Review Boards) have been approved under OMB control number 0910–0755.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: November 29, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–26333 Filed 12–3–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–3815]

Agency Information Collection Activities; Proposed Collection; Comment Request; Electronic Submission of Medical Device Registration and Listing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with electronic submission of medical device registration and listing.

DATES: Submit either electronic or written comments on the collection of information by February 4, 2019.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before February 4, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of February 4, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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–2015–N–3815 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Electronic Submission of Medical Device Registration and Listing.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly

available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Electronic Submission of Medical Device Registration and Listing—21 CFR Part 807, Subparts A Through D

OMB Control Number 0910–0625—Extension

Under section 510 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360) and part 807, subparts A through D (21 CFR part 807, subparts A through D), medical device establishment owners and operators are required to electronically submit establishment registration and device listing information.

Complete and accurate registration and listing information is necessary to accomplish a number of statutory and regulatory objectives, such as: (1) Identification of establishments producing marketed medical devices, (2) identification of establishments producing a specific device when that device is in short supply or is needed for national emergency, (3) facilitation of recalls for devices marketed by owners and operators of device establishments, (4) identification and cataloguing of marketed devices, (5) administering postmarketing surveillance programs for devices, (6) identification of devices marketed in violation of the law, (7) identification and control of devices imported into the country from foreign establishments, (8) and scheduling and planning inspections of registered establishments under section 704 of the FD&C Act (21 U.S.C. 374).

Respondents to this information collection are owners or operators of establishments that engage in the manufacturing, preparation, propagation, compounding, or processing of a device or devices, who must register their establishments and submit listing information for each of their devices in commercial distribution. Notwithstanding certain exceptions, foreign device establishments that manufacture, prepare, propagate, compound, or process a device that is imported or offered for import into the United States must also comply with the registration and listing requirements. The number of respondents is based on data from the FDA Unified Registration and Listing System.

Burden estimates are based on recent experience with the existing medical device registration and listing program, electronic system operating experience, and previous data estimates.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	FDA form No.	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
807.20(a)(5) [2]—Submittal of Manufacturer Information by Initial Importers	3673	5,736	1	5,736	1.75	10,038
807.20(a)(5) [3]—Submittal of Manufacturer Information by Initial Importers	3673	5,736	1	5,736	0.1	574
807.21(a) [2]—Creation of Electronic System Account	3673	2,937	1	2,937	0.5	1,469
807.21(b) [3]—Annual Request for Waiver from Electronic Registration and Listing		1	1	1	1	1
807.21(b) [2]—Initial Request for Waiver from Electronic Registration and Listing for		1	1	1	1	1
807.22(a) [2]—Initial Registration and Listing	3673	3,467	1	3,467	1	3,467
807.22(b)(1) [3]—Annual Registration	3673	23,403	1	23,403	0.5	11,702

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

21 CFR section	FDA form No.	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
807.22(b)(2) [3]—Other Updates of Registration	3673	2,687	1	2,687	0.5	1,344
807.22(b)(3) [3]—Annual Update of Listing Information	3673	22,607	1	22,607	0.5	11,304
807.26(e) [3]—Labeling and Advertisement Submitted at FDA Request		71	1	71	1	71
807.34(a) [2]—Initial Registration and Listing when Electronic Filing Waiver Granted		1	1	1	1	1
807.34(a) [3]—Annual Registration and Listing when Electronic Filing Waiver Granted		1	1	1	1	1
807.40(b)(2) [3]—Annual Update of US Agent Information	3673	1,615	1	1,615	0.5	808
807.40(b)(3) [3]—US Agent Responses to FDA Requests for Information	3673	1,535	1	1,535	0.25	384
807.41(a) [3]—Identification of Initial Importers by Foreign Establishments	3673	12,983	1	12,983	0.5	6,492
807.41(b) [3]—Identification of Other Parties that Facilitate Import by Foreign Establishments	3673	12,983	1	12,983	0.5	6,492
Total One Time Burden						14,975
Total Recurring Burden						39,173

[1] Totals are rounded to the nearest whole number.
[2] One-Time Burden—Firm only provides initially.
[3] Recurring Burden—Firm is required to review annually.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR section	Number of respondents	Annual frequency per recordkeeper	Total annual records	Hours per record	Total hours
807.25(d) [2]—List of Officers, Directors, and Partners	22,338	1	22,338	.25 (15 minutes)	5,585
807.26 [2]—Labeling and Advertisements Available for Review	17,032	4	68,128	.5 (30 minutes)	34,064
Total					39,649

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Recurring burden—Firm is required to keep records.

The following adjustments and program changes resulted in a 5,672-hour decrease to the overall total hour burden estimate for this information collection request.

- We adjusted the number of respondents based on updated registration and listing data.
- In the reporting burden table, we corrected the table footnotes to accurately indicate whether the information collection (IC) is a one-time or reoccurring burden.
- We also adjusted some of the IC descriptions in the table for increased clarity.
- We updated our estimate of Hours per Response for ''807.22(a) Initial Registration and Listing'' (+ 0.5 hours), ''807.22(b)(1) Annual Registration'' (− 0.25 hours), and ''807.22(b)(3) Annual Update of Listing Information'' (− 0.25 hours). Based on our review of the program, we believe these changes to the burden estimate will more accurately reflect the current preparation time for these ICs.

Dated: November 28, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–26303 Filed 12–3–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0609]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of

information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by January 3, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0806. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance for Industry: Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification

OMB Control Number 0910–0806—Extension

This information collection supports the previously captioned Agency guidance and associated Form FDA 3911. The Drug Supply Chain Security Act (DSCSA) (Title II of Pub. L. 113–54) added new section 582(h)(2) to the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360eee–1(h)(2)), requiring FDA to issue guidance to aid trading partners in identifying a suspect product and terminating a notification regarding an illegitimate product and, for a manufacturer, a product with a high risk of illegitimacy. *Suspect product* is defined in section 581(21) of the FD&C Act (21 U.S.C. 360eee(21)), as a product for which there is reason to believe it: (1) Is potentially counterfeit, diverted, or stolen; (2) is potentially intentionally adulterated such that the product would result in serious adverse health consequences or death to humans; (3) is potentially the subject of a fraudulent transaction; or (4) appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans.

Beginning January 1, 2015, section 582 of the FD&C Act requires certain trading partners, upon determining that a product in their possession or control is a suspect product, to quarantine the product while they promptly conduct an investigation to determine whether the product is an illegitimate product. *Illegitimate product* is defined in section 581(8) of the FD&C Act as a product for which credible evidence shows that it: (1) Is counterfeit, diverted, or stolen; (2) is intentionally adulterated such that the product would result in serious adverse health consequences or death to humans; (3) is the subject of a fraudulent transaction; or (4) appears otherwise unfit for distribution such that the product would be reasonably likely to result in serious adverse health consequences or death to humans. Also beginning January 1, 2015, trading partners must, upon determining that a product in their possession or control is illegitimate, notify FDA and all immediate trading partners that they have reason to believe they may have received the illegitimate product not later than 24 hours after making the determination. Under section 582(b)(4)(B)(ii)(II) of the FD&C Act, manufacturers are additionally required to notify FDA and any immediate trading partners that they believe may possess a product manufactured by or purportedly manufactured by the manufacturer not later than 24 hours after the determination is made or being notified by FDA or a trading partner that the product has a high risk of illegitimacy.

Under section 202 of the DSCSA, manufacturers, repackagers, wholesale distributors, and dispensers (*e.g.,* pharmacies) must: (1) Notify FDA when they have determined that a product in their possession or control is illegitimate (and, for manufacturers, when they have determined or been notified by FDA or a trading partner that a product has a high risk of illegitimacy); (2) notify certain immediate trading partners about an illegitimate product that they may have received (and, for manufacturers, that a product has a high risk of illegitimacy); (3) terminate notifications regarding illegitimate products (and, for manufacturers, a product with a high risk of illegitimacy), in consultation with FDA, when the notifications are no longer necessary; and (4) notify immediate trading partners when the notifications are terminated. Trading partners should use Form FDA 3911 to submit notifications and requests for terminations of notifications to FDA. Form FDA 3911 is available on FDA's web page (*https://www.accessdata.fda.gov/scripts/cder/email/drugnotification.cfm*).

A. Notifications to FDA

Under section 582(b)(4)(B)(ii)(I), (c)(4)(B)(ii), (d)(4)(B)(ii), and (e)(4)(B)(ii) of the FD&C Act, as amended by the DSCSA, and beginning not later than January 1, 2015, a manufacturer, repackager, wholesale distributor, or dispenser who determines that a product in its possession or control is illegitimate must notify FDA of that determination not later than 24 hours after the determination is made. In addition, section 582(b)(4)(B)(ii)(II) of the FD&C Act requires manufacturers to notify FDA when a manufacturer determines that a product poses a high risk of illegitimacy.

We originally estimated that all manufacturers, repackagers, wholesale distributors, and dispensers would collectively submit 5,000 notifications per year. This estimate included the notifications by trading partners that have determined that illegitimate product is in their possession or control, as well as notifications by manufacturers that have determined a product poses a high risk of illegitimacy. As discussed in our **Federal Register** notice of June 11, 2014 (79 FR 33564), the estimate was based on our experience with field alert reports (Form FDA 3331) that holders of approved drug applications are required to submit for certain drug quality issues (21 CFR 314.81(b)(1)) and with reports of the falsification of drug sample records, diversion, loss, and known theft of prescription drug samples as currently required under § 203.37 (21 CFR 203.37). Upon evaluation of the number of notifications we received for fiscal years 2016 and 2017, however, we are lowering our estimate to 150 notifications.

We are also combining the estimates for manufacturers and repackagers because FDA's establishment and drug product listing database indicates that many companies perform activities of both manufacturers and repackagers. Although the DSCSA specifically defines dispensers, for estimation purposes, we are using estimates for pharmacies in general terms based on those that must comply with the new requirements under section 582(d) of the FD&C Act.

Because manufacturers, repackagers, and wholesale distributors are collectively responsible for prescription drugs from the point of manufacturing through distribution in the drug supply chain, we assume that most notifications of illegitimate products are

submitted by these three trading partners. The total number of respondents is comprised of 80 percent manufacturers (120), 15 percent wholesale distributors (22), and 5 percent pharmacies (8).

We estimate that the number of annual notifications will vary from 0 to 2 for manufacturers/repackagers, as well as from pharmacies, with the vast majority of companies making no notifications. Although FDA's establishment and drug product listing database currently contains registrations for approximately 6,500 manufacturers and repackagers, we estimate that approximately 120 manufacturers/repackagers will notify us of illegitimate products an average of one time per year. Although we estimate approximately 69,000 pharmacy sites in the United States, based on data from the National Association of Chain Drug Stores, the National Community Pharmacists Association, and the American Hospital Association, we estimate that approximately 8 pharmacies will notify FDA of illegitimate product an average of one time per year. According to the Healthcare Distribution Alliance (formerly known as Healthcare Distribution Management Association), approximately 30 wholesale distributors are responsible for over 90 percent of drug distributions; based on sales and because FDA is estimating that over 2,200 small wholesale distributors might be responsible for the remaining 10 percent of drug sales, we estimate that wholesale distributors will be responsible for making about an average of 1 notification per year to account for the estimated 22 notifications that FDA will receive regarding illegitimate product. Each notification should include information about the person or entity initiating the notification, the product determined to be illegitimate or having a high risk of illegitimacy, and a description of the circumstances surrounding the event that prompted the notification. We estimate that each notification will take about 1 hour, as reflected in table 1.

B. Notifications to Trading Partners of an Illegitimate Product or Product With a High Risk of Illegitimacy

Under section 582(b)(4)(B)(ii)(I), (c)(4)(B)(ii), (d)(4)(B)(ii), and (e)(4)(B)(ii) of the FD&C Act, a trading partner who determines that a product in its possession is illegitimate must also notify all immediate trading partners that they believe may have received such illegitimate product not later than 24 hours after the determination is made. In addition, under section 582(b)(4)(B)(ii)(II) of the FD&C Act, a manufacturer is required to notify all immediate trading partners that the manufacturer believes may possess a product manufactured by or purported to be manufactured by the manufacturer not later than 24 hours after the determination is made or being notified by FDA or a trading partner that the product has a high risk of illegitimacy.

Because the extent of distribution of any illegitimate product is likely to vary from one situation to another, we assume a wide distribution of each illegitimate product. We estimate that, for each notification made by a manufacturer or repackager to FDA, approximately 30 trading partners (based on the number of distributors) will also be notified. This results in approximately 3,600 notifications annually to trading partners of manufacturers/repackagers. This estimate includes the notifications by manufacturers and repackagers who have determined that illegitimate product is in their possession or control, as well as notifications by manufacturers that have determined that a product poses a high risk of illegitimacy.

We estimate that a large wholesale distributor may have up to 4,500 trading partners, but a small wholesale distributor may have 200 trading partners, for an average of approximately 2,350. We originally estimated that a wholesale distributor would notify all 2,350 trading partners for each of the illegitimate products identified. However, we are lowering our estimate as a result of our experience with the collection and informal feedback from industry to reflect that 22 respondents will make 1,175 disclosures for a total of 25,850 disclosures annually; and that each disclosure will require approximately 12 minutes, for a total of 5,170 hours annually.

We estimate that a pharmacy purchases prescription drugs from an average of two wholesale distributors. Therefore, a pharmacy would notify 2 trading partners for each of the 8 illegitimate products identified, resulting in approximately 16 notifications annually to pharmacy trading partners.

Manufacturers/repackagers, wholesale distributors, and pharmacies may notify their trading partners using existing systems and processes used for similar types of communications. Such communications may include, but are not limited to, posting notifications on a company website, sending an email, telephoning, or mailing or faxing a letter or notification. The information contained in the notification to the immediate trading partner should be the same as or based on the notification that was already submitted to FDA. We estimate that, for all trading partners, each notification of immediate trading partners will take approximately 0.2 hour (12 minutes). The estimated total burden hours that manufacturers/repackagers, wholesale distributors, and pharmacies will take to notify trading partners is approximately 5,893 hours annually, as reflected in table 2.

C. Consultations With FDA and Termination of Notification

Section 582(b)(4)(B)(iv), (c)(4)(B)(iv), (d)(4)(B)(iv), and (e)(4)(B)(iv) of the FD&C Act requires that a trading partner who determines, in consultation with FDA, that a notification made under section 582(b)(4)(B)(ii), (c)(4)(B)(ii), (d)(4)(B)(ii), or (e)(4)(B)(ii) is no longer necessary must terminate the notification. The guidance for industry sets forth the process by which trading partners should consult with FDA to terminate notifications that are no longer necessary.

Each request for termination of notification must include information about the person or entity initiating the request for termination, the illegitimate product or product with a high risk of illegitimacy, the notification that was issued, and an explanation about what actions have taken place or what information has become available that make the notification no longer necessary. Trading partners should also include the FDA-assigned incident number associated with the initial notification on the request for termination. The request for a termination will be viewed as a request for consultation with FDA. We estimate that the same amount of time will be required to provide the information necessary to request termination as is required to make the notification. The time required to investigate and resolve an illegitimate product notification will vary, but we assume that each notification will eventually be terminated. We assume that the number of requests for termination of a notification per year will be the same as the original number of notifications for a given year. The estimated total burden hours of making requests for termination of notifications to FDA is 150 hours annually, as reflected in table 3.

D. Notifications to Trading Partners That a Notification Has Been Terminated

Section 582(b)(4)(B)(iv), (c)(4)(B)(iv), (d)(4)(B)(iv), and (e)(4)(B)(iv) of the

FD&C Act requires that a trading partner who, in consultation with FDA, terminates a notification made under section 582(b)(4)(B)(ii)(I) or (II), (c)(4)(B)(ii), (d)(4)(B)(ii), or (e)(4)(B)(ii) must also promptly inform previously-notified immediate trading partners that the notification has been terminated. We estimate that the burden for notifying trading partners of an illegitimate product and the number of trading partners notified will be the same as the estimates for notification of termination. The estimated total burden hours of notifying trading partners that the notification is terminated is approximately 5,893 hours annually, as reflected in table 4.

In the **Federal Register** of September 6, 2018 (83 FR 45254), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN—NOTIFICATIONS TO FDA [1]

Respondent description	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Manufacturers and Repackagers	120	1	120	1	120
Wholesale Distributors	22	1	22	1	22
Dispensers	8	1	8	1	8
Total					150

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN FOR NOTIFICATIONS TO TRADING PARTNERS OF AN ILLEGITIMATE PRODUCT [1]

Respondent description	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Manufacturers and Repackagers	120	30	3,600	0.20 (12 minutes)	720
Wholesale Distributors	22	1,175	25,850	0.20 (12 minutes)	5,170
Dispensers	8	2	16	0.20 (12 minutes)	3
Total					5,893

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 3—ESTIMATED ANNUAL REPORTING BURDEN FOR CONSULTATION WITH FDA AND TERMINATION OF NOTIFICATION [1]

Respondent description	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Manufacturers and Repackagers	120	1	120	1	120
Wholesale Distributors	22	1	22	1	22
Dispensers	8	1	8	1	8
Total					150

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 4—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN FOR NOTIFICATIONS TO TRADING PARTNERS OF AN ILLEGITIMATE PRODUCT TERMINATION [1]

Respondent description	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Manufacturers and Repackagers	120	30	3,600	0.2 (12 minutes)	720
Wholesale Distributors	22	1,175	25,850	0.2 (12 minutes)	5,170
Dispensers	8	2	16	0.2 (12 minutes)	3
Total					5,893

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Cumulatively, the total estimated burden is 12,086 annual hours, which reflects a significant decrease. We base this adjustment on our experience with the information collection since its establishment and implementation.

Dated: November 28, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–26295 Filed 12–3–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–5928]

Post-Complete Response Letter Meetings Between the Food and Drug Administration and Abbreviated New Drug Application Applicants Under Generic Drug User Fee Amendments; 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 ''Post-Complete Response Letter Meetings Between FDA and ANDA Applicants Under GDUFA.'' This guidance is intended to clarify the criteria for granting post-complete response letter (CRL) meeting requests and the scope of discussions for granted meeting requests. This guidance provides procedures that will promote well-managed post-CRL meetings and help ensure that such meetings are scheduled and conducted in accordance with the commitments made by FDA in connection with the reauthorization of the Generic Drug User Fee Amendments for Fiscal Years 2018–2022 (GDUFA II).

DATES: The announcement of the guidance is published in the **Federal Register** on December 4, 2018.

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–2017–D–5928 for ''Post-Complete Response Letter Meetings Between FDA and ANDA Applicants Under GDUFA.'' 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. 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: Lisa Bercu, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 240–402–6902.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Post-Complete Response Letter Meetings Between FDA and ANDA Applicants Under GDUFA.'' GDUFA was reauthorized (GDUFA II) on August 18, 2017, in order to facilitate timely access to high quality, affordable generic medicines. In accordance with the GDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2018–2022 (GDUFA II Goals or Commitment Letter) that accompanied the legislation, FDA committed to schedule and conduct 90 percent of post-CRL meetings within prescribed time frames.

As described in the GDUFA II Commitment Letter, post-CRL meetings will be used by applicants ''to seek clarification concerning deficiencies identified in a CRL.'' Under GDUFA II, post-CRL meetings are available for both major and minor CRLs and for first and subsequent review cycles. FDA will grant any complete post-CRL meeting request that satisfies the criteria outlined in section IV of this guidance. FDA will only grant post-CRL meeting requests that pose questions to clarify identified deficiencies. Other issues, including questions requiring further Agency review, disputes about classification of complete response amendments, or new information submitted by the applicant, will not be addressed in a post-CRL meeting.

This guidance finalizes the draft guidance announced in the **Federal Register** on October 16, 2017 (82 FR 48093). The Agency considered comments on the draft guidance while finalizing the guidance. Generally, we revised the draft guidance to provide clarifying information on the process for submitting post-CRL meeting requests and the criteria for granting post-CRL meeting requests. Changes from the draft guidance include information on the process for an abbreviated new drug application (ANDA) applicant to change the list of meeting participants and clarification on when a post-CRL meeting request may be denied.

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 ''Post-Complete Response Letter Meetings Between FDA and ANDA Applicants Under GDUFA.'' 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. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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 21 CFR part 314 have been approved under OMB control number 0910–0001.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: November 28, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–26285 Filed 12–3–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–E–4282]

Determination of Regulatory Review Period for Purposes of Patent Extension; TRULANCE

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for TRULANCE and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (see the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by February 4, 2019. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by June 3, 2019. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before February 4, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of February 4, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2017–E–4282 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; TRULANCE.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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 § 10.20 (21 CFR 10.20) and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product, TRULANCE (plecanatide) indicated in adults for treatment of chronic idiopathic constipation. Subsequent to this approval, the USPTO received a patent term restoration application for TRULANCE (U.S. Patent No. 7,041,786) from Synergy Pharmaceuticals, Inc. and the USPTO requested FDA's assistance in determining the patent's eligibility for patent term restoration. In a letter dated September 20, 2017, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of TRULANCE represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for TRULANCE is 3,186 days. Of this time, 2,829 days occurred during the testing phase of the regulatory review period, while 357 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i)) became effective:* May 2, 2008. FDA has verified the applicant's claim that the date the investigational new drug application became effective was May 2, 2008.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* January 29, 2016. FDA has verified the applicant's claim that the new drug application (NDA) for TRULANCE (NDA 208745) was initially submitted on January 29, 2016.

3. *The date the application was approved:* January 19, 2017. FDA has verified the applicant's claim that NDA 208745 was approved on January 19, 2017.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,771 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: Must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: November 28, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–26289 Filed 12–3–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–E–3650]

Determination of Regulatory Review Period for Purposes of Patent Extension; OCALIVA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for OCALIVA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (see the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by February 4, 2019. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by June 3, 2019. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before February 4, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of February 4, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2017–E–3650 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; OCALIVA.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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 § 10.20 (21 CFR 10.20) and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product, OCALIVA (obeticholic acid). OCALIVA is

indicated for treatment of primary biliary cholangitis in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA, or as monotherapy in adults unable to tolerate UDCA. Subsequent to this approval, the USPTO received a patent term restoration application for OCALIVA (U.S. Patent No. 7,138,390) from Intercept Pharmaceuticals, Inc. and the USPTO requested FDA's assistance in determining the patent's eligibility for patent term restoration. In a letter dated September 20, 2017, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of OCALIVA represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for OCALIVA is 3,742 days. Of this time, 3,408 days occurred during the testing phase of the regulatory review period, while 334 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i)) became effective:* March 1, 2006. The applicant claims February 26, 2006, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was March 1, 2006, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* June 29, 2015. The applicant claims June 26, 2015, as the date the new drug application (NDA) for OCALIVA (NDA 207999) was initially submitted. However, FDA records indicate that NDA 207999 was submitted on June 29, 2015.

3. *The date the application was approved:* May 27, 2016. FDA has verified the applicant's claim that NDA 207999 was approved on May 27, 2016.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,826 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: Must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: November 28, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–26288 Filed 12–3–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–E–3547]

Determination of Regulatory Review Period for Purposes of Patent Extension; EXABLATE NEURO MODEL 4000 TYPE 1.0 SYSTEM

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for EXABLATE NEURO MODEL 4000 TYPE 1.0 SYSTEM (EXABLATE) and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that medical device.

DATES: Anyone with knowledge that any of the dates as published (see the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by February 4, 2019. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by June 3, 2019. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before February 4, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of February 4, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2017–E–3547 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; EXABLATE.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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 § 10.20 (21 CFR 10.20) and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA has approved for marketing the medical device EXABLATE. EXABLATE is indicated for use in the unilateral thalamotomy treatment of idiopathic essential tremor patients with medication-refractory tremor. Patients must be at least age 22. The designated area in the brain responsible for the movement disorder symptoms (ventralis intermedius) must be identified and accessible for targeted thermal ablation by the EXABLATE device. Subsequent to this approval, the USPTO received a patent term restoration application for EXABLATE (U.S. Patent No. 6,612,988) from Brigham and Women's Hospital, Inc. and InSightec, Ltd., and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated August 1, 2017, FDA advised the USPTO that this medical device had undergone a regulatory review period and that the approval of EXABLATE represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for EXABLATE is 2,050 days. Of this time, 1,785 days occurred during the testing phase of the regulatory review period, while 265 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360j(g)) involving this device became effective:* December 2, 2010. FDA has verified the applicant's claim that the date the investigational device exemption (IDE) required under section 520(g) of the FD&C Act for human tests to begin became effective was December 2, 2010.

2. *The date an application was initially submitted with respect to the device under section 515 of the FD&C Act (21 U.S.C. 360e):* October 21, 2015. The applicant claims October 20, 2015, as the date the premarket approval application (PMA) for EXABLATE (PMA P150038) was initially submitted. However, FDA records indicate that PMA P150038 was submitted on October 21, 2015.

3. *The date the application was approved:* July 11, 2016. FDA has verified the applicant's claim that PMA P150038 was approved on July 11, 2016.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,158 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination

regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: November 28, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–26282 Filed 12–3–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Solicitation for Written Comments on Proposed Objectives for Healthy People 2030; Correction

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Health, Office of Disease Prevention and Health Promotion.

ACTION: Notice; correction.

SUMMARY: The Department of Health and Human Services published a document in the **Federal Register** of November 27, 2018, concerning request for comments on the proposed Healthy People 2030 objectives. The document contained an incorrect date.

FOR FURTHER INFORMATION CONTACT: Ayanna Johnson, *HP2030@hhs.gov.*

Correction

In the **Federal Register** of November 27, 2018, in FR Doc. 2018–25836, on pages 60876–60877, correct the ''Dates'' caption to read:

DATES: Written comments must be submitted by January 17, 2019.

Dated: November 27, 2018.

Don Wright,

Deputy Assistant Secretary for Health (Disease Prevention and Health Promotion).

[FR Doc. 2018–26299 Filed 12–3–18; 8:45 am]

BILLING CODE 4150–32–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, 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 General Medical Sciences Special Emphasis Panel; National Research Mentoring Network (NRMN) U24 Center Applications.

Date: December 12, 2018.

Time: 12:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, Room 3AN18, 45 Center Drive, Bethesda, MD 20892.

Contact Person: Rebecca H. Johnson, Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, Natcher Building, Room 3AN18C, Bethesda, MD 20892, 301–594–2771, *johnsonrh@nigms.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. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: November 28, 2018.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–26281 Filed 12–3–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Current List of HHS-Certified Laboratories and Instrumented Initial Testing Facilities Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) notifies federal agencies of the laboratories and Instrumented Initial Testing Facilities (IITF) currently certified to meet the standards of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines).

A notice listing all currently HHS-certified laboratories and IITFs is published in the **Federal Register** during the first week of each month. If any laboratory or IITF certification is suspended or revoked, the laboratory or IITF will be omitted from subsequent lists until such time as it is restored to full certification under the Mandatory Guidelines.

If any laboratory or IITF has withdrawn from the HHS National Laboratory Certification Program (NLCP) during the past month, it will be listed at the end and will be omitted from the monthly listing thereafter.

This notice is also available on the internet at *http://www.samhsa.gov/workplace.*

FOR FURTHER INFORMATION CONTACT: Charles LoDico, Division of Workplace Programs, SAMHSA/CSAP, 5600 Fishers Lane, Room 16N02C, Rockville, Maryland 20857; 240–276–2600 (voice).

SUPPLEMENTARY INFORMATION: The Department of Health and Human Services (HHS) notifies federal agencies of the laboratories and Instrumented Initial Testing Facilities (IITF) currently certified to meet the standards of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines). The Mandatory Guidelines were first published in the **Federal Register** on April 11, 1988 (53 FR 11970), and subsequently revised in the **Federal Register** on June 9, 1994 (59 FR 29908); September 30, 1997 (62 FR 51118); April 13, 2004 (69 FR 19644); November 25, 2008 (73 FR 71858); December 10, 2008 (73 FR 75122); April 30, 2010 (75 FR 22809); and on January 23, 2017 (82 FR 7920).

The Mandatory Guidelines were initially developed in accordance with

Executive Order 12564 and section 503 of Public Law 100–71. The ''Mandatory uidelines for Federal Workplace Drug Testing Programs,'' as amended in the revisions listed above, requires strict standards that laboratories and IITFs must meet in order to conduct drug and specimen validity tests on urine specimens for federal agencies.

To become certified, an applicant laboratory or IITF must undergo three rounds of performance testing plus an on-site inspection. To maintain that certification, a laboratory or IITF must participate in a quarterly performance testing program plus undergo periodic, on-site inspections.

Laboratories and IITFs in the applicant stage of certification are not to be considered as meeting the minimum requirements described in the HHS Mandatory Guidelines. A HHS-certified laboratory or IITF must have its letter of certification from HHS/SAMHSA (formerly: HHS/NIDA), which attests that it has met minimum standards.

In accordance with the Mandatory Guidelines dated January 23, 2017 (82 FR 7920), the following HHS-certified laboratories and IITFs meet the minimum standards to conduct drug and specimen validity tests on urine specimens:

HHS-Certified Instrumented Initial Testing Facilities

Dynacare, 6628 50th Street NW, Edmonton, AB Canada T6B 2N7, 780–784–1190, (Formerly: Gamma-Dynacare Medical Laboratories)

HHS-Certified Laboratories

ACM Medical Laboratory, Inc., 160 Elmgrove Park, Rochester, NY 14624, 844–486–9226

Alere Toxicology Services, 1111 Newton St., Gretna, LA 70053, 504–361–8989/800–433–3823, (Formerly: Kroll Laboratory Specialists, Inc., Laboratory Specialists, Inc.)

Alere Toxicology Services, 450 Southlake Blvd., Richmond, VA 23236, 804–378–9130, (Formerly: Kroll Laboratory Specialists, Inc., Scientific Testing Laboratories, Inc.; Kroll Scientific Testing Laboratories, Inc.)

Baptist Medical Center-Toxicology Laboratory, 11401 I–30, Little Rock, AR 72209–7056, 501–202–2783, (Formerly: Forensic Toxicology Laboratory Baptist Medical Center)

Clinical Reference Laboratory, Inc., 8433 Quivira Road, Lenexa, KS 66215–2802, 800–445–6917

Cordant Health Solutions, 2617 East L Street, Tacoma, WA 98421, 800–442–0438, (Formerly: STERLING Reference Laboratories)

DrugScan, Inc., 200 Precision Road, Suite 200, Horsham, PA 19044, 800–235–4890

Dynacare,* 245 Pall Mall Street, London, ONT, Canada N6A 1P4, 519–679–1630, (Formerly: Gamma-Dynacare Medical Laboratories)

ElSohly Laboratories, Inc., 5 Industrial Park Drive, Oxford, MS 38655, 662–236–2609

Laboratory Corporation of America Holdings, 7207 N Gessner Road, Houston, TX 77040, 713–856–8288/800–800–2387

Laboratory Corporation of America Holdings, 69 First Ave., Raritan, NJ 08869, 908–526–2400/800–437–4986 (Formerly: Roche Biomedical Laboratories, Inc.)

Laboratory Corporation of America Holdings, 1904 TW Alexander Drive, Research Triangle Park, NC 27709, 919–572–6900/800–833–3984 (Formerly: LabCorp Occupational Testing Services, Inc., CompuChem Laboratories, Inc.; CompuChem Laboratories, Inc., A Subsidiary of Roche Biomedical Laboratory; Roche CompuChem Laboratories, Inc., A Member of the Roche Group)

Laboratory Corporation of America Holdings, 1120 Main Street, Southaven, MS 38671, 866–827–8042/800–233–6339 (Formerly: LabCorp Occupational Testing Services, Inc.; MedExpress/National Laboratory Center)

LabOne, Inc. d/b/a Quest Diagnostics, 10101 Renner Blvd., Lenexa, KS 66219, 913–888–3927/800–873–8845 (Formerly: Quest Diagnostics Incorporated; LabOne, Inc.; Center for Laboratory Services, a Division of LabOne, Inc.)

MedTox Laboratories, Inc., 402 W County Road D, St. Paul, MN 55112, 651–636–7466/800–832–3244

Legacy Laboratory Services—MetroLab, 1225 NE 2nd Ave., Portland, OR 97232, 503–413–5295/800–950–5295

Minneapolis Veterans Affairs Medical Center, Forensic Toxicology Laboratory, 1 Veterans Drive, Minneapolis, MN 55417, 612–725–2088, Testing for Veterans Affairs (VA) Employees Only

National Toxicology Laboratories, Inc., 1100 California Ave., Bakersfield, CA 93304, 661–322–4250/800–350–3515

One Source Toxicology Laboratory, Inc., 1213 Genoa-Red Bluff, Pasadena, TX 77504, 888–747–3774 (Formerly: University of Texas Medical Branch, Clinical Chemistry Division; UTMB Pathology-Toxicology Laboratory)

Pacific Toxicology Laboratories, 9348 DeSoto Ave., Chatsworth, CA 91311, 800–328–6942 (Formerly: Centinela Hospital Airport Toxicology Laboratory)

Pathology Associates Medical Laboratories, 110 West Cliff Dr., Spokane, WA 99204, 509–755–8991/800–541–7891x7

Phamatech, Inc., 15175 Innovation Drive, San Diego, CA 92128, 888–635–5840

Quest Diagnostics Incorporated, 1777 Montreal Circle, Tucker, GA 30084, 800–729–6432 (Formerly: SmithKline Beecham Clinical Laboratories; SmithKline Bio-Science Laboratories)

Quest Diagnostics Incorporated, 400 Egypt Road, Norristown, PA 19403, 610–631–4600/877–642–2216 (Formerly: SmithKline Beecham Clinical Laboratories; SmithKline Bio-Science Laboratories)

Redwood Toxicology Laboratory, 3700 Westwind Blvd., Santa Rosa, CA 95403, 800–255–2159

U.S. Army Forensic Toxicology Drug Testing Laboratory, 2490 Wilson St., Fort George G. Meade, MD 20755–5235, 301–677–7085, Testing for Department of Defense (DoD) Employees Only

* The Standards Council of Canada (SCC) voted to end its Laboratory Accreditation Program for Substance Abuse (LAPSA) effective May 12, 1998. Laboratories certified through that program were accredited to conduct forensic urine drug testing as required by U.S. Department of Transportation (DOT) regulations. As of that date, the certification of those accredited Canadian laboratories will continue under DOT authority. The responsibility for conducting quarterly performance testing plus periodic on-site inspections of those LAPSA-accredited laboratories was transferred to the U.S. HHS, with the HHS' NLCP contractor continuing to have an active role in the performance testing and laboratory inspection processes. Other Canadian laboratories wishing to be considered for the NLCP may apply directly to the NLCP contractor just as U.S. laboratories do.

Upon finding a Canadian laboratory to be qualified, HHS will recommend that DOT certify the laboratory (**Federal Register**, July 16, 1996) as meeting the minimum standards of the Mandatory Guidelines published in the **Federal Register** January 23, 2017 (82 FR 7920). After receiving DOT certification, the laboratory will be included in the monthly list of HHS-certified laboratories and participate in the NLCP certification maintenance program.

Charles P. LoDico,

Chemist.

[FR Doc. 2018–26279 Filed 12–3–18; 8:45 am]

BILLING CODE 4160–20–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2018–1046]

Information Collection Request to Office of Management and Budget; OMB Control Number: 1625–0001

AGENCY: Coast Guard, DHS.

ACTION: Sixty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the U.S. Coast Guard intends to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting an extension of its approval for the following collection of information: 1625–0001, Report of Marine Casualty and Chemical Testing of Commercial Vessel Personnel; without change. Our ICR describes the information we seek to collect from the public. Before submitting this ICR to OIRA, the Coast Guard is inviting comments as described below.

DATES: Comments must reach the Coast Guard on or before February 4, 2019.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG–2018–1046] to the Coast Guard using the Federal eRulemaking Portal at *https://www.regulations.gov.* See the ''Public participation and request for comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

A copy of the ICR is available through the docket on the internet at *https://www.regulations.gov.* Additionally, copies are available from: Commandant (CG–612), ATTN: Paperwork Reduction Act Manager, U.S. Coast Guard, 2703 Martin Luther King Jr Ave. SE, STOP 7710, Washington, DC 20593–7710.

FOR FURTHER INFORMATION CONTACT: Mr. Anthony Smith, Office of Information Management, telephone 202–475–3532, or fax 202–372–8405, for questions on these documents.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This Notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology. In response to your comments, we may revise this ICR or decide not to seek an extension of approval for the Collection. We will consider all comments and material received during the comment period.

We encourage you to respond to this request by submitting comments and related materials. Comments must contain the OMB Control Number of the ICR and the docket number of this request, [USCG–2018–1046], and must be received by February 4, 2019.

Submitting Comments

We encourage you to submit comments through the Federal eRulemaking Portal at *https://www.regulations.gov.* If your material cannot be submitted using *https://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at *https://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.

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

Information Collection Request

Title: Report of Marine Casualty and Chemical Testing of Commercial Vessel Personnel.

OMB Control Number: 1625–0001.

Summary: Marine casualty information is needed for Coast Guard investigations of commercial vessel casualties involving death, vessel damage, etc., as mandated by Congress. Chemical testing information is needed to improve Coast Guard detection/reduction of drug use by mariners.

Need: Section 6101 of 46 U.S.C., as delegated by the Secretary of Homeland Security to the Commandant, authorizes the Coast Guard to prescribe regulations for the reporting of marine casualties involving death, serious injury, material loss of property, material damage affecting the seaworthiness of a vessel, or significant harm to the environment. It also requires information on the use of alcohol be included in a marine casualty report. Section 7503 of 46 U.S.C. authorizes the Coast Guard to deny the issuance of licenses, certificates of registry, and merchant mariner's documents (seaman's papers) to users of dangerous drugs. Similarly, 46 U.S.C. 7704 requires the Coast Guard to revoke such papers unless a holder provides satisfactory proofs that the holder has successfully completed a rehabilitation program acceptable to the U.S. Coast Guard and is determined to be, by a competent substance abuse professional, free from misuse of chemical substances and that the risk of subsequent misuse of chemical substances is sufficiently low to justify returning to safety-sensitive positions.

Forms: CG–2692, Report of Marine Casualty, Commercial Diving Casualty, or OCS-related Casualty; CG–2692A, Barge Addendum; CG–2692B, Report of Mandatory Chemical Testing Following a Serious Marine Incident Involving Vessels in Commercial Service; CG–2692C, Personnel Casualty Addendum; CG–2692D, Involved Persons and Witnesses Addendum.

Respondents: Vessel owners and operators.

Frequency: On occasion.

Hour Burden Estimate: The estimated burden has increased from 22,939 hours to 22,980 hours a year due to an increase in the estimated number of responses.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended.

Dated: November 28, 2018.

James D. Roppel,

Acting Chief, Office of Information Management, U.S. Coast Guard.

[FR Doc. 2018–26280 Filed 12–3–18; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7001–N–59]

30-Day Notice of Proposed Information Collection: HUD Acquisition Regulation

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: HUD submitted the proposed information collection requirement described below to the Office of Management and Budget (OMB) for review, in accordance with the Paperwork Reduction Act. The purpose of this notice is to allow for 30 days of public comment.

DATES: *Comments Due Date:* January 3, 2019.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; fax: 202–395–5806, Email: *OIRA Submission@omb.eop.gov*

FOR FURTHER INFORMATION CONTACT: Colette Pollard, Reports Management Officer, QMAC, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email *Colette.Pollard@hud.gov,* or telephone 202–402–3400. This is not a toll-free number. Person with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

The **Federal Register** notice that solicited public comment on the information collection for a period of 60 days was published on April 2, 2018 at 83 FR 14022.

A. Overview of Information Collection

Title of Information Collection: HUD Acquisition Regulation (HUDAR) (48 CFR 24).

OMB Approved Number: 2535–0091.

Type of Request: This is an extension of a currently approved collection. The HUDAR supplements the Federal Acquisition Regulation (FAR). Information collection required of the public is solely in connection with the acquisition process.

Form Number: HUD–770.

Description of the need for the information and proposed use: The HUDAR (48 CFR 24) contains the Department's supplement to the Federal Acquisition Regulations (FAR) 48 CFR Chapter 1. The FAR sets forth uniform policies and procedures applicable to Federal agencies in the procurement of personal property and non-personal services (including construction) and the procurement of real property by lease.

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Annual cost
HUDAR:						44.28	
2452.204–70	20.00	1.00	20.00	16.00	320.00	44.28	$14,169.60
2452.209–70	10.00	1.00	10.00	0.50	5.00	44.28	221.40
2452.209–72	2.00	1.00	2.00	1.00	2.00	44.28	88.56
2452.215–70	150.00	1.00	150.00	80.00	12000.00	44.28	531,360.00
2452.215–70, Alt I	25.00	1.00	25.00	40.00	1000.00	44.28	44,280.00
2452.215–72	25.00	4.00	100.00	2.00	200.00	44.28	8,856.00
2452.216–72	2.00	4.00	8.00	2.00	16.00	44.28	708.48
2452.216–75	2.00	4.00	8.00	40.00	320.00	44.28	14,169.60
2452.216–78, Alt II	5.00	1.00	5.00	4.00	20.00	44.28	885.60
2452.219–70	50.00	1.00	50.00	0.50	25.00	44.28	1,107.00
2452.219–74	1.00	1.00	1.00	16.00	16.00	44.28	708.48
2452.227–70	5.00	1.00	5.00	40.00	200.00	44.28	8,856.00
2452.237–70	150.00	1.00	150.00	1.00	150.00	44.28	6,642.00
2452.237–75 (initial)	100.00	1.00	100.00	8.00	800.00	44.28	35,424.00
2452.237–75 (report)	100.00	4.00	400.00	8.00	3200.00	44.28	141,696.00
2452.237–81	20.00	1.00	20.00	0.50	10.00	44.28	442.80
2452.239–70	100.00	1.00	100.00	8.00	800.00	44.28	35,424.00
2452.239–70 (report)	100.00	4.00	400.00	8.00	3200.00	44.28	141,696.00
2452.242–71 (plan)	40.00	4.00	160.00	8.00	1280.00	44.28	56,678.40
2452.242–71 (report)	10.00	4.00	40.00	6.00	240.00	44.28	10,627.20
2452.227–70	1.00	1.00	1.00	8.00	8.00	44.28	354.24
Contractor Release	150.00	1.00	150.00	1.00	150.00	44.28	6,642.00
Contractor Assignment of Rebates, Credits	10.00	1.00	10.00	1.00	10.00	44.28	442.80
	1078.00		1915.00		23972.00		1,061,480.16

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond: Including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

C. Authority:

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: November 20, 2018.

Colette Pollard,

Department Reports Management Officer, Office of the Chief Information Officer.

[FR Doc. 2018–26339 Filed 12–3–18; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7008–N–01]

60-Day Notice of Proposed Information Collection: Comment Request: Agency Information Collection Activities: Race and Ethnic Data Collection

AGENCY: Office of Strategic Planning and Management, Grants Management and Oversight Division, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* February 4, 2019.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW, Room 4176, Washington, DC 20410–5000; telephone 202–402–3400 (this is not a toll-free number) or email at *Colette.Pollard@hud.gov* for a copy of the proposed form. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

Electronic Submission of Comments. Interested persons may also submit comments electronically through the Federal eRulemaking Portal at *www.regulations.gov.* HUD strongly encourages commenters to submit comments electronically. Electronic submission of comments allows the commenter maximum time to prepare and submit a comment, ensures timely receipt by HUD, and enables HUD to make them immediately available to the public. Comments submitted electronically through the *www.regulations.gov* website can be viewed by other commenters and interested members of the public. Commenters should follow the instructions provided on that site to submit comments electronically.

Note: To receive consideration as public comments, comments must be submitted through one of the methods specified above. Again, all submissions must refer to the docket number and title of the notice.

FOR FURTHER INFORMATION CONTACT: Ann vom Eigen, Grants Management and Oversight Division, Office of Strategic Planning and Management, Department of Housing and Urban Development, 451 Seventh St. SW, Room 3156, Washington, DC 20410 or by email *Ann.H.vomEigen@hud.gov* or telephone 202–402–2146. This is not a toll-free number. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

Copies of the proposed data collection form may be requested from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that the Department will submit the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended). HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Standardized Form for Collecting Information Regarding Race and Ethnic Data.

Type of Request: Reinstatement, without change, of a previously approved collection for which approval has expired.

OMB Control Number: 2535–0113.

Form Number: Race and Ethnic Data Reporting Form (HUD–27061).

Description of the need for the information and proposed use: The information collected through HUD's standardized Form for the Collection of Race and Ethnic Data is required under 24 CFR—PART 1—Nondiscrimination in Federally Assisted Programs of the Department of Housing and Urban Development—Effectuation of the Title VI of the Civil Rights Act of 1964. HUD's Title VI regulations, specifically 24 CFR 1.6, require recipients of Federal financial assistance to maintain and submit racial and ethnic data so HUD may determine whether such programs comply with Title VI data collection requirements. HUD must offer individuals who are responding to agency data requests for race the option of selecting one or more of five racial categories. HUD must also treat ethnicity as a category separate from race.

Title VI requires recipients of HUD funding to maintain records, make them available to responsible Department officials, and if requested, submit compliance reports. For example, HUD grant programs may request information during program monitoring and compliance reviews to ensure compliance with the nondiscrimination requirements of Title VI.

Estimation of the total numbers of hours needed to prepare the information collection including number of respondents, frequency of response, and hours of response: The form is used by program offices when they negotiate their awards and is maintained on site by the recipient. As HUD initiates approximately 12,000 awards on an annual basis, we expect that there will be 12,000 respondents on an annual basis. HUD estimates that it will take one hour to complete the form, at $60.74 per hour.[1] The total estimated burden would thus reach $728,880.00 on an annual basis. Retrieving the report and providing it to the Department upon request using the same $60.74 cost could reach an additional $182,000 on an annual basis, bringing the total to $911,000.

Estimation of the Cost to the Federal government: HUD estimates the cost of the maximum burden on HUD staff would total at most $732,960.00. This estimate is based on the assumption that each form would be reviewed for 15 minutes by two HUD employees on an annual basis.[2]

B. Solicitation of Public Comment

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points.

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

[1] Estimated cost for respondents is calculated from the June 2018 Department of Labor Bureau of Labor Statistics report on Employer Costs for Employee Compensation determined that the hourly rate of management, professional and related wages and salaries averaged $41.71 per hour plus $19.03 per hour for fringe benefits for a total $60.74 per hour.

[2] Federal staff time is estimated for a GS–13 step 5 hourly rate at $52.66 per hour (from the Office of Personnel Management and the table with Washington-Baltimore-Arlington locality pay), plus 16% fringe benefit for a total of $61.08 per hour.

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including using appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Affected Public who will be Asked or Required to Respond: The primary respondents are HUD award recipients including, but not limited to, state agencies, local governments, public housing authorities, institutions of higher education, faith based organizations, and non-profit and for profit organizations devoted to community development, housing the homeless, and other activities.

C. Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: November 19, 2018.

Christopher K. Walsh,

Acting Director, Office of Strategic Planning and Management.

[FR Doc. 2018–26338 Filed 12–3–18; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS–HQ–IA–2018–0086; FXIA16710900000–178–FF09A30000]

Foreign Endangered Species; Marine Mammals; Receipt of Permit Applications

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of permit applications.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), invite the public to comment on applications to conduct certain activities with foreign species that are listed as endangered under the Endangered Species Act (ESA) and foreign or native species for which the Service has jurisdiction under the Marine Mammal Protection Act (MMPA). With some exceptions, the ESA and the MMPA prohibit activities with listed species unless Federal authorization is issued that allows such activities. The ESA and MMPA also require that we invite public comment before issuing permits for endangered species or marine mammals.

DATES: We must receive comments by January 3, 2019.

ADDRESSES:

Obtaining Documents: The applications, application supporting materials, and any comments and other materials that we receive will be available for public inspection at *http://www.regulations.gov* in Docket No. FWS–HQ–IA–2018–0086.

Submitting Comments: When submitting comments, please specify the name of the applicant and the permit number at the beginning of your comment. You may submit comments by one of the following methods:

- *Internet: http://www.regulations.gov.* Search for and submit comments on Docket No. FWS–HQ–IA–2018–0086.
- *U.S. mail or hand-delivery:* Public Comments Processing, Attn: Docket No. FWS–HQ–IA–2018–0086; U.S. Fish and Wildlife Service Headquarters, MS: BPHC; 5275 Leesburg Pike; Falls Church, VA 22041–3803.

For more information, see Public Comment Procedures under **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Monica Thomas, by phone at 703–358–2104, via email at *DMAFR@fws.gov,* or via the Federal Relay Service at 800–877–8339.

SUPPLEMENTARY INFORMATION:

I. Public Comment Procedures

A. How do I comment on submitted applications?

You may submit your comments and materials by one of the methods in **ADDRESSES**. We will not consider comments sent by email or fax, or to an address not in **ADDRESSES**. We will not consider or include in our administrative record comments we receive after the close of the comment period (see **DATES**).

When submitting comments, please specify the name of the applicant and the permit number at the beginning of your comment. Provide sufficient information to allow us to authenticate any scientific or commercial data you include. The comments and recommendations that will be most useful and likely to influence agency decisions are: (1) Those supported by quantitative information or studies; and (2) those that include citations to, and analyses of, the applicable laws and regulations.

B. May I review comments submitted by others?

You may view and comment on others' public comments on *http://www.regulations.gov,* unless our allowing so would violate the Privacy Act (5 U.S.C. 552a) or Freedom of Information Act (5 U.S.C. 552).

C. Who will see my comments?

If you submit a comment at *http://www.regulations.gov,* your entire comment, including any personal identifying information, will be posted on the website. If you submit a hardcopy comment that includes personal identifying information, such as your address, phone number, or email address, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. Moreover, all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available for public disclosure in their entirety.

II. Background

To help us carry out our conservation responsibilities for affected species, and in consideration of section 10(a)(1)(A) of the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), and section 104(c) of the Marine Mammal Protection Act of 1972, as amended (MMPA; 16 U.S.C. 1361 *et seq.*), we invite public comments on permit applications before final action is taken. With some exceptions, the ESA and MMPA prohibit activities with listed species unless Federal authorization is issued that allows such activities. Permits issued under section 10 of the ESA allow activities for scientific purposes or to enhance the propagation or survival of the affected species. Regulations regarding permit issuance under the ESA are in title 50 of the Code of Federal Regulations in part 17. ESA permits cover a wide range of activities pertaining to foreign listed species, including import, export, and activities in the United States. Concurrent with publishing this notice in the **Federal Register**, we are forwarding copies of the marine mammal applications to the Marine Mammal Commission and the Committee of Scientific Advisors for their review.

III. Permit Applications

We invite comments on the following applications.

A. Endangered Species

Applicant: Minnesota Zoological Gardens, Apple Valley, MN; Permit No. 91440C

The applicant requests a captive-bred wildlife registration under 50 CFR 17.21(g) to enhance the propagation or survival of the species for: Golden lion

tamarin (*Leonthopithecus rosalia*), cotton-top tamarin (*Saguinus Oedipus*), Asian dhole (*Cuon alpinus*), Asian wild horse (*Equus Przewalski*), Amur leopard (*Panthera pardus orientalis*), Siberian tiger (*Panthera tigris altaica*), White-cheeked gibbon (*Hylobates leucogenys*), Ring-tailed lemur (*Lemur catta*), Malayan tapir (*Tapirus indicus*), Rothschild's mynah (*Leucopsar rothschildi*), African penguin (*Spheniscus demersus*), West African dwarf crocodile (*Osteolaemus tetraspis tetraspis*), and komodo monitor (*Varanus komodoensis*). This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Cord Offermann, Austin, TX; Permit No. 05160B

The applicant requests renewal of a captive-bred wildlife registration under 50 CFR 17.21(g) for the following species to enhance the propagation or survival of the species: Radiated tortoise (*Astrochelys radiata*), Galapagos giant tortoise (*Chelonoidis niger*), and spotted pond turtle (*Geoclemys hamiltonii*). This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Chicago Zoological Society dba Brookfield Zoo, Brookfield, IL; Permit No. 84889C

The applicant requests renewal of a captive-bred wildlife registration under 50 CFR 17.21(g) for the following species to enhance the propagation or survival of the species: Grevy's zebra (*Equus grevyi*), Siberian tiger (*Panthera tigris altaica*), lesser slow loris (*Nycticebus pygmaeus*), African dwarf crocodile (*Osteolaemus tetraspis*), and clouded leopard (*Neofelis nebulosa*). This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Uno Mas Ranch, Bandera, TX; Permit No. 02149D

The applicant requests a permit authorizing the culling of excess Arabian oryx (*Oryx leucoryx*) from the captive herd maintained at their facility, to enhance the species' propagation and survival. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Gary Reeder, Flagstaff, AZ; Permit No. 09831D

The applicant requests a permit to import a sport-hunted trophy of one male bontebok (*Damaliscus pygargus pygargus*) culled from a captive herd maintained under the management program of the Republic of South Africa, for the purpose of enhancing the propagation or survival of the species.

B. Endangered Marine Mammals and Marine Mammals

Applicant: ABR, Inc.—Environmental Research and Services, Fairbanks, AK; Permit No. 75595C

The applicant requests a permit for authorization to conduct aerial and boat surveys of northern sea otters (*Enhydra lutris kenyoni*) in Kamishak Bay of Cook Inlet. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: USGS Alaska Science Center, Anchorage, AK; Permit No. 85339C

The applicant requests a permit for authorization to conduct research on captive polar bears (*Ursus maritimus*) housed in various U.S. zoological facilities. This notification covers activities to be conducted by the applicant over a 5-year period.

IV. Next Steps

If we issue permits to any of the applicants listed in this notice, we will publish a notice in the **Federal Register**. You may locate the notice announcing the permit issuance by searching *http://www.regulations.gov* for the permit number listed above in this document. For example, to find information about the potential issuance of Permit No. 12345A, you would go to *regulations.gov* and search for ''12345A''.

V. Authority

We issue this notice under the authority of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*), and its implementing regulations, and the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*), and its implementing regulations.

Monica Thomas,

Management Analyst, Branch of Permits, Division of Management Authority.

[FR Doc. 2018–26215 Filed 12–3–18; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[190A2100DD/AAKC001030/A0A501010.999900253G]

Indian Gaming; Approval of Tribal-State Class III Gaming Compact Amendment in the State of Oklahoma

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: The State of Oklahoma entered into an amendment with the Osage Nation governing certain forms of class III gaming; this notice announces the approval of the Osage Nation and State of Oklahoma Gaming Compact: Non-house-banked Table Games Supplement.

DATES: The amendment takes effect on December 4, 2018.

FOR FURTHER INFORMATION CONTACT: Ms. Paula L. Hart, Director, Office of Indian Gaming, Office of the Deputy Assistant Secretary—Policy and Economic Development, Washington, DC 20240, (202) 219–4066.

SUPPLEMENTARY INFORMATION: Under section 11 of the Indian Gaming Regulatory Act (IGRA), 25 U.S.C. 2701 *et seq.,* the Secretary of the Interior shall publish in the **Federal Register** notice of approved Tribal-State compacts for the purpose of engaging in Class III gaming activities on Indian lands. As required by IGRA and 25 CFR 293.4, all compacts and amendments are subject to review and approval by the Secretary. The amendment authorizes the Tribe to engage in certain additional class III gaming activities, provides for the application of existing revenue sharing agreements to the additional forms of class III gaming, and designates how the State will distribute revenue sharing funds.

Dated: November 16, 2018.

Tara Sweeney,

Assistant Secretary—Indian Affairs.

[FR Doc. 2018–26298 Filed 12–3–18; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[190A2100DD/AAKC001030/A0A501010.999900]

HEARTH Act Approval of Prairie Band Potawatomi Nation Regulations

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: On September 18, 2018, the Bureau of Indian Affairs (BIA) approved the Prairie Band Potawatomi Nation Business Site Leasing Ordinance under the Helping Expedite and Advance Responsible Tribal Homeownership Act of 2012 (HEARTH Act). With this approval, the Tribe is authorized to enter into business and other authorized purposes leases without further BIA approval.

FOR FURTHER INFORMATION CONTACT: Ms. Sharlene Round Face, Bureau of Indian Affairs, Division of Real Estate Services, 1849 C Street NW, MS–4642–MIB

Washington, DC 20240, or by telephone at (202) 208–3615.

SUPPLEMENTARY INFORMATION:

I. Summary of the HEARTH Act

The HEARTH Act makes a voluntary, alternative land leasing process available to Tribes, by amending the Indian Long-Term Leasing Act of 1955, 25 U.S.C. 415. The HEARTH Act authorizes Tribes to negotiate and enter into agricultural and business leases of Tribal trust lands with a primary term of 25 years, and up to two renewal terms of 25 years each, without the approval of the Secretary of the Interior (Secretary).

The HEARTH Act also authorizes Tribes to enter into leases for residential, recreational, religious or educational purposes for a primary term of up to 75 years without the approval of the Secretary. Participating Tribes develop tribal leasing regulations, including an environmental review process, and then must obtain the Secretary's approval of those regulations prior to entering into leases. The HEARTH Act requires the Secretary to approve Tribal regulations if the Tribal regulations are consistent with the Department of the Interior's (Department) leasing regulations at 25 CFR part 162 and provide for an environmental review process that meets requirements set forth in the HEARTH Act. This notice announces that the Secretary, through the Assistant Secretary—Indian Affairs, has approved the Tribal regulations for the Prairie Band Potawatomi Nation.

II. Federal Preemption of State and Local Taxes

The Department's regulations governing the surface leasing of trust and restricted Indian lands specify that, subject to applicable Federal law, permanent improvements on leased land, leasehold or possessory interests, and activities under the lease are not subject to State and local taxation and may be subject to taxation by the Indian Tribe with jurisdiction. See 25 CFR 162.017. As explained further in the preamble to the final regulations, the Federal government has a strong interest in promoting economic development, self-determination, and Tribal sovereignty. 77 FR 72,440, 72,447–48 (December 5, 2012). The principles supporting the Federal preemption of State law in the field of Indian leasing and the taxation of lease-related interests and activities applies with equal force to leases entered into under Tribal leasing regulations approved by the Federal government pursuant to the HEARTH Act.

Section 5 of the Indian Reorganization Act, 25 U.S.C. 5108, preempts State and local taxation of permanent improvements on trust land. *Confederated Tribes of the Chehalis Reservation* v. *Thurston County,* 724 F.3d 1153, 1157 (9th Cir. 2013) (citing *Mescalero Apache Tribe* v. *Jones,* 411 U.S. 145 (1973)). Similarly, section 5108 preempts state taxation of rent payments by a lessee for leased trust lands, because ''tax on the payment of rent is indistinguishable from an impermissible tax on the land.'' *See Seminole Tribe of Florida* v. *Stranburg,* No. 14–14524, *13–*17, n.8 (11th Cir. 2015). In addition, as explained in the preamble to the revised leasing regulations at 25 CFR part 162, Federal courts have applied a balancing test to determine whether State and local taxation of non-Indians on the reservation is preempted. *White Mountain Apache Tribe* v. *Bracker,* 448 U.S. 136, 143 (1980). The *Bracker* balancing test, which is conducted against a backdrop of ''traditional notions of Indian self-government,'' requires a particularized examination of the relevant State, Federal, and Tribal interests. We hereby adopt the *Bracker* analysis from the preamble to the surface leasing regulations, 77 FR at 72,447–48, as supplemented by the analysis below.

The strong Federal and Tribal interests against State and local taxation of improvements, leaseholds, and activities on land leased under the Department's leasing regulations apply equally to improvements, leaseholds, and activities on land leased pursuant to Tribal leasing regulations approved under the HEARTH Act. Congress's overarching intent was to ''allow Tribes to exercise greater control over their own land, support self-determination, and eliminate bureaucratic delays that stand in the way of homeownership and economic development in Tribal communities.'' 158 Cong. Rec. H. 2682 (May 15, 2012). The HEARTH Act was intended to afford Tribes ''flexibility to adapt lease terms to suit [their] business and cultural needs'' and to ''enable [Tribes] to approve leases quickly and efficiently.'' *Id.* at 5–6.

Assessment of State and local taxes would obstruct these express Federal policies supporting Tribal economic development and self-determination, and also threaten substantial Tribal interests in effective Tribal government, economic self-sufficiency, and territorial autonomy. *See Michigan* v. *Bay Mills Indian Community,* 134 S. Ct. 2024, 2043 (2014) (Sotomayor, J., concurring) (determining that ''[a] key goal of the Federal Government is to render Tribes more self-sufficient, and better positioned to fund their own sovereign functions, rather than relying on Federal funding''). The additional costs of State and local taxation have a chilling effect on potential lessees, as well as on a Tribe that, as a result, might refrain from exercising its own sovereign right to impose a Tribal tax to support its infrastructure needs. *See id.* at 2043–44 (finding that State and local taxes greatly discourage Tribes from raising tax revenue from the same sources because the imposition of double taxation would impede Tribal economic growth).

Similar to BIA's surface leasing regulations, Tribal regulations under the HEARTH Act pervasively cover all aspects of leasing. *See* 25 U.S.C. 415(h)(3)(B)(i) (requiring Tribal regulations be consistent with BIA surface leasing regulations). Furthermore, the Federal government remains involved in the Tribal land leasing process by approving the Tribal leasing regulations in the first instance and providing technical assistance, upon request by a Tribe, for the development of an environmental review process. The Secretary also retains authority to take any necessary actions to remedy violations of a lease or of the Tribal regulations, including terminating the lease or rescinding approval of the Tribal regulations and reassuming lease approval responsibilities. Moreover, the Secretary continues to review, approve, and monitor individual Indian land leases and other types of leases not covered under the Tribal regulations according to the Part 162 regulations.

Accordingly, the Federal and Tribal interests weigh heavily in favor of preemption of State and local taxes on lease-related activities and interests, regardless of whether the lease is governed by Tribal leasing regulations or Part 162. Improvements, activities, and leasehold or possessory interests may be subject to taxation by the Prairie Band Potawatomi Nation.

Dated: September 18, 2018.

Tara Sweeney,

Assistant Secretary—Indian Affairs.

[FR Doc. 2018–26340 Filed 12–3–18; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLNV952000 L14400000.BJ0000.LXSSF2210000.241A; MO #4500130147]

Filing of Plats of Survey; NV

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The purpose of this notice is to inform the public and interested State and local government officials of the filing of Plats of Survey in Nevada.

DATES: Unless otherwise stated filing is applicable at 10:00 a.m. on the dates indicated below.

FOR FURTHER INFORMATION CONTACT: Michael O. Harmening, Chief Cadastral Surveyor for Nevada, Bureau of Land Management, Nevada State Office, 1340 Financial Blvd., Reno, NV 89502–7147, phone: 775–861–6490. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: 1. The Supplemental Plat of the following described lands was officially filed at the Bureau of Land Management (BLM) Nevada State Office, Reno, Nevada on August 10, 2018:

The supplemental plat, in one sheet, showing new lottings in the SW¼SW¼ of section 8, Township 33 North, Range 70 East, Mount Diablo Meridian, Nevada, under Group No. 987, was accepted August 9, 2018. This supplemental plat was prepared to meet certain administrative needs of the Bureau of Land Management.

The supplemental plat listed above is now the basic records for describing lands for all authorized purposes. These records have been placed in the open files at the BLM Nevada State Office and are available to the public as a matter of information. Copies of the surveys and related field notes may be furnished to the public upon payment of the appropriate fees.

Dated: November 20, 2018.

Michael O. Harmening,

Chief Cadastral Surveyor for Nevada.

[FR Doc. 2018–26248 Filed 12–3–18; 8:45 am]

BILLING CODE 4310–HC–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 731–TA–1392–1393 (Final)]

Polytetrafluoroethylene (PTFE) Resin From China and India; Determination

On the basis of the record [1] developed in the subject investigations, the United States International Trade Commission (''Commission'') determines, pursuant to the Tariff Act of 1930 (''the Act''), that an industry in the United States is not materially injured or threatened with material injury by reason of imports of polytetrafluoroethylene (PTFE) resin from China and India that have been found by the U.S. Department of Commerce (''Commerce'') to be sold in the United States at less than fair value (''LTFV'').[2] [3] [4]

Background

The Commission, pursuant to section 735(b) of the Act (19 U.S.C. 1673d(b)), instituted these investigations effective September 28, 2017, following receipt of a petition filed with the Commission and Commerce by The Chemours Company FC LLC, Wilmington, Delaware. Effective February 28, 2018, the Commission established a general schedule for the conduct of the final phase of its investigation on PTFE resin, following a preliminary determination by Commerce that imports of subject PTFE resin were subsidized by the government of India. Notice of the scheduling of the final phase of the Commission's investigations and of a public hearing to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** on March 23, 2018 (83 FR 12815). The hearing was held in Washington, DC, on May 17, 2018, and all persons who requested the opportunity were permitted to appear in person or by counsel. The Commission subsequently issued its final negative determination regarding subsidized imports of PTFE from India on July 6, 2018 (83 FR 32150, July 11, 2018). Following notification of final determinations by Commerce that imports of PTFE resin from China and India were being sold at LTFV within the meaning of section 735(b) of the ACT (19 U.S.C. 1673(a)), notice of the supplemental scheduling of the final phase of the Commission's antidumping duty investigations was given by posting copies of the notice in the Office of the Secretary, U.S. International trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** on October 11, 2018 (83 FR 51501).

The Commission made these determinations pursuant to section 735(b) of the Act (19 U.S.C. 1673d(b)). It completed and filed its determinations in these investigations on November 13, 2018. The views of the Commission are contained in USITC Publication 4841 (November 2018), entitled *Polytetrafluoroethylene (PTFE) Resin from China and India: Investigation Nos. 731–TA–1392–1393 (Final).*

By order of the Commission.

Issued: November 29, 2018.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2018–26324 Filed 12–3–18; 8:45 am]

BILLING CODE 7020–02–P

[1] The record is defined in sec. 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

[2] 83 FR 48590 and 83 FR 48594 (September 26, 2018).

[3] Whether the establishment of an industry in the United States is materially retarded is not an issue in these investigations.

[4] Commissioner Kearns did not participate in these investigations.

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1073]

Certain Thermoplastic-Encapsulated Electric Motors, Components Thereof, and Products and Vehicles Containing Same II; Notice of Request for Statements on the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the presiding administrative law judge has issued a final initial determination on a section 337 violation and a recommended determination on remedy, the public interest, and bonding in the above-captioned investigation. The Commission is soliciting comments on public interest issues raised by the recommended relief, should the Commission find a violation. This notice is soliciting public interest comments from the public only. Parties are to file public interest submissions pursuant to Commission rules.

FOR FURTHER INFORMATION CONTACT: Lucy Grace D. Noyola, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone 202–

205–3438. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*https://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 202–205–1810.

SUPPLEMENTARY INFORMATION: Section 337 of the Tariff Act of 1930 provides that if the Commission finds a violation it shall exclude the articles concerned from the United States unless, after considering the effect of such exclusion upon the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers, it finds that such articles should not be excluded from entry. 19 U.S.C. 1337(d)(1). A similar provision applies to cease and desist orders. 19 U.S.C. 1337(f)(1).

The Commission is soliciting comments on public interest issues raised by the recommended relief should the Commission find a violation, specifically whether the Commission should issue: (1) A limited exclusion order (''LEO'') directed to certain infringing thermoplastic-encapsulated electric motors, components thereof, and products and vehicles containing same; and (2) cease and desist orders (''CDOs'') against respondents Aisin Holdings of America, Inc. of Seymour, Indiana; Aisin Technical Center of America, Inc. of Northville, Michigan; Aisin World Corporation of America of Northville, Michigan; Toyota Motor North America, Inc. of New York, New York; Toyota Motor Sales, U.S.A., Inc. of Torrance, California; Toyota Motor Engineering & Manufacturing North America, Inc. of Erlanger, Kentucky; Toyota Motor Manufacturing, Indiana, Inc. of Princeton, Indiana; and Toyota Motor Manufacturing, Kentucky, Inc. of Georgetown, Kentucky.

The Commission is interested in further development of the record on the public interest in these investigations. Accordingly, parties are to file public interest submissions pursuant to pursuant to 19 CFR 210.50(a)(4). In addition, members of the public are hereby invited to file submissions of no more than five (5) pages, inclusive of attachments, concerning the public interest in light of the administrative law judge's Recommended Determination on remedy, the public interest, and bonding issued in this investigation on November 27, 2018. Comments should address whether issuance of the LEO and CDOs in this investigation, should the Commission find a violation, would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) Explain how the articles potentially subject to the recommended orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the recommended orders;

(iii) identify like or directly competitive articles that complainants, their licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainants, complainants' licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the recommended exclusion order and/or a cease and desist order within a commercially reasonable time; and

(v) explain how the LEO and CDO would impact consumers in the United States.

Written submissions from the public must be filed no later than close of business on Monday, January 7, 2019.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above and submit 8 true paper copies to the Office of the Secretary by noon the next day pursuant to section 210.4(f) of the Commission's Rules of Practice and Procedure (19 CFR 210.4(f)). Submissions should refer to the investigation number (''Inv. No. 337–TA–1073'') in a prominent place on the cover page and/or the first page. *See* Handbook on Filing Procedures, *https://www.usitc.gov/secretary/documents/handbook_on_filing_procedures.pdf.* Persons with questions regarding filing should contact the Secretary (202–205–2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this Investigation may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel,[1] solely for cybersecurity purposes. All non-confidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of sections 201.10 and 210.50 of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.50).

By order of the Commission.

Issued: November 28, 2018.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2018–26274 Filed 12–3–18; 8:45 am]

BILLING CODE 7020–02–P

[1] All contract personnel will sign appropriate nondisclosure agreements.

DEPARTMENT OF JUSTICE

[OMB Number 1122–0021]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension of a Currently Approved Collection

AGENCY: Office on Violence Against Women, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Department of Justice, Office on Violence Against Women (OVW) 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 February 4, 2019.

FOR FURTHER INFORMATION CONTACT: Written comments and/or suggestion regarding the items contained in this notice, especially the estimated public burden and associated response time, should be directed to Cathy Poston, Office on Violence Against Women, at 202–514–5430 or *Catherine.poston@usdoj.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:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension of a currently approved collection.

(2) *Title of the Form/Collection:* Semi-Annual Progress Report for Grantees from Grants to Enhance Culturally and Linguistically Specific Services for Victims of Domestic Violence, Dating Violence, Sexual Assault, and Stalking Program (Culturally and Linguistically Specific Services Program).

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form Number: 1122–0021. U.S. Department of Justice, Office on Violence Against Women.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* The affected public includes the approximately 50 grantees of the Culturally and Linguistically Specific Services Program. The program funds projects that promote the maintenance and replication of existing successful domestic violence, dating violence, sexual assault, and stalking community-based programs providing culturally and linguistically specific services and other resources. The program also supports the development of innovative culturally and linguistically specific strategies and projects to enhance access to services and resources for victims of violence against women.

(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 that it will take the approximately 50 respondents (Culturally and Linguistically Specific Services Program grantees) approximately one hour to complete a semi-annual progress report. The semi-annual progress report is divided into sections that pertain to the different types of activities in which grantees may engage. A Culturally and Linguistically Specific Services Program grantee will only be required to complete the sections of the form that pertain to its own specific activities.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total annual hour burden to complete the data collection forms is 100 hours, that is 50 grantees completing a form twice a year with an estimated completion time for the form being one hour.

If additional information is required contact: Melody Braswell, Deputy Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E, 405B, Washington, DC 20530.

Dated: November 28, 2018.

Melody Braswell,

Department Clearance Officer, PRA, U.S. Department of Justice.

[FR Doc. 2018–26221 Filed 12–3–18; 8:45 am]

BILLING CODE 4410–FX–P

DEPARTMENT OF JUSTICE

[OMB Number 1122–0028]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension of a Currently Approved Collection

AGENCY: Office on Violence Against Women, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Department of Justice, Office on Violence Against Women (OVW) 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 February 4, 2019.

FOR FURTHER INFORMATION CONTACT: Written comments and/or suggestion regarding the items contained in this notice, especially the estimated public burden and associated response time, should be directed to Cathy Poston, Office on Violence Against Women, at 202–514–5430 or *Catherine.poston@usdoj.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:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Semi-annual Progress Report for Children and Youth Exposed to Violence Program.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form Number: 1122–0028. U.S. Department of Justice, Office on Violence Against Women.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* The affected public includes the approximately 25 grantees under the Consolidated Grant Program to Address Children and Youth Experiencing

Domestic and Sexual Assault and Engage Men and Boys as Allies (hereafter referred to as the Consolidated Youth Program) enacted in the FY 2012–2018 appropriation acts, which consolidated four previously authorized and appropriated programs into one comprehensive program. The four programs included in these consolidations were: Services to Advocate for and Respond to Youth (Youth Services), Grants to Assist Children and Youth Exposed to Violence (CEV), Engaging Men and Youth in Preventing Domestic Violence (EMY), and Supporting Teens through Education and Prevention (STEP).

The Consolidated Youth Program supports projects designed to provide coordinated community responses that support child, youth and young adult victims through direct services, training, coordination and collaboration, effective intervention, treatment, response, and prevention strategies. The Consolidated Youth Program creates a unique opportunity for communities to increase collaboration among non-profit victim service providers; violence prevention, and children (0–10), youth (11–18), young adult (19–24) and men-serving organizations; tribes and tribal governments; local government agencies; schools; and programs that support men's role in combating sexual assault, domestic violence, dating violence and stalking.

(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 that it will take the approximately 25 respondents (grantees from the Consolidated Youth Program) approximately one hour to complete a semi-annual progress report. The semi-annual progress report is divided into sections that pertain to the different types of activities in which grantees may engage. A Consolidated Youth Program grantee will only be required to complete the sections of the form that pertain to its own specific activities.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total annual hour burden to complete the data collection forms is 50 hours, that is 25 grantees completing a form twice a year with an estimated completion time for the form being one hour.

If additional information is required contact: Melody Braswell, Deputy Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E, 405B, Washington, DC 20530.

Dated: November 28, 2018.

Melody Braswell,

Department Clearance Officer, PRA U.S. Department of Justice.

[FR Doc. 2018–26219 Filed 12–3–18; 8:45 am]

BILLING CODE 4410–FX–P

DEPARTMENT OF JUSTICE

[OMB Number 1122–0001]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension of a Currently Approved Collection

AGENCY: Office on Violence Against Women, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Department of Justice, Office on Violence Against Women (OVW) 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 February 4, 2019.

FOR FURTHER INFORMATION CONTACT: Written comments and/or suggestion regarding the items contained in this notice, especially the estimated public burden and associated response time, should be directed to Cathy Poston, Office on Violence Against Women, at 202–514–5430 or *Catherine.poston@usdoj.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:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of information collection:* Extension of a currently approved collection.

(2) *Title of the form/collection:* Certification of Compliance with the Statutory Eligibility Requirements of the Violence Against Women Act as Amended.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form Number: 1122–0001. U.S. Department of Justice, Office on Violence Against Women.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* The affected public includes STOP formula grantees (50 states, the District of Columbia and five territories (Guam, Puerto Rico, American Samoa, Virgin Islands, Northern Mariana Islands). The STOP Violence Against Women Formula Grant Program was authorized through the Violence Against Women Act of 1994 and reauthorized and amended in 2000, 2005, and 2013. The purpose of the STOP Formula Grant Program is to promote a coordinated, multi-disciplinary approach to improving the criminal justice system's response to violence against women. It envisions a partnership among law enforcement, prosecution, courts, and victim advocacy organizations to enhance victim safety and hold offenders accountable for their crimes of violence against women. The Department of Justice's Office on Violence Against Women (OVW) administers the STOP Formula Grant Program funds which must be distributed by STOP state administrators according to statutory formula (as amended in 2000, 2005 and 2013).

(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 that it will take the approximately 56 respondents (state administrators from the STOP Formula Grant Program) less than one hour to complete a Certification of Compliance with the Statutory Eligibility Requirements of the Violence Against Women Act, as Amended.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total annual hour burden to complete the Certification is less than 56 hours.

If additional information is required contact: Melody Braswell, Deputy Clearance Officer, United States

Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E, 405B, Washington, DC 20530.

Dated: November 28, 2018.

Melody Braswell,

Department Clearance Officer, PRA, U.S. Department of Justice.

[FR Doc. 2018–26220 Filed 12–3–18; 8:45 am]

BILLING CODE 4410–FX–P

DEPARTMENT OF JUSTICE

[OMB Number 1122–0022]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension of a Currently Approved Collection

AGENCY: Office on Violence Against Women, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Department of Justice, Office on Violence Against Women (OVW) 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 February 4, 2019.

FOR FURTHER INFORMATION CONTACT: Written comments and/or suggestion regarding the items contained in this notice, especially the estimated public burden and associated response time, should be directed to Cathy Poston, Office on Violence Against Women, at 202–514–5430 or *Catherine.poston@usdoj.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:

(1) *Type of Information Collection:* Extension of a currently approved collection.

(2) *Title of the Form/Collection:* Annual Progress Report for the Sexual Assault Services Formula Grant Program (SASP).

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form Number: 1122–0022. U.S. Department of Justice, Office on Violence Against Women.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* The affected public includes the approximately 606 administrators and subgrantees of the SASP. SASP grants support intervention, advocacy, accompaniment, support services, and related assistance for adult, youth, and child victims of sexual assault, family and household members of victims, and those collaterally affected by the sexual assault. The SASP supports the establishment, maintenance, and expansion of rape crisis centers and other programs and projects to assist those victimized by sexual assault. The grant funds are distributed by SASP state administrators to subgrantees as outlined under the provisions of the Violence Women Act.

(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 that it will take the approximately 606 respondents (SASP administrators and subgrantees) approximately one hour to complete an annual progress report. The annual progress report is divided into sections that pertain to the different types of activities in which subgrantees may engage. A SASP subgrantee will only be required to complete the sections of the form that pertain to its own specific activities.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total annual hour burden to complete the data collection form is 606 hours, that is 606 administrators and subgrantees completing a form once a year with an estimated completion time for the form being one hour.

If additional information is required contact: Melody Braswell, Deputy Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E, 405B, Washington, DC 20530.

Dated: November 28, 2018.

Melody Braswell,

Department Clearance Officer, PRA, U.S. Department of Justice.

[FR Doc. 2018–26218 Filed 12–3–18; 8:45 am]

BILLING CODE 4410–FX–P

DEPARTMENT OF JUSTICE

Office of Justice Programs

[OMB Number 1121–0335]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension, Without Change, of a Currently Approved Collection; National Motor Vehicle Title Information System (NMVTIS)

AGENCY: Office of Justice Programs, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Department of Justice, Office of Justice Programs, Bureau of Justice Assistance, has submitted the following information collection request for review and clearance in accordance with the Paperwork Reduction Act of 1995.

DATES: The Department of Justice encourages public comment and will accept input until February 4, 2019.

FOR FURTHER INFORMATION CONTACT: If you have additional comments, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Todd Brighton at 1–202–532–5105, Bureau of Justice Assistance, Office of Justice Programs, U.S. Department of Justice, 810 7th Street NW, Washington, DC 20531 or by email at *Todd.Brighton@usdoj.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 National Motor Vehicle Title Information System (NMVTIS), including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms

of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension of currently approved collection.

(2) *The Title of the Form/Collection:* National Motor Vehicle Title Information System (NMVTIS).

(3) *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* None. Bureau of Justice Assistance, Office of Justice Programs, United States Department of Justice.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: Auto recyclers, junk yards and salvage yards are required to report information into NMVTIS. The Anti-Car Theft Act, defines junk and salvage yards ''as individuals or entities engaged in the business of acquiring or owning junk or salvage automobiles for resale in their entirety or as spare parts or for rebuilding, restoration, or crushing.'' Included in this definition are scrap-vehicle shredders and scrap-metal processors, as well as ''pull- or pick-apart yards,'' salvage pools, salvage auctions, and other types of auctions, businesses, and individuals that handle salvage vehicles (including vehicles declared a ''total loss'').

Abstract: Reporting information on junk and salvage vehicles to the National Motor Vehicle Title Information System (NMVTIS)—supported by the U.S. Department of Justice (DOJ)—is required by federal law. Under federal law, junk and salvage yards must report certain information to NMVTIS on a monthly basis. This legal requirement has been in place since March 2009, following the promulgation of regulations (28 CFR part 25) to implement the junk- and salvage-yard reporting provisions of the Anti-Car Theft Act (codified at 49 U.S.C. 30501—30505). Accordingly, a junk or salvage yard within the United States must, on a monthly basis, provide an inventory to NMVTIS of the junk or salvage automobiles that it obtained (in whole or in part) in the prior month. 28 CFR 25.56(a).

An NMVTIS Reporting Entity includes any individual or entity that meets the federal definition, found in the NMVTIS regulations at 28 CFR 25.52, for a ''junk yard'' or ''salvage yard.'' According to those regulations, a junk yard is defined as ''an individual or entity engaged in the business of acquiring or owning junk automobiles for—(1) Resale in their entirety or as spare parts; or (2) Rebuilding, restoration, or crushing.'' The regulations define a salvage yard as ''an individual or entity engaged in the business of acquiring or owning salvage automobiles for—(1) Resale in their entirety or as spare parts; or (2) Rebuilding, restoration, or crushing.'' These definitions include vehicle remarketers and vehicle recyclers, including scrap vehicle shredders and scrap metal processors as well as ''pull- or pick-apart yards,'' salvage pools, salvage auctions, used automobile dealers, and other types of auctions handling salvage or junk vehicles (including vehicles declared by any insurance company to be a ''total loss'' regardless of any damage assessment). Businesses that operate on behalf of these entities or individual domestic or international salvage vehicle buyers, sometimes known as ''brokers'' may also meet these regulatory definitions of salvage and junk yards. It is important to note that industries not specifically listed in the junk yard or salvage yard definition may still meet one of the definitions and, therefore, be subject to the NMVTIS reporting requirements.

An individual or entity meeting the junk yard or salvage yard definition is subject to the NMVTIS reporting requirements if that individual or entity handles 5 or more junk or salvage motor vehicles per year and is engaged in the business of acquiring or owning a junk automobile or a salvage automobile for—''(1) Resale in their entirety or as spare parts; or (2) Rebuilding, restoration, or crushing.'' Reporting entities can determine whether a vehicle is junk or salvage by referring to the definitions provided in the NMVTIS regulations at 28 CFR 25.52. An NMVTIS Reporting Entity is required to report specific information to NMVTIS within one month of receiving such a vehicle, and failure to report may result in assessment of a civil penalty of $1,000 per violation.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* There are currently approximately 8,000 businesses that report on a regular basis into NMVTIS. The estimate for the average amount of time for each business to report varies: 30–60 minutes (estimated). The states and insurance companies already are capturing most of the data needed to be reported, and the reporting consists of electronic, batch uploaded information. So, for those automated companies the reporting time is negligible. For smaller junk and salvage yard operators who would enter the data manually, it is estimated that it will take respondents an average of 30–60 minutes per month to respond.

(6) *An estimate of the total public burden (in hours) associated with the collection:* An estimate of the total public burden (in hours) associated with the collection is 48,000 to 96,000 hours.

Total Annual Reporting Burden:

8,000 × 30 minutes per month (12 times per year) = 48,000

8,000 × 60 minutes per month (12 times per year) = 96,000

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: November 28, 2018.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2018–26217 Filed 12–3–18; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF LABOR

Employee Benefits Security Administration

Advisory Council on Employee Welfare and Pension Benefit Plans; Notice of Charter Renewal

In accordance with section 512(a)(1) of the Employee Retirement Income Security Act of 1974 (ERISA) and the provisions of the Federal Advisory Committee Act and its implementing regulations issued by the General Services Administration (GSA), the charter for the Advisory Council on Employee Welfare and Pension Benefit Plans is renewed.

The Advisory Council on Employee Welfare and Pension Benefit Plans shall advise the Secretary of Labor on technical aspects of the provisions of ERISA and shall provide reports and/or recommendations each year on its findings to the Secretary of Labor. The Council shall be composed of fifteen members appointed by the Secretary. Not more than eight members of the Council shall be of the same political party. Three of the members shall be representatives of employee organizations (at least one of whom shall be a representative of any organization members of which are participants in a multiemployer plan); three of the members shall be representatives of employers (at least one of whom shall be a representative

of employers maintaining or contributing to multiemployer plans); three members shall be representatives appointed from the general public (one of whom shall be a person representing those receiving benefits from a pension plan); and there shall be one representative each from the fields of insurance, corporate trust, actuarial counseling, investment counseling, investment management, and accounting.

The Advisory Council will report to the Secretary of Labor. It will function solely as an advisory body and in compliance with the provisions of the Federal Advisory Committee Act, and its charter will be filed under the Act. For further information, contact Larry I. Good, Executive Secretary, Advisory Council on Employee Welfare and Pension Benefit Plans, U.S. Department of Labor, 200 Constitution Avenue NW, Washington, DC 20210, telephone (202) 693–8668.

Signed at Washington, DC this 27th day of November, 2018.

Preston Rutledge,

Assistant Secretary, Employee Benefits Security Administration.

[FR Doc. 2018–26261 Filed 12–3–18; 8:45 am]

BILLING CODE 4510–29–P

NUCLEAR REGULATORY COMMISSION

[NRC–2018–0001]

Sunshine Act Meetings

TIME AND DATE: Weeks of December 3, 10, 17, 24, 31, 2018, January 7, 2019.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and Closed.

MATTERS TO BE CONSIDERED:

Week of December 3, 2018

Monday, December 3, 2018

10:00 a.m. Briefing on Equal Employment Opportunity, Affirmative Employment, and Small Business (Public); (Contact: Larniece McKoy Moore: 301–415–1942)

This meeting will be webcast live at the Web address—*http://www.nrc.gov/.*

Thursday, December 6, 2018

10:00 a.m. Meeting with Advisory Committee on Reactor Safeguards (Public); (Contact: Mark Banks: 301–415–3718)

This meeting will be webcast live at the Web address—*http://www.nrc.gov/.*

Week of December 10, 2018—Tentative

There are no meetings scheduled for the week of December 10, 2018.

Week of December 17, 2018—Tentative

There are no meetings scheduled for the week of December 17, 2018.

Week of December 24, 2018—Tentative

There are no meetings scheduled for the week of December 24, 2018.

Week of December 31, 2018—Tentative

There are no meetings scheduled for the week of December 31, 2018.

Week of January 7, 2019—Tentative

There are no meetings scheduled for the week of January 7, 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 30th day of November 2018.

For the Nuclear Regulatory Commission.

Denise L. McGovern,

Policy Coordinator, Office of the Secretary.

[FR Doc. 2018–26454 Filed 11–30–18; 4:15 pm]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2018–0267]

Applications and Amendments to Facility Operating Licenses and Combined Licenses Involving Proposed No Significant Hazards Considerations and Containing Sensitive Unclassified Non-Safeguards Information and Order Imposing Procedures for Access to Sensitive Unclassified Non-Safeguards Information

AGENCY: Nuclear Regulatory Commission.

ACTION: License amendment request; notice of opportunity to comment, request a hearing, and petition for leave to intervene; order imposing procedures.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) received and is considering approval of four amendment requests. The amendment requests are for North Anna Power Station, Unit Nos. 1 and 2; Shearon Harris Nuclear Power Plant, Unit 1; H. B. Robinson Steam Electric Plant Unit No. 2; and Virgil C. Summer Nuclear Station, Unit No. 1. For each amendment request, the NRC proposes to determine that they involve no significant hazards consideration. Because each amendment request contains sensitive unclassified non-safeguards information (SUNSI) an order imposes procedures to obtain access to SUNSI for contention preparation.

DATES: Comments must be filed by January 3, 2019. A request for a hearing must be filed by February 4, 2019. Any potential party as defined in section 2.4 of title 10 of the *Code of Federal Regulations* (10 CFR), who believes access to SUNSI is necessary to respond to this notice must request document access by December 14, 2018.

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–2018–0267. Address questions about Docket IDs in *Regulations.gov* to Jennifer Borges; telephone: 301–287–9127; email: *Jennifer.Borges@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* May Ma, Office of Administration, Mail Stop: TWFN–7–A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Lynn Ronewicz, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–1927, email: *Lynn.Ronewicz@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2018–0267, facility name, unit number(s), plant docket number, application date, and subject when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2018–0267.
- *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 (if it is available in ADAMS) is provided the first time that it is mentioned in this document.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID NRC–2018–0267, facility name, unit number(s), plant docket number, application date, and subject in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *http://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

Pursuant to Section 189a.(2) of the Atomic Energy Act of 1954, as amended (the Act), the NRC is publishing this notice. The Act requires the Commission to publish notice of any amendments issued, or proposed to be issued and grants the Commission the authority to issue and make immediately effective any amendment to an operating license or combined license, as applicable, upon a determination by the Commission that such amendment involves no significant hazards consideration, notwithstanding the pendency before the Commission of a request for a hearing from any person.

This notice includes notices of amendments containing SUNSI.

III. Notice of Consideration of Issuance of Amendments to Facility Operating Licenses and Combined Licenses, Proposed No Significant Hazards Consideration Determination, and Opportunity for a Hearing

The Commission has made a proposed determination that the following amendment requests involve no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated, or (2) create the possibility of a new or different kind of accident from any accident previously evaluated, or (3) involve a significant reduction in a margin of safety. The basis for this proposed determination for each amendment request is shown below.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of 60 days after the date of publication of this notice. The Commission may issue the license amendment before expiration of the 60-day period provided that its final determination is that the amendment involves no significant hazards consideration. In addition, the Commission may issue the amendment prior to the expiration of the 30-day comment period if circumstances change during the 30-day comment period such that failure to act in a timely way would result, for example, in derating or shutdown of the facility. If the Commission takes action prior to the expiration of either the comment period or the notice period, it will publish a notice of issuance in the **Federal Register**. If the Commission makes a final no significant hazards consideration determination, any hearing will take place after issuance. The Commission expects that the need to take this action will occur very infrequently.

A. Opportunity To Request a Hearing and Petition for Leave To Intervene

Within 60 days after the date of publication of this notice, any persons (petitioner) whose interest may be affected by this action may file a request for a hearing and petition for leave to intervene (petition) with respect to the action. Petitions shall be filed in accordance with the Commission's ''Agency Rules of Practice and Procedure'' in 10 CFR part 2. Interested persons should consult a current copy of 10 CFR 2.309. The NRC's regulations are accessible electronically from the NRC Library on the NRC's website at *http://www.nrc.gov/reading-rm/doc-collections/cfr/.* Alternatively, a copy of the regulations is available at the NRC's Public Document Room, located at One White Flint North, Room O1–F21, 11555 Rockville Pike (First Floor), Rockville, Maryland 20852. If a petition is filed, the Commission or a presiding officer will rule on the petition and, if appropriate, a notice of a hearing will be issued.

As required by 10 CFR 2.309(d) the petition should specifically explain the reasons why intervention should be permitted with particular reference to the following general requirements for standing: (1) The name, address, and telephone number of the petitioner; (2) the nature of the petitioner's right under the Act to be made a party to the proceeding; (3) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (4) the possible effect of any decision or order which may be entered in the proceeding on the petitioner's interest.

In accordance with 10 CFR 2.309(f), the petition must also set forth the

specific contentions which the petitioner seeks to have litigated in the proceeding. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner must provide a brief explanation of the bases for the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to the specific sources and documents on which the petitioner intends to rely to support its position on the issue. The petition must include sufficient information to show that a genuine dispute exists with the applicant or licensee on a material issue of law or fact. Contentions must be limited to matters within the scope of the proceeding. The contention must be one which, if proven, would entitle the petitioner to relief. A petitioner who fails to satisfy the requirements at 10 CFR 2.309(f) with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene. Parties have the opportunity to participate fully in the conduct of the hearing with respect to resolution of that party's admitted contentions, including the opportunity to present evidence, consistent with the NRC's regulations, policies, and procedures.

Petitions must be filed no later than 60 days from the date of publication of this notice. Petitions and motions for leave to file new or amended contentions that are filed after the deadline will not be entertained absent a determination by the presiding officer that the filing demonstrates good cause by satisfying the three factors in 10 CFR 2.309(c)(1)(i) through (iii). The petition must be filed in accordance with the filing instructions in the ''Electronic Submissions (E-Filing)'' section of this document.

If a hearing is requested, and the Commission has not made a final determination on the issue of no significant hazards consideration, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to establish when the hearing is held. If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing would take place after issuance of the amendment. If the final determination is that the amendment request involves a significant hazards consideration, then any hearing held would take place before the issuance of the amendment unless the Commission finds an imminent danger to the health or safety of the public, in which case it will issue an appropriate order or rule under 10 CFR part 2.

A State, local governmental body, Federally-recognized Indian Tribe, or agency thereof, may submit a petition to the Commission to participate as a party under 10 CFR 2.309(h)(1). The petition should state the nature and extent of the petitioner's interest in the proceeding. The petition should be submitted to the Commission no later than 60 days from the date of publication of this notice. The petition must be filed in accordance with the filing instructions in the ''Electronic Submissions (E-Filing)'' section of this document, and should meet the requirements for petitions set forth in this section, except that under 10 CFR 2.309(h)(2) a State, local governmental body, or Federally-recognized Indian Tribe, or agency thereof does not need to address the standing requirements in 10 CFR 2.309(d) if the facility is located within its boundaries. Alternatively, a State, local governmental body, Federally-recognized Indian Tribe, or agency thereof may participate as a non-party under 10 CFR 2.315(c).

If a hearing is granted, any person who is not a party to the proceeding and is not affiliated with or represented by a party may, at the discretion of the presiding officer, be permitted to make a limited appearance pursuant to the provisions of 10 CFR 2.315(a). A person making a limited appearance may make an oral or written statement of his or her position on the issues but may not otherwise participate in the proceeding. A limited appearance may be made at any session of the hearing or at any prehearing conference, subject to the limits and conditions as may be imposed by the presiding officer. Details regarding the opportunity to make a limited appearance will be provided by the presiding officer if such sessions are scheduled.

B. Electronic Submissions (E-Filing)

All documents filed in NRC adjudicatory proceedings, including a request for hearing and petition for leave to intervene (petition), any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities that request to participate under 10 CFR 2.315(c), must be filed in accordance with the NRC's E-Filing rule (72 FR 49139; August 28, 2007, as amended at 77 FR 46562; August 3, 2012). The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases to mail copies on electronic storage media. Detailed guidance on making electronic submissions may be found in the Guidance for Electronic Submissions to the NRC and on the NRC website at *http://www.nrc.gov/site-help/e-submittals.html.* Participants may not submit paper copies of their filings unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at *hearing.docket@nrc.gov,* or by telephone at 301–415–1677, to (1) request a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign submissions and access the E-Filing system for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a petition or other adjudicatory document (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the hearing in this proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public website at *http://www.nrc.gov/site-help/e-submittals/getting-started.html.* Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit adjudicatory documents. Submissions must be in Portable Document Format (PDF). Additional guidance on PDF submissions is available on the NRC's public website at *http://www.nrc.gov/site-help/electronic-sub-ref-mat.html.* A filing is considered complete at the time the document is submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email notice confirming receipt of the document. The E-Filing system also distributes an email notice that provides access to the

document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the document on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before adjudicatory documents are filed so that they can obtain access to the documents via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC's Electronic Filing Help Desk through the ''Contact Us'' link located on the NRC's public website at *http://www.nrc.gov/site-help/e-submittals.html,* by email to *MSHD.Resource@nrc.gov,* or by a toll-free call at 1–866–672–7640. The NRC Electronic Filing Help Desk is available between 9 a.m. and 6 p.m., Eastern Time, Monday through Friday, excluding government holidays.

Participants who believe that they have a good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing stating why there is good cause for not filing electronically and requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, 11555 Rockville Pike, Rockville, Maryland 20852, Attention: Rulemaking and Adjudications Staff. Participants filing adjudicatory documents in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service. A presiding officer, having granted an exemption request from using E-Filing, may require a participant or party to use E-Filing if the presiding officer subsequently determines that the reason for granting the exemption from use of E-Filing no longer exists.

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket which is available to the public at *https://adams.nrc.gov/ehd,* unless excluded pursuant to an order of the Commission or the presiding officer. If you do not have an NRC-issued digital ID certificate as described above, click cancel when the link requests certificates and you will be automatically directed to the NRC's electronic hearing dockets where you will be able to access any publicly available documents in a particular hearing docket. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or personal phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. For example, in some instances, individuals provide home addresses in order to demonstrate proximity to a facility or site. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submission.

South Carolina Electric & Gas Company, South Carolina Public Service Authority, Docket No. 50–395, Virgil C. Summer Nuclear Station, Unit No. 1, Fairfield County, South Carolina

Date of amendment request: August 29, 2018. A publicly-available version is in ADAMS under Accession No. ML18242A658.

Description of amendment request: This amendment request contains sensitive unclassified non-safeguards information (SUNSI). The amendment would revise license conditions and approve changes to plant modifications evaluated using fire probabilistic risk assessment methods and approaches that have been accepted previously in Amendment No. 199 or that have been accepted for another nuclear power plant station and approve performance-based alternatives for Chapter 3, National Fire Protection Association (NFPA) 805 (10 CFR 50.48(c)(2)(vii)), specifically, NFPA 805, Section 3.3.4, ''Insulation Materials,'' and NFPA 805, Section 3.3.5.1, ''Wiring above Suspended Ceilings.''

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The purpose of this amendment is to provide updated information associated with the modifications that were described and committed to in the VCSNS [Virgil C. Summer Nuclear Station] License Amendment Request and subsequently approved by the NRC. This amendment also provides updated information related to Nuclear Safety Compliance Strategies (including recovery actions). The NRC considers that NFPA 805 provides an acceptable methodology and performance criteria for licensees to identify fire protection requirements that are an acceptable alternative to the 10 CFR part 50, Appendix R, fire protection features (69 FR 33536; June 16, 2004).

Operation of VCSNS in accordance with the proposed amendment does not result in a significant increase in the probability or consequences of accidents previously evaluated. The proposed amendment does not affect accident initiators or precursors as described in the VCSNS Safety Analysis Report (SAR), nor does it adversely alter design assumptions, conditions, or configurations of the facility, and it does not adversely impact the ability of structures, systems, or components (SSCs) to perform their intended function to mitigate the consequences of accidents described and evaluated in the SAR. The proposed amendment does not adversely alter safety-related systems nor affect the way in which safety-related systems perform their functions as required by the accident analysis. The SSCs required to safely shut down the reactor and to maintain it in a safe shutdown condition will remain capable of performing the associated design functions.

Therefore, this change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

Implementation of the new risk-informed, performance-based fire protection licensing basis, with the revised modifications and Nuclear Safety Compliance Strategies complies with the requirements in 10 CFR 50.48(a) and 10 CFR 50.48(c), as well as the guidance contained in RG [Regulatory Guide] 1.205, and does not result in new or different kinds of accidents. The requirements in NFPA 805 address only fire protection and the impacts of fire effects on the plant have been evaluated. The proposed amendment does not involve new failure mechanisms or malfunctions that could initiate a new or different kind of accident beyond those already analyzed in the SAR.

Therefore, this change does not create the possibility of a new or different kind of accident from an accident previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

The proposed amendment has been evaluated to ensure that risk and safety margins are maintained within acceptable limits. The risk evaluations for plant changes

in relation to the potential for reducing a safety margin, were measured quantitatively for acceptability using the delta risk (*i.e.,* change in core damage frequency and change in large early release frequency) criteria from Section 5.3.5, ''Acceptance Criteria,'' of Nuclear Energy Institute 04–02, ''Guidance for Implementing a Risk-Informed, Performance-based Fire Protection Program under 10 CFR 50.48(c),'' as well as the guidance contained in RG 1.205. Engineering analyses, which may include engineering evaluations, probabilistic safety assessments, and fire modeling calculations, have been performed to demonstrate that the performance-based methods of NFPA 805 do not result in a significant reduction in the margin of safety.

Therefore, this change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Kathryn M. Sutton, Morgan, Lewis & Bockius LLP, 1111 Pennsylvania Avenue NW, Washington, DC 20004.

NRC Branch Chief: Michael T. Markley.

Duke Energy Progress, LLC, Docket No. 50–400, Shearon Harris Nuclear Power Plant, Unit 1 (Shearon Harris or HNP), Wake and Chatham Counties, North Carolina

Duke Energy Progress, LLC, Docket No. 50–261, H. B. Robinson Steam Electric Plant Unit No. 2 (Robinson or RNP), Darlington County, South Carolina

Date of amendment request: October 19, 2017, as supplemented by letters dated June 5, 2018; October 15, 2018; and November 6, 2018. Publicly-available versions are in ADAMS under Accession Nos. ML17292A040, ML18156A209, ML18288A276, and ML18310A131, respectively.

Description of amendment request: The supplement dated June 5, 2018, contains sensitive unclassified non-safeguards information (SUNSI). The NRC staff previously made a proposed determination that the license amendment request dated October 19, 2017, involves no significant hazards consideration (83 FR 166; January 2, 2018). Subsequently, by letter dated November 6, 2018, the licensee provided additional information that expanded the scope of the amendment request as originally noticed. Accordingly, this notice supersedes the previous notice in its entirety. The proposed amendment request consists of five changes that would revise the Technical Specifications (TSs) to support the allowance of Duke Energy to self-perform core reload design and safety analyses. These changes would (1) add the NRC-approved COPERNIC Topical Report (TR) to the list of TRs for Shearon Harris and Robinson and revise the peak fuel centerline temperature equation in Robinson TS 2.1.1.2 and Shearon Harris TS 2.1.1.b to be the equation used by COPERNIC; (2) relocate several TS parameters to the Core Operating Limits Reports for Shearon Harris and Robinson; (3) revise the Robinson TS moderator temperature coefficient maximum upper limit, (4) revise the Sharon Harris TS definition of shutdown margin consistent with Technical Specifications Task Force (TSTF) Traveler TSTF–248, Revision 0 (ADAMS Accession No. ML040611010), ''Revise Shutdown Margin Definition for Stuck Rod Exception''; and (5) revise the Robinson and Shearon Harris power distribution limits limiting condition for operation actions and surveillance requirements, as well as the Robinson Reactor Protection System Instrumentation Table 3.3.1–1 to allow operation of a reactor core designed using the DPC–NE–2011–P [proprietary], ''Nuclear Design Methodology Report for Core Operating Limits of Westinghouse Reactors,'' methodology. (A redacted version, designated as DPC–NE–2011, is publicly-available under ADAMS Accession No. ML16125A420.)

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

COPERNIC

The proposed change adds a topical report for an NRC-reviewed and approved fuel performance code to the list of topical reports in RNP and HNP Technical Specifications (TS), which is administrative in nature and has no impact on a plant configuration or system performance relied upon to mitigate the consequences of an accident. The list of topical reports in the TS used to develop the core operating limits does not impact either the initiation of an accident or the mitigation of its consequences.

The proposed change also revises a limit on peak fuel centerline temperature in the RNP and HNP TS that is based on a NRC reviewed and approved fuel performance code, and does not require a physical change to plant systems, structures, or components. Plant operations and analysis will continue to be in accordance with the licensing basis. The peak fuel centerline temperature limit provides protection to the fuel and is consistent with the safety analysis.

Relocate TS Parameters to the COLR

The proposed change relocates certain cycle-specific core operating limits from the RNP and HNP TS to the Core Operating Limits Report (COLR). The cycle-specific values must be calculated using the NRC approved methodologies listed in the COLR section of the TS. Because the parameter limits are determined using the NRC methodologies, they will continue to be within the limit assumed in the accident analysis. As a result, neither the probability nor the consequences of any accident previously evaluated will be affected.

RNP MTC TS Change

The proposed change revises the RNP Technical Specification maximum upper Moderator Temperature Coefficient (MTC) limit. Revision of the MTC limit does not affect the performance of any equipment used to mitigate the consequences of an analyzed accident. There is no impact on the source term or pathways assumed in accidents previously assumed. No analysis assumptions are violated and there are no adverse effects on the factors that contribute to offsite or onsite dose as the result of an accident.

HNP TSTF–248

The proposed change revises the HNP Technical Specification definition of Shutdown Margin (SDM) consistent with existing NRC-approved definition. The proposed revision to the SDM definition will result in analytical flexibility for determining SDM. Revision of the SDM definition does not affect the performance of any equipment used to mitigate the consequences of an analyzed accident. There is no impact on the source term or pathways assumed in accidents previously assumed. No analysis assumptions are violated and there are no adverse effects on the factors that contribute to offsite or onsite dose as the result of an accident.

DPC–NE–2011–P TS Changes

The proposed change revises the RNP and HNP TS to allow operation of a reactor core designed using the DPC–NE–2011–P methodology. The DPC–NE–2011–P methodology has already been approved by the NRC for use at RNP and HNP. Revision of the TS to align with the NRC-approved methodology does not affect the performance of any equipment used to mitigate the consequences of an analyzed accident. There is no impact on the source term or pathways assumed in accidents previously assumed. No analysis assumptions are violated and there are no adverse effects on the factors that contribute to offsite or onsite dose as the result of an accident.

Therefore, the proposed changes do not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of

accident from any accident previously evaluated?

Response: No.

COPERNIC

The proposed change adds a topical report for an NRC-reviewed and approved fuel performance code to the list of topical reports in HNP and RNP TS, which is administrative in nature and has no impact on a plant configuration or on system performance. The proposed change updates the list of NRC-approved topical reports used to develop the core operating limits. There is no change to the parameters within which the plant is normally operated. The possibility of a new or different kind of accident is not created.

The proposed change also revises a limit on peak fuel centerline temperature in the RNP and HNP TS that is based on a NRC reviewed and approved fuel performance code, and does not require physical changes to plant systems, structures, or components. Specifying peak fuel centerline temperature ensures that the fuel design limits are met. Operations and analysis will continue to be in compliance with NRC regulations. Revising the peak fuel centerline temperature limit does not affect any accident initiators that would create a new accident.

Relocate TS Parameters to the COLR

The proposed change relocates certain cycle-specific core operating limits from the RNP and HNP TS to the COLR. No new or different accidents result from utilizing the proposed change. The changes do not involve a physical alteration of the plant (*i.e.,* no new or different type of equipment will be installed) or a change in the methods governing normal plant operation. In addition, the changes do not impose any new or different requirements or eliminate any existing requirements. The changes do not alter assumptions made in the safety analyses. The proposed changes are consistent with the safety analyses assumptions and current plant operating practice.

RNP MTC TS Change

The proposed change revises the RNP Technical Specification maximum upper MTC limit. The proposed change does not physically alter the plant; that is, no new or different type of equipment will be installed. Therefore the proposed change could also not initiate an equipment malfunction that would result in a new or different type of accident from any previously evaluated. This change does not create new failure modes or mechanisms which are not identifiable during testing, and no new accident precursors are generated.

HNP TSTF–248

Revising the HNP Technical Specification definition of SDM would not require revision to any SDM boron calculations. Rather, it would afford the analytical flexibility for determining SDM for a particular circumstance. The proposed change does not physically alter the plant; that is, no new or different type of equipment will be installed. Therefore the proposed change could also not initiate an equipment malfunction that would result in a new or different type of accident from any previously evaluated. This change does not create new failure modes or mechanisms which are not identifiable during testing, and no new accident precursors are generated.

DPC–NE–2011–P TS Changes

The proposed change revises the RNP and HNP TS to allow operation of a reactor core designed using the DPC–NE–2011–P methodology. The DPC–NE–2011–P methodology has already been approved by the NRC for use at RNP and HNP. The proposed change does not physically alter the plant, that is, no new or different type of equipment will be installed. Therefore the proposed change could also not initiate an equipment malfunction that would result in a new or different type of accident from any previously evaluated. Operating the reactor in accordance with the NRC-approved methodology will ensure that the core will operate within safe limits. This change does not create new failure modes or mechanisms which are not identifiable during testing, and no new accident precursors are generated.

Therefore, the proposed changes do not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

Margin of safety is related to the confidence in the ability of the fission product barriers to perform their design functions during and following an accident. These barriers include the fuel cladding, the reactor coolant system, and the containment system.

COPERNIC

The proposed change adds a topical report for an NRC-reviewed and approved fuel performance code to the list of topical reports in HNP and RNP TS, which is administrative in nature and does not amend the cycle specific parameters presently required by the TS. The individual TS continue to require operation of the plant within the bounds of the limits specified in the COLR. The proposed change to the list of analytical methods referenced in the COLR does not impact the margin of safety.

The proposed change also revises a limit on peak fuel centerline temperature in the RNP and HNP TS that is based on a NRC reviewed and approved fuel performance code, and does not require physical changes to plant systems, structures, or components. Plant operations and analysis will continue to be in accordance with the licensing basis. Revising the peak fuel centerline temperature limit defined by the NRC reviewed and approved fuel performance code will continue to ensure that applicable design and safety limits are satisfied such that the fission product barriers will continue to perform their design functions and thereby margin of safety is not reduced.

Relocate TS Parameters to the COLR

The proposed change relocates certain cycle-specific core operating limits from the RNP and HNP TS to the COLR. This change will have no effect on the margin of safety. The relocated cycle-specific parameters will continue to be calculated using NRC-approved methodologies and will provide the same margin of safety as the values currently located in the TS.

RNP MTC TS Change

The proposed change revises the RNP Technical Specification maximum upper MTC limit. The MTC limit change does not impact the reliability of the fission product barriers to function.

Radiological dose to plant operators or to the public will not be impacted as a result of the proposed change. The current Updated Final Safety Analysis Report (UFSAR) Chapter 15 analyses of record remain bounding with the proposed change to the maximum upper MTC limit. Therefore, all of the applicable acceptance criteria continue to be met for each of the analyses with the revised maximum upper MTC limit.

HNP TSTF–248

The proposed revision to the HNP Technical Specification definition of SDM does not impact the reliability of the fission product barriers to function. Radiological dose to plant operators or to the public will not be impacted as a result of the proposed change. Adequate SDM will continue to be ensured for all operational conditions.

DPC–NE–2011–P TS Changes

The proposed change revises the RNP and HNP TS to allow operation of a reactor core designed using the DPC–NE–2011–P methodology. As a portion of the overall Duke Energy methodology for cycle reload safety analyses, DPC–NE–2011–P has already been approved by the NRC for use at RNP and HNP. The proposed change will continue to ensure that applicable design and safety limits are satisfied such that the fission product barriers will continue to perform their design functions. Operation of the reactor in accordance with the DPC–NE–2011–P methodology will ensure the margin of safety is not reduced.

Therefore, the proposed changes do not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Kathryn B. Nolan, Deputy General Counsel, Duke Energy Corporation, 550 South Tryon Street, Mail Code DEC45A, Charlotte, NC 28202.

NRC Branch Chief: Undine Shoop.

Virginia Electric and Power Company, Docket Nos. 50–338 and 50–339, North Anna Power Station (North Anna), Units No. 1 and No. 2, Louisa County, Virginia

Date of amendment request: July 12, 2018. A publicly-available version is in ADAMS under Package Accession No. ML18198A133.

Description of amendment request: This amendment request contains sensitive unclassified non-safeguards information (SUNSI). The amendments would revise the Technical Specification (TS) requirements to add Framatome Topical Report EMF–2328(P)(A), Revision 0, ''PWR Small Break [loss-of-coolant accident] LOCA Evaluation Model, S–RELAP5 Based,'' as supplemented by the North Anna-specific application report ANP–3467P, Revision 0, ''North Anna Fuel-Vendor Independent Small Break LOCA Analysis Licensing Report,'' to the list of methodologies approved for reference in the Core Operating Limits Report (COLR) in TS 5.6.5.b at North Anna, Unit Nos. 1 and 2. Framatome Topical Report EMF–2328(P)(A), as supplemented by the North Anna-specific application report, replaces two existing COLR references for the current Westinghouse Small Break LOCA Evaluation Model. The amendments would also remove one obsolete COLR reference in TS 5.6.5.b that supported use of the Advanced Mark-BW (AMBW) fuel product, since the AMBW fuel product is not planned to be used in future North Anna cores.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed change to TS 5.6.5.b permits the use of an NRC-approved methodology for analysis of the Small Break Loss of Coolant Accident (SBLOCA) to determine if North Anna Power Station (NAPS) Units 1 and 2 continue to meet the applicable design and safety analysis acceptance criteria. The proposed change to the list of NRC-approved methodologies in TS 5.6.5.b has no direct impact upon plant operation or configuration. The list of methodologies in TS 5.6.5.b does not impact either the initiation of an accident or the mitigation of its consequences.

The results of the revised SBLOCA transient analysis and existing pre-transient oxidation limits demonstrate that NAPS Units 1 and 2 continue to satisfy the 10 CFR 50.46(b)(1–3) Emergency Core Cooling System performance acceptance criteria using an NRC-approved evaluation model.

Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed change will not create the possibility of a new or different accident due to credible new failure mechanisms, malfunctions, or accident initiators not previously considered. There is no change to the parameters within which the plant is normally operated, and thus, the possibility of a new or different type of accident is not created.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed amendment involve a significant reduction in a margin of safety?

Response: No.

No design basis or safety limits are exceeded or altered by this change. Approved methodologies have been used to ensure that the plant continues to meet applicable design criteria and safety analysis acceptance criteria.

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Lillian M. Cuoco, Senior Counsel, Dominion Resources Services, Inc., 120 Tredegar Street, RS–2, Richmond, VA 23219.

Branch Chief: Undine Shoop.

Order Imposing Procedures for Access to Sensitive Unclassified Non-Safeguards Information for Contention Preparation

South Carolina Electric & Gas Company, South Carolina Public Service Authority, Docket No. 50–395, Virgil C. Summer Nuclear Station, Unit No. 1, Fairfield County, South Carolina

Duke Energy Progress, LLC, Docket No. 50–400, Shearon Harris Nuclear Power Plant, Unit 1, Wake and Chatham Counties, North Carolina

Duke Energy Progress, LLC, Docket No. 50–261, H. B. Robinson Steam Electric Plant Unit No. 2, Darlington County, South Carolina

Virginia Electric and Power Company, Docket Nos. 50–338 and 50–339, North Anna Power Station, Units No. 1 and No. 2, Louisa County, Virginia

A. This Order contains instructions regarding how potential parties to this proceeding may request access to documents containing Sensitive Unclassified Non-Safeguards Information (SUNSI).

B. Within 10 days after publication of this notice of hearing and opportunity to petition for leave to intervene, any potential party who believes access to SUNSI is necessary to respond to this notice may request access to SUNSI. A ''potential party'' is any person who intends to participate as a party by demonstrating standing and filing an admissible contention under 10 CFR 2.309. Requests for access to SUNSI submitted later than 10 days after publication of this notice will not be considered absent a showing of good cause for the late filing, addressing why the request could not have been filed earlier.

C. The requester shall submit a letter requesting permission to access SUNSI to the Office of the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemakings and Adjudications Staff, and provide a copy to the Deputy General Counsel for Hearings and Administration, Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. The expedited delivery or courier mail address for both offices is: U.S. Nuclear Regulatory Commission, 11555 Rockville Pike, Rockville, Maryland 20852. The email address for the Office of the Secretary and the Office of the General Counsel are *Hearing.Docket@nrc.gov* and *RidsOgcMailCenter.Resource@nrc.gov,* respectively.[1] The request must include the following information:

(1) A description of the licensing action with a citation to this **Federal Register** notice;

(2) The name and address of the potential party and a description of the potential party's particularized interest that could be harmed by the action identified in C.(1); and

(3) The identity of the individual or entity requesting access to SUNSI and the requester's basis for the need for the information in order to meaningfully participate in this adjudicatory proceeding. In particular, the request must explain why publicly available versions of the information requested would not be sufficient to provide the basis and specificity for a proffered contention.

D. Based on an evaluation of the information submitted under paragraph C.(3) the NRC staff will determine within 10 days of receipt of the request whether:

(1) There is a reasonable basis to believe the petitioner is likely to

[1] While a request for hearing or petition to intervene in this proceeding must comply with the filing requirements of the NRC's ''E-Filing Rule,'' the initial request to access SUNSI under these procedures should be submitted as described in this paragraph.

establish standing to participate in this NRC proceeding; and

(2) The requestor has established a legitimate need for access to SUNSI.

E. If the NRC staff determines that the requestor satisfies both D.(1) and D.(2) above, the NRC staff will notify the requestor in writing that access to SUNSI has been granted. The written notification will contain instructions on how the requestor may obtain copies of the requested documents, and any other conditions that may apply to access to those documents. These conditions may include, but are not limited to, the signing of a Non-Disclosure Agreement or Affidavit, or Protective Order [2] setting forth terms and conditions to prevent the unauthorized or inadvertent disclosure of SUNSI by each individual who will be granted access to SUNSI.

F. Filing of Contentions. Any contentions in these proceedings that are based upon the information received as a result of the request made for SUNSI must be filed by the requestor no later than 25 days after receipt of (or access to) that information. However, if more than 25 days remain between the petitioner's receipt of (or access to) the information and the deadline for filing all other contentions (as established in the notice of hearing or opportunity for hearing), the petitioner may file its SUNSI contentions by that later deadline.

G. Review of Denials of Access.

(1) If the request for access to SUNSI is denied by the NRC staff after a determination on standing and requisite need, the NRC staff shall immediately notify the requestor in writing, briefly stating the reason or reasons for the denial.

(2) The requester may challenge the NRC staff's adverse determination by filing a challenge within 5 days of receipt of that determination with: (a) The presiding officer designated in this proceeding; (b) if no presiding officer has been appointed, the Chief Administrative Judge, or if he or she is unavailable, another administrative judge, or an Administrative Law Judge with jurisdiction pursuant to 10 CFR 2.318(a); or (c) if another officer has been designated to rule on information access issues, with that officer.

(3) Further appeals of decisions under this paragraph must be made pursuant to 10 CFR 2.311.

H. Review of Grants of Access. A party other than the requester may challenge an NRC staff determination granting access to SUNSI whose release would harm that party's interest independent of the proceeding. Such a challenge must be filed within 5 days of the notification by the NRC staff of its grant of access and must be filed with: (a) The presiding officer designated in this proceeding; (b) if no presiding officer has been appointed, the Chief Administrative Judge, or if he or she is unavailable, another administrative judge, or an Administrative Law Judge with jurisdiction pursuant to 10 CFR 2.318(a); or (c) if another officer has been designated to rule on information access issues, with that officer.

If challenges to the NRC staff determinations are filed, these procedures give way to the normal process for litigating disputes concerning access to information. The availability of interlocutory review by the Commission of orders ruling on such NRC staff determinations (whether granting or denying access) is governed by 10 CFR 2.311.[3]

I. The Commission expects that the NRC staff and presiding officers (and any other reviewing officers) will consider and resolve requests for access to SUNSI, and motions for protective orders, in a timely fashion in order to minimize any unnecessary delays in identifying those petitioners who have standing and who have propounded contentions meeting the specificity and basis requirements in 10 CFR part 2. The attachment to this Order summarizes the general target schedule for processing and resolving requests under these procedures.

It is so ordered.

Dated at Rockville, Maryland, on November 16, 2018.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,

Secretary of the Commission.

ATTACHMENT 1—GENERAL TARGET SCHEDULE FOR PROCESSING AND RESOLVING REQUESTS FOR ACCESS TO SENSITIVE UNCLASSIFIED NON-SAFEGUARDS INFORMATION IN THIS PROCEEDING

Day	Event/activity
0	Publication of **Federal Register** notice of hearing and opportunity to petition for leave to intervene, including order with instructions for access requests.
10	Deadline for submitting requests for access to Sensitive Unclassified Non-Safeguards Information (SUNSI) with information: Supporting the standing of a potential party identified by name and address; describing the need for the information in order for the potential party to participate meaningfully in an adjudicatory proceeding.
60	Deadline for submitting petition for intervention containing: (i) Demonstration of standing; and (ii) all contentions whose formulation does not require access to SUNSI (+25 Answers to petition for intervention; +7 petitioner/requestor reply).
20	U.S. Nuclear Regulatory Commission (NRC) staff informs the requester of the staff's determination whether the request for access provides a reasonable basis to believe standing can be established and shows need for SUNSI. (NRC staff also informs any party to the proceeding whose interest independent of the proceeding would be harmed by the release of the information.) If NRC staff makes the finding of need for SUNSI and likelihood of standing, NRC staff begins document processing (preparation of redactions or review of redacted documents).
25	If NRC staff finds no "need" or no likelihood of standing, the deadline for petitioner/requester to file a motion seeking a ruling to reverse the NRC staff's denial of access; NRC staff files copy of access determination with the presiding officer (or Chief Administrative Judge or other designated officer, as appropriate). If NRC staff finds "need" for SUNSI, the deadline for any party to the proceeding whose interest independent of the proceeding would be harmed by the release of the information to file a motion seeking a ruling to reverse the NRC staff's grant of access.
30	Deadline for NRC staff reply to motions to reverse NRC staff determination(s).
40	(Receipt +30) If NRC staff finds standing and need for SUNSI, deadline for NRC staff to complete information processing and file motion for Protective Order and draft Non-Disclosure Affidavit. Deadline for applicant/licensee to file Non-Disclosure Agreement for SUNSI.

[2] Any motion for Protective Order or draft Non-Disclosure Affidavit or Agreement for SUNSI must be filed with the presiding officer or the Chief Administrative Judge if the presiding officer has not yet been designated, within 30 days of the deadline for the receipt of the written access request.

[3] Requesters should note that the filing requirements of the NRC's E-Filing Rule (72 FR 49139; August 28, 2007, as amended at 77 FR 46562; August 3, 2012) apply to appeals of NRC staff determinations (because they must be served on a presiding officer or the Commission, as applicable), but not to the initial SUNSI request submitted to the NRC staff under these procedures.

ATTACHMENT 1—GENERAL TARGET SCHEDULE FOR PROCESSING AND RESOLVING REQUESTS FOR ACCESS TO SENSITIVE UNCLASSIFIED NON-SAFEGUARDS INFORMATION IN THIS PROCEEDING—Continued

Day	Event/activity
A	If access granted: Issuance of presiding officer or other designated officer decision on motion for protective order for access to sensitive information (including schedule for providing access and submission of contentions) or decision reversing a final adverse determination by the NRC staff.
A + 3	Deadline for filing executed Non-Disclosure Affidavits. Access provided to SUNSI consistent with decision issuing the protective order.
A + 28	Deadline for submission of contentions whose development depends upon access to SUNSI. However, if more than 25 days remain between the petitioner's receipt of (or access to) the information and the deadline for filing all other contentions (as established in the notice of opportunity to request a hearing and petition for leave to intervene), the petitioner may file its SUNSI contentions by that later deadline.
A + 53	(Contention receipt +25) Answers to contentions whose development depends upon access to SUNSI.
A + 60	(Answer receipt +7) Petitioner/Intervenor reply to answers.
>A + 60	Decision on contention admission.

[FR Doc. 2018–25452 Filed 12–3–18; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2018–0134]

Fuel Cycle Safety, Safeguards, and Environmental Review Interim Staff Guidance

AGENCY: Nuclear Regulatory Commission.

ACTION: Interim staff guidance; withdrawal.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is announcing the withdrawal of several Interim Staff Guidance (ISG) documents associated with fuel cycle facilities. These documents are being withdrawn because the guidance contained in the documents have since been incorporated into NUREG–1520, ''Standard Review Plan for Fuel Cycle Facilities License Applications.''

DATES: The withdrawal of the Fuel Cycle Safety, Safeguards, and Environmental Review ISG documents were issued on December 4, 2018.

ADDRESSES: Please refer to Docket ID NRC–2018–0134 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking Website:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2018–0134. Address questions about NRC dockets in *Regulations.gov* to Jennifer Borges; telephone: 301–287–9127; email: *Jennifer.Borges@nrc.gov*. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the 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 (if it is available in ADAMS) is provided the first time that it is mentioned in this document. In addition, for the convenience of the reader, the ADAMS accession numbers are provided in a table in the ''Availability of Documents'' section of this document.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Jennifer Fisher, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–1456, email: *Jennifer.Fisher@nrc.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

The NRC is withdrawing select Fuel Cycle Safety, Safeguards, and Environmental Review ISG documents because the content was incorporated in NUREG–1520, ''Standard Review Plan for Fuel Cycle Facilities License Applications'' (ADAMS Accession No. ML15176A258). The content in NUREG–1520 supersedes the original ISG and therefore these documents are being withdrawn. In some instances, the ISG was incorporated in its entirety and at other times only sections that were still relevant at the date of publish were included. The following ISG documents are being withdrawn:

FCSS–ISG–01, ''Qualitative Criteria for Evaluation of Likelihood'' (ADAMS Accession No. ML051520236), was incorporated in NUREG–1520, Chapter 3, Appendix B, ''Qualitative Criteria for Evaluation of Likelihood.''

FCSS–ISG–03, ''Nuclear Criticality Safety Performance Requirements and Double Contingency Principle'' (ADAMS Accession No. ML050690302), was incorporated in NUREG–1520, Chapter 5, Appendix A, ''Nuclear Criticality Performance Requirements and Double-Contingency Principle.''

FCSS–ISG–05, ''Additional Reporting Requirements of 10 CFR 70.74'' (ADAMS Accession No. ML053630228), is superseded by NUREG–1520, Chapter 5, Section 5.4.1, ''Nuclear Criticality Safety; Acceptance Criteria; Regulatory Requirements.''

FCSS–ISG–08, ''Natural Phenomena Hazards'' (ADAMS Accession No. ML052650305), was incorporated into NUREG–1520, Chapter 3, Appendix D, ''Natural Phenomena Hazards.''

FCSS–ISG–09, ''Initiating Event Frequencies'' (ADAMS Accession No. ML051520323), was incorporated into NUREG–1520, Chapter 3, Appendix C, ''Initiating Event Frequency.''

FCSS–ISG–10, ''Justification for Minimum Margin of Subcriticality for Safety'' (ADAMS Accession No. ML061650370), was incorporated into NUREG–1520, Chapter 5, Appendix B, ''Justification for Minimum Margin of Subcriticality for Safety.''

II. Availability of Documents

Document title	ADAMS accession No.
NUREG–1520, Standard Review Plan for Fuel Cycle Facilities License Applications	ML15176A258
FCSS–ISG–01, Qualitative Criteria for Evaluation of Likelihood	ML051520236
FCSS–ISG–03, Nuclear Criticality Safety Performance Requirements and Double Contingency Principle	ML050690302
FCSS–ISG–05, Additional Reporting Requirements of 10 CFR 70.74	ML053630228
FCSS–ISG–08, Natural Phenomena Hazards	ML052650305
FCSS–ISG–09, Initiating Event Frequencies	ML051520323
FCSS–ISG–10, Justification for Minimum Margin of Subcriticality for Safety	ML061650370

Dated at Rockville, Maryland, this 28th day of November 2018.

For the Nuclear Regulatory Commission.

David Tiktinsky,

Acting Chief, Facility Licensing and Oversight Branch, Division of Fuel Cycle Safety, Safeguards, and Environmental Review, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2018–26225 Filed 12–3–18; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2018–0269]

Biweekly Notice; Applications and Amendments to Facility Operating Licenses and Combined Licenses Involving No Significant Hazards Considerations

AGENCY: Nuclear Regulatory Commission.

ACTION: Biweekly notice.

SUMMARY: Pursuant to the Atomic Energy Act of 1954, as amended (the Act), the U.S. Nuclear Regulatory Commission (NRC) is publishing this regular biweekly notice. The Act requires the Commission to publish notice of any amendments issued, or proposed to be issued, and grants the Commission the authority to issue and make immediately effective any amendment to an operating license or combined license, as applicable, upon a determination by the Commission that such amendment involves no significant hazards consideration, notwithstanding the pendency before the Commission of a request for a hearing from any person.

This biweekly notice includes all notices of amendments issued, or proposed to be issued, from November 6, 2018, to November 19, 2018. The last biweekly notice was published on November 20, 2018.

DATES: Comments must be filed by January 3, 2019. A request for a hearing must be filed by February 4, 2019.

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–2018–0269. Address questions about Docket IDs in *Regulations.gov* to Jennifer Borges; telephone: 301–287–9127; email: *Jennifer.Borges@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* May Ma, Office of Administration, Mail Stop: TWFN–7–A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Lynn Ronewicz, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington DC 20555–0001; telephone: 301–415–1927, email: *Lynn.Ronewicz@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2018–0269, facility name, unit number(s), plant docket number, application date, and subject when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2018–0269.
- *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 (if it is available in ADAMS) is provided the first time that it is mentioned in this document.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID NRC–2018–0269, facility name, unit number(s), plant docket number, application date, and subject in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *http://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

Pursuant to the Atomic Energy Act of 1954, as amended (the Act), the U.S. Nuclear Regulatory Commission (NRC) is publishing this regular biweekly notice. The Act requires the Commission to publish notice of any amendments issued, or proposed to be issued, and grants the Commission the authority to issue and make immediately effective any amendment to an operating license or combined license, as applicable, upon a determination by the Commission that such amendment involves no significant hazards consideration, notwithstanding the pendency before the Commission of a request for a hearing from any person.

III. Notice of Consideration of Issuance of Amendments to Facility Operating Licenses and Combined Licenses and Proposed No Significant Hazards Consideration Determination

The Commission has made a proposed determination that the following amendment requests involve no significant hazards consideration. Under the Commission's regulations in § 50.92 of title 10 of the *Code of Federal Regulations* (10 CFR), this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. The basis for this proposed determination for each amendment request is shown below.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of 60 days after the date of publication of this notice. The Commission may issue the license amendment before expiration of the 60-day period provided that its final determination is that the amendment involves no significant hazards consideration. In addition, the Commission may issue the amendment prior to the expiration of the 30-day comment period if circumstances change during the 30-day comment period such that failure to act in a timely way would result, for example in derating or shutdown of the facility. If the Commission takes action prior to the expiration of either the comment period or the notice period, it will publish in the **Federal Register** a notice of issuance. If the Commission makes a final no significant hazards consideration determination, any hearing will take place after issuance. The Commission expects that the need to take this action will occur very infrequently.

A. Opportunity To Request a Hearing and Petition for Leave To Intervene

Within 60 days after the date of publication of this notice, any persons (petitioner) whose interest may be affected by this action may file a request for a hearing and petition for leave to intervene (petition) with respect to the action. Petitions shall be filed in accordance with the Commission's ''Agency Rules of Practice and Procedure'' in 10 CFR part 2. Interested persons should consult a current copy of 10 CFR 2.309. The NRC's regulations are accessible electronically from the NRC Library on the NRC's website at *http://www.nrc.gov/reading-rm/doc-collections/cfr/.* Alternatively, a copy of the regulations is available at the NRC's Public Document Room, located at One White Flint North, Room O1–F21, 11555 Rockville Pike (first floor), Rockville, Maryland 20852. If a petition is filed, the Commission or a presiding officer will rule on the petition and, if appropriate, a notice of a hearing will be issued.

As required by 10 CFR 2.309(d) the petition should specifically explain the reasons why intervention should be permitted with particular reference to the following general requirements for standing: (1) The name, address, and telephone number of the petitioner; (2) the nature of the petitioner's right under the Act to be made a party to the proceeding; (3) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (4) the possible effect of any decision or order which may be entered in the proceeding on the petitioner's interest.

In accordance with 10 CFR 2.309(f), the petition must also set forth the specific contentions which the petitioner seeks to have litigated in the proceeding. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner must provide a brief explanation of the bases for the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to the specific sources and documents on which the petitioner intends to rely to support its position on the issue. The petition must include sufficient information to show that a genuine dispute exists with the applicant or licensee on a material issue of law or fact. Contentions must be limited to matters within the scope of the proceeding. The contention must be one which, if proven, would entitle the petitioner to relief. A petitioner who fails to satisfy the requirements at 10 CFR 2.309(f) with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene. Parties have the opportunity to participate fully in the conduct of the hearing with respect to resolution of that party's admitted contentions, including the opportunity to present evidence, consistent with the NRC's regulations, policies, and procedures.

Petitions must be filed no later than 60 days from the date of publication of this notice. Petitions and motions for leave to file new or amended contentions that are filed after the deadline will not be entertained absent a determination by the presiding officer that the filing demonstrates good cause by satisfying the three factors in 10 CFR 2.309(c)(1)(i) through (iii). The petition must be filed in accordance with the filing instructions in the ''Electronic Submissions (E-Filing)'' section of this document.

If a hearing is requested, and the Commission has not made a final determination on the issue of no significant hazards consideration, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to establish when the hearing is held. If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing would take place after issuance of the amendment. If the final determination is that the amendment request involves a significant hazards consideration, then any hearing held would take place before the issuance of the amendment unless the Commission finds an imminent danger to the health or safety of the public, in which case it will issue an appropriate order or rule under 10 CFR part 2.

A State, local governmental body, Federally-recognized Indian Tribe, or agency thereof, may submit a petition to the Commission to participate as a party under 10 CFR 2.309(h)(1). The petition should state the nature and extent of the petitioner's interest in the proceeding. The petition should be submitted to the Commission no later than 60 days from the date of publication of this notice. The petition must be filed in accordance with the filing instructions in the ''Electronic Submissions (E-Filing)'' section of this document, and should meet the requirements for petitions set forth in this section, except that under 10 CFR 2.309(h)(2) a State, local governmental body, or Federally-recognized Indian Tribe, or agency thereof, does not need to address the standing requirements in 10 CFR 2.309(d) if the facility is located within

its boundaries. Alternatively, a State, local governmental body, Federally-recognized Indian Tribe, or agency thereof, may participate as a non-party under 10 CFR 2.315(c).

If a hearing is granted, any person who is not a party to the proceeding and is not affiliated with or represented by a party may, at the discretion of the presiding officer, be permitted to make a limited appearance pursuant to the provisions of 10 CFR 2.315(a). A person making a limited appearance may make an oral or written statement of his or her position on the issues but may not otherwise participate in the proceeding. A limited appearance may be made at any session of the hearing or at any prehearing conference, subject to the limits and conditions as may be imposed by the presiding officer. Details regarding the opportunity to make a limited appearance will be provided by the presiding officer if such sessions are scheduled.

B. Electronic Submissions (E-Filing)

All documents filed in NRC adjudicatory proceedings, including a request for hearing and petition for leave to intervene (petition), any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities that request to participate under 10 CFR 2.315(c), must be filed in accordance with the NRC's E-Filing rule (72 FR 49139; August 28, 2007, as amended at 77 FR 46562; August 3, 2012). The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases to mail copies on electronic storage media. Detailed guidance on making electronic submissions may be found in the Guidance for Electronic Submissions to the NRC and on the NRC website at *http://www.nrc.gov/site-help/e-submittals.html.* Participants may not submit paper copies of their filings unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at *hearing.docket@nrc.gov,* or by telephone at 301–415–1677, to (1) request a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign submissions and access the E-Filing system for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a petition or other adjudicatory document (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the hearing in this proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public website at *http://www.nrc.gov/site-help/e-submittals/getting-started.html.* Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit adjudicatory documents. Submissions must be in Portable Document Format (PDF). Additional guidance on PDF submissions is available on the NRC's public website at *http://www.nrc.gov/site-help/electronic-sub-ref-mat.html.* A filing is considered complete at the time the document is submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email notice confirming receipt of the document. The E-Filing system also distributes an email notice that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the document on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before adjudicatory documents are filed so that they can obtain access to the documents via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC's Electronic Filing Help Desk through the ''Contact Us'' link located on the NRC's public website at *http://www.nrc.gov/site-help/e-submittals.html,* by email to *MSHD.Resource@nrc.gov,* or by a toll-free call at 1–866–672–7640. The NRC Electronic Filing Help Desk is available between 9 a.m. and 6 p.m., Eastern Time, Monday through Friday, excluding government holidays.

Participants who believe that they have a good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing stating why there is good cause for not filing electronically and requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, 11555 Rockville Pike, Rockville, Maryland 20852, Attention: Rulemaking and Adjudications Staff. Participants filing adjudicatory documents in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service. A presiding officer, having granted an exemption request from using E-Filing, may require a participant or party to use E-Filing if the presiding officer subsequently determines that the reason for granting the exemption from use of E-Filing no longer exists.

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket which is available to the public at *https://adams.nrc.gov/ehd,* unless excluded pursuant to an order of the Commission or the presiding officer. If you do not have an NRC-issued digital ID certificate as described above, click cancel when the link requests certificates and you will be automatically directed to the NRC's electronic hearing dockets where you will be able to access any publicly available documents in a particular hearing docket. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or personal phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. For example, in some instances, individuals provide home addresses in order to demonstrate proximity to a facility or site. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submission.

For further details with respect to these license amendment application(s), see the application for amendment which is available for public inspection in ADAMS and at the NRC's PDR. For additional direction on accessing

information related to this document, see the ''Obtaining Information and Submitting Comments'' section of this document.

Union Electric Company, Docket No. 50–483, Callaway Plant, Unit 1, Callaway County, Missouri

Date of amendment request: September 4, 2018. A publicly-available version is in ADAMS under Accession No. ML18247A467.

Description of amendment request: The amendment would revise Emergency Action Levels (EALs) CA6.1, ''Cold Shutdown/Refueling System Malfunction—Hazardous event affecting a SAFETY SYSTEM needed for the current operating MODE: Alert,'' and SA9.1, ''System Malfunction—Hazardous event affecting a SAFETY SYSTEM needed for the current operating MODE: Alert.'' The amendment would also add a new definition for the term ''Loss of Safety Function (LOSF),'' while redefining the term ''Visible Damage,'' and deleting the term Initiating Condition (IC) HG1 and associated EAL HG1.1, ''Hazard—Hostile Action resulting in loss of physical control of the facility: General Emergency,'' within the Callaway Plant's Radiological Emergency Response Plan (RERP).

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed changes to the Callaway Plant emergency action levels do not impact the physical function of plant structures, systems, or components (SSC) or the manner in which SSCs perform their design function. The proposed changes have no effect on accident initiators or precursors, nor do they alter design assumptions. The proposed changes do not alter or prevent the ability of SSCs to perform their intended function to mitigate the consequences of an initiating event within assumed acceptance limits. No operating procedures or administrative controls that function to prevent or mitigate accidents are affected by the proposed changes. Therefore, the proposed changes do not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed changes do not involve a physical alteration of the plant (*i.e.,* no new or different type of equipment will be installed, and no equipment will be removed), nor do the proposed changes involve a change in the method of plant operation. The proposed changes will not introduce failure modes that could result in a new accident, nor do the changes alter assumptions made in the safety analysis. Therefore, the proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed amendment involve a significant reduction in a margin of safety?

Response: No.

There is no change being made to safety analysis assumptions, safety limits, or limiting safety system settings that would adversely affect plant safety as a result of the proposed changes. There are no changes to setpoints or environmental conditions of any SSC or the mariner in which any SSC is operated. Margins of safety are unaffected by the proposed changes. The applicable requirements of 10 CFR 50.47 and 10 CFR 50, Appendix E will continue to be met. Therefore, the proposed changes do not involve any reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: John O'Neill, Pillsbury Winthrop Shaw Pittman LLP, 2300 N Street NW, Washington, DC 20037.

NRC Branch Chief: Robert J. Pascarelli.

Pacific Gas and Electric Company, Docket Nos. 50–275 and 50–323, Diablo Canyon Nuclear Power Plant, Units 1 and 2 (DCPP), San Luis Obispo County, California

Date of amendment request: September 12, 2018. A publicly-available version is in ADAMS under Accession No. ML18255A368.

Description of amendment request: The proposed amendments would revise the Emergency Plan for DCPP to extend staff augmentation times for Emergency Response Organization (ERO) functions.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed increase in staff augmentation times has no effect on normal plant operation or on any accident initiator or precursors and does not impact the function of plant structures, systems, or components. The proposed change does not alter or prevent the ability of the ERO to perform their intended functions to mitigate the consequences of an accident or event. The ability of the ERO to respond adequately to radiological emergencies has been demonstrated as acceptable in a staffing analysis as required by 10 CFR 50 Appendix E.IV.A.9.

Therefore, the proposed DCPP Emergency Plan changes do not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed change does not impact the accident analysis. The change does not involve a physical alteration of the plant (*i.e.,* no new or different type of equipment will be installed), a change in the method of plant operation, or new operator actions. The proposed change does not introduce failure modes that could result in a new accident, and the change does not alter assumptions made in the safety analysis. This proposed change increases the staff augmentation response times in the DCPP Emergency Plan, which are demonstrated as acceptable through a staffing analysis as required by 10 CFR 50 Appendix E.IV.A.9. The proposed change does not alter or prevent the ability of the ERO to perform their intended functions to mitigate the consequences of an accident or event.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

Margin of safety is associated with confidence in the ability of the fission product barriers (*i.e.,* fuel cladding, reactor coolant system pressure boundary, and containment structure) to limit the level of radiation dose to the public. The proposed change is associated with the DCPP Emergency Plan staffing and does not impact operation of the plant or its response to transients or accidents. The change does not affect the Technical Specifications. The proposed change does not involve a change in the method of plant operation, and no accident analyses will be affected by the proposed change. Safety analysis acceptance criteria are not affected by this proposed change.

A staffing analysis and a functional analysis were performed for the proposed change on the timeliness of performing major tasks for the functional areas of the DCPP Emergency Plan. The analyses concluded that an extension in staff augmentation times would not significantly affect the ability to perform the required Emergency Plan tasks. Therefore, the proposed change is determined to not adversely affect the ability to meet 10 CFR 50.54(q)(2), the requirements of 10 CFR 50 Appendix E, and the emergency

planning standards as described in 10 CFR 50.47 (b).

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Jennifer Post, Pacific Gas and Electric Company, P.O. Box 7442, San Francisco, CA 94120.

NRC Branch Chief: Robert J. Pascarelli.

Southern Nuclear Operating Company, Inc.; Georgia Power Company; Oglethorpe Power Corporation; Municipal Electric Authority of Georgia; and City of Dalton, Georgia, Docket Nos. 50–321 and 50–366, Edwin I. Hatch Nuclear Plant, Unit Nos. 1 and 2, Appling County, Georgia

Date of amendment request: June 29, 2018. A publicly-available version is in ADAMS under Accession No. ML18180A396.

Description of amendment request: The amendments would revise the Technical Specification (TS) requirements for the Hatch Nuclear Plant, Unit Nos. 1 and 2. Specifically, the amendments would increase the allowable values (AV) specified in TS Table 3.3.5.1–1 for automatic transfer of the high pressure coolant injection (HPCI) pump suction alignment from the condensate storage tank (CST) to the suppression pool for Unit Nos. 1 and 2. The proposed change would also increase the AV specified in TS Table 3.3.5.2–1 for automatic transfer of the reactor core isolation cooling (RCIC) pump suction alignment from the CST to the suppression pool for Unit No. 1.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed change ensures the HPCI and RCIC pump automatic suction transfer functions from the CST to the suppression pool occur without introducing the possibility of vortex formation or air intrusion in the HPCI or RCIC pump suction path. The water level of the CST on automatic suction transfer of the HPCI and RCIC systems to the suppression pool is not an initiator or precursor to any accident previously evaluated. The CST water source is not assumed to mitigate the consequences for any design basis accident, but is assumed as a water source for the RCIC when mitigating a station blackout event. The revised AV will ensure the RCIC can perform this function.

Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed change ensures the HPCI and RCIC pump automatic suction transfer functions from the CST to the suppression pool occur without introducing the possibility of vortex formation or air intrusion in the HPCI or RCIC pump suction path. HPCI, RCIC, and CST design functions are unaffected by this change. The change to the HPCI and RCIC automatic suction transfer functions would not create the possibility of any credible failure mechanism not considered in the design and licensing basis. Additionally, no new credible failure modes for the CST are introduced by the proposed changes.

Therefore, the proposed changes do not create the possibility of a new or different kind of accident from any previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

The proposed change ensures the HPCI and RCIC pump automatic suction transfer functions from the CST to the suppression pool occur without introducing the possibility of vortex formation or air intrusion in the HPCI or RCIC pump suction path. The applicable margins of safety are the AVs for the HPCI and RCIC pump automatic suction transfer functions. The proposed change increases the margin of safety by revising the affected AVs to address more severe circumstances than considered in the current AVs. The proposed change does not exceed or alter a design basis or safety limit.

Therefore, the proposed change does not involve a significant reduction in the margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Millicent Ronnlund, Vice President and General Counsel, Southern Nuclear Operating Co., Inc., P.O. Box 1295, Birmingham, AL 35201–1295.

NRC Branch Chief: Michael T. Markley.

Southern Nuclear Operating Company, Inc.; Georgia Power Company; Oglethorpe Power Corporation; Municipal Electric Authority of Georgia; and City of Dalton, Georgia, Docket Nos. 50–321 and 50–366, Edwin I. Hatch Nuclear Plant, Unit Nos. 1 and 2, Appling County, Georgia

Date of amendment request: August 6, 2018. A publicly-available version is in ADAMS under Accession No. ML18218A297.

Description of amendment request: The amendments would revise the technical specification (TS) end state for the required actions of the drywell spray function of the residual heat removal system for the Hatch Nuclear Plant, Unit Nos. 1 and 2. Specifically, TS 3.6.2.5, ''Residual Heat Removal (RHR) Drywell Spray,'' would be revised to modify the required end state of Cold Shutdown (Mode 4) to the new required end state of Hot Shutdown (Mode 3) if the needed action statements are not met for Unit Nos. 1 and 2.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below, with NRC staff edits in square brackets:

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The RHR drywell spray function is not an initiator of any accident previously evaluated but is assumed to mitigate some accidents previously evaluated. However, the proposed change does not alter the design or safety function of the RHR system, including the drywell spray mode. The proposed change revises the end state when the time allowed by TS to continue operation is exceeded for the drywell spray mode of the RHR system. This request is limited to an end state where entry into the shutdown mode is for a short interval and the primary purpose is to correct the initiating condition and return to power operation as soon as practical. Risk insights from both the qualitative and quantitative risk assessment were used to support a change in end state for similar boiling water reactor (BWR) systems as summarized in GE [General Electric] topical report NEDC–32988. These assessments provide an integrated discussion of deterministic and probabilistic issues focusing on specific TSs used to support similar TS end states and associated restrictions. SNC [Southern Nuclear Operating Company] finds that the risk insights also support the conclusion of the proposed change to the RHR drywell spray TS. Therefore, the probability of an accident previously evaluated is not significantly increased, if at all.

The consequences of accidents previously evaluated that assume the drywell spray

function in accident mitigation are based on the plant operating with the reactor critical and at power. A DBA in hot shutdown would be considerably less severe than a DBA [design-basis accident] occurring during power operation since hot shutdown is associated with lower initial energy level and reduced decay heat load. The risk and defense-in-depth reasoning, provided in GE topical report NEDC–32988, supports the conclusion that hot shutdown is as safe as cold shutdown (if not safer) for repairing an inoperable RHR subsystem. SNC concludes the proposed change is acceptable in light of defense-in-depth considerations and because the time spent in hot shutdown to perform the repair is infrequent and limited. Therefore, the consequences of any accident that assumes the drywell spray function are not significantly affected by this change.

Consequently, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed change does not change the design function or operation of the RHR drywell spray function. No plant modifications or changes to the plant configuration or method of operation are involved. If risk is assessed and managed, allowing a change to the end state for the RHR drywell spray TS when the allowed time for remaining in power operation with one or more RHR drywell spray subsystem inoperable is exceeded, *i.e.,* entry into hot shutdown rather than cold shutdown to repair equipment, will not introduce new failure modes or effects and will not, in the absences of other unrelated failures, lead to an accident whose consequences exceed the consequences of accidents previously evaluated. The addition of a requirement to assess and manage the risk introduced by this change and the commitment to adhere to the industry guidance related to TS end states further minimizes possible concerns.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed amendment involve a significant reduction in a margin of safety?

Response: No.

The proposed change does not affect any of the controlling values of parameters used to avoid exceeding regulatory or licensing limits. The proposed change does not exceed or alter the design basis or safety limits, or any limiting safety system settings. The requirement for the drywell spray mode of the RHR system to perform its designated safety function is unaffected. The risk assessment approach used in the GE topical report NEDC–32988 is comprehensive and follows NRC staff guidance. The risk assessment, summarized in GE topical report NEDC–32988, included evaluations of systems with similar functions as the drywell spray function of the RHR system. In addition, the NEDC–32988 risk analyses show that the criteria of the three-tiered approach for allowing TS changes, in accordance with NRC staff guidance, are met. The risk assessments used to justify TS changes associated with containment heat removal systems are also applicable [to] the RHR drywell spray TS because these systems perform an equivalent function as the drywell spray mode of the RHR system and there are no unique aspects of the RHR drywell spray containment heat removal function that would change the conclusion that a hot shutdown end state is acceptable. The risk assessment used to justify the TS change associated with fission product cleanup systems is also applicable to the RHR drywell spray TS because the systems are functionally similar and there are no aspects of the HNP [Hatch Nuclear Plant] RHR drywell spray fission product cleanup function that would change the conclusion that a hot shutdown end state is acceptable. Therefore, SNC has determined that the acceptability of hot shutdown end state for systems previously evaluated with similar functions is also acceptable for the HNP RHR drywell spray TS. As such, the net change to the margin of safety as a result of the proposed change is insignificant.

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Millicent Ronnlund, Vice President and General Counsel, Southern Nuclear Operating Co., Inc., P.O. Box 1295, Birmingham, AL 35201–1295.

NRC Branch Chief: Michael T. Markley.

Tennessee Valley Authority (TVA), Docket No. 50–391, Watts Bar Nuclear Plant (WBN), Unit 2, Rhea County, Tennessee

Date of amendment request: March 5, 2018. A publicly-available version is in ADAMS under Accession No. ML18064A192.

Description of amendment request: The amendment would revise WBN Unit 2 Operating License (OL) Condition 2.C(4) to permit the use of the PAD4TCD computer program to continue to establish core operating limits until the WBN Unit 2 steam generators (SGs) are replaced with SGs equivalent to those in WBN Unit 1. The proposed change to allow the continued use of PAD4TCD to establish core operating limits until the installation of the WBN Unit 2 replacement SGs reflects TVA's plan for transitioning to PAD5 as part of the full spectrum loss-of-coolant accident (LOCA) Evaluation Methodology.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The Emergency Core Cooling System (ECCS) response to a large break LOCA as described in the WBN Unit 2 dual-unit Updated Final Safety Analysis Report (UFSAR) Section 15.4.1 incorporated an explicit evaluation of the effects of TCD [thermal conductivity degradation]. The UFSAR evaluation considered fuel burn-up values that represent multi-cycle cores where the effects of TCD would be more evident. These analyses showed that the criteria specified in Title 10 of the *Code of Federal Regulations* (CFR) § 50.46 are met. The core design process evaluates each reload core to verify that no fuel rods exceed the peaking limits shown in the WBN dual-unit UFSAR Table 15.4–24. This ensures that the LOCA analysis in the WBN Unit 2 dual-unit UFSAR remains bounding for future operating cycles.

The change to WBN Unit 2 OL Condition 2.C(4) does not change the safety analysis or any plant feature or design. Thus, it is concluded that a significant increase in the consequences of an accident previously evaluated will not occur as a result of the proposed change.

Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated. The proposed change to WBN Unit 2 OL condition 2.C(4) does not change or modify the plant design, introduce any new modes of plant operation, change or modify the design of the ECCS, or change or modify the accident analyses presented in the UFSAR.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any previously evaluated.

3. Does the proposed amendment involve a significant reduction in a margin of safety?

Response: No.

The LOCA safety analysis for WBN Unit 2 as described in the UFSAR explicitly accounts for the effect of TCD. The results of this analysis has established that WBN Unit 2 can operate safely in the unlikely event that a design basis LOCA event occurs, there are large margins to the regulatory limits when explicitly accounting for TCD. This proposed change to OL condition 2.C(4) does not change this analysis or its conclusions. Thus, the proposed change does not result in a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: General Counsel, Tennessee Valley Authority, 400 West Summit Hill Drive, 6A West Tower, Knoxville, TN 37902.

NRC Branch Chief: Undine Shoop.

III. Notice of Issuance of Amendments to Facility Operating Licenses and Combined Licenses

During the period since publication of the last biweekly notice, the Commission has issued the following amendments. The Commission has determined for each of these amendments that the application complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR chapter I, which are set forth in the license amendment.

A notice of consideration of issuance of amendment to facility operating license or combined license, as applicable, proposed no significant hazards consideration determination, and opportunity for a hearing in connection with these actions, was published in the **Federal Register** as indicated.

Unless otherwise indicated, the Commission has determined that these amendments satisfy the criteria for categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for these amendments. If the Commission has prepared an environmental assessment under the special circumstances provision in 10 CFR 51.22(b) and has made a determination based on that assessment, it is so indicated.

For further details with respect to the action, see (1) the applications for amendment; (2) the amendment; and (3) the Commission's related letter, Safety Evaluation, and/or Environmental Assessment, as indicated. All of these items can be accessed as described in the ''Obtaining Information and Submitting Comments'' section of this document.

Exelon Generation Company, LLC, Docket Nos. STN 50–456 and STN 50–457, Braidwood Station, Units 1 and 2, Will County, Illinois

Date of amendment request: February 1, 2018, as supplemented by letters dated July 9, 2018, and August 3, 2018. Publicly-available versions are in ADAMS under Accession Nos. ML18036A227, ML18191B304, and ML18215A421, respectively.

Brief description of amendments: The amendments revised the licensing basis for protection from tornado-generated missiles by identifying the TORMIS Computer Code as the methodology used for assessing tornado-generated missile protection of unprotected plant structures, systems, and components.

Date of issuance: November 8, 2018.

Effective date: As of the date of issuance and shall be implemented within 90 days from the date of issuance.

Amendment Nos: 199 (Unit 1) and 199 (Unit 2). A publicly-available version is in ADAMS under Accession No. ML18291A980; documents related to these amendments are listed in the related Safety Evaluation enclosed with the amendments.

Renewed Facility Operating License Nos. NPF–72 and NPF–77: The amendments revised the licensing basis.

Date of initial notice in ***Federal Register:*** May 22, 2018 (83 FR 23734). The supplemental letters dated July 9, 2018, and August 3, 2018, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the NRC staff's original proposed no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated November 8, 2018.

No significant hazards consideration comments received: No.

Exelon Generation Company, LLC, Docket Nos. 50–317 and 50–318, Calvert Cliffs Nuclear Power Plant (Calvert Cliffs), Units 1 and 2, Calvert County, Maryland; Exelon Generation Company, LLC, Docket Nos. 50–220 and 50–410, Nine Mile Point Nuclear Station (Nine Mile Point), Units 1 and 2, Oswego County, New York; Exelon Generation Company, LLC, Docket No. 50–244, R. E. Ginna Nuclear Power Plant (Ginna), Wayne County, New York

Date of amendment request: March 26, 2018.

Brief description of amendments: The amendments revised the licenses to eliminate the Nuclear Advisory Committee requirements for each facility.

Date of issuance: November 15, 2018.

Effective date: As of the date of issuance and shall be implemented within 60 days of the date of issuance.

Amendment Nos.: 327 (Calvert Cliffs, Unit 1), 305 (Calvert Cliffs, Unit 2), 232 (Nine Mile Point, Unit 1), 173 (Nine Mile Point, Unit 2), and 133 (Ginna). A publicly-available version is in ADAMS under Accession No. ML18309A301. Documents related to these amendments are listed in the Safety Evaluation enclosed with the amendments.

Renewed Facility Operating License Nos. DPR–53, DPR–69, DPR–63, NPF–69, and DPR–18: The amendments revised the Renewed Facility Operating Licenses.

Date of initial notice in ***Federal Register:*** May 8, 2018 (83 FR 20861).

The Commission's related evaluation of the amendments is contained in a safety evaluation dated November 15, 2018.

No significant hazards consideration comments received: No.

Energy Northwest, Docket No. 50–397, Columbia Generating Station, Benton County, Washington

Date of amendment request: December 18, 2017.

Brief description of amendment: The amendment revised Section 4.2 of Appendix B, ''Environmental Protection Plan (Nonradiological),'' of the Columbia Generating Station Renewed Facility Operating License to incorporate the terms and conditions of the incidental take statement included in the biological opinion issued by the National Marine Fisheries Service on March 10, 2017.

Date of issuance: November 8, 2018.

Effective date: As of the date of issuance and shall be implemented within 60 days from the date of issuance.

Amendment No.: 252. A publicly-available version is in ADAMS under Accession No. ML18283A125; documents related to this amendment are listed in the Safety Evaluation enclosed with the amendment.

Renewed Facility Operating License No. NPF–21: The amendment revised the Renewed Facility Operating License and Environmental Protection Plan.

Date of initial notice in ***Federal Register:*** March 13, 2018 (83 FR 10916).

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated November 8, 2018.

No significant hazards consideration comments received: No.

Indiana Michigan Power Company, Docket Nos. 50–315 and 50–316, Donald C. Cook Nuclear Plant, Unit Nos. 1 and 2, Berrien County, Michigan

Date of amendment request: June 11, 2018.

Brief description of amendments: The amendments allow for deviation from National Fire Protection Association 805 requirements to allow the use of performance-based methods for flexible metallic conduit in configurations other than to connect components, and for flexible metallic conduit in lengths greater than short lengths.

Date of issuance: November 16, 2018.

Effective date: As of the date of issuance and shall be implemented within 90 days of issuance.

Amendment Nos.: 342 (Unit 1) and 324 (Unit 2). A publicly-available version is in ADAMS under Accession No. ML18284A254; documents related to these amendments are listed in the Safety Evaluation enclosed with the amendments.

Renewed Facility Operating License Nos. DPR–58 and DPR–74: The amendments revised the Renewed Facility Operating Licenses.

*Date of initial notice in **Federal Register:*** August 28, 2018 (83 FR 43905).

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated November 16, 2018.

No significant hazards consideration comments received: No.

Indiana Michigan Power Company, Docket Nos. 50–315 and 50–316, Donald C. Cook Nuclear Plant, Unit Nos. 1 and 2, Berrien County, Michigan

Date of amendment request: November 7, 2017, as supplemented by letters dated January 19, 2018, and August 14, 2018.

Brief description of amendments: The amendments revised the Emergency Plan to move the Technical Support Center to a different location in a new facility located within the existing protected area.

Date of issuance: November 13, 2018.

Effective date: As of the date of issuance and shall be implemented within 180 days of issuance.

Amendment Nos.: 341 (Unit No. 1) and 323 (Unit No. 2). A publicly-available version is in ADAMS under Accession No. ML18249A019; documents related to these amendments are listed in the Safety Evaluation enclosed with the amendments.

Renewed Facility Operating License Nos. DPR–58 and DPR–74: The amendments revised the Renewed Facility Operating Licenses.

*Date of initial notice in **Federal Register:*** January 2, 2018 (83 FR 169). The supplemental letters dated January 19, 2018, and August 14, 2018, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the NRC staff's original proposed no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated November 13, 2018.

No significant hazards consideration comments received: No.

Southern Nuclear Operating Company, Docket Nos. 50–348 and 50–364, Joseph M. Farley Nuclear Plant, Units 1 and 2, Houston County, Alabama

Date of amendment request: December 21, 2017, as supplemented by letter dated June 7, 2018.

Brief description of amendments: The amendments change Technical Specification (TS) 3.3.2, ''Engineered Safety Feature Actuation System (ESFAS) Instrumentation,'' by adding TS Actions that allow time to restore one high steam flow channel per steam line to Operable status before requiring a unit shutdown in the event two channels in one or more steam lines are discovered inoperable due to the trip setting not within Allowable Value.

Date of issuance: November 7, 2018.

Effective date: As of the date of issuance and shall be implemented within 30 days of issuance.

Amendment Nos.: 221 (Unit 1) and 218 (Unit 2). A publicly-available version is in ADAMS under Accession No. ML18271A207; documents related to these amendments are listed in the Safety Evaluation enclosed with the amendments.

Renewed Facility Operating License Nos. NPF–2 and NPF–8: The amendments revised the Renewed Facility Operating Licenses and TSs.

*Date of initial notice in **Federal Register:*** July 31, 2018 (83 FR 36977).

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated November 7, 2018.

No significant hazards consideration comments received: No.

Exelon Generation Company, LLC, Docket No. 50–244, R. E. Ginna Nuclear Power Plant, Wayne County, New York

Date of amendment request: November 16, 2017.

Brief description of amendment: The amendment revised the R. E. Ginna Nuclear Power Plant Technical Specifications for selected Reactor Trip System (RTS) and Engineered Safety Feature Actuation System (ESFAS) instrumentation channels. The change allows selected RTS (Table 3.3.1–1) and ESFAS instrumentation channels (Table 3.3.2–1) to be bypassed during surveillance testing. Additionally, the change allows RTS and ESFAS input relays to be excluded from the Channel Operational Test. The change allows testing of Nuclear Instrumentation System power range functions, which are part of the RTS, with a permanently installed bypass capability, while other RTS and ESFAS functions will be capable of being bypassed utilizing permanent connections in the racks to connect a portable test box.

Date of issuance: November 13, 2018.

Effective date: As of the date of issuance and shall be implemented within 60 days of issuance.

Amendment No.: 132. A publicly-available version is in ADAMS under Accession No. ML18213A369; documents related to this amendment are listed in the Safety Evaluation enclosed with the amendment.

Renewed Facility Operating License No. DPR–18: The amendment revised the Renewed Facility Operating License and Technical Specifications.

*Date of initial notice in **Federal Register:*** February 6, 2018 (83 FR 5281).

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated November 13, 2018.

No significant hazards consideration comments received: No.

Entergy Louisiana, LLC, and Entergy Operations, Inc., Docket No. 50–458, River Bend Station, Unit 1, West Feliciana Parish, Louisiana

Date of amendment request: November 15, 2017, as supplemented by letter dated April 26, 2018.

Brief description of amendment: The amendment revised the River Bend Station, Unit 1, Technical Specifications by replacing the existing specifications related to ''operations with a potential for draining the reactor vessel'' with revised requirements for reactor pressure vessel water inventory control to protect Safety Limit 2.1.1.3. Safety Limit 2.1.1.3 requires reactor vessel water level to be greater than the top of active irradiated fuel. The amendment adopted changes with variations, as noted in the license amendment request, and was based on the NRC-approved safety evaluation for Technical Specifications Task Force (TSTF) Traveler TSTF–542, Revision 2, ''Reactor Pressure Vessel Water

Inventory Control,'' dated December 20, 2016.

Date of issuance: November 7, 2018.

Effective date: As of the date of issuance and shall be implemented within 120 days from the date of issuance.

Amendment No.: 193. A publicly-available version is in ADAMS under Accession No. ML18267A341; documents related to this amendment are listed in the Safety Evaluation enclosed with the amendment.

Facility Operating License No. NPF–47: The amendment revised the Facility Operating License and Technical Specifications.

*Date of initial notice in **Federal Register:*** January 30, 2018 (83 FR 4292). The supplemental letter dated April 26, 2018, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the NRC staff's original proposed no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated November 7, 2018.

No significant hazards consideration comments received: No.

Florida Power & Light Company, Docket Nos. 50–250 and 50–251, Turkey Point Nuclear Generating Unit Nos. 3 and 4, Miami-Dade County, Florida

Date of amendment request: December 21, 2017, as supplemented by letter dated June 12, 2018.

Brief description of amendments: The amendments revised the Technical Specifications (TSs) pertaining to the Engineered Safety Features Actuation System instrumentation to resolve non-conservative actions associated with the Containment ventilation isolation and the Control Room ventilation isolation functions. In addition, the amendments revised the Control Room ventilation isolation function to no longer credit Containment radiation monitoring instrumentation, eliminated redundant radiation monitoring instrumentation requirements, eliminated select core alterations applicability requirements, relocated radiation monitoring and Reactor Coolant System leakage detection requirements within the TSs to align with their respective functions, and relocated the Spent Fuel Pool area monitoring requirements to licensee-controlled documents.

Date of issuance: November 14, 2018.

Effective date: As of the date of issuance and shall be implemented within 90 days of issuance.

Amendment Nos.: 283 (Unit No. 3) and 277 (Unit No. 4). A publicly-available version is in ADAMS under Accession No. ML18255A360; documents related to these amendments are listed in the Safety Evaluation enclosed with the amendments.

Renewed Facility Operating License Nos. DPR–31 and DPR–41: The amendments revised the Renewed Facility Operating Licenses and TSs.

*Date of initial notice in **Federal Register:*** February 27, 2018 (83 FR 8516). The supplemental letter dated June 12, 2018, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the NRC staff's original proposed no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated November 14, 2018.

No significant hazards consideration comments received: No.

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated November 14, 2018.

No significant hazards consideration comments received: No.

Dated at Rockville, Maryland, on November 20, 2018.

For the Nuclear Regulatory Commission.

Craig G. Erlanger,

Director, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2018–25728 Filed 12–3–18; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Meeting of the Advisory Committee on Reactor Safeguards (ACRS) Subcommittee on Planning and Procedures

The ACRS Subcommittee on Planning and Procedures will hold a meeting on December 5, 2018, at the U.S. Nuclear Regulatory Commission, Three White Flint North, 11601 Landsdown Street, Conference Rooms 1C3–1C5, North Bethesda, MD 20852.

The meeting will be open to public attendance.

The agenda for the subject meeting shall be as follows: *Wednesday, December 5, 2018—12:00 p.m. until 1:00 p.m.*

The Subcommittee will discuss proposed ACRS activities and related matters. The Subcommittee will gather information, analyze relevant issues and facts, and formulate proposed positions and actions, as appropriate, for deliberation by the Full Committee.

Members of the public desiring to provide oral statements and/or written comments should notify the Designated Federal Official (DFO), Quynh Nguyen (Telephone 301–415–5844 or email: *Quynh.Nguyen@nrc.gov*) five days prior to the meeting, if possible, so that arrangements can be made. Thirty-five hard copies of each presentation or handout should be provided to the DFO thirty minutes before the meeting. In addition, one electronic copy of each presentation should be emailed to the DFO one day before the meeting. If an electronic copy cannot be provided within this timeframe, presenters should provide the DFO with a CD containing each presentation at least thirty minutes before the meeting. Electronic recordings will be permitted only during those portions of the meeting that are open to the public. The public bridgeline number for the meeting is 866–822–3032, passcode 8272423. Detailed procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on October 4, 2017 (82 FR 46312).

Information regarding changes to the agenda, whether the meeting has been canceled or rescheduled, and the time allotted to present oral statements can be obtained by contacting the identified DFO. Moreover, in view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with the DFO if such rescheduling would result in a major inconvenience.

If attending this meeting, please enter through the Three White Flint North building, 11601 Landsdown Street, North Bethesda, MD 20852. After registering with Security, please proceed to conference room 1C3–1C5, located directly behind the security desk on the first floor. You may contact Mr. Theron Brown (Telephone 301–415–6702) for assistance or to be escorted to the meeting room.

Dated: November 28, 2018.

Christopher Brown,

Acting Chief, Technical Support Branch, Advisory Committee on Reactor Safeguards.

[FR Doc. 2018–26226 Filed 12–3–18; 8:45 am]

BILLING CODE 7590–01–P

OCCUPATIONAL SAFETY AND HEALTH REVIEW COMMISSION

Privacy Act of 1974; System of Records

AGENCY: Occupational Safety and Health Review Commission.

ACTION: Notice of a Modified System of Records.

SUMMARY: In accordance with the Privacy Act of 1974, the Occupational Safety and Health Review Commission (OSHRC) is revising the notice for Privacy Act system-of-records OSHRC–10.

DATES: Comments must be received by OSHRC on or before January 3, 2019. The revised system of records will become effective on that date, without any further notice in the **Federal Register**, unless comments or government approval procedures necessitate otherwise.

ADDRESSES: You may submit comments by any of the following methods:

- *Email: rbailey@oshrc.gov.* Include ''PRIVACY ACT SYSTEM OF RECORDS'' in the subject line of the message.
- *Fax:* (202) 606–5417.
- *Mail:* One Lafayette Centre, 1120 20th Street NW, Ninth Floor, Washington, DC 20036–3457.
- *Hand Delivery/Courier:* same as mailing address.

Instructions: All submissions must include your name, return address, and email address, if applicable. Please clearly label submissions as ''PRIVACY ACT SYSTEM OF RECORDS.''

FOR FURTHER INFORMATION CONTACT: Ron Bailey, Attorney-Advisor, Office of the General Counsel, via telephone at (202) 606–5410, or via email at *rbailey@oshrc.gov.*

SUPPLEMENTARY INFORMATION: The Privacy Act of 1974, 5 U.S.C. 552a(e)(4), requires federal agencies such as OSHRC to publish in the **Federal Register** notice of any new or modified system of records. OSHRC is revising the name of OSHRC–10—currently ''Database of Commission and ALJ Decisions on OSHRC website''—to ''Database of Commission and ALJ Decisions, and other case-related documents, on OSHRC website.'' The purpose of this revision is to reflect that, in addition to Commission and Administrative Law Judge (ALJ) decisions, other case-related materials are posted on oshrc.gov, mostly on the e-FOIA Reading Room and Open Government web pages. Also, through OSHRC's website, members of the public may subscribe to ''E-Alerts,'' a service which provides updates via the individual's email when new information is posted on the website, including Commission and ALJ decisions and documents on the Open Government web page. This system, therefore, maintains a listing of the names of individuals who subscribe to this service and their email addresses. In addition, the system location, storage location and safeguards, and the retention and disposal policy have been revised to account for a new web server location—*Americaneagle.com*. Further, the system manager has been revised to account for a change in the name of the pertinent position within the agency.

Finally, OSHRC has previously relied on blanket routine uses to describe the circumstances under which records may be disclosed. Going forward, as revised notices are published for new and modified systems of records, a full description of the routine uses—rather than a reference to blanket routine uses—will be included in each notice. With one exception, this is simply a change in format that has not resulted in any substantive changes to the routine uses for this system of records. The one substantive change is the revision to a routine use that permits disclosure of records to the Government Printing Office to allow for publication of decisions on the Commission's website. With the change in web server location and the expansion of documents posted on *oshrc.gov*, this routine use has been revised to allow for disclosure of Commission and ALJ decisions, and case-related documents, to *Americaneagle.com*.

Finally, due to a previous rescission of a system-of-records notice, OSHRC–8 currently has no system of records assigned to it. OSHRC–10 is thus being renumbered as OSHRC–8.

The notice for OSHRC–8, provided below in its entirety, is as follows.

SYSTEM NAME AND NUMBER:

Database of Commission and ALJ Decisions, and Other Case-Related Documents, on OSHRC website, OSHRC–8.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Records are located on a web server at *Americaneagle.com*, 2600 South River Road, DES Plaines, IL 60018. The Office of the Executive Director is responsible for the records in this system. The office is located at 1120 20th Street NW, Ninth Floor, Washington, DC 20036–3457.

SYSTEM MANAGER(S):

Supervisory Information Technology Specialist, OSHRC, 1120 20th Street NW, Ninth Floor, Washington, DC 20036–3457; (202) 606–5100.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 552; 29 U.S.C. 661(g); OMB Memorandum M–10–06; OMB Memorandum M–16–16.

PURPOSE(S) OF THE SYSTEM:

This system of records is maintained in order to make Commission and ALJ decisions, as well as other case-related documents, more accessible to the public and agency employees.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

This system of records covers all individuals referenced and described in Commission and ALJ decisions, and other case-related documents posted on OSHRC's website, including sole proprietors who were cited by OSHA, employees and other witnesses, attorney and non-attorney representatives of each party, and the Commissioners and ALJs. This system also covers individuals who subscribe to ''E-Alerts'' on OSHRC's website.

CATEGORIES OF RECORDS IN THE SYSTEM:

This system of records includes final decisions issued by the Commission since 1972, and final decisions issued by the ALJs since 1993. This system also includes documents posted on OSHRC's Open Government web page, including select orders issued by ALJs and the Commission, briefing notices issued since 2010, listings of new cases received since 2010, and monthly docket reports issued since 2010. In addition, this system includes certain documents posted in OSHRC's e-FOIA Reading Room, including case filings in select Commission cases. The documents may contain the following information: (1) The names and locations (city and state) of the individuals representing each party; (2) the names of sole proprietors cited by OSHA, as well as employees and other witnesses, and information describing those individuals, including job title and duties, medical history, and other descriptive information that is relevant to the disposition of a case; and (3) the names and job titles of the Commissioners and ALJs. Finally, this system includes a separate database that contains the names and email addresses of those individuals who subscribe to ''E-Alerts.''

RECORD SOURCE CATEGORIES:

Information in this system of records is derived from case records that are

developed during litigation before the Commission and/or the ALJs and, thus, the information may come from individuals who are the subjects of the records or from other sources. Information—names and email addresses—also comes from individuals who subscribe to ''E-Alerts.''

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

In addition to disclosures generally permitted under 5 U.S.C. 552a(b), all or a portion of the records or information contained in this system of records may be disclosed as a routine use pursuant to 5 U.S.C. 552a(b)(3) under the circumstances or for the purposes described below, to the extent such disclosures are compatible with the purposes for which the information was collected:

(1) To the Department of Justice (DOJ), or to a court or adjudicative body before which OSHRC is authorized to appear, when any of the following entities or individuals—(a) OSHRC, or any of its components; (b) any employee of OSHRC in his or her official capacity; (c) any employee of OSHRC in his or her individual capacity where DOJ (or OSHRC where it is authorized to do so) has agreed to represent the employee; or (d) the United States, where OSHRC determines that litigation is likely to affect OSHRC or any of its components—is a party to litigation or has an interest in such litigation, and OSHRC determines that the use of such records by DOJ, or by a court or other tribunal, or another party before such tribunal, is relevant and necessary to the litigation.

(2) To an appropriate agency, whether federal, state, local, or foreign, charged with investigating or prosecuting a violation or enforcing or implementing a law, rule, regulation, or order, when a record, either on its face or in conjunction with other information, indicates a violation or potential violation of law, which includes civil, criminal or regulatory violations, and such disclosure is proper and consistent with the official duties of the person making the disclosure.

(3) To a federal, state, or local agency maintaining civil, criminal or other relevant enforcement information, such as current licenses, if necessary to obtain information relevant to an OSHRC decision concerning the hiring, appointment, or retention of an employee; the issuance, renewal, suspension, or revocation of a security clearance; the execution of a security or suitability investigation; the letting of a contract; or the issuance of a license, grant or other benefit.

(4) To a federal, state, or local agency, in response to that agency's request for a record, and only to the extent that the information is relevant and necessary to the requesting agency's decision in the matter, if the record is sought in connection with the hiring, appointment, or retention of an employee; the issuance, renewal, suspension, or revocation of a security clearance; the execution of a security or suitability investigation; the letting of a contract; or the issuance of a license, grant or other benefit by the requesting agency.

(5) To an authorized appeal grievance examiner, formal complaints manager, equal employment opportunity investigator, arbitrator, or other duly authorized official engaged in investigation or settlement of a grievance, complaint, or appeal filed by an employee, only to the extent that the information is relevant and necessary to the case or matter.

(6) To OPM in accordance with the agency's responsibilities for evaluation and oversight of federal personnel management.

(7) To officers and employees of a federal agency for the purpose of conducting an audit, but only to the extent that the record is relevant and necessary to this purpose.

(8) To OMB in connection with the review of private relief legislation at any stage of the legislative coordination and clearance process, as set forth in Circular No. A–19.

(9) To a Member of Congress or to a person on his or her staff acting on the Member's behalf when a written request is made on behalf and at the behest of the individual who is the subject of the record.

(10) To the National Archives and Records Administration (NARA) for records management inspections and such other purposes conducted under the authority of 44 U.S.C. 2904 and 2906.

(11) To appropriate agencies, entities, and persons when: (a) OSHRC suspects or has confirmed that there has been a breach of the system of records; (b) OSHRC has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, OSHRC, the Federal Government, or national security; and (c) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with OSHRC's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

(12) To NARA, Office of Government Information Services (OGIS), to the extent necessary to fulfill its responsibilities in 5 U.S.C. 552(h), to review administrative agency policies, procedures and compliance with FOIA, and to facilitate OGIS' offering of mediation services to resolve disputes between persons making FOIA requests and administrative agencies.

(13) To another federal agency or federal entity, when OSHRC determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (a) responding to a suspected or confirmed breach or (b) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

(14) To the public, via OSHRC's website, pursuant to 29 U.S.C. 661(g), which states that ''[e]very official act of the Commission shall be entered of record, and its hearings and records shall be open to the public.'' Only personal information that is relevant and necessary to the disposition of OSHRC cases will be included in these decisions.

(15) To *Americaneagle.com* to make certain that decisions published on OSHRC's website are current.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are stored on a web server located at *Americaneagle.com*.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records are listed on OSHRC's website by case name, docket number, and date, and can also be retrieved by using the search engine on the website's homepage to conduct a simplified Boolean search. Records are also retrievable by the names and email addresses of those who subscribe to ''E-Alerts.''

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Records are retained and disposed of in accordance with OSHRC Records Control Schedule N1–455–11–003.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

OSHRC requests updates for its website through a secure portal which in turn updates a queue for posting by *Americaneagle.com*. *Americaneagle .com* secures information on the web server in accordance with federal standards. Access to the names and

email addresses of those who subscribe to ''E-Alerts'' is limited to system administrators.

RECORD ACCESS PROCEDURES:

Individuals who wish to gain access to their records should notify: Privacy Officer, OSHRC, 1120 20th Street NW, Ninth Floor, Washington, DC 20036–3457. For an explanation on how such requests should be drafted, refer to 29 CFR 2400.6 (procedures for requesting records).

CONTESTING RECORD PROCEDURES:

Individuals who wish to contest their records should notify: Privacy Officer, OSHRC, 1120 20th Street NW, Ninth Floor, Washington, DC 20036–3457. For an explanation on the specific procedures for contesting the contents of a record, refer to 29 CFR 2400.8 (Procedures for requesting amendment), and 29 CFR 2400.9 (Procedures for appealing).

NOTIFICATION PROCEDURES:

Individuals interested in inquiring about their records should notify: Privacy Officer, OSHRC, 1120 20th Street NW, Ninth Floor, Washington, DC 20036–3457. For an explanation on how such requests should be drafted, refer to 29 CFR 2400.5 (notification), and 29 CFR 2400.6 (procedures for requesting records).

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

September 24, 2007, 72 FR 54301; August 4, 2008, 73 FR 45256; October 5, 2015, 80 FR 60182; and September 28, 2017, 82 FR 45324.

Dated: November 26, 2018.

Nadine N. Mancini,

General Counsel, Senior Agency Official for Privacy.

[FR Doc. 2018–26276 Filed 12–3–18; 8:45 am]

BILLING CODE 7600–01–P

PENSION BENEFIT GUARANTY CORPORATION

Proposed Submission of Information Collection for OMB Review; Comment Request; Request for Coverage Determination

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Notice of intent to request OMB approval of information collection.

SUMMARY: The Pension Benefit Guaranty Corporation (PBGC) intends to request that the Office of Management and Budget (OMB) approve, under the Paperwork Reduction Act, a collection of information necessary for PBGC to determine whether a plan is covered under title IV of the Employee Retirement Security Income Act of 1974. This notice informs the public of PBGC's intent and solicits public comment on the collection of information.

DATES: Comments must be submitted on or before February 4, 2019.

ADDRESSES: Comments may be submitted by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Email: paperwork.comments@pbgc.gov.*
- *Mail or Hand Delivery:* Regulatory Affairs Division, Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street NW, Washington, DC 20005–4026.

All submissions received must include the agency's name (Pension Benefit Guaranty Corporation, or PBGC) and refer to the Coverage Determination Request Form. All comments received will be posted without change to PBGC's website, *http://www.pbgc.gov,* including any personal information provided.

Copies of the collection of information may also be obtained by writing to Disclosure Division, Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street NW, Washington, DC 20005–4026, or calling 202–326–4040 during normal business hours. TTY users may call the Federal relay service toll-free at 800–877–8339 and ask to be connected to 202–326–4040. PBGC's laws and procedures for coverage determinations may be accessed on PBGC's website at *http://www.pbgc.gov.*

FOR FURTHER INFORMATION CONTACT: Melissa Rifkin (*rifkin.melissa@pbgc.gov*), Attorney, Regulatory Affairs Division, Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street NW, Washington, DC 20005–4026; 202–326–4400, extension 6563. (TTY users may call the Federal relay service toll-free at 800–877–8339 and ask to be connected to 202–326–4400, extension 6563.)

SUPPLEMENTARY INFORMATION: PBGC insures defined benefit pension plans covered under title IV of the Employee Retirement Income Security Act of 1974 (ERISA). Covered plans are those described in section 4021(a) of ERISA but not those described in section 4021(b)(1)–(13). If a question arises about whether a plan is covered under title IV, PBGC may make a coverage determination.

The proposed form and instructions would be used by a plan sponsor or plan administrator to request a coverage determination and would be suitable for all types of requests. The proposed form would highlight the four plan types for which coverage determinations are most frequently requested: (1) Church plans as listed in section 4021(b)(3) of ERISA; (2) plans that are established and maintained exclusively for the benefit of plan sponsors' substantial owners as listed in section 4021(b)(9); (3) plans covering, since September 2, 1974, no more than 25 active participants that are established and maintained by professional services employers as listed in section 4021(b)(13); and (4) Puerto Rico-based plans within the meaning of section 1022(i)(1) of ERISA.

PBGC needs this information collection to determine whether a plan is covered or not covered under title IV. Information provided to PBGC would be confidential to the extent provided in the Freedom of Information Act and the Privacy Act.

PBGC estimates that 425 forms would be submitted each year. PBGC estimates that each form would require approximately 20 hours to complete by a combination of plan office staff (50%) and outside professionals (attorneys and actuaries) (50%). PBGC estimates an annual hour burden of 4,250 hours (based on plan office time). The estimated dollar equivalent of this hour burden, based on an assumed hourly rate of $75 for administrative, clerical, and supervisory time is $318,750. PBGC estimates an annual cost burden of $1,487,500 (based on 4,250 professional hours assuming an average hourly rate of $350).

PBGC intends to request that OMB approve PBGC's use of this form for three years. 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.

PBGC is soliciting public comments 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 methodologies 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 submission of responses.

Issued in Washington, DC.

Hilary Duke,

Assistant General Counsel for Regulatory Affairs, Pension Benefit Guaranty Corporation.

[FR Doc. 2018–26278 Filed 12–3–18; 8:45 am]

BILLING CODE 7709–02–P

OFFICE OF PERSONNEL MANAGEMENT

Submission for Review: Rollover Election (RI 38–117), Rollover Information (RI 38–118), and Special Tax Notice Regarding Rollovers (RI 37–22), 3206–0212

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), Rollover Election (RI 38–117), Rollover Information (RI 38–118), and Special Tax Notice Regarding Rollovers (RI 37–22).

DATES: Comments are encouraged and will be accepted until February 4, 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 via electronic mail to *Cyrus.Benson@opm.gov* or faxed to (202) 606–0910.

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. 3206–0212). 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.

RI 38–117, Rollover Election, is used to collect information from each payee affected by a change in the tax code so that OPM can make payment in accordance with the wishes of the payee. RI 38–118, Rollover Information, explains the election. RI 37–22, Special Tax Notice Regarding Rollovers, provides more detailed information.

Analysis

Agency: Retirement Operations, Retirement Services, Office of Personnel Management.

Title: Rollover Election, Rollover Information, and Special Tax Notice Regarding Rollover.

OMB Number: 3206–0212.

Frequency: On occasion.

Affected Public: Individuals or Households.

Number of Respondents: 1,500.

Estimated Time per Respondent: 40 minutes.

Total Burden Hours: 1,000.

Office of Personnel Management.

Alexys Stanley,

Regulatory Affairs Analyst.

[FR Doc. 2018–26262 Filed 12–3–18; 8:45 am]

BILLING CODE 6325–38–P

OFFICE OF PERSONNEL MANAGEMENT

Submission for Review: Health Benefits Election Form, SF 2809

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), Health Benefits Election, SF 2809.

DATES: Comments are encouraged and will be accepted until February 4, 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.

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. 3206–0160). 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.

The Health Benefits Election Form is used by Federal employees, annuitants other than those under the Civil Service Retirement System (CSRS) and the Federal Employees Retirement System (FERS) including individuals receiving benefits from the Office of Workers' Compensation Programs, former spouses eligible for benefits under the Spouse Equity Act of 1984, and separated employees and former dependents eligible to enroll under the Temporary Continuation of Coverage provisions of the FEHB law (5 U.S.C. 8905a). A different form (OPM 2809) is used by CSRS and FERS annuitants whose health benefit enrollments are administered by OPM's Retirement Operations.

Analysis

Agency: Federal Employee Insurance Operations, Office of Personnel Management.

Title: Health Benefits Election Form.

OMB Number: 3206–0160.

Frequency: On Occasion.

Affected Public: Individuals or Households.

Number of Respondents: 18,000.

Estimated Time per Respondent: 30 minutes.

Total Burden Hours: 9,000.

Office of Personnel Management.

Alexys Stanley,

Regulatory Affairs Analyst.

[FR Doc. 2018–26263 Filed 12–3–18; 8:45 am]

BILLING CODE 6325–38–P

POSTAL SERVICE

Privacy Act of 1974; System of Records

AGENCY: Postal Service™.

ACTION: Notice of establishment of new system of records.

SUMMARY: The United States Postal Service® (Postal Service) is proposing to establish a new Customer Privacy Act System of Records (SOR) to support the Change of Address and Hold Mail services.

DATES: This system will become effective without further notice on January 3, 2019 unless, in response to comments received on or before that date, the Postal Service makes any substantive change to the purposes or routine uses set forth, or to expand the availability of information in this system, as described in this notice. If the Postal Service determines that certain portions of this SOR should not be implemented, or that implementation of certain portions should be postponed in light of comments received, the Postal Service may choose to implement the remaining portions of the SOR on the stated effective date, and will provide notice of that action.

ADDRESSES: Comments may be mailed or delivered to the Privacy and Records Management Office, United States Postal Service, 475 L'Enfant Plaza SW, Room 1P830, Washington, DC 20260–1101. Copies of all written comments will be available at this address for public inspection and photocopying between 8 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Janine Castorina, Chief Privacy and Records Management Officer, Privacy and Records Management Office, 202–268–3069 or *privacy@usps.gov.*

SUPPLEMENTARY INFORMATION: This notice is in accordance with the Privacy Act requirement that agencies publish their systems of records in the **Federal Register** when there is a revision, change, or addition, or when the agency establishes a new system of records. The Postal Service is establishing a new system of records to support the new Address Matching Database that is being implemented to facilitate the prevention of fraudulent Change of Address and Hold Mail requests through address matching across Postal Service customer systems.

I. Background

In an effort to enhance the security of mailing services, the Postal Service is using a new Address Matching Database to identify, prevent and mitigate potential fraudulent activity within the Change of Address and Hold Mail processes.

II. Rationale for Changes to USPS Privacy Act Systems of Records

The Postal Service is using a new Address Matching Database to facilitate mail fraud prevention for Change of Address and Hold Mail services through address matching across Postal Service customer systems. Specifically, the Address Matching Database will establish a dataflow across existing Postal Service customer systems and applications and confirm if there is an address match when a new Change of Address or Hold Mail request is submitted. The Address Matching Database will also confirm the presence of a Change of Address or Hold Mail request for the same address. With the exception of Change of Address requests subject to protective court orders, the Address Matching Database will send email or text message confirmation notifications to customers who submit a Change of Address and/or Hold Mail request. The Address Matching Database will also generate aggregate data analytics that will help guide business decisions and efforts to mitigate potential fraud as it relates to the Change of Address and Hold Mail processes. Additionally, this information will be used to improve the customer experience by helping the Postal Service maintain up-to-date user records across customer systems and minimizing the risk of fraudulent transactions.

Privacy and Security

For more than two centuries, the Postal Service has maintained a brand that customers trust to protect the privacy and security of their information. The new Address Matching Database will enhance the confidentiality and privacy of mail delivery services by improving the security of Change of Address and Hold Mail processes. The new Address Matching Database will also protect Postal Service customers from becoming potential victims of mail fraud and identity theft. Other policies that ensure the security and confidentiality of personal information are described below in the Safeguards section of the new Address Matching for Mail Fraud Detection and Prevention SOR.

III. Description of the New System of Records

Pursuant to 5 U.S.C. 552a(e)(11), interested persons are invited to submit written data, views, or arguments to this proposal. A report of the establishment of this SOR has been sent to Congress and to the Office of Management and Budget for their evaluations. The Postal Service does not expect the establishment of this SOR to have any adverse effect on individual privacy rights. Accordingly, for the reasons stated above, the Postal Service proposes a new system of records as follows:

USPS 800.050

SYSTEM NAME:

Address Matching for Mail Fraud Detection and Prevention.

SYSTEM LOCATION:

USPS National Customer Support Center (NCSC) and USPS IT Eagan Host Computing Services Center.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Customers requesting Change of Address mail forwarding, or Hold Mail services.

CATEGORIES OF RECORDS IN THE SYSTEM:

1. *Customer information:* For Change of Address requests, old and new address, email address(es), telephone numbers and device identification; for Hold Mail, address, email address(es), and telephone numbers.

2. *Online user information:* Device identification.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

18 U.S.C. 1341, 1343 and 3061; 39 U.S.C. 401, 403, 404, 3003 and 3005.

PURPOSE(S):

1. To enhance the customer experience by improving the security of Change of Address (COA) and Hold Mail processes.

2. To protect USPS customers from becoming potential victims of mail fraud and identity theft.

3. To identify and mitigate potential fraud in the COA and Hold Mail processes.

4. To verify a customer's identity when applying for COA and Hold Mail services.

5. To facilitate mail fraud prevention for COA and Hold Mail services through address matching across USPS customer systems.

6. To facilitate the provision of accurate and reliable mail and package delivery services.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Standard routine uses 1. through 7, 10 and 11. apply.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Automated databases.

RETRIEVABILITY:

Retrieval is accomplished by a computer-based system, using one or more of the following elements: ZIP Code(s), address, telephone number, email address, device identification and/or IP address.

SAFEGUARDS:

Electronic records, computers, and computer storage media are located in controlled-access areas under supervision of program personnel. Access to records is limited to individuals whose official duties require such access. Contractors and licensees are subject to contract controls and unannounced on-site audits and inspections.

Computers are protected by mechanical locks, card key systems, or other physical access control methods. The use of computer systems is regulated with installed security software, computer logon identifications, and operating system controls including access controls, terminal and transaction logging, and file management software.

Online data transmission is protected by encryption, dedicated lines, and authorized access codes.

RETENTION AND DISPOSAL:

COA and Hold Mail records are retained in an electronic database for 10 years from the effective date.

Electronic records existing on computer storage media are destroyed according to the applicable USPS media sanitization practice.

SYSTEM MANAGER(S) AND ADDRESS:

Vice President, Product Innovation, United States Postal Service, 475 L'Enfant Plaza SW, Washington, DC 20260.

NOTIFICATION PROCEDURE:

Customers wanting to know if information about them is maintained in this system of records must address inquiries in writing to the system manager. Inquiries must contain name, address, email, and other identifying information.

RECORD ACCESS PROCEDURES:

Requests for access must be made in accordance with the Notification Procedure above and the USPS Privacy Act regulations regarding access to records and verification of identity under 39 CFR 266.5.

CONTESTING RECORD PROCEDURES:

See *Notification Procedure* and *Record Access Procedures* above.

RECORD SOURCE CATEGORIES:

Individual customers requesting Change of Address, mail forwarding, or Hold Mail services and other USPS customer systems.

* * * * *

Brittany M. Johnson,

Attorney, Federal Compliance.

[FR Doc. 2018–26310 Filed 12–3–18; 8:45 am]

BILLING CODE P

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension: Rule 17f–4, SEC File No. 270–232, OMB Control No. 3235–0225.

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) (the ''Paperwork Reduction Act''), the Securities and Exchange Commission (the ''Commission'') is soliciting comments on the collection of information summarized below. The Commission plans to submit this existing collection of information to the Office of Management and Budget for extension and approval.

Section 17(f) (15 U.S.C. 80a–17(f)) under the Investment Company Act of 1940 (the ''Act'') [1] permits registered management investment companies and their custodians to deposit the securities they own in a system for the central handling of securities (''securities depositories''), subject to rules adopted by the Commission.

Rule 17f–4 (17 CFR 270.17f–4) under the Act specifies the conditions for the use of securities depositories by funds [2] and their custodians.

The Commission staff estimates that 142 respondents (including an estimated 80 active funds that may deal directly with a securities depository, an estimated 49 custodians, and 13 possible securities depositories) [3] are subject to the requirements in rule 17f–4. The rule is elective, but most, if not all, funds use depository custody arrangements.[4]

[1] 15 U.S.C. 80a.

[2] As amended in 2003, rule 17f–4 permits any registered investment company, including a unit investment trust or a face-amount certificate company, to use a security depository. *See* Custody of Investment Company Assets With a Securities Depository, Investment Company Act Release No. 25934 (Feb. 13, 2003) (68 FR 8438 (Feb. 20, 2003)). The term ''fund'' is used in this Notice to mean a registered investment company.

[3] The Commission staff estimates that, as permitted by the rule, an estimated 2% of all active funds may deal directly with a securities depository instead of using an intermediary. The number of custodians is estimated based on information from Morningstar Direct℠. The Commission staff estimates the number of possible securities depositories by adding the 12 Federal Reserve Banks and one active registered clearing agency. The Commission staff recognizes that not all of these entities may currently be acting as a securities depository for fund securities.

[4] Based on responses to Item 18 of Form N–SAR (17 CFR 274.101), approximately 97 percent of

Rule 17f–4 contains two general conditions. First, a fund's custodian must be obligated, at a minimum, to exercise due care in accordance with reasonable commercial standards in discharging its duty as a securities intermediary to obtain and thereafter maintain financial assets. If the fund deals directly with a depository, the depository's contract or written rules for its participants must provide that the depository will meet similar obligations. All funds that deal directly with securities depositories in reliance on rule 17f–4 should have either modified their contracts with the relevant securities depository, or negotiated a modification in the securities depository's written rules when the rule was amended. Therefore, we estimate there is no ongoing burden associated with this collection of information.[5]

Second, the custodian must provide, promptly upon request by the fund, such reports as are available about the internal accounting controls and financial strength of the custodian. If a fund deals directly with a depository, the depository's contract with or written rules for its participants must provide that the depository will provide similar financial reports. Custodians and depositories usually transmit financial reports to funds twice each year.[6] The Commission staff estimates that 49 custodians spend approximately 914 hours (by support staff) annually in transmitting such reports to funds.[7] In addition, approximately 80 funds (*i.e.,* two percent of all funds) deal directly with a securities depository and may request periodic reports from their depository. Commission staff estimates that depositories spend approximately 19 hours (by support staff) annually transmitting reports to the 80 funds.[8] The total annual burden estimate for compliance with rule 17f–4's reporting requirement is therefore 933 hours.[9]

If a fund deals directly with a securities depository, rule 17f–4 requires that the fund implement internal control systems reasonably designed to prevent an unauthorized officer's instructions (by providing at least for the form, content, and means of giving, recording, and reviewing all officers' instructions). All funds that seek to rely on rule 17f–4 should have already implemented these internal control systems when the rule was amended. Therefore, there is no ongoing burden associated with this collection of information requirement.[10]

Based on the foregoing, the Commission staff estimates that the total annual hour burden of the rule's collection of information requirements is 933 hours.

The estimate of average burden hours is made solely for the purposes of the Paperwork Reduction Act. This estimate is not derived from a comprehensive or even representative survey or study of the costs of Commission rules.

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 control number.

Written comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (b) the accuracy of the Commission's estimate of the burden of the collections of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burdens 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 in writing within 60 days of this publication.

Please direct your written comments to Charles Riddle, Acting Director/Chief Information Officer, Securities and Exchange Commission, C/O Candace Kenner, 100 F Street NE, Washington, DC 20549; or send an email to: *PRA_Mailbox@sec.gov.*

Dated: November 28, 2018.

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–26327 Filed 12–3–18; 8:45 am]

BILLING CODE 8011–01–P

funds' custodians maintain some or all fund securities in a securities depository pursuant to rule 17f–4.

[5] The Commission staff assumes that new funds relying on 17f–4 would choose to use a custodian instead of directly dealing with a securities depository because of the high costs associated with maintaining an account with a securities depository. Thus, new funds would not be subject to this condition.

[6] The estimated 49 custodians would handle requests for reports from 3,917 fund clients (approximately 80 fund clients per custodian) and the depositories from the remaining 80 funds that choose to deal directly with a depository. It is our understanding based on staff conversations with industry representatives that custodians and depositories transmit these reports to clients in the normal course of their activities as a good business practice regardless of whether they are requested. Therefore, for purposes of this PRA estimate, the Commission staff assumes that custodians transmit the reports to all fund clients.

[7] (3,917 fund clients × 2 reports) = 7,834 transmissions. The staff estimates that each transmission would take approximately 7 minutes for a total of approximately 914 hours (7 minutes × 7,834 transmissions).

[8] (80 fund clients who may deal directly with a securities depository × 2 reports) = 160 transmissions. The staff estimates that each transmission would take approximately 7 minutes for a total of approximately 19 hours (7 minutes × 160 transmissions).

[9] 914 hours for custodians and 19 hours for securities depositories.

[10] The Commission staff assumes that new funds relying on 17f–4 would choose to use a custodian instead of directly dealing with a securities depository because of the high costs associated with maintaining an account with a securities depository. Thus new funds would not be subject to this condition.

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–84671; File No. SR–NASDAQ–2018–096]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 4756(c)(2)

November 28, 2018.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 16, 2018, The Nasdaq Stock Market LLC (''Nasdaq'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to allow the Exchange to aggregate Displayed odd-lot Orders across price levels for transmission to network processors as the Exchange's best priced Order under Rule 4756(c)(2). While these amendments are effective upon filing, the Exchange has designated the proposed amendments to be operative in the first quarter of 2019, and will announce the precise date by Equity Trader Alert at least thirty days prior to implementation.

The text of the proposed rule change is available on the Exchange's website at *http://nasdaq.cchwallstreet.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange is proposing to amend Rule 4756 to allow the Exchange to aggregate Displayed [3] odd-lot Orders across price levels for transmission to network processors as the Exchange's best ranked Displayed Order(s), which is based on how NYSE Arca, Inc. handles such orders pursuant to NYSE Arca Rule 7.36–E(b)(3).[4] Rule 4756 concerns entry and display of Quotes [5] and Orders,[6] and paragraph (c) thereunder provides how the System [7] will display Quotes and Orders submitted to the System. Rule 4756(c)(2), which the Exchange is proposing to amend, describes what the Exchange transmits to the network processors as the Exchange's best priced Order. Specifically, Rule 4756(c)(2) provides that, for each System Security,[8] the aggregate size of all Quotes and Orders at the best price to buy and sell resident in the System will be transmitted for display to the appropriate network processor, unless the aggregate size is less than one round lot, in which case the aggregate size will be displayed in the System Book Feed [9] but not be transmitted to a network processor.[10] Thus, pursuant to Rule 4756(c)(2) Orders with an aggregate size of less than one round lot at a particular price level are displayed in the System Book Feed, but are not transmitted to a network processor. For example, if the Nasdaq best bid is $10.00, and there are the following three odd-lot Orders resting displayed on the Nasdaq Book with no other interest resting on the Nasdaq Book—25 shares to buy at $10.00, 25 shares to buy at $9.99, and 50 shares to buy at $9.98—the System will not transmit any of these Orders to the appropriate processor, but rather will post them to the System Book Feed.[11]

The Exchange is proposing to amend Rule 4756(c)(2) to allow the Exchange to aggregate odd-lot sized Displayed Orders at multiple price points that equal at least a round lot for purposes of transmitting the Exchange's best ranked Displayed Order(s) to the appropriate processor. In assigning a price to such aggregated odd-lot Orders, the Exchange would use the highest (lowest) price to buy (sell) wherein the aggregate size of all displayed buy (sell) interest in the System greater (less) than or equal to that price is one round lot or greater. Consequently, because the aggregated Displayed odd-lot Orders represent the best price available on the Exchange, they would be transmitted to the network processor as such. Using the example above, all three odd-lot Orders resting displayed on the Nasdaq Book would be aggregated into a round lot Order and reported to the appropriate processor for quoting at a price of $9.98.[12] The Exchange is proposing to amend Rule 4756(c)(2) to add four new subparagraphs to the rule, which provide that the Exchange will transmit to the appropriate processor the highest (lowest) price to buy (sell) wherein the aggregate size of all displayed buy (sell) interest in the System greater (less) than or equal to that price is one round lot or greater, and that the aggregate size of all displayed buy (sell) interest in the System greater (less) than or equal to that price will be transmitted rounded down to the nearest round lot.[13]

The Exchange is also proposing to make clarifying changes to Rule 4756(c)(2). Currently, the rule does not note that the obligation to report the highest (lowest) aggregate Displayed interest to buy (sell) arises from Rule 602 of Regulation NMS. The Exchange is amending the rule to affirmatively state that the transmission to the appropriate network processor is done pursuant to Rule 602 of Regulation NMS. The Exchange is also deleting the text concerning the display in the System Book Feed of all Quotes and Orders at the best price to buy and sell resident in the System that are less than one round lot. The Exchange believes that this text is redundant of paragraph (1) of Rule 4756(c) and serves no purpose under the clarified rule. The Exchange notes that the clarifying changes do not alter how it currently handles Quotes and Orders for display and trade reporting.

The Exchange plans to implement the change proposed herein in the first quarter of 2019, and will announce the precise date by Equity Trader Alert at least thirty days prior to implementation.

[3] Display is an Order Attribute that allows the price and size of an Order to be displayed to market participants via market data feeds. Certain Order Types may be non-displayed if they are not assigned a Display Order Attribute, and all non-displayed Orders may be referred to as ''Non-Displayed Orders'' (*See* Rule 4703(b)(3)(A) [sic]). In contrast, an Order with a Display Order Attribute may be referred to as a ''Displayed Order.'' *See* Rule 4703(k).

[4] *See* Securities Exchange Act Release No. 74796 (April 23, 2015), 80 FR 23838 (April 29, 2015) (SR–NYSEArca–2015–08).

[5] The term ''Quote'' means a single bid or offer quotation submitted to the System by a Market Maker or Nasdaq Electronic Communications Network and designated for display (price and size) next to the Participant's Market Participant Identifier in the Nasdaq Book. Quotes are entered in the form of Orders with Attribution (as defined in Rule 4703). Accordingly, all Quotes are also Orders. *See* Rule 4701(d).

[6] The term ''Order'' means an instruction to trade a specified number of shares in a specified System Security submitted to the Nasdaq Market Center by a Participant. An ''Order Type'' is a standardized set of instructions associated with an Order that define how it will behave with respect to pricing, execution, and/or posting to the Nasdaq Book when submitted to Nasdaq. An ''Order Attribute'' is a further set of variable instructions that may be associated with an Order to further define how it will behave with respect to pricing, execution, and/or posting to the Nasdaq Book when submitted to Nasdaq. The available Order Types and Order Attributes, and the Order Attributes that may be associated with particular Order Types, are described in Rules 4702 and 4703. One or more Order Attributes may be assigned to a single Order; provided, however, that if the use of multiple Order Attributes would provide contradictory instructions to an Order, the System will reject the Order or remove non-conforming Order Attributes. *See* Rule 4701(e).

[7] The term ''Nasdaq Market Center,'' or ''System'' shall mean the automated system for order execution and trade reporting owned and operated by The Nasdaq Stock Market LLC. *See* Rule 4701(a).

[8] The term ''System Securities'' shall mean (1) all securities listed on Nasdaq and (2) all securities subject to the Consolidated Tape Association Plan and the Consolidated Quotation Plan except securities specifically excluded from trading via a list of excluded securities posted on *www.nasdaqtrader.com. See* Rule 4701(b).

[9] The term ''System Book Feed'' shall mean a data feed for System Securities, generally known as the TotalView ITCH feed. *See* Rule 4701(l).

[10] Consequently, the Exchange currently will aggregate and transmit to the network processor odd-lot Orders at a particular price level if such Orders aggregate to at least one round lot and are priced better than the best-priced round lot interest on the Nasdaq Book.

[11] The Exchange notes that the network processors only accept quotations in round lots. As a consequence, if aggregated Orders do not equal a round lot the Exchange will round down to the nearest round lot for purposes of reporting to the appropriate network processor. This proposal does not change this process.

[12] The Exchange notes that it is not proposing to change how it processes Orders for execution. Thus, Orders resting on the Nasdaq Book will be executed in price/display/time priority pursuant to Rule 4757.

[13] *Supra* note 10 [sic].

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[14] in general, and furthers the objectives of Section 6(b)(5) of the Act,[15] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest, because the proposed change would remove impediments to and perfect the mechanism of a free and open market and a national market system by allowing the Exchange to aggregate odd lot Orders across multiple price levels for purposes of determining the Exchange's best ranked Displayed Order(s) for transmission to the appropriate network processor. The proposed change will provide market participants with greater visibility into liquidity available on the Exchange via the appropriate network processor. Because arriving marketable contra-side Orders execute in price-time priority against resting odd-lot Orders priced better than resting round-lot Orders, the Exchange believes that it is appropriate to display such odd-lot interest on the public data feeds as the Exchange's best bid or offer if in the aggregate, they equal a round lot or more. The Exchange further believes that aggregating such odd-lot Orders at the highest (lowest) price to buy (sell) wherein the aggregate size of all buy (sell) interest in the System greater (less) than or equal to that price is one round lot or greater would remove impediments to and perfect the mechanism of a free and open market because it represents the best aggregated execution price for incoming sell (buy) Orders. The Exchange notes that the incoming marketable interest would receive price improvement when executing against any odd-lot orders priced better than the aggregated displayed price. Last, the Exchange believes that the proposed clarifying changes will help promote a better understanding of the operation of the rule. As noted above, the clarifying changes do not alter how the Exchange currently handles Quotes and Orders for display and trade reporting.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. As noted above, the Exchange is copying functionality that is currently in use by a competitor exchange. The proposed change may increase the Exchange's position at the National Best Bid and Offer, thus allowing the Exchange to receive greater Order flow and, consequently, executions. This is the same benefit that the competitor exchange has received since adopting the process proposed herein. Thus, the proposed change is a competitive response, but does not place any burden on competition because it is copying a process used by a competitor exchange, which was approved by the Commission.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act[16] and Rule 19b–4(f)(6) thereunder.[17]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act.

Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NASDAQ–2018–096 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2018–096. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2018–096 and should be submitted on or before December 26, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–26270 Filed 12–3–18; 8:45 am]

BILLING CODE 8011–01–P

[14] 15 U.S.C. 78f(b).

[15] 15 U.S.C. 78f(b)(5).

[16] 15 U.S.C. 78s(b)(3)(A).

[17] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[18] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Investment Advisers Act Release No. 5068; 803–00244]

Apollo Management, L.P.

November 28, 2018.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice.

Notice of application for an exemptive order under Section 206A of the Investment Advisers Act of 1940 (the ''Act'') and Rule 206(4)–5(e).

Applicant: Apollo Management, L.P. (the ''Applicant'' or ''Adviser'').

Summary of Application: Applicant requests that the Commission issue an order under section 206A of the Act and rule 206(4)–5(e) exempting it from rule 206(4)–5(a)(1) under the Act to permit Applicant to receive compensation from certain government entities for investment advisory services provided to government entities within the two-year period following a contribution by a covered associate of the Applicant to an official of the government entities.

Filing Dates: The application was filed on January 19, 2018, and an amended and restated application was filed on August 23, 2018.

Hearing or Notification of Hearing: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving Applicant with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on December 26, 2018, and should be accompanied by proof of service on Applicant, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons may request notification of a hearing by writing to the Commission's Secretary.

ADDRESSES: Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090. Applicant: Apollo Management, L.P., 9 W 57th Street, New York, NY 10019.

FOR FURTHER INFORMATION CONTACT: Nick Cordell, Senior Counsel, or Aaron Gilbride, Branch Chief, at (202) 551–6825 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's website at *http://www.sec.gov/rules/iareleases.shtml* or by calling (202) 551–8090.

Applicant's Representations

1. Applicant is registered with the Commission as an investment adviser pursuant to the Act. Applicant acts as adviser to private funds exempt from registration under the Investment Company Act of 1940.

2. The individual who made the campaign contribution that triggered the two-year compensation ban (the ''Contribution'') is Stephanie Drescher (the ''Contributor''). The Contributor is the Global Head of Business Development & Investor Relationship Management. The Contributor supervises the team that does most of the day-to-day solicitation of government entities and other prospective investors, and personally participates in some solicitations. Applicant submits that, because the Contributor supervises and participates in the solicitation of government entities, she is, and at all relevant times was, a covered associate pursuant to rule 206(4)–5(f)(2)(i).

3. Two investors in funds advised by the Adviser, Client A and Client B, are Ohio state pension funds. The Clients are government entities as defined in Rule 206(4)–5(f)(5)(i).

4. The recipient of the Contribution was John Kasich (the ''Official''), the Governor of Ohio, in his campaign for President of the United States. The investment decisions of each Client are overseen by a board of trustees or directors (the ''Board'' or the ''Boards''), to which the Governor appoints certain members. The Applicant submits that due to the power of appointment, the Governor is an ''official'' of each Client under rule 206(4)–5.

5. The Contribution that triggered rule 206(4)–5's prohibition on compensation under rule 206(4)–5(a)(1) was made online on April 22, 2016 (''the Contribution Date'') for the amount of $1,000 to the Official's campaign for President of the United States. Applicant submits that the Contribution was not motivated by any desire to influence the award of investment advisory business and that the Contributor had no intention to seek, and no action was taken either by the Contributor or the Applicant to obtain, any direct or indirect influence from the Official or any other person. Applicant represents that the Contribution was motivated by the Contributor's belief that the Official was the candidate in the in the Republican field most in line with her views. Applicant further represents that the Contributor did not attend any campaign events for the Official and did not have any contact with the Official or the Official's campaign staff, and that she contributed to the presidential campaign of Hillary Clinton that same month. The Contributor did not solicit or coordinate any other contributions for the Official. Applicant also represents that, at the time of the Contribution, the Contributor was focused on the presidential election and forgot to pre-clear the contribution as required by the Adviser's policies and procedures. The Contributor was the only employee of the Adviser with knowledge of the Contribution prior to its discovery by the Adviser.

6. The Applicant discovered the Contribution in December 2016 during a search of the public record for political contributions. While the Applicant's compliance department noted the lack of pre-clearance as a violation of the Adviser's policy, it did not identify that the Contribution triggered a ban on compensation under rule 206(4)–5(a)(1). Media coverage of another investment adviser's application for an exemptive order related to a contribution to the Official prompted the Applicant to review its records in October 2017, at which point the Applicant identified the Contribution as triggering a ban on compensation under rule 206(4)–5(a)(1). The Contributor requested a refund of the full $1,000 and received a refund on November 9, 2017. Applicant represents that all compensation earned that is attributable to the Clients' investments since the Contribution Date has been placed in escrow pending the outcome of this Application.

7. The Applicant's Political Contributions Policy (the ''Policy'') was adopted and implemented before the proposal of rule 206(4)–5 and was further amended before the rule's implementation date. The Applicant submits that at the time of the Contribution, the Policy required, and continues to require, that all employees pre-clear all contributions (including contributions made by family members that the employee financially supports) to any person (including any election committee for any person) who was, at the time of the contribution, an incumbent, candidate, or successful candidate for federal, state, or local office. There is no *de minimis* exception from the pre-clearance requirement. Under the existing Policy, the Adviser requires employees to certify annually to their compliance with the Policy and sends quarterly reminders about the Policy and its pre-clearance

requirement. In light of changes made to the Policy after the discovery of the Contribution, future quarterly compliance alerts will highlight in the reminders that federal contributions are covered. In addition, the Adviser periodically conducts searches of public websites for contributions made by employees.

Applicant's Legal Analysis

1. Rule 206(4)–5(a)(1) under the Act prohibits a registered investment adviser from providing investment advisory services for compensation to a government entity within two years after a contribution to an official of a government entity is made by the investment adviser or any covered associate of the investment adviser. Each of the Clients is a ''government entity,'' as defined in rule 206(4)–5(f)(5), the Contributor is a ''covered associate'' as defined in rule 206(4)–5(f)(2), and the Official is an ''official'' as defined in rule 206(4)–5(f)(6).

2. Section 206A of the Act authorizes the Commission to ''conditionally or unconditionally exempt any person or transaction . . . from any provision or provisions of [the Act] or of any rule or regulation thereunder, if and to the extent that such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of [the Act].''

3. Rule 206(4)–5(e) provides that the Commission may conditionally or unconditionally grant an exemption to an investment adviser from the prohibition under rule 206(4)–5(a)(1) upon consideration of the factors listed below, among others:

(1) Whether the exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act;

(2) Whether the investment adviser: (i) Before the contribution resulting in the prohibition was made, adopted and implemented policies and procedures reasonably designed to prevent violations of the rule; and (ii) prior to or at the time the contribution which resulted in such prohibition was made, had no actual knowledge of the contribution; and (iii) after learning of the contribution: (A) Has taken all available steps to cause the contributor involved in making the contribution which resulted in such prohibition to obtain a return of the contribution; and (B) has taken such other remedial or preventive measures as may be appropriate under the circumstances;

(3) Whether, at the time of the contribution, the contributor was a covered associate or otherwise an employee of the investment adviser, or was seeking such employment;

(4) The timing and amount of the contribution which resulted in the prohibition;

(5) The nature of the election (*e.g.,* federal, state or local); and

(6) The contributor's apparent intent or motive in making the contribution which resulted in the prohibition, as evidenced by the facts and circumstances surrounding such contribution.

4. Applicant requests an order pursuant to section 206A and rule 206(4)–5(e), exempting them from the two-year prohibition on compensation imposed by rule 206(4)–5(a)(1) with respect to investment advisory services provided to the Clients within the two-year period following the Contribution.

5. Applicant submits that the exemption is necessary and appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Applicant further submits that the other factors set forth in rule 206(4)–5(e) similarly weigh in favor of granting an exemption to the Applicant to avoid consequences disproportionate to the violation.

6. Applicant contends that given the nature of the Contribution, and the lack of any evidence that the Adviser or the Contributor intended to, or actually did, interfere with any Client's merit-based process for the selection or retention of advisory services, the Clients' interests are best served by allowing the Adviser and their Clients to continue their relationship uninterrupted. Applicant states that causing the Adviser to forgo the impacted compensation attributable to the two-year period would result in a financial loss of approximately $9 million or 9,000 times the amount of the Contribution. Applicant suggests that the policy underlying rule 206(4)–5 is served by ensuring that no improper influence is exercised over investment decisions by governmental entities as a result of campaign contributions and not by withholding compensation as a result of unintentional violations.

7. Applicant represents that the Policy was adopted and published well before the Contribution Date. Applicant further represents that, the Policy has conformed to the requirements of rule 206(4)–5 and has been more rigorous than rule 206(4)–5's requirements as the Policy requires internet testing.

8. Applicant asserts that at no time did any employee or covered associate of the Adviser or any of its affiliates, other than the Contributor know of the Contribution until after it had happened.

9. Applicant asserts that after learning of the Contribution, the Adviser caused the Contributor to obtain a full refund of the Contribution. Applicant submits that in response to the contribution, the Adviser implemented enhancements to the Policy that include: (a) Requiring covered associates to certify their compliance with the Policy and report any contributions made; (b) enhancing training for employees and compliance staff; and (c) developing a written checklist-style procedures document for preclearing and reviewing contributions to prevent any future issues.

10. Applicant states that the Contributor is and has, at all relevant times, been a covered associate of the Adviser.

11. Applicant asserts that the bulk of Client A's investments predate the Contribution and that the Contributor had no direct contact with Client B. Applicant further asserts that the investment transactions with the Clients were done on an arm's length basis and the Contributor and the Applicant took no action to obtain any direct or indirect influence from the Official.

12. Applicant submits that neither the Adviser nor the Contributor sought to interfere with the Clients' merit-based selection process for advisory services, nor did they seek to negotiate higher fees or greater ancillary benefits than would be achieved in arms' length transactions. Applicant further submits that there was no violation of the Adviser's fiduciary duty to deal fairly or disclose material conflicts given the absence of any intent or action by the Adviser or the Contributor to influence the selection process. Applicant contends that in the case of the Contribution, the imposition of the two-year prohibition on compensation does not achieve rule 206(4)–5's purposes and would result in consequences disproportionate to the mistake that was made.

For the Commission, by the Division of Investment Management, under delegated authority.

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–26264 Filed 12–3–18; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–84667; File No. SR–ICEEU–2018–010]

Self-Regulatory Organizations; ICE Clear Europe Limited; Notice of Filing of Proposed Rule Change Relating to Amendments to the ICE Clear Europe CDS Risk Policy (the "CDS Risk Policy"), CDS Clearing Back-Testing Policy (the "Back-Testing Policy") and CDS Stress-Testing Policy (the "Stress-Testing Policy") (Collectively, the "CDS Policies")

November 28, 2018.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 13, 2018, ICE Clear Europe Limited (''ICE Clear Europe'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule changes described in Items I, II, and III below, which Items have been prepared by ICE Clear Europe. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

ICE Clear Europe proposes to modify and update certain provisions of its risk policies related to CDS Contracts.

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, ICE Clear Europe 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. ICE Clear Europe has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

(a) Purpose

ICE Clear Europe proposes to modify and update certain provisions of its risk policies related to CDS Contracts.

CDS Risk Policy

The proposed amendments to the CDS Risk Policy incorporate an overall Board risk appetite and limit framework, on terms consistent with other existing Clearing House policies, including the existing Stress-Testing Policy. The framework contemplates use of Board-level risk appetite statements, risk appetite metrics and management risk limits, and is subject to review at least annually.

The proposed amendments specifically address periodic reviews of margin requirements and the related margin methodology and parameters. Under the revised policy, the clearing risk department is required to perform such a review at least monthly, consistent with applicable legal requirements. The results of the monthly review will be presented by the head of first line clearing risk to the Clearing House's Model Oversight Committee (''MOC''). The head of first line clearing risk reports to the President of ICE Clear Europe and manages ICE Clear Europe's first line clearing risk team including default management, liquidity risk, market risk and counterparty risk. At the end of each quarter, the clearing risk department will share its monthly reviews from the quarter with the Risk Oversight Department (''ROD''), which performs a second-line review. The head of second line clearing risk then will present the results of this quarterly review to the MOC. The head of second line clearing risk is the Chief Risk Officer and reports to the President and the senior independent director of ICE Clear Europe. The amendments also clarify that proposed margin methodology changes resulting from the review process are presented by the clearing risk department to the Board for approval.

The amendments specify in further detail the timing of back-testing and stress-testing. Consistent with applicable law, these amendments require that: (a) ICE Clear Europe's clearing risk department conduct back-testing at least once each day using standard predetermined parameters and assumptions; and (b) ICE Clear Europe conducts sensitivity analyses of its margin models and review parameters and assumptions for back-testing on at least a monthly basis, and more frequently than monthly when the relevant products cleared or markets served display high volatility or become less liquid or when the size or concentration of positions held by Clearing Members increases or decreases significantly.

With respect to stress testing, the amendments require that the clearing risk department conduct stress-testing at least once each day using standard predetermined parameters and assumptions, which are reviewed on at least a monthly basis and more frequently when the relevant products cleared or markets served display high volatility or become less liquid or when the size or concentration of positions held by Clearing Members increases or decreases significantly.

The proposed amendments also update certain details regarding policy governance and reporting. The amendments specify that the models used to support the policy objectives of the policy are subject to an annual independent validation and governance oversight which may be performed by an independent member of the ROD or an external validator. The CDS Risk Policy owner, who is the CDS Risk Director and part of the clearing risk department, is responsible for ensuring that the policy remains up-to-date and is reviewed, with the support of the ROD. The amendments further specify the role of the clearing risk department and ROD with respect to policy adherence and the role of the Risk Working Group (''RWG'') (which consists of risk personnel of Clearing Members, and provides guidance on risk management matters, including review of margin and stress testing parameters), Trading Advisory Committee (''TAC'') (which advises on pricing processes) and MOC (which is responsible for overall model risk management of the Clearing House, and for oversight of the periodic reviews described above, as discussed further below). The policy includes further detail as to the composition and role of the RWG and MOC. The amendments also address escalation and reporting of any deviations from the policy, as well as compliance with regulatory reporting and filing requirements.

Certain changes have also been made to update references to various committees and departments of ICE Clear Europe, to correct typographical and similar errors, to update cross-references, and to remove an unnecessary reference to ICE Clear Credit.

Back-Testing Policy

The proposed amendments to the Back-Testing Policy include the risk appetite and limit framework also proposed to be included in the CDS Risk Policy, as discussed above. The amendments also include the same additional provisions relating to the timing of back-testing and related sensitivity analysis discussed above in the context of the CDS Risk Policy. In addition, the amendments clarify the meaning of certain confidence levels

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

used in the back-testing process, as levels representing the confidence to which models are expected to perform. The amendments also remove a reference to the 99% quantile used before EMIR implementation. In the guidelines relating to remediation of poor back-testing, the amendments state explicitly that portfolio back-testing is done using a confidence level of 99.5% or higher.

As with the amendments to the CDS Risk Policy, the amendments update the provisions regarding policy governance and reporting. The Back-Testing Policy specifies that the models used to support the objectives of the policy are subject to an annual independent validation and governance oversight which may be performed by an independent member of the ROD or an external validator. The Back-Testing Policy owner, who is the CDS Risk Director and part of the clearing risk department, is responsible for ensuring that it remains up-to-date and is reviewed, with the support of the ROD. The clearing risk department, with the support of the ROD, is responsible for adherence to the policy and relevant appetite metrics. The amendments also address escalation and reporting of any deviations from the policy, as well as compliance with regulatory reporting and filing requirements.

Various other changes have also been made to update references to various committees and departments of ICE Clear Europe, to correct typographical and similar errors and to update cross-references.

Stress-Testing Policy

The Stress-Testing Policy is being amended to include the same provisions relating to the timing of stress testing discussed above in the context of the CDS Risk Policy. Other changes to the Stress-Testing Policy are made to reflect the role of the Board Risk Committee, in addition to the CDS Risk Committee, in reviewing and overseeing stress-testing, in order to ensure that both committees are sufficiently informed to advise the Board on the safety and soundness of the risk management approach and to provide a mechanism for management and the committees to test the level of protection offered in potential scenarios they believe are plausible.

(b) Statutory Basis

ICE Clear Europe believes that the changes described herein are consistent with the requirements of Section 17A of the Act [3] and the regulations thereunder applicable to it. Section 17A(b)(3)(F) of the Act [4] in particular requires, among other things, that the rules of the clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions and, to the extent applicable, derivative agreements, contracts and transactions, to assure the safeguarding of securities and funds in the custody or control of the clearing agency or for which it is responsible and the protection of investors, and, in general, protect investors and the public interest. The proposed amendments are designed to modify key CDS risk management policies to state more clearly certain risk management requirements for CDS Contracts, including the timing of periodic review of margin requirements and related risk parameters, stress-testing and back-testing. The amendments also adopt various enhancements to the review and governance processes for those policies. In ICE Clear Europe's view, the amendments will enhance overall risk management of the Clearing House, and thereby promote the prompt and accurate clearance of transactions and further the public interest in sound operation of clearing agencies, within the meaning of Section 17A(b)(3)(F).[5] The amendments are not intended to effect, and are thus consistent with, the Clearing House's existing provisions relating to the safeguarding of funds and securities in the custody or control of the Clearing House or for which it is responsible, within the meaning of that section.

ICE Clear Europe also believes that the amendments are consistent with specific requirements of Rule 17Ad–22.[6] Rules 17Ad–22(e)(4)(vi)(A) [7] and (e)(6)(vi)(A) [8] require clearing agencies to implement reasonably designed policies and procedures to conduct stress-testing of their total financial resources and back-testing of their margin model at least once each day using standard predetermined parameters and assumptions. In compliance with these requirements, proposed amendments to the CDS Policies specify that ICE Clear Europe must conduct stress-testing of its total financial resources and back-testing of its margin model at least once each day using all standard predetermined parameters and assumptions.

Pursuant to Rule 17Ad–22(b)(2),[9] clearing agencies must have policies and procedures reasonably designed to review their margin models and parameters at least monthly. The proposed amendments to the CDS Risk Policy are consistent with this requirement. Rules 17Ad–22(e)(4)(vi)(B) [10] and 17Ad–22(e)(6)(vi)(B) [11] also require a clearing

[3] 15 U.S.C. 78q–1.

[4] 15 U.S.C. 78q–1(b)(3)(F).

[5] 15 U.S.C. 78q–1(b)(3)(F).

[6] 17 CFR 240.17Ad–22.

[7] 17 CFR 240.17Ad–22(e)(4)(vi)(A). The rule states that ''[e]ach covered clearing agency shall establish, implement, maintain and enforce written policies and procedures reasonably designed to, as applicable:

(4) Effectively identify, measure, monitor, and manage its credit exposures to participants and those arising from its payment, clearing, and settlement processes, including by:

(vi) Testing the sufficiency of its total financial resources available to meet the minimum financial resource requirements under paragraphs (e)(4)(i) through (iii) of this section, as applicable, by:

A. Conducting stress testing of its total financial resources once each day using standard predetermined parameters and assumptions''.

[8] 17 CFR 240.17Ad–22(e)(6)(vi)(A). The rule states that ''[e]ach covered clearing agency shall establish, implement, maintain and enforce written policies and procedures reasonably designed to, as applicable:

(6) Cover, if the covered clearing agency provides central counterparty services, its credit exposures to its participants by establishing a risk-based margin system that, at a minimum:

(vi) Is monitored by management on an ongoing basis and is regularly reviewed, tested, and verified by:

A. Conducting backtests of its margin model at least once each day using standard predetermined parameters and assumptions''.

[9] 17 CFR 240.17Ad–22(b)(2). The rule states that ''[a] registered clearing agency that performs central counterparty services shall establish, implement, maintain and enforce written policies and procedures reasonably designed to:

(2) Use margin requirements to limit its credit exposures to participants under normal market conditions and use risk-based models and parameters to set margin requirements and review such margin requirements and the related risk-based models and parameters at least monthly.''

[10] 17 CFR 240.17Ad–22(e)(4)(vi)(B). The rule states that ''[e]ach covered clearing agency shall establish, implement, maintain and enforce written policies and procedures reasonably designed to, as applicable:

(4) Effectively identify, measure, monitor, and manage its credit exposures to participants and those arising from its payment, clearing, and settlement processes, including by:

(iv) Testing the sufficiency of its total financial resources available to meet the minimum financial resource requirements under paragraphs (e)(4)(i) through (iii) of this section, as applicable, by:

B. Conducting a comprehensive analysis on at least a monthly basis of the existing stress-testing scenarios, models, and underlying parameters and assumptions, and considering modifications to ensure they are appropriate for determining the covered clearing agency's required level of default protection in light of current and evolving market conditions''.

[11] 17 CFR 240.17Ad–22(e)(6)(vi)(B). The rule states that ''[e]ach covered clearing agency shall establish, implement, maintain and enforce written policies and procedures reasonably designed to, as applicable:

(6) Cover, if the covered clearing agency provides central counterparty services, its credit exposures to its participants by establishing a risk-based margin system that, at a minimum:

(vi) Is monitored by management on an ongoing basis and is regularly reviewed, tested, and verified by:

Continued

agency to have policies and procedures reasonably designed to review its stress-testing scenarios, models, and underlying parameters and assumptions, and its parameters and assumptions for back-testing its margin model. The proposed amendments to the CDS Risk Policy, CDS Back-Testing Policy and CDS Stress Testing Policy, as discussed above, are consistent with these requirements, as they provide that reviews of the margin requirements and the parameters and assumptions relating to margin models, stress-testing and back-testing must be performed on at least a monthly basis. As a result, ICE Clear Europe believes that these amendments to the CDS Policies are in compliance with Rules 17Ad–22(b)(2),[12] 17Ad–22(e)(4)(vi)(B)[13] and 17Ad–22(e)(6)(vi)(B).[14]

Rules 17Ad–22(e)(4)(vi)(C)[15] and 17Ad–22(e)(6)(vi)(C)[16] require clearing agencies to review parameters and assumptions more frequently than monthly when the products cleared or markets served display high volatility or become less liquid or when the size or concentration of positions held by their participants increases significantly. In compliance with this requirement, the proposed amendments to the CDS Policies specifically require that reviews of parameters and assumptions underlying margin models, stress-testing and back-testing must be performed more frequently when the relevant products display high volatility or become less liquid or when the size or concentration of positions held by Clearing Members increases or decreases significantly. Further, Rules 17Ad–22(e)(4)(vi)(D)[17] and 17Ad–22(e)(6)(vi)(D)[18] require clearing agencies to report the results of the reviews conducted pursuant to Rules 17Ad–22(e)(4)(vi)(B) and (C)[19] as well as 17Ad–22(e)(6)(vi)(B) and (C)[20] to appropriate decision makers, including but not limited to the board or the risk management committee. In compliance with this requirement, as noted above, at the end of each quarter, the clearing risk department shares its monthly reviews for that quarter with the ROD which performs a second-line review and the head of second line clearing risk presents the results of its review to the MOC.

Rule 17Ad–22(b)(4)[21] requires clearing agencies to perform an annual model validation, including a performance evaluation, of their margin models and the related parameters and assumptions. Rules 17Ad–22(e)(4)(vii)[22] and 17Ad–22(e)(6)(vii),[23] also require clearing agencies to have policies and procedures in place to ensure the performance of a model validation of their credit risk models, margin system, and related models not less than annually. In compliance with these requirements, proposed amendments to the CDS Policies specifically state that the models used to support their objectives are subject to a validation that shall be performed on an annual basis by a member of the ROD or an external validator.

Rule 17Ad–22(e)(2)[24] requires clearing agencies to establish reasonably

B. Conducting a sensitivity analysis of its margin model and a review of its parameters and assumptions for backtesting on at least a monthly basis, and considering modifications to ensure the backtesting practices are appropriate for determining the adequacy of the covered clearing agency's margin resources''.

[12] 17 CFR 240.17Ad–22(b)(2).

[13] 17 CFR 240.17Ad–22(e)(4)(vi)(B).

[14] 17 CFR 240.17Ad–22(e)(6)(vi)(B).

[15] 17 CFR 240.17Ad–22(e)(4)(vi)(C). The rule states that ''[e]ach covered clearing agency shall establish, implement, maintain and enforce written policies and procedures reasonably designed to, as applicable:

(4) Effectively identify, measure, monitor, and manage its credit exposures to participants and those arising from its payment, clearing, and settlement processes, including by:

(vi) Testing the sufficiency of its total financial resources available to meet the minimum financial resource requirements under paragraphs (e)(4)(i) through (iii) of this section, as applicable, by:

C. Conducting a comprehensive analysis of stress testing scenarios, models, and underlying parameters and assumptions more frequently than monthly when the products cleared or markets served display high volatility or become less liquid, or when the size or concentration of positions held by the covered clearing agency's participants increases significantly''.

[16] 17 CFR 240.17Ad–22(e)(6)(vi)(C). The rule states that ''[e]ach covered clearing agency shall establish, implement, maintain and enforce written policies and procedures reasonably designed to, as applicable: (6) Cover, if the covered clearing agency provides central counterparty services, its credit exposures to its participants by establishing a risk-based margin system that, at a minimum:

(vi) Is monitored by management on an ongoing basis and is regularly reviewed, tested, and verified by:

C. Conducting a sensitivity analysis of its margin model and a review of its parameters and assumptions for backtesting more frequently than monthly during periods of time when the products cleared or markets served display high volatility or become less liquid, or when the size or concentration of positions held by the covered clearing agency's participants increases or decreases significantly''.

[17] 17 CFR 240.17Ad–22(e)(4)(vi)(D). The rule states that ''[e]ach covered clearing agency shall establish, implement, maintain and enforce written policies and procedures reasonably designed to, as applicable: (4) Effectively identify, measure, monitor, and manage its credit exposures to participants and those arising from its payment, clearing, and settlement processes, including by:

(vi) Testing the sufficiency of its total financial resources available to meet the minimum financial resource requirements under paragraphs (e)(4)(i) through (iii) of this section, as applicable, by:

D. Reporting the results of its analyses under paragraphs (e)(4)(vi)(B) and (C) of this section to appropriate decision makers at the covered clearing agency, including but not limited to, its risk management committee or board of directors, and using these results to evaluate the adequacy of and adjust its margin methodology, model parameters, models used to generate clearing or guaranty fund requirements, and any other relevant aspects of its credit risk management framework, in supporting compliance with the minimum financial resources requirements set forth in paragraphs (e)(4)(i) through (iii) of this section ''.

[18] 17 CFR 240.17Ad–22(e)(6)(vi)(D). The rule states that ''[e]ach covered clearing agency shall establish, implement, maintain and enforce written policies and procedures reasonably designed to, as applicable: (6) Cover, if the covered clearing agency provides central counterparty services, its credit exposures to its participants by establishing a risk-based margin system that, at a minimum:

(vi) Is monitored by management on an ongoing basis and is regularly reviewed, tested, and verified by:

D. Reporting the results of its analyses under paragraphs (e)(6)(vi)(B) and (C) of this section to appropriate decision makers at the covered clearing agency, including but not limited to, its risk management committee or board of directors, and using these results to evaluate the adequacy of and adjust its margin methodology, model parameters, and any other relevant aspects of its credit risk management framework''.

[19] 17 CFR 240.17Ad–22(e)(4)(vi)(B) and (C).

[20] 17 CFR 240.17Ad–22(e)(6)(vi)(B) and (C).

[21] 17 CFR 240.17Ad–22(b)(4). The rule states that ''[a] registered clearing agency that performs central counterparty services shall establish, implement, maintain and enforce written policies and procedures reasonably designed to:

(4) Provide for an annual model validation consisting of evaluating the performance of the clearing agency's margin models and the related parameters and assumptions associated with such models by a qualified person who is free from influence from the persons responsible for the development or operation of the models being validated''.

[22] 17 CFR 240.17Ad–22(e)(4)(vii). The rule states that ''[e]ach covered clearing agency shall establish, implement, maintain and enforce written policies and procedures reasonably designed to, as applicable:

(4) Effectively identify, measure, monitor, and manage its credit exposures to participants and those arising from its payment, clearing, and settlement processes, including by:

(vii) Performing a model validation for its credit risk models not less than annually or more frequently as may be contemplated by the covered clearing agency's risk management framework established pursuant to paragraph (e)(3) of this section.''

[23] 17 CFR 240.17Ad–22(e)(6)(vii). The rule states that ''[e]ach covered clearing agency shall establish, implement, maintain and enforce written policies and procedures reasonably designed to, as applicable: (6) Cover, if the covered clearing agency provides central counterparty services, its credit exposures to its participants by establishing a risk-based margin system that, at a minimum:

(vii) Requires a model validation for the covered clearing agency's margin system and related models to be performed not less than annually, or more frequently as may be contemplated by the covered clearing agency's risk management framework established pursuant to paragraph (e)(3) of this section''.

[24] 17 CFR 240.17 Ad–22(e)(2). The rule states that ''[e]ach covered clearing agency shall establish, implement, maintain and enforce written policies and procedures reasonably designed to, as applicable:

(2) Provide for governance arrangements that:

(i) Are clear and transparent

designed policies and procedures to provide for governance arrangements that are clear and transparent and specify clear and direct lines of responsibility. To facilitate compliance with this requirement, the proposed amendments to the CDS Policies more clearly define the roles and responsibilities of the MOC, the RWG and the TAC and other personnel with respect to ongoing review of the margin methodology, stress testing and back-testing.

(B) Clearing Agency's Statement on Burden on Competition

ICE Clear Europe does not believe the proposed rule changes would have any impact, or impose any burden, on competition not necessary or appropriate in furtherance of the purpose of the Act. The amendments to the CDS Policies apply to all CDS Contracts and are intended to strengthen risk management relating to these products. ICE Clear Europe does not believe the amendments will have any direct effect on Clearing Members, other market participants or the market for cleared products generally. As a result, ICE Clear Europe does not believe the amendments will materially affect the cost of, or access to, clearing. To the extent the amendments may have an impact on margin levels, ICE Clear Europe believes such changes will be appropriate in furtherance of the risk management of the Clearing House. Therefore, ICE Clear Europe does not believe the proposed rule changes impose any burden on competition that is inappropriate in furtherance of the purposes of the Act.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments relating to the proposed rule changes have not been solicited or received. ICE Clear Europe will notify the Commission of any written comments received by ICE Clear Europe.

(ii) Clearly prioritize the safety and efficiency of the covered clearing agency;

(iii) Support the public interest requirements in Section 17A of the Act (15 U.S.C. 78q–1) applicable to clearing agencies, and the objectives of owners and participants;

(iv) Establish that the board of directors and senior management have appropriate experience and skills to discharge their duties and responsibilities;

(v) Specify clear and direct lines of responsibility; and

(vi) Consider the interests of participants' customers, securities issuers and holders, and other relevant stakeholders of the covered clearing agency''.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove the proposed rule change or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*) or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–ICEEU–2018–010 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–ICEEU–2018–010. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filings will also be available for inspection and copying at the principal office of ICE Clear Europe and on ICE Clear Europe's website at *https://www.theice.com/clear-europe/regulation.* 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–ICEEU–2018–010 and should be submitted on or before December 26, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[25]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–26266 Filed 12–3–18; 8:45 am]

BILLING CODE 8011–01–P

[25] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meetings

TIME AND DATE: 2:00 p.m. on Thursday, December 6, 2018.

PLACE: The meeting will be held at the Commission's headquarters, 100 F Street NE, Washington, DC 20549.

STATUS: This meeting will be closed to the public.

MATTERS TO BE CONSIDERED: Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the closed meeting. Certain staff members who have an interest in the matters also may be present.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(3), (5), (6), (7), (8), 9(B) and (10) and 17 CFR 200.402(a)(3), (a)(5), (a)(6), (a)(7), (a)(8), (a)(9)(ii) and (a)(10), permit consideration of the scheduled matters at the closed meeting.

Commissioner Roisman, as duty officer, voted to consider the items listed for the closed meeting in closed session.

The subject matters of the closed meeting will be:

Institution and settlement of injunctive actions;

Institution and settlement of administrative proceedings;

Resolution of litigation claims; and

Other matters relating to enforcement proceedings.

At times, changes in Commission priorities require alterations in the scheduling of meeting items.

CONTACT PERSON FOR MORE INFORMATION: For further information and to ascertain what, if any, matters have been added, deleted or postponed; please contact Brent J. Fields from the Office of the Secretary at (202) 551–5400.

Dated: November 29, 2018.

Brent J. Fields,

Secretary.

[FR Doc. 2018–26402 Filed 11–30–18; 11:15 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:

Rule 17g–4, SEC File No. 270–566, OMB Control No. 3235–0627

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (''PRA''), the Securities and Exchange Commission (''Commission'') is soliciting comments on the existing collection of information provided for in Rule 17g–4 (17 CFR 240.17g–4) under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*) (''Exchange Act''). The Commission plans to submit this existing collection of information to the Office of Management and Budget (''OMB'') for extension and approval.

The Credit Rating Agency Reform Act of 2006 added a new section 15E, ''Registration of Nationally Recognized Statistical Rating Organizations,'' [1] to the Exchange Act. Pursuant to the authority granted under section 15E of the Exchange Act, the Commission adopted Rule 17g–4, which requires that a nationally recognized statistical rating organization (''NRSRO'') establish, maintain, and enforce written policies and procedures to prevent the misuse of material nonpublic information, including policies and procedures reasonably designed to prevent: (a) The inappropriate dissemination of material nonpublic information obtained in connection with the performance of credit rating services; (b) a person within the NRSRO from trading on material nonpublic information; and (c) the inappropriate dissemination of a pending credit rating action.[2]

There are 10 credit rating agencies registered with the Commission as NRSROs under section 15E of the Exchange Act, which have already established the policies and procedures required by Rule 17g–4. Based on staff experience, an NRSRO is estimated to spend an average of approximately 10 hours per year reviewing its policies and procedures regarding material nonpublic information and updating them (if necessary), resulting in an average industry-wide annual hour burden of approximately 100 hours.[3]

Written comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's estimates of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information on respondents; 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 in writing within 60 days of this publication.

The Commission may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

Please direct your written comments to: Charles Riddle, Acting Chief Information Officer, Securities and Exchange Commission, c/o Candace Kenner, 100 F St NE, Washington, DC 20549 or send an email to: *PRA_Mailbox@sec.gov*.

Dated: November 28, 2018.

Eduardo Aleman,

Assistant Secretary.

[FR Doc. 2018–26326 Filed 12–3–18; 8:45 am]

BILLING CODE 8011–01–P

[1] 15 U.S.C. 78o–7.

[2] *See* 17 CFR 240.17g–4; Release No. 34–55231 (Feb. 2, 2007), 72 FR 6378 (Feb. 9, 2007); Release No. 34–55857 (June 5, 2007), 72 FR 33564 (June 18, 2007).

[3] 10 currently registered NRSROs × 10 hours = 100 hours.

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–84669; File No. SR–ICEEU–2018–018]

Self-Regulatory Organizations; ICE Clear Europe Limited; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change, Relating to Amendments to Futures and Options Risk Procedures (the ''F&O Risk Procedures'') [1]

November 28, 2018.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on November 16, 2018, ICE Clear Europe Limited (''ICE Clear Europe'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule changes described in Items I, II, and III below, which Items have been prepared primarily by ICE Clear Europe. ICE Clear Europe filed the proposed rule changes pursuant to Section 19(b)(3)(A) of the Act [4] and Rule 19b–4(f)(4)(ii) thereunder,[5] so that the proposal was immediately effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

ICE Clear Europe proposes to make certain amendments to the F&O Risk Procedures to enhance monitoring and addressing potential uncollateralized exposure to Clearing Members during overnight hours.

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, ICE Clear Europe 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. ICE Clear Europe has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

[1] Capitalized terms used but not defined herein have the meanings specified in the ICE Clear Europe Clearing Rules (the ''Rules'').

[2] 15 U.S.C. 78s(b)(1).

[3] 17 CFR 240.19b–4.

[4] 15 U.S.C. 78s(b)(3)(A).

[5] 17 CFR 240.19b–4(f)(4)(ii).

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

(a) Purpose

ICE Clear Europe is amending its F&O Risk Procedures to enhance certain procedures for monitoring and addressing potential uncollateralized exposure to Clearing Members during overnight hours. The amendments supplement certain enhancements to intraday margining that the Clearing House has recently implemented.[6]

The proposed amendments apply to F&O Contracts that are margined using a one-business day margin period of risk.[7] The revised procedures contemplate that the Clearing House can make margin calls outside of the standard margin hours (specifically, before 7:30 and after 20:00 London time), but recognize that Clearing Members may have reduced operational capabilities to provide additional margin during those times. The amended policy sets out procedures under which uncollateralized exposures for such contracts will be monitored by the Credit Risk Department (''CRD'') overnight. Pursuant to the proposed amendments, the CRD monitors margin exposures in near real time and senior CRD team members are alerted if Clearing Member exposures breach the margin threshold. The senior CRD person will decide whether to issue a margin call or require the Clearing Member to take other risk reducing actions, taking into account factors such as the particular member, its known operational capabilities and those of its APS bank, the product, market circumstances and the type and materiality of the exposure. If such Clearing Member cannot be contacted, does not reduce its positions or does not meet a margin call, the senior CRD person will further escalate to ICEU's President (or delegate) and together decide on an appropriate response, which may include temporarily accepting the risk, suspending the relevant account or holding the Clearing Member in default. If ICEU's President or delegate cannot be contacted, then the senior CRD person shall make the decision. Relevant regulators will be contacted should ICEU decide to hold a Clearing Member in default.

The amendments also clarify the applicability of a specified overnight buffer to contracts using a one-day margin period of risk, and removes a reference to the buffer amount being locked at end of day (in light of the overnight monitoring procedures discussed above). Certain other typographical corrections and similar clarifications are also made.

(b) Statutory Basis

ICE Clear Europe believes that the proposed amendments are consistent with the requirements of Section 17A of the Act[8] and the regulations thereunder applicable to it, including the standards under Rule 17Ad–22.[9] Section 17A(b)(3)(F) of the Act[10] requires, among other things, that the rules of a clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions and, to the extent applicable, derivative agreements, contracts, and transactions, to assure the safeguarding of securities and funds in the custody or control of the clearing agency or for which it is responsible, and the protection of investors and the public interest. As discussed above, the proposed amendments to the F&O Risk Procedures are intended to enhance ICE Clear Europe's ability to monitor and limit its exposure to Clearing Members during overnight trading hours. This will facilitate the Clearing House's ability to manage risk generally, and therefore promote the prompt and accurate clearance and settlement of transactions, and further the public interest in the sound operation of clearing agencies. (The amendments should not affect the safeguarding of securities or funds in the custody or control of the Clearing House or for which it is responsible.) As a result, in ICE Clear Europe's view, the amendments are consistent with the requirements of Section 17A(b)(3)(F) of the Act.

The amendments are also consistent with relevant requirements of Rule 17Ad–22 regarding margin and credit risk management.[11] Rule 17Ad–22(b)(1) and (2)[12] in particular require that ICE Clear Europe measure its credit exposure at least once per day and use margin requirements to limit its exposures to participants under normal market conditions. Consistent with these requirements, the proposed amendments facilitate additional measurement of credit exposures during overnight trading hours and to collect margin or take other action if appropriate to reduce its credit risk to Clearing Members. The proposed amendments are also consistent with Rule 17Ad–22(e)(4)(i),[13] as the additional ability to conduct overnight margining will help the Clearing House maintain sufficient financial resources to cover its credit exposures to Clearing Members. Rule 17Ad–22(e)(6)(ii)[14] requires that clearing agencies have sufficient operational capacity to make intraday margin calls in defined circumstances and extending ICE Clear Europe's ability to make such margin calls or to take other action, as appropriate in the circumstances, into the overnight period facilitates compliance with this requirement.

[6] See Exchange Act Release No. 34–84375 (SR–ICEEU–2018–012), 83 FR 51715 (Oct. 12, 2018).

[7] Such contracts are generally F&O energy contracts. The amendments are intended to be consistent with certain additional risk management requirements that apply to such contracts under European Market Infrastructure Regulation (EMIR) implementing regulations, specifically Article 26(1)(c) of Commission Delegated Regulation (EU) No. 153/2013 of 19 December 2012 supplementing Regulation (EU) No. 648/2012 of the European Parliament and of the Council with regard to regulatory technical standards on requirements for central counterparties, as amended by Commission Delegated Regulation (EU) 2016/822 of 21 April 2016 as regards the time horizons for the liquidation period to be considered for the different classes of financial instruments.

[8] 15 U.S.C. 78q–1.

[9] 17 CFR 240.17Ad–22.

[10] 15 U.S.C. 78q–1(b)(3)(F).

[11] 17 CFR 240.17Ad–22.

[12] 17 CFR 240.17Ad–22(b)(1) and (2). The rule states that: [a] registered clearing agency that performs central counterparty services shall establish, implement, maintain and enforce written policies and procedures reasonably designed to:

(1) Measure its credit exposures to its participants at least once a day and limit its exposures to potential losses from defaults by its participants under normal market conditions so that the operations of the clearing agency would not be disrupted and non-defaulting participants would not be exposed to losses that they cannot anticipate or control.

(2) Use margin requirements to limit its credit exposures to participants under normal market conditions and use risk-based models and parameters to set margin requirements and review such margin requirements and the related risk-based models and parameters at least monthly.''

[13] 17 CFR 240.17Ad–22(e)(4)(i). The rule states that: ''[e]ach covered clearing agency shall establish, implement, maintain and enforce written policies and procedures reasonably designed to, as applicable: (4) Effectively identify, measure, monitor, and manage its credit exposures to participants and those arising from its payment, clearing, and settlement processes, including by: (i) Maintaining sufficient financial resources to cover its credit exposure to each participant fully with a high degree of confidence;''

[14] 17 CFR 240.17Ad–22(e)(6) which states that ''[e]ach covered clearing agency shall establish, implement, maintain and enforce written policies and procedures reasonably designed to, as applicable: (6) Cover, if the covered clearing agency provides central counterparty services, its credit exposures to its participants by establishing a risk-based margin system that, at a minimum:

(ii) Marks participant positions to market and collects margin, including variation margin or equivalent charges if relevant, at least daily and includes the authority and operational capacity to make intraday margin calls in defined circumstances;''

(B) Clearing Agency's Statement on Burden on Competition

ICE Clear Europe does not believe the proposed rule changes would have any impact, or impose any burden, on competition not necessary or appropriate in furtherance of the purposes of the Act. The changes are being proposed in order to enhance ICE Clear Europe's ability to limit its credit exposure during overnight trading hours. The amendments will apply to all F&O Clearing Members that trade contracts in the relevant category. ICE Clear Europe does not believe the amendments will generally affect the overall cost of clearing for F&O Clearing Members or other market participants or otherwise affect access to clearing generally. The amendments may require F&O Clearing Members to post margin, or take other action, outside of the standard margin call window, but such changes are designed to better manage Clearing House risk and are tailored to the risks presented by such F&O Clearing Members and the positions they carry. As a result, any additional burdens placed on F&O Clearing Members will be appropriate in furtherance of enhancing risk management, and are not intended to disadvantage any particular Clearing Member. As a result, ICE Clear Europe believes that any impact on competition is appropriate in furtherance of the purposes of the Act.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments relating to the proposed amendments have not been solicited or received by ICE Clear Europe. ICE Clear Europe will notify the Commission of any comments received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and paragraph (f) of Rule 19b–4 thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*) or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–ICEEU–2018–018 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–ICEEU–2018–018. 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 that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filings will also be available for inspection and copying at the principal office of ICE Clear Europe and on ICE Clear Europe's website at *https://www.theice.com/clear-europe/regulation#rule-filing.*

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–ICEEU–2018–018 and should be submitted on or before December 26, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

Eduardo Aleman,

Assistant Secretary.

[FR Doc. 2018–26268 Filed 12–3–18; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–84673; File No. SR–NYSEAMER–2018–50]

Self-Regulatory Organizations; NYSE American LLC; Notice of Filing and Immediate Effectiveness of Proposed Change To Amend Certain of Its Listing Fees

November 28, 2018.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the ''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on November 21, 2018, NYSE American LLC (the ''Exchange'' or ''NYSE American'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend certain of its listing fees. The proposed change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

[15] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C.78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Section 141 of the NYSE American Company Guide to amend certain of its listing fee provisions. The amended fees will take effect in the 2019 calendar year. The following are the proposed fee increases:

- The annual fee for a common stock with 50 million shares or less outstanding would increase from $40,000 to $45,000.
- The annual fee for a common stock with more than 50 million and up to 75 million shares outstanding would increase from $50,000 to $60,000.
- The annual fee for a common stock with more than 75 million shares outstanding would increase from $60,000 to $70,000.

As described below, the Exchange proposes to make the aforementioned fee increases to better reflect the Exchange's costs related to listing equity securities and the corresponding value of such listing to issuers.

The Exchange also proposes to remove a number of references in Section 141 to fees that are no longer applicable as they were superseded by new fee rates specified in the rule text.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[4] in general, and furthers the objectives of Section 6(b)(4)[5] of the Act, in particular, in that it is designed to provide for the equitable allocation of reasonable dues, fees, and other charges. The Exchange also believes that the proposed rule change is consistent with Section 6(b)(5) of the Act,[6] in that it is designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that it represents an equitable allocation of reasonable fees to increase the various listing fees as set forth above because of the increased costs incurred by the Exchange since it established the current rates. In that regard, the Exchange notes that its general costs have increased since its most recent fee adjustments, including due to price inflation. In addition, the Exchange continues to improve and increase the services it provides to listed companies. These improvements include the continued development and enhancement of an interactive web-based platform designed to improve communication between the Exchange and listed companies, the availability to listed companies of the Exchange's new state-of-the-art conference facilities at 11 Wall Street, and continued development of an investor relations tool available to all listed companies which provides companies with information enabling them to better understand the trading and ownership of their securities and the cost of providing content for inclusion in that tool.

The above fee changes are not unfairly discriminatory because the same fee schedule will apply to all listed issuers. Further, the Exchange operates in a competitive environment and its fees are constrained by competition in the marketplace. Other venues currently list all of the categories of securities covered by the proposed fees and if a company believes that the Exchange's fees are unreasonable it can decide either not to list its securities or to list them on an alternative venue.

The proposed removal of text relating to fees that are no longer applicable is ministerial in nature and has no substantive effect.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is designed to ensure that the fees charged by the Exchange accurately reflect the services provided and benefits realized by listed companies. The market for listing services is extremely competitive. Each listing exchange has a different fee schedule that applies to issuers seeking to list securities on its exchange. Issuers have the option to list their securities on these alternative venues based on the fees charged and the value provided by each listing. Because issuers have a choice to list their securities on a different national securities exchange, the Exchange does not believe that the proposed fee changes impose a burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A)[7] of the Act and subparagraph (f)(2) of Rule 19b–4[8] thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[9] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEAMER–2018–50 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEAMER–2018–50. 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

[4] 15 U.S.C. 78f(b).

[5] 15 U.S.C. 78f(b)(4).

[6] 15 U.S.C. 78f(b)(5).

[7] 15 U.S.C. 78s(b)(3)(A).

[8] 17 CFR 240.19b–4(f)(2).

[9] 15 U.S.C. 78s(b)(2)(B).

internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEAMER–2018–50 and should be submitted on or before December 26, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[10]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–26272 Filed 12–3–18; 8:45 am]

BILLING CODE 8011–01–P

[10] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–84670; File No. SR–BatsBZX–2017–34]

Self-Regulatory Organizations; Bats BZX Exchange, Inc.; Notice of Filing of Amendment No. 2 To Proposed Rule Change To Introduce Cboe Market Close, a Closing Match Process for Non-BZX Listed Securities Under New Exchange Rule 11.28

November 28, 2018.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Exchange Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 4, 2018, the Bats BZX Exchange, Inc. (now known as Cboe BZX Exchange, Inc.) (''BZX'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') Amendment No. 2 to the proposed rule change as described in Item I below, which Item has been prepared by the Exchange and is reproduced below verbatim in Section I.

The proposed rule change seeks to adopt Cboe Market Close, a closing match process for non-BZX Listed Securities. On January 17, 2018, after consideration of the record for the proposed rule change, the Division of Trading and Markets, pursuant to delegated authority,[3] approved the proposed rule change, as modified by Amendment No. 1 (''Approval Order'').[4] On January 31, 2018, pursuant to Commission Rule of Practice 430,[5] NYSE Group, Inc. (''NYSE'') and The Nasdaq Stock Market LLC (''Nasdaq'') each filed petitions for review of the Approval Order. Pursuant to Commission Rule of Practice 431(e), the Approval Order is stayed by the filing with the Commission of a notice of intention to petition for review.[6] On March 1, 2018, the Commission issued a scheduling order, pursuant to Commission Rule of Practice 431, granting the petitions for review of the Approval Order and providing until March 22, 2018 for any party or other person to file a written statement in support of or in opposition to the Approval Order.[7] In statements filed with the Commission, two parties stated, among other arguments, that Cboe Market Close would cause BZX to violate Rule 201 of Regulation SHO.[8] BZX subsequently filed Amendment No. 2 to the proposed rule change to address this comment. Because of this change, the Commission is publishing this notice to solicit comments on the proposed rule change, as amended, from interested persons.

I. Amendment No. 2 to SR–BatsBZX–2017–34

Cboe BZX Exchange, Inc. (''BZX'' or the ''Exchange'') is filing this Partial Amendment No. 2 to SR–BatsBZX–2017–34, which was originally filed with the Securities and Exchange Commission (the ''Commission'') on May 5, 2017 (the ''Proposal''). The Proposal was published for comment in the **Federal Register** on May 22, 2017, and approved by the Division of Trading and Markets pursuant to delegated authority on January 17, 2018.[9] On January 24, 2018, the Commission stayed the Proposal,[10] and the Proposal is currently pending Commission review.

The Proposal seeks to introduce the Cboe Market Close, an innovative closing match process for non-BZX Listed Securities that is designed to match buy and sell Market-On-Close (''MOC'') orders at the official closing price for such security published by the primary listing market. The Exchange proposed the Cboe Market Close in response to interest from market participants, particularly buy-side firms, who seek an alternative to participation on the primary listing market's closing auction while still receiving an execution at the official closing price. The Exchange continues to believe that the proposed functionality promotes the maintenance of a free and open market because it would increase competition for order flow at the close, which is highly concentrated at the primary listing markets today, without impacting price discovery.

The purpose of this amendment is to amend the Proposal at Interpretations and Policies .04 to BZX Rule 11.28, which would be a new rule that provides for the handling of short sale MOC orders that are designated for participation in the Cboe Market Close. Specifically, the Exchange proposes to reject short sale MOC orders entered pursuant to BZX Rule 11.28 in order to comply with its obligations under Rule 201 of Regulation SHO.[11] MOC orders marked short exempt are not subject to the short sale circuit breaker restrictions under Regulation SHO, and would

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 17 CFR 200.30 3(a)(12).

[4] *See* Exchange Act Release No. 82522, 83 FR 3205 (January 23, 2018).

[5] 17 CFR 201.430.

[6] 17 CFR 201.431(e). *See* Letter from Secretary of the Commission to Christopher Solgan, Assistant General Counsel, Cboe Global Markets, Inc., dated January 24, 2018 (providing notice of receipt of notices of intention to petition for review of delegated action and stay of order), available at *https://www.sec.gov/rules/sro/batsbzx/2018/sr-batsbzx-2017-34-letter-from-secretary-to-cboe.pdf.*

[7] *See* Exchange Act Release No. 82794, 83 FR 9561 (March 6, 2018). On March 16, 2018, the Office of Secretary, acting by delegated authority, issued an order on behalf of the Commission granting a motion for an extension of time to file statements on or before April 12, 2018. *See* Exchange Act Release No. 82896, 83 FR 12633 (Mar. 22, 2018).

[8] *See* NYSE Statement in Opposition to the Division's Order Approving a Rule to Introduce Cboe Market Close, at 31–34 (April 12, 2018); Statement of the Nasdaq Stock Market LLC in Opposition to Order Granting Approval of a Proposed Rule Change, as Modified by Amendment No. 1, to Introduce Cboe Market Close, at 26 (April 12, 2018).

[9] *See* Securities Exchange Act Release Nos. 80683 (May 16, 2017), 82 FR 23320 (May 22, 2017) (Notice); 82522 (January 7, 2018), 83 FR 3205 (January 23, 2017) (Approval Order) (SR-BatsBZX–2017–34).

[10] *See* Letter from Secretary of the Commission to Christopher Solgan, Assistant General Counsel, Cboe Global Markets, Inc., dated January 24, 2018.

[11] 17 CFR 242.201.

therefore be accepted for participation in the Cboe Market Close.

19b–4 and Exhibit 1 Changes

1. *The Exchange proposes to add the following sentences to the purpose section of the Proposal at the end of the first paragraph on page 8 of the 19b–4 and page 21 of the Exhibit 1:*

All short sale MOC orders designated for participation in the Cboe Market Close must be identified as ''short'' or ''short exempt'' pursuant to Exchange Rule 11.19(a).[12] MOC orders marked short will be rejected so as to maintain compliance with the Exchange's obligations under Rule 201 of Regulation SHO in the event a short sale circuit breaker is triggered and the official closing price determined by the primary listing market is not above the national best bid. MOC orders marked short exempt, which are not subject to short sale circuit breaker restrictions under Regulation SHO, will be accepted and processed in accordance with the proposed rules.

2. *The Exchange proposes to add the following paragraphs to the basis section of the Proposal immediately prior to the Exchange's statement on burden on competition on page 14 of the 19b–4 and page 28 of the Exhibit 1:*

The Exchange also believes that the proposed language relating to short sale handling is consistent with the Act and the rules and regulations thereunder. Rules 201(b)(1)(i) and (ii) of Regulation SHO generally require that trading centers such as the Exchange establish, maintain, and enforce written policies and procedures reasonably designed to: (i) Prevent the execution or display of a short sale order of a covered security at a price that is less than or equal to the current national best bid (''price restriction'') if the price of that covered security decreases by 10% or more from the covered security's closing price;[13] and (ii) impose this price restriction for the remainder of the day and the following day.[14]

The Cboe Market Close contemplates the pairing of MOC orders at the MOC Cut-Off Time of 3:35 p.m. ET, and the ultimate execution of those orders at the official closing price determined by the closing auction of the primary listing market at 4:00 p.m. ET. As a result, it is possible that a short sale MOC order paired at the MOC Cut-off Time would not be eligible for execution at the ultimate execution price determined by the primary listing market when the closing auction is conducted. Should a short sale circuit breaker be triggered due to a 10% decline in the price of the security from the previous day's closing price, a short sale MOC order executed at 4 p.m. ET would be required to be executed above the national best bid. MOC orders paired in the Cboe Market Close, however, are entitled to an execution at the official closing price, which may be lower than, equal to, or above the national best bid. Thus, it is possible that the eventual execution of a short sale MOC order at 4 p.m. ET may violate the requirements of Rule 201(b)(1). Specifically, it would be a violation of Regulation SHO to execute a short sale MOC order at the official closing price if a short sale circuit breaker is triggered, either before or after the MOC Cut-off Time, and the official closing price is less than or equal to the national best bid.

To prevent this result and maintain compliance with Rule 201 of Regulation SHO, the Exchange is proposing to reject all short sale MOC orders that are designated for participation in the Cboe Market Close. Rejecting short sale MOC orders will ensure that the Exchange is able to execute the MOC orders that are accepted and paired at the MOC Cut-off Time as contemplated by the Cboe Market Close. Furthermore, rejecting these orders would ensure that market participants are provided an opportunity to enter any short interest on the primary listing market, which may be able to re-price such interest to a permitted price if a short sale circuit breaker has been triggered.[15] The Exchange therefore believes that the proposed handling of short sale MOC orders is consistent with the protection of investors and the public interest.

In addition, Rule 201(b)(1)(iii)(B) of Regulation SHO provides that the Rule 201 policies and procedures described above must be reasonably designed to permit the execution or display of a short sale order of a covered security marked ''short exempt'' without regard to whether the order is at a price that is less than or equal to the current national best bid. As a result, MOC orders marked short exempt are not subject to the short sale price restrictions of Regulation SHO, and may be executed without regard to whether such execution is at a price that is less than or equal to the current national best bid. The Exchange therefore proposes to provide that orders marked short exempt will be accepted by the System. The Exchange will pair and execute these orders in the same manner as other MOC orders designated for participation in the Cboe Market Close.

II. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change, as amended, is consistent with the Exchange 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–BatsBZX–2017–34 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR-BatsBZX–2017–34. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal offices of the Exchange. All comments received will be posted without change.

Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish

[12] Exchange Rule 11.19(a) provides that all short sale orders shall be identified as ''short'' or ''short exempt'' when entered into the System.

[13] The closing price is as determined by the listing market for the covered security as of the end of regular trading hours on the prior day.

[14] This price restriction applies when a national best bid for the covered security is calculated and disseminated on a current and continuing basis by a plan processor pursuant to an effective national market system plan.

[15] *See e.g.,* New York Stock Exchange LLC Rule 7.16(f)(5)(A), which permits the re-pricing of short sale orders during the duration of the short sale circuit breaker.

to make available publicly. All submissions should refer to File Number SR–BatsBZX–2017–34, and should be submitted on or before December 26, 2018.

By the Commission.

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–26269 Filed 12–3–18; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–84668; File No. SR–BX–2018–057]

Self-Regulatory Organizations; Nasdaq BX, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Exchange's Transaction Fees at Equity 7, Section 118

November 28, 2018.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 16, 2018, Nasdaq BX, Inc. (''BX'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Exchange's transaction fees at Equity 7, Section 118 to: (i) Eliminate a fee assessed for displayed orders; (ii) adopt a new fee for displayed orders; (iii) adopt a new fee for non-displayed orders; and (iv) adopt a Qualified Market Maker Program and a related fee.

The text of the proposed rule change is available on the Exchange's website at *http://nasdaqbx.cchwallstreet.com/,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend the Exchange's transaction fees at Equity 7, Section 118 to: (i) Eliminate a fee assessed for displayed orders; (ii) adopt a new fee for displayed orders; (iii) adopt a new fee for non-displayed orders; and (iv) adopt a Qualified Market Maker Program and a related fee.[3]

First Change

The purpose of the first change is to eliminate a $0.0018 per share executed fee assessed for displayed orders. To qualify for the current fee, a member must add liquidity equal to or exceeding the member's Growth Target. The Growth Target is the liquidity the member added in January 2017 as a percent of total Consolidated Volume[4] plus 0.04% of total Consolidated Volume. The fee tier has not provided adequate incentive to attract liquidity to the Exchange. Accordingly, the Exchange is proposing to eliminate the fee.

Second Change

The purpose of the second change is to adopt a new $0.0016 per share executed fee assessed for displayed orders. To qualify for the proposed fee, a member must add liquidity equal to or exceeding 0.06% of total Consolidated Volume during a month, and remove liquidity equal to or exceeding 0.40% of total Consolidated Volume during a month. The proposed new fee is similar to existing fees assessed for displayed orders, which require a certain level of total Consolidated Volume added during a month to qualify; however, the proposed new fee will also include a qualification requirement that a member remove a certain level of total Consolidated Volume during the month.

Third Change

The purpose of the third change is to adopt a new $0.0020 per share executed fee for non-displayed orders (other than orders with Midpoint pegging). To qualify for the proposed fee, a member must meet the Qualified Market Maker Program qualification criteria and add 0.10% of total Consolidated Volume of non-displayed liquidity. The proposed new fee is similar to the certain existing fees assessed for non-displayed orders, which requires a certain level of total Consolidated Volume added during a month to qualify; however, the proposed new fee will also include a qualification requirement that a member also qualify for the Qualified Market Maker Program. The Qualified Market Maker Program, which is being proposed herein and is discussed immediately below, will require a member to provide market-improving behavior in the form of quoting and provision of total Consolidated Volume.

Fourth Change

The purpose of the fourth change is to adopt a Qualified Market Maker (''QMM'') Program and a related fee. A QMM is a member that makes a significant contribution to market quality by providing liquidity at the national best bid and offer (''NBBO'') in a large number of securities for a significant portion of the day. A QMM may be, but is not required to be, a registered market maker in any security; thus, the QMM designation does not by itself impose a two-sided quotation obligation or convey any of the benefits associated with being a registered market maker. The designation will, however, reflect the QMM's commitment to provide meaningful and consistent support to market quality and price discovery by extensive quoting at the NBBO in a large number of securities. Thus, the program is designed to attract liquidity both from traditional market makers and from other firms that are willing to commit capital to support liquidity at the NBBO. In return for providing the required contribution of market-improving liquidity, a QMM will be assessed a lower rate for executions of displayed

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The Exchange initially filed the proposed pricing changes on November 1, 2018 (SR–BX–2018–053). On November 6, 2018, the Exchange withdrew that filing and replaced it with SR–BX–2018–054, which corrected a description of the quoting obligation under the QMM Program rule and made a technical correction to the purpose discussion. On November 16, 2018, the Exchange withdrew SR–BX–2018–054 and submitted this filing, which makes technical changes and provides further description of the QMM Program.

[4] The term ''Consolidated Volume'' shall mean the total consolidated volume reported to all consolidated transaction reporting plans by all exchanges and trade reporting facilities during a month in equity securities, excluding executed orders with a size of less than one round lot. For purposes of calculating Consolidated Volume and the extent of a member's trading activity the date of the annual reconstitution of the Russell Investments Indexes shall be excluded from both total Consolidated Volume and the member's trading activity. *See* Equity 7, Section 118.

orders in securities priced at $1 or more per share that provide liquidity on the Exchange System. Through the use of this incentive, the Exchange hopes to provide improved trading conditions for all market participants through narrower bid-ask spreads and increased depth of liquidity available at the inside market. In addition, the program reflects an effort to use financial incentives to encourage a wider variety of members to make positive commitments to promote market quality.

To be designated as a QMM, a member must quote at the NBBO at least 25% of the time during regular market hours in an average of at least 400 securities per day during a month, and provide add volume of at least 0.125% of total Consolidated Volume during the month. In return for its contributions, the Exchange will assess a lower rate for executions of displayed orders in securities priced at $1 or more per share that provide liquidity on the Exchange System. Specifically, the Exchange is proposing to charge a fee of $0.0016 per share executed with respect to all displayed orders in securities priced at $1 or more per share that provide liquidity.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[5] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[6] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Commission and the courts have repeatedly expressed their preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, while adopting a series of steps to improve the current market model, the Commission highlighted the importance of market forces in determining prices and revenues of self-regulatory organizations and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [7]

Likewise, in *NetCoalition* v. *Securities and Exchange Commission* [8] (''NetCoalition'') the D.C. Circuit upheld the Commission's use of a market-based approach in evaluating the fairness of market data fees against a challenge claiming that Congress mandated a cost-based approach.[9] As the court emphasized, the Commission ''intended in Regulation NMS that 'market forces, rather than regulatory requirements' play a role in determining the market data . . . to be made available to investors and at what cost.'' [10]

Further, ''[n]o one disputes that competition for order flow is 'fierce.' . . . As the SEC explained, '[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their order-routing agents, have a wide range of choices of where to route orders for execution'; [and] 'no exchange can afford to take its market share percentages for granted' because 'no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers'. . . .'' [11]

First Change

The Exchange believes that elimination of the $0.0018 per share executed fee assessed for displayed orders that provide liquidity is reasonable because the Exchange continues to provide similar fees to members that meet the qualification criteria required to receive the fee. In this regard, the Exchange will provide four fee tiers ranging from $0.0017 per share executed to $0.0013 per share executed. For example, the Exchange assesses a fee of $0.0017 per share executed for displayed orders entered by a member that adds liquidity equal to or exceeding 0.15% of total Consolidated Volume during a month. Thus, members will continue to have opportunities to receive fees lower than the $0.0018 per share executed fee that is being eliminated.

The Exchange believes that elimination of the $0.0018 per share executed fee assessed for displayed orders is an equitable allocation and is not unfairly discriminatory because the fee has not significantly provided incentive to market participants to provide the required level of total Consolidated Volume to receive the fee, and consequently the Exchange believes that it should eliminate the fee. The Exchange notes that it continues to provide opportunities to its members to qualify for fees lower than the $0.0018 per share executed fee assessed for displayed orders that provide liquidity.

Second Change

The Exchange believes that the proposed $0.0016 per share executed fee is reasonable because it is similar to the fees currently assessed by the Exchange for displayed orders that provide liquidity. As noted above, the Exchange provides other fee tiers for displayed orders ranging from $0.0017 per share executed to $0.0013 per share executed. For example, the Exchange assesses a fee of $0.0017 per share executed for displayed orders entered by a member that adds liquidity equal to or exceeding 0.15% of total Consolidated Volume during a month. The proposed fee will provide another opportunity to members to receive a similar fee in return for certain levels of participation on the Exchange as measured by total Consolidated Volume.

The Exchange believes that the proposed $0.0016 per share executed fee is an equitable allocation and is not unfairly discriminatory because the Exchange will apply the same fee to all similarly situated members. To qualify for the new fee, a member must provide certain minimum levels of total Consolidated Volume in both transactions that add and remove liquidity. The qualification criteria ensure that members qualifying for this fee are meaningfully participating on the Exchange in a given month. The Exchange notes that any member may qualify for the proposed fee if it meets the levels of total Consolidated Volume required by the fee's qualification criteria. Thus, the Exchange believes that this additional new fee provides all of its members with choice and flexibility, and is therefore an equitable allocation and not unfairly discriminatory.

Third Change

The Exchange believes that the proposed $0.0020 per share executed fee for non-displayed orders that provide liquidity (other than orders with Midpoint pegging) is reasonable because it is similar to other fees that the Exchange assesses for non-displayed liquidity. For example, the Exchange currently assesses a fee of $0.0024 per share executed for non-displayed orders (other than orders with Midpoint pegging) entered by a member that adds 0.06% of total Consolidated Volume of non-displayed liquidity. The Exchange assesses a fee of $0.0030 per share

[5] 15 U.S.C. 78f(b).

[6] 15 U.S.C. 78f(b)(4) and (5).

[7] Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (''Regulation NMS Adopting Release'').

[8] *NetCoalition* v. *SEC,* 615 F.3d 525 (D.C. Cir. 2010).

[9] *See NetCoalition,* at 534–535.

[10] *Id.* at 537.

[11] *Id.* at 539 (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782–83 (December 9, 2008) (SR–NYSEArca–2006–21)).

executed for all other non-displayed orders.[12] The proposed fee will provide members with an opportunity to receive a lower fee for execution of their non-displayed orders. As a consequence, the Exchange believes that the proposed fee is reasonable.

The Exchange believes that the proposed $0.0020 per share executed fee for non-displayed orders (other than orders with Midpoint pegging) is an equitable allocation and is not unfairly discriminatory because the Exchange will apply the same fee to all similarly situated members. Similar to the existing $0.0024 per share executed fee for non-displayed orders (other than orders with Midpoint pegging), the proposed new fee requires that a member provide a certain level of total Consolidated Volume of non-displayed liquidity added. In addition to total Consolidated Volume, the proposed new fee also requires that a member qualify as a QMM under the proposed QMM Program, which requires that a member both quotes at the NBBO at least 25% of the time during regular market hours in an average of at least 400 securities per day during the month, and provides add volume of at least 0.125% total Consolidated Volume. Thus, not only must a member provide a certain level of total Consolidated Volume in non-displayed liquidity added, but it also must provide a certain level of total Consolidated Volume in both displayed and non-displayed liquidity added and quoting activity at the NBBO. The Exchange notes that any member may qualify as a QMM, and in turn also qualify for the proposed non-displayed fee, if the member chooses to provide the levels of liquidity and quoting at the NBBO required by the QMM Program and new fee qualification criteria. As a consequence, the Exchange believes that the proposed fee is an equitable allocation and not unfairly discriminatory.

Fourth Change

The Exchange believes that the proposed $0.0016 per share executed fee of the QMM Program for displayed orders that provide liquidity is reasonable because it is similar to other fees assessed by the Exchange for displayed orders that provide liquidity. In addition to the proposed $0.0016 per share executed fee described above, the Exchange also has other fee tiers for displayed orders ranging from $0.0017 per share executed to $0.0013 per share executed. For example, the Exchange assesses a fee of $0.0017 per share executed for displayed orders entered by a member that adds liquidity equal to or exceeding 0.15% of total Consolidated Volume during a month. The proposed fee will provide another opportunity to members to be assessed a similar fee in return for certain levels of participation on the Exchange as measured by total Consolidated Volume. Unlike other fees currently assessed for displayed orders, the proposed QMM Program fee also requires a significant level of quoting at the NBBO. Thus, the proposed fee is set at a level that is reflective of the beneficial contributions of market participants that quote significantly at the NBBO and provide significant liquidity.

The Exchange believes that the proposed $0.0016 per share executed fee and qualification criteria of the QMM Program are an equitable allocation and are not unfairly discriminatory because the Exchange will apply the same fee to all similarly situated members. Moreover, the proposed qualification criteria requires a member to provide a certain level of total Consolidated Volume in both displayed and non-displayed liquidity added and to quote significantly at the NBBO. Any member may provide the level of total Consolidated Volume and quote at the NBBO at the levels required by the qualification criteria of the QMM Program. Similar to the other current fee qualification criteria, the QMM Program requires a member to provide a certain level of total Consolidated Volume to qualify. Unlike other current fee qualification criteria, the proposed QMM Program requires a member to quote at the NBBO at least 25% of the time during regular market hours in an average of at least 400 securities per day during the month. The Exchange notes that Nasdaq also has a QMM Program, in which Nasdaq members are required to quote at the NBBO at least 25% of the time during regular market hours.[13] In contrast to the Exchange's proposal, Nasdaq requires a member to quote at the NBBO in an average of at least 1,000 securities per day during the month. The Exchange believes that a lower requirement of 400 securities per day during the month is appropriate given the smaller size and volumes of the Exchange in comparison to Nasdaq. For these reasons, the Exchange believes that the proposed QMM Program fee and qualification criteria are an equitable allocation and are not unfairly discriminatory.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. In terms of inter-market competition, the Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive or rebate opportunities available at other venues to be more favorable. In such an environment, the Exchange must continually adjust its fees to remain competitive with other exchanges and with alternative trading systems that have been exempted from compliance with the statutory standards applicable to exchanges. Because competitors are free to modify their own fees in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited.

In this instance, the proposed changes to the fees assessed members for execution of all securities priced at $1 or more per share that it trades do not impose a burden on competition because the Exchange's execution services are completely voluntary and subject to extensive competition both from other exchanges and from off-exchange venues. The proposed new fees provide opportunities to members to receive lower fees for transactions in both displayed and non-displayed orders. The fees are designed to provide incentive to members to improve the market by requiring certain levels of total Consolidated Volume to qualify for the fees. Similarly, the QMM Program fee provides members the opportunity to be assessed lower fees for transactions if they improve the market by providing both significant total Consolidated Volume and quoting at the NBBO meaningfully in a large number of securities. In sum, the proposed changes are designed to make the Exchange a more desirable venue on which to transact; however, if the changes proposed herein are unattractive to market participants, it is likely that the Exchange will lose market share as a result. Accordingly, the Exchange does not believe that the proposed changes will impair the ability of members or competing order execution venues to maintain their competitive standing in the financial markets.

[12] The Exchange also assesses fees less than $0.0030 per share executed for orders with Midpoint pegging, which are non-displayed orders, if the member meets certain qualification criteria. *See* Equity 7, Section 118(a).

[13] *See* Nasdaq Rule 7014(d)(2).

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[14]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml);* or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–BX–2018–057 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number *SR–BX–2018–057.* This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number *SR–BX–2018–057* and should be submitted on or before December 26, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–26267 Filed 12–3–18; 8:45 am]

BILLING CODE 8011–01–P

[14] 15 U.S.C. 78s(b)(3)(A)(ii).

[15] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–84674; File No. SR–BX–2018–058]

Self-Regulatory Organizations; Nasdaq BX, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 4756(c)(2)

November 28, 2018.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 16, 2018, Nasdaq BX, Inc. (''BX'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to allow the Exchange to aggregate Displayed odd-lot Orders across price levels for transmission to network processors as the Exchange's best priced Order under Rule 4756(c)(2). While these amendments are effective upon filing, the Exchange has designated the proposed amendments to be operative in the first quarter of 2019, and will announce the precise date by Equity Trader Alert at least thirty days prior to implementation.

The text of the proposed rule change is available on the Exchange's website at *http://nasdaqbx.cchwallstreet.com/,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange is proposing to amend Rule 4756 to allow the Exchange to aggregate Displayed [3] odd-lot Orders across price levels for transmission to network processors as the Exchange's best ranked Displayed Order(s), which is based on how NYSE Arca, Inc. handles such orders pursuant to NYSE Arca Rule 7.36–E(b)(3).[4] Rule 4756 concerns entry and display of Quotes [5]

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Display is an Order Attribute that allows the price and size of an Order to be displayed to market participants via market data feeds. Certain Order Types may be non-displayed if they are not assigned a Display Order Attribute, and all non-displayed Orders may be referred to as ''Non-Displayed Orders'' (*See* Rule 4703(b)(3)(A) [sic]). In contrast, an Order with a Display Order Attribute may be referred to as a ''Displayed Order.'' *See* Rule 4703(k).

[4] *See* Securities Exchange Act Release No. 74796 (April 23, 2015), 80 FR 23838 (April 29, 2015) (SR–NYSEArca–2015–08).

[5] The term ''Quote'' means a single bid or offer quotation submitted to the System by a Market Maker or Equities Electronic Communications Network and designated for display (price and size) next to the Participant's Market Participant Identifier in the Exchange Book. Quotes are entered in the form of Orders with Attribution (as defined in Rule 4703). Accordingly, all Quotes are also Orders. *See* Rule 4701(d).

and Orders,[6] and paragraph (c) thereunder provides how the System[7] will display Quotes and Orders submitted to the System. Rule 4756(c)(2), which the Exchange is proposing to amend, describes what the Exchange transmits to the network processors as the Exchange's best priced Order. Specifically, Rule 4756(c)(2) provides that, for each System Security,[8] the aggregate size of all Quotes and Orders at the best price to buy and sell resident in the System will be transmitted for display to the appropriate network processor, unless the aggregate size is less than one round lot, in which case the aggregate size will be displayed in the System Book Feed[9] but not be transmitted to a network processor.[10] Thus, pursuant to Rule 4756(c)(2) Orders with an aggregate size of less than one round lot at a particular price level are displayed in the System Book Feed, but are not transmitted to a network processor. For example, if the Exchange best bid is $10.00, and there are the following three odd-lot Orders resting displayed on the Exchange Book with no other interest resting on the Exchange Book—25 shares to buy at $10.00, 25 shares to buy at $9.99, and 50 shares to buy at $9.98—the System will not transmit any of these Orders to the appropriate processor, but rather will post them to the System Book Feed.[11]

The Exchange is proposing to amend Rule 4756(c)(2) to allow the Exchange to aggregate odd-lot sized Displayed Orders at multiple price points that equal at least a round lot for purposes of transmitting the Exchange's best ranked Displayed Order(s) to the appropriate processor. In assigning a price to such aggregated odd-lot Orders, the Exchange would use the highest (lowest) price to buy (sell) wherein the aggregate size of all displayed buy (sell) interest in the System greater (less) than or equal to that price is one round lot or greater. Consequently, because the aggregated Displayed odd-lot Orders represent the best price available on the Exchange, they would be transmitted to the network processor as such. Using the example above, all three odd-lot Orders resting displayed on the Exchange Book would be aggregated into a round lot Order and reported to the appropriate processor for quoting at a price of $9.98.[12] The Exchange is proposing to amend Rule 4756(c)(2) to add four new subparagraphs to the rule, which provide that the Exchange will transmit to the appropriate processor the highest (lowest) price to buy (sell) wherein the aggregate size of all displayed buy (sell) interest in the System greater (less) than or equal to that price is one round lot or greater, and that the aggregate size of all displayed buy (sell) interest in the System greater (less) than or equal to that price will be transmitted rounded down to the nearest round lot.[13]

The Exchange is also proposing to make clarifying changes to Rule 4756(c)(2). Currently, the rule does not note that the obligation to report the highest (lowest) aggregate Displayed interest to buy (sell) arises from Rule 602 of Regulation NMS. The Exchange is amending the rule to affirmatively state that the transmission to the appropriate network processor is done pursuant to Rule 602 of Regulation NMS. The Exchange is also deleting the text concerning the display in the System Book Feed of all Quotes and Orders at the best price to buy and sell resident in the System that are less than one round lot. The Exchange believes that this text is redundant of paragraph (1) of Rule 4756(c) and serves no purpose under the clarified rule. The Exchange notes that the clarifying changes do not alter how it currently handles Quotes and Orders for display and trade reporting.

The Exchange plans to implement the change proposed herein in the first quarter of 2019, and will announce the precise date by Equity Trader Alert at least thirty days prior to implementation.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[14] in general, and furthers the objectives of Section 6(b)(5) of the Act,[15] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest, because the proposed change would remove impediments to and perfect the mechanism of a free and open market and a national market system by allowing the Exchange to aggregate odd lot Orders across multiple price levels for purposes of determining the Exchange's best ranked Displayed Order(s) for transmission to the appropriate network processor. The proposed change will provide market participants with greater visibility into liquidity available on the Exchange via the appropriate network processor. Because arriving marketable contra-side Orders execute in price-time priority against resting odd-lot Orders priced better than resting round-lot Orders, the Exchange believes that it is appropriate to display such odd-lot interest on the public data feeds as the Exchange's best bid or offer if in the aggregate, they equal a round lot or more. The Exchange further believes that aggregating such odd-lot Orders at the highest (lowest) price to buy (sell) wherein the aggregate size of all buy (sell) interest in the System greater (less) than or equal to that price is one round lot or greater would remove impediments to and perfect the mechanism of a free and open market because it represents the best aggregated execution price for incoming sell (buy) Orders. The Exchange notes that the incoming marketable interest would receive price improvement when executing against any odd-lot orders priced better than the aggregated displayed price. Last, the

[6] The term ''Order'' means an instruction to trade a specified number of shares in a specified System Security submitted to the System by a Participant. An ''Order Type'' is a standardized set of instructions associated with an Order that define how it will behave with respect to pricing, execution, and/or posting to the Exchange Book when submitted to the System. An ''Order Attribute'' is a further set of variable instructions that may be associated with an Order to further define how it will behave with respect to pricing, execution, and/or posting to the Exchange Book when submitted to the System. The available Order Types and Order Attributes, and the Order Attributes that may be associated with particular Order Types, are described in Rules 4702 and 4703. One or more Order Attributes may be assigned to a single Order; provided, however, that if the use of multiple Order Attributes would provide contradictory instructions to an Order, the System will reject the Order or remove non-conforming Order Attributes. *See* Rule 4701(e).

[7] The term ''Nasdaq BX Equities Market'' or ''System'' shall mean the automated system for order execution and trade reporting owned and operated by the Exchange. *See* Rule 4701(a).

[8] The term ''System Securities'' shall mean any NMS stock, as defined in SEC Rule 600 except securities specifically excluded from trading via a list of excluded securities posted on *www.nasdaqtrader.com. See* Rule 4701(b).

[9] The term ''System Book Feed'' shall mean a data feed for System Securities, generally known as the BX TotalView ITCH feed. *See* Rule 4701(l).

[10] Consequently, the Exchange currently will aggregate and transmit to the network processor odd-lot Orders at a particular price level if such Orders aggregate to at least one round lot and are priced better than the best-priced round lot interest on the Exchange Book.

[11] The Exchange notes that the network processors only accept quotations in round lots. As a consequence, if aggregated Orders do not equal a round lot the Exchange will round down to the nearest round lot for purposes of reporting to the appropriate network processor. This proposal does not change this process.

[12] The Exchange notes that it is not proposing to change how it processes Orders for execution. Thus, Orders resting on the Exchange Book will be executed in price/display/time priority pursuant to Rule 4757.

[13] *Supra* note 10 [sic].

[14] 15 U.S.C. 78f(b).

[15] 15 U.S.C. 78f(b)(5).

Exchange believes that the proposed clarifying changes will help promote a better understanding of the operation of the rule. As noted above, the clarifying changes do not alter how the Exchange currently handles Quotes and Orders for display and trade reporting.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. As noted above, the Exchange is copying functionality that is currently in use by a competitor exchange. The proposed change may increase the Exchange's position at the National Best Bid and Offer, thus allowing the Exchange to receive greater Order flow and, consequently, executions. This is the same benefit that the competitor exchange has received since adopting the process proposed herein. Thus, the proposed change is a competitive response, but does not place any burden on competition because it is copying a process used by a competitor exchange, which was approved by the Commission.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act [16] and Rule 19b–4(f)(6) thereunder.[17]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule–comments@sec.gov.* Please include File Number SR–BX–2018–058 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–BX–2018–058. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–BX–2018–058 and should be submitted on or before December 26, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

Eduardo A. Aleman,

Assistant Secretary.

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[16] 15 U.S.C. 78s(b)(3)(A).

[17] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[18] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–84672; File No. SR–Phlx–2018–75]

Self-Regulatory Organizations; Nasdaq PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 3306(c)(2)

November 28, 2018.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 16, 2018, Nasdaq PHLX LLC (''Phlx'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to allow the Exchange to aggregate Displayed odd-lot Orders across price levels for transmission to network processors as the Exchange's best priced Order under Rule 3306(c)(2). While these amendments are effective upon filing, the Exchange has designated the proposed amendments to be operative in the first quarter of 2019, and will announce the precise date by Equity Trader Alert at least thirty days prior to implementation.

The text of the proposed rule change is available on the Exchange's website at *http://nasdaqphlx.cchwallstreet.com/,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange is proposing to amend Rule 3306 to allow the Exchange to aggregate Displayed [3] odd-lot Orders across price levels for transmission to network processors as the Exchange's best ranked Displayed Order(s), which is based on how NYSE Arca, Inc. handles such orders pursuant to NYSE Arca Rule 7.36–E(b)(3).[4] Rule 3306 concerns entry and display of Quotes [5] and Orders,[6] and paragraph (c) thereunder provides how the System [7] will display Quotes and Orders submitted to the System. Rule 3306(c)(2), which the Exchange is proposing to amend, describes what the Exchange transmits to the network processors as the Exchange's best priced Order. Specifically, Rule 3306(c)(2) provides that, for each System Security,[8] the aggregate size of all Quotes and Orders at the best price to buy and sell resident in the System will be transmitted for display to the appropriate network processor, unless the aggregate size is less than one round lot, in which case the aggregate size will be displayed in the System Book Feed [9] but not be transmitted to a network processor.[10] Thus, pursuant to Rule 3306(c)(2) Orders with an aggregate size of less than one round lot at a particular price level are displayed in the System Book Feed, but are not transmitted to a network processor. For example, if the Exchange best bid is $10.00, and there are the following three odd-lot Orders resting displayed on the PSX Book with no other interest resting on the PSX Book—25 shares to buy at $10.00, 25 shares to buy at $9.99, and 50 shares to buy at $9.98—the System will not transmit any of these Orders to the appropriate processor, but rather will post them to the System Book Feed.[11]

The Exchange is proposing to amend Rule 3306(c)(2) to allow the Exchange to aggregate odd-lot sized Displayed Orders at multiple price points that equal at least a round lot for purposes of transmitting the Exchange's best ranked Displayed Order(s) to the appropriate processor. In assigning a price to such aggregated odd-lot Orders, the Exchange would use the highest (lowest) price to buy (sell) wherein the aggregate size of all displayed buy (sell) interest in the System greater (less) than or equal to that price is one round lot or greater. Consequently, because the aggregated Displayed odd-lot Orders represent the best price available on the Exchange, they would be transmitted to the network processor as such. Using the example above, all three odd-lot Orders resting displayed on the PSX Book would be aggregated into a round lot Order and reported to the appropriate processor for quoting at a price of $9.98.[12] The Exchange is proposing to amend Rule 3306(c)(2) to add four new subparagraphs to the rule, which provide that the Exchange will transmit to the appropriate processor the highest (lowest) price to buy (sell) wherein the aggregate size of all displayed buy (sell) interest in the System greater (less) than or equal to that price is one round lot or greater, and that the aggregate size of all displayed buy (sell) interest in the System greater (less) than or equal to that price will be transmitted rounded down to the nearest round lot.[13]

The Exchange is also proposing to make clarifying changes to Rule 3306(c)(2). Currently, the rule does not note that the obligation to report the highest (lowest) aggregate Displayed interest to buy (sell) arises from Rule 602 of Regulation NMS. The Exchange is amending the rule to affirmatively state that the transmission to the appropriate network processor is done pursuant to Rule 602 of Regulation NMS. The Exchange is also deleting the text concerning the display in the System Book Feed of all Quotes and Orders at the best price to buy and sell resident in the System that are less than one round lot. The Exchange believes that this text is redundant of paragraph (1) of Rule 3306(c) and serves no purpose under the clarified rule. The Exchange notes that the clarifying changes do not alter how it currently handles Quotes and Orders for display and trade reporting.

The Exchange plans to implement the change proposed herein in the first quarter of 2019, and will announce the precise date by Equity Trader Alert at least thirty days prior to implementation.

[3] Display is an Order Attribute that allows the price and size of an Order to be displayed to market participants via market data feeds. Certain Order Types may be non-displayed if they are not assigned a Display Order Attribute, and all non-displayed Orders may be referred to as ''Non-Displayed Orders'' (*See* Rule 3301A(b)(3)(A)). In contrast, an Order with a Display Order Attribute may be referred to as a ''Displayed Order.'' *See* Rule 3301B(k).

[4] *See* Securities Exchange Act Release No. 74796 (April 23, 2015), 80 FR 23838 (April 29, 2015) (SR–NYSEArca–2015–08).

[5] The term ''Quote'' means a single bid or offer quotation submitted to the System by a Market Maker or Equities Electronic Communications Network and designated for display (price and size) next to the Participant's Market Participant Identifier in the PSX Book. Quotes are entered in the form of Orders with Attribution (as defined in Rule 3301B). Accordingly, all Quotes are also Orders. *See* Rule 3301(d).

[6] The term ''Order'' means an instruction to trade a specified number of shares in a specified System Security submitted to the System by a Participant. An ''Order Type'' is a standardized set of instructions associated with an Order that define how it will behave with respect to pricing, execution, and/or posting to the PSX Book when submitted to the System. An ''Order Attribute'' is a further set of variable instructions that may be associated with an Order to further define how it will behave with respect to pricing, execution, and/or posting to the PSX Book when submitted to the System. The available Order Types and Order Attributes, and the Order Attributes that may be associated with particular Order Types, are described in Rules 3301A and 3301B. One or more Order Attributes may be assigned to a single Order; provided, however, that if the use of multiple Order Attributes would provide contradictory instructions to an Order, the System will reject the Order or remove non-conforming Order Attributes. *See* Rule 3301(e).

[7] The term ''PSX'' or ''System'' shall mean the automated system for order execution and trade reporting owned and operated by the Exchange. *See* Rule 3301(a).

[8] The term ''System Securities'' shall mean any NMS stock, as defined in SEC Rule 600 except securities specifically excluded from trading via a list of excluded securities posted on *www.nasdaqtrader.com. See* Rule 3301(b).

[9] The term ''System Book Feed'' shall mean a data feed for System Securities, generally known as the PSX TotalView ITCH feed. *See* Rule 3301(l).

[10] Consequently, the Exchange currently will aggregate and transmit to the network processor odd-lot Orders at a particular price level if such Orders aggregate to at least one round lot and are priced better than the best-priced round lot interest on the PSX Book.

[11] The Exchange notes that the network processors only accept quotations in round lots. As a consequence, if aggregated Orders do not equal a round lot the Exchange will round down to the nearest round lot for purposes of reporting to the appropriate network processor. This proposal does not change this process.

[12] The Exchange notes that it is not proposing to change how it processes Orders for execution. System Orders are executed in accordance with one of two execution algorithms: Price/Time or Pro Rata. *See* Rule 3307. Thus, Orders resting on the Exchange Book will be executed pursuant to the price/time execution algorithm or pro rata execution algorithm consistent with Rule 3307. Likewise, the algorithm used for execution does not affect what is provided to the network processor as the Exchange's best priced Order.

[13] *Supra* note 10 [sic].

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[14] in general, and furthers the objectives of Section 6(b)(5) of the Act,[15] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest, because the proposed change would remove impediments to and perfect the mechanism of a free and open market and a national market system by allowing the Exchange to aggregate odd lot Orders across multiple price levels for purposes of determining the Exchange's best ranked Displayed Order(s) for transmission to the appropriate network processor. The proposed change will provide market participants with greater visibility into liquidity available on the Exchange via the appropriate network processor. Because arriving marketable contra-side Orders execute in price-time priority or pro-rata priority against resting odd-lot Orders priced better than resting round-lot Orders, the Exchange believes that it is appropriate to display such odd-lot interest on the public data feeds as the Exchange's best bid or offer if in the aggregate, they equal a round lot or more. The Exchange further believes that aggregating such odd-lot Orders at the highest (lowest) price to buy (sell) wherein the aggregate size of all buy (sell) interest in the System greater (less) than or equal to that price is one round lot or greater would remove impediments to and perfect the mechanism of a free and open market because it represents the best aggregated execution price for incoming sell (buy) Orders. The Exchange notes that the incoming marketable interest would receive price improvement when executing against any odd-lot orders priced better than the aggregated displayed price. Last, the Exchange believes that the proposed clarifying changes will help promote a better understanding of the operation of the rule. As noted above, the clarifying changes do not alter how the Exchange currently handles Quotes and Orders for display and trade reporting.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. As noted above, the Exchange is copying functionality that is currently in use by a competitor exchange. The proposed change may increase the Exchange's position at the National Best Bid and Offer, thus allowing the Exchange to receive greater Order flow and, consequently, executions. This is the same benefit that the competitor exchange has received since adopting the process proposed herein. Thus, the proposed change is a competitive response, but does not place any burden on competition because it is copying a process used by a competitor exchange, which was approved by the Commission.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act [16] and Rule 19b–4(f)(6) thereunder.[17]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–Phlx–2018–75 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–Phlx–2018–75. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–Phlx–2018–75 and should be submitted on or before December 26, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–26271 Filed 12–3–18; 8:45 am]

BILLING CODE 8011–01–P

[14] 15 U.S.C. 78f(b).

[15] 15 U.S.C. 78f(b)(5).

[16] 15 U.S.C. 78s(b)(3)(A).

[17] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[18] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meeting

TIME AND DATE: Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Public Law 94–409, that the Securities and Exchange Commission staff will hold a Municipal Securities Disclosure Conference on Thursday, December 6, 2018, beginning at 9:30 a.m. ET.

PLACE: The meeting will be held in the Auditorium, Room L–002, at the Commission's headquarters, 100 F Street NE, Washington, DC 20549.

STATUS: The conference will begin at 9:30 a.m. ET and will be open to the public. Seating will be on a first-come, first-served basis. Doors will open at 8:00 a.m. Visitors will be subject to security checks. The conference will be webcast on the Commission's website at *www.sec.gov.*

MATTERS TO BE CONSIDERED: The agenda for the conference will include topics related to municipal securities disclosure. Panelists will include industry experts, regulators and issuers. Panelists will be discussing topics such as financial distress and municipal securities disclosure, lessons from municipal disclosure enforcement cases, developments in disclosure technology and the future of municipal securities disclosure. This Sunshine Act notice is being issued because a majority of the Commission may attend the conference.

CONTACT PERSON FOR MORE INFORMATION: For further information, please contact Brent J. Fields from the Office of the Secretary at (202) 551–5400.

Dated: November 29, 2018.

Brent J. Fields,

Secretary.

[FR Doc. 2018–26401 Filed 11–30–18; 11:15 am]

BILLING CODE 8011–01–P

DEPARTMENT OF STATE

[Public Notice: 10622]

Notice of Public Meeting

The Department of State will conduct an open meeting at 1:00 p.m. on Wednesday, January 16, 2019, in Room 5J16–15 of the Douglas A. Munro Coast Guard Headquarters Building at St. Elizabeth's, 2703 Martin Luther King Jr. Avenue SE, Washington, DC 20593. The primary purpose of the meeting is to prepare for the sixth session of the International Maritime Organization's (IMO) Sub-Committee on Ship Design and Construction to be held at the IMO headquarters, London, United Kingdom, February 4–8, 2019.

The agenda items to be considered include:

—Adoption of the agenda
—Decisions of other bodies
—Revised SOLAS regulation II–1/3–8 and associated guidelines (MSC.1/Circ.1175) and new guidelines for safe mooring operations for all ships
—Review SOLAS chapter II–1, parts B–2 to B–4, to ensure consistency with parts B and B–1 with regard to watertight integrity
—Finalization of second generation intact stability criteria
—Mandatory instrument and/or provisions addressing safety standards for the carriage of more than 12 industrial personnel on board vessels engaged on international voyages
—Amendments to the 2011 ESP Code
—Safety measures for non-SOLAS ships operating in polar waters
—Unified interpretation to provisions of IMO safety, security, and environment-related Conventions
—Biennial status report and provisional agenda for SDC 6
—Election of Chairman and Vice-Chairman for 2019
—Any other business
—Report to the Maritime Safety Committee

Members of the public may attend this meeting up to the seating capacity of the room. Upon request to the meeting coordinator, members of the public may also participate via teleconference, up to the capacity of the teleconference phone line. To access the teleconference line, participants should call (202) 475–4000 and use Participant Code: 887 809 72. To facilitate the building security process, and to request reasonable accommodation, those who plan to attend should contact the meeting coordinator, LT Jonathan Duffett, by email at *Jonathan.B.Duffett@uscg.mil,* or by phone at (202) 372–1022, or in writing at 2703 Martin Luther King Jr. Ave. SE, Stop 7509, Washington DC 20593–7509 not later than January 9, 2019, seven days prior to the meeting. Requests made after January 9, 2019 might not be able to be accommodated. Please note that due to security considerations, two valid, government issued photo identifications must be presented to gain entrance to the Coast Guard Headquarters building. The building is accessible by taxi, public transportation, and privately owned conveyance (upon request). In the case of inclement weather where the U.S. Government is closed or delayed, a public meeting may be conducted virtually by calling (202) 475–4000 or 1–855–475–2447, Participant code: 887 809 72. The meeting coordinator will confirm whether the virtual public meeting will be utilized. Members of the public can find out whether the U.S. Government is delayed or closed by visiting *www.opm.gov/status/.*

Joel C. Coito,

Coast Guard Liaison Officer, Office of Ocean and Polar Affairs, Department of State.

[FR Doc. 2018–26336 Filed 12–3–18; 8:45 am]

BILLING CODE 4710–09–P

DEPARTMENT OF STATE

[Public Notice: 10626]

Notice of Determinations; Culturally Significant Objects Imported for Exhibition—Determinations: ''Lucio Fontana: On the Threshold'' Exhibition

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that certain objects to be included in the exhibition ''Lucio Fontana: On the Threshold,'' imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to loan agreements with the foreign owners or custodians. I also determine that the exhibition or display of the exhibit objects at The Metropolitan Museum of Art, New York, New York, from on or about January 21, 2019, until on or about April 14, 2019, and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Elliot Chiu, Attorney-Adviser, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing address is U.S. Department of State, L/PD, SA–5, Suite 5H03, Washington, DC 20522–0505.

SUPPLEMENTARY INFORMATION: The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), E.O. 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28,

2000, and Delegation of Authority No. 236–19 of November 16, 2018.

Jennifer Z. Galt,

Principal Deputy Assistant Secretary for Educational and Cultural Affairs, Department of State.

[FR Doc. 2018–26407 Filed 12–3–18; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Agency Information Collection Activities: Requests for Comments; Clearance of Renewed Approval of Information Collection: Training and Qualification Requirements for Check Airmen and Flight Instructors

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval for [a new or to renew an] information collection. The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on September 19, 2018. The information collected is used to allow some experienced pilots who would otherwise qualify as flight instructors or check airmen, but who are not medically eligible to hold the requisite medical certificate, to perform flight instructor or check airmen functions.

DATES: Written comments should be submitted by January 3, 2019.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the attention of the Desk Officer, Department of Transportation/FAA, and sent via electronic mail to *oira_submission@omb.eop.gov,* or faxed to (202) 395–6974, or mailed to the Office of Information and Regulatory Affairs, Office of Management and Budget, Docket Library, Room 10102, 725 17th Street NW, Washington, DC 20503.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

FOR FURTHER INFORMATION CONTACT: Barbara Hall at (940) 594–5913, or by email at: *Barbara.L.Hall@faa.gov.*

SUPPLEMENTARY INFORMATION:

OMB Control Number: 2120–0600.

Title: Training and Qualification Requirements for Check Airmen and Flight Instructors.

Form Numbers: There are no forms associated with this collection of information.

Type of Review: Renewal of an information collection.

Background: The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on September 19, 2018 (83 FR 47398). Under the authority of Title 49 CFR, Section 44701, Title 14 CFR prescribes the terms, conditions, and limitations as are necessary to ensure safety in air transportation. Federal Aviation Regulations (FAR) parts 121.411(d), 121.412(d), 135.337(d), and 135.338(d) require the collection of this data. This collection is necessary to insure that instructors and check airmen have completed necessary training and checking required to perform instructor and check airmen functions.

Respondents: There are approximately 3,100 check airmen and flight instructors.

Frequency: Information is collected on occasion.

Estimated Average Burden per Response: 15 seconds.

Estimated Total Annual Burden: 12.5 hours.

Issued in Washington, DC, on November 29, 2018.

Barbara Hall,

FAA Information Collection Clearance Officer, IT Enterprises Business Services Division, ASP–110.

[FR Doc. 2018–26329 Filed 12–3–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2012–0091]

Petition for Waiver of Compliance

Under part 211 of Title 49 Code of Federal Regulations (CFR), this document provides the public notice that by a letter dated November 20, 2018, CSX Transportation, Inc. (CSX) petitioned the Federal Railroad Administration (FRA) to include CSX in a waiver of compliance from certain provisions of the Federal railroad safety regulations contained at 49 CFR part 232, *Brake System Safety Standards for Freight and Other Non-Passenger Trains and Equipment.* FRA assigned the petition Docket Number FRA–2012–0091.

Specifically, CSX seeks relief with respect to the application of 49 CFR 232.205(c)(1)—*Class I brake test-initial terminal inspection* and § 232.207(b)(1)—*Class IA brake tests-1,000-mile inspection* for trains operating in distributive power mode. CSX requests to extend the maximum allowable brake pipe air flow from the present regulatory limit of 60 cubic feet per minute (CFM) to 90 CFM for distributed power-equipped trains under specified operating conditions.

On March 26, 2013, FRA granted a pilot test waiver to the BNSF Railway Company for these same provisions. Canadian National Railway and Canadian Pacific Railway were added as parties to the test waiver on November 21, 2014, and Union Pacific Railroad was added on March 4, 2015. On May 3, 2017, FRA granted a change in status from a test waiver to a waiver of compliance. CSX is petitioning FRA to make CSX a party to the same waiver. If granted, CSX states it would agree to comply with the same conditions as set forth in FRA's May 3, 2017 letter.

A copy of the petition, as well as any written communications concerning the petition, is available for review online at *www.regulations.gov* and in person at the U.S. Department of Transportation's (DOT) Docket Operations Facility, 1200 New Jersey Avenue SE, W12–140, Washington, DC 20590. The Docket Operations Facility is open from 9 a.m. to 5 p.m., Monday through Friday, except Federal Holidays.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested parties desire an opportunity for oral comment and a public hearing, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number and may be submitted by any of the following methods:

• *Website: http://www.regulations.gov*. Follow the online instructions for submitting comments.

• *Fax:* 202–493–2251.

• *Mail:* Docket Operations Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE, W12–140, Washington, DC 20590.

• *Hand Delivery:* 1200 New Jersey Avenue SE, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

Communications received by January 3, 2019 will be considered by FRA before final action is taken. Comments received after that date will be considered if practicable.

Anyone can search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). Under 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its processes. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *https://www.transportation.gov/privacy.* See also *https://www.regulations.gov/privacyNotice* for the privacy notice of *regulations.gov*.

Issued in Washington, DC.

Robert C. Lauby,

Associate Administrator for Railroad Safety, Chief Safety Officer.

[FR Doc. 2018–26293 Filed 12–3–18; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2018–0075]

Petition for Waiver of Compliance

Under part 211 of Title 49 of the Code of Federal Regulations (CFR), this provides the public notice that on September 26, 2018, CSX Transportation (CSX) petitioned the Federal Railroad Administration (FRA) for a waiver of compliance from certain provisions of the Federal railroad safety regulations contained at 49 CFR part 232, *Brake System Safety Standards for Freight and Other Non-Passenger Trains and Equipment; End of Train Devices.* Specifically, CSX requests relief for certain trains from the requirements of § 232.205, *Class I brake test-initial terminal inspection,* and § 232.207, *Class IA brake tests—1,000-mile inspection*. FRA assigned the request docket number FRA–2018–0075.

CSX requests an extension of the mileage limits for certain trains listed in Attachment A of its petition from 1,000 miles, as specified in §§ 232.205 and 232.207, to (up to) 1,052 miles. CSX also requests that qualified persons (instead of qualified mechanical inspectors) be allowed to inspect these trains, and that these trains be allowed to make multiple pick-ups and set-outs. CSX states that allowing the identified trains to travel up to an additional 52 miles before completing the Class 1A brake test will not compromise the safety of CSX operations, does not increase the risk of an accident or incident, nor jeopardize employees or the general public.

A copy of the petition, as well as any written communications concerning the petition, is available for review online at *www.regulations.gov* and in person at the U.S. Department of Transportation's (DOT) Docket Operations Facility, 1200 New Jersey Avenue SE, W12–140, Washington, DC 20590. The Docket Operations Facility is open from 9 a.m. to 5 p.m., Monday through Friday, except Federal Holidays.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment and a public hearing, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number and may be submitted by any of the following methods:

• *Website: http://www.regulations.gov*. Follow the online instructions for submitting comments.

• *Fax:* 202–493–2251.

• *Mail:* Docket Operations Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE, W12–140, Washington, DC 20590.

• *Hand Delivery:* 1200 New Jersey Avenue SE, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

Communications received by January 3, 2019 will be considered by FRA before final action is taken. Comments received after that date will be considered if practicable.

Anyone can search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). Under 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its processes. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *https://www.transportation.gov/privacy.* See also *http://www.regulations.gov/#!privacyNotice* for the privacy notice of *regulations.gov*.

Issued in Washington, DC.

Robert C. Lauby,

Associate Administrator for Safety Chief Safety Officer.

[FR Doc. 2018–26292 Filed 12–3–18; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2018–0097]

Petition for Special Approval of Alternate Standard

Under part 238 of Title 49 of the Code of Federal Regulations (CFR), this provides the public notice that by a letter dated November 2, 2018, the American Public Transportation Association (APTA) petitioned the Federal Railroad Administration (FRA) for a Special Approval of an alternate standard for 49 CFR 238.311(a), *Single car test,* as prescribed in 49 CFR 238.21(b), *Special approval procedure.* FRA assigned the request docket number FRA–2018–0097.

APTA requests consideration for Special Approval of the submitted alternate standard identified as APTA PR–M–S–005–98, Rev. 4, ''Code of Tests for Passenger Car Equipment Using Single Car Testing,'' as the latest update to APTA Standard SS–M–005–98, ''Code of Tests for Passenger Car Equipment Using Single Car Testing Device,'' as specified in 49 CFR 238.311. APTA states the new revision updates procedures to assure uniform full-service reductions, the order of tests has been rearranged to facilitate the testing process, and provisions for testing electronic air brakes have been added. A summary of the changes made to the previous revisions can be found on page 26 of the proposed alternate standard,

which has been posted to the public docket for this proceeding. APTA further states that because no fundamental changes to the base air test requirements were made, no detailed analysis of safety equivalency with the previous approved standard is necessary.

Copies of these documents and the petition, as well as any written communications concerning the petition, are available for review online at *www.regulations.gov* and in person at the U.S. Department of Transportation's (DOT) Docket Operations Facility, 1200 New Jersey Avenue SE, W12–140, Washington, DC 20590. The Docket Operations Facility is open from 9 a.m. to 5 p.m., Monday through Friday, except Federal Holidays.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment and a public hearing, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number and may be submitted by any of the following methods:

- *Website: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* Docket Operations Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE, W12–140, Washington, DC 20590.
- *Hand Delivery:* 1200 New Jersey Avenue SE, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

Communications received by January 3, 2019 will be considered by FRA before final action is taken. Comments received after that date will be considered if practicable.

Anyone can search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). Under 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its processes. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *https://www.transportation.gov/privacy.* See also *http://www.regulations.gov/#!privacyNotice* for the privacy notice of *regulations.gov.*

Issued in Washington, DC.

Robert C. Lauby,

Associate Administrator for Safety Chief Safety Officer.

[FR Doc. 2018–26291 Filed 12–3–18; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

Limitation on Claims Against Proposed Public Transportation Projects

AGENCY: Federal Transit Administration (FTA), DOT.

ACTION: Notice.

SUMMARY: This notice announces final environmental action taken by the Federal Transit Administration (FTA) for a project in New York City, New York. The purpose of this notice is to announce publicly the environmental decision by FTA on the subject project and to activate the limitation on any claims that may challenge this final environmental action.

DATES: By this notice, FTA is advising the public of final agency actions subject to 23 U.S.C. 139(l). A claim seeking judicial review of FTA actions announced herein for the listed public transportation project will be barred unless the claim is filed on or before May 3, 2019.

FOR FURTHER INFORMATION CONTACT: Nancy-Ellen Zusman, Assistant Chief Counsel, Office of Chief Counsel, (312) 353–2577 or Juliet Bochicchio, Environmental Protection Specialist, Office of Environmental Programs, (202) 366–9348. FTA is located at 1200 New Jersey Avenue SE, Washington, DC 20590. Office hours are from 9:00 a.m. to 5:00 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION: Notice is hereby given that FTA has taken final agency action by issuing certain approvals for the public transportation project listed below. The action on the project, as well as the laws under which such action was taken, are described in the documentation issued in connection with the project to comply with the National Environmental Policy Act (NEPA) and in other documents in the FTA environmental project file for the project. Interested parties may contact either the project sponsor or the relevant FTA Regional Office for more information. Contact information for FTA's Regional Offices may be found at *https://www.fta.dot.gov.*

This notice applies to all FTA decisions on the listed project as of the issuance date of this notice and all laws under which such action was taken, including, but not limited to, NEPA [42 U.S.C. 4321–4375], Section 4(f) requirements [23 U.S.C. 138, 49 U.S.C. 303], Section 106 of the National Historic Preservation Act [54 U.S.C. 306108], and the Clean Air Act [42 U.S.C. 7401–7671q]. This notice does not, however, alter or extend the limitation period for challenges of project decisions subject to previous notices published in the **Federal Register**. The project and action that is the subject of this notice follow:

Project name and location: The Metropolitan Transportation Authority (MTA) Second Avenue Subway Phase 2 Project, New York City, NY. *Project sponsor:* Metropolitan Transportation Authority. *Project description:* The Second Avenue Subway (SAS) Phase 2 Project includes the construction of the second phase of a new subway between 96th Street and 125th Street, in Manhattan, New York. SAS Phase 2 would connect to the recently completed Phase 1, which extended the existing Q subway service from 63rd Street to 96th Street. SAS Phase 2 will extend the Q subway service north to 125th Street. The MTA evaluated a modified design of Phase 2 in a supplemental environmental assessment (SEA) which evaluated environmental impact areas considered in the 2004 Final Environmental Impact Statement (FEIS) to determine whether the modified design would result in any new significant environmental impacts not disclosed in the FEIS or require mitigation measures not identified in the FEIS. Based on review of the SEA and consideration of public and agency comments, FTA issued a finding of no significant impact (FONSI) that the modified design will not result in new significant impacts on the environment and no new mitigation measures will be required; and therefore, the conclusions of the FEIS and ROD remain valid. This notice only applies to the discrete actions taken by FTA at this time, as described below. Nothing in this notice affects FTA's previous decisions, or notice thereof, for this project. *Final agency actions:* Finding of No Significant Impact for the Second Avenue Subway Phase 2 New York City, New York, dated November 15, 2018. *Supporting documentation:* Supplemental Environmental Assessment to the Second Avenue

Subway Final Environmental Impact Statement: Phase 2, dated July 12, 2018.

Elizabeth S. Riklin,

Deputy Associate Administrator for Planning and Environment.

[FR Doc. 2018–26254 Filed 12–3–18; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2018–0173]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel LOKI 42′ Cruising Catamaran With Fixed Keels; Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirements of the coastwise trade laws to allow the carriage of no more than twelve passengers for hire on vessels, which are three years old or more. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before January 3, 2019.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2018–0173 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2018–0173 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2018–0173, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–453, Washington, DC 20590. Telephone 202–366–9309, email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel LOKI is:

—*Intended Commercial Use of Vessel:* ''Coastal passenger charter use''

—*Geographic Region Including Base of Operations:* ''California'' (Base of Operations: Newport Beach, Ca)

—*Vessel Length and Type:* 42′ cruising catamaran with fixed keels

The complete application is available for review identified in the DOT docket as MARAD–2018–0173 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the vessel name, state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov.,* keyword search MARAD–2018–0173 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Department of Transportation, Maritime Administration, Office of Legislation and Regulations, MAR–225, W24–220, 1200 New Jersey Avenue SE, Washington, DC 20590. Include a cover letter setting forth with specificity the basis for any such claim and, if possible, a summary of your submission that can be made available to the public.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121) * * *

Dated: November 28, 2018.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2018–26236 Filed 12–3–18; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2018–0166]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel ALYOSHA; Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirements of the coastwise trade laws to allow the carriage of no more than twelve passengers for hire on vessels, which are three years old or more. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before January 3, 2019.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2018–0166 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD 2018–0166 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2018–0166, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–453, Washington, DC 20590. Telephone 202–366–9309, Email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel ALYOSHA is:

—*Intended Commercial Use of Vessel:* Private charters in Ocean City, Maryland and in the Port of Baltimore, Maryland. The intended length of charters will short trips of between 3–4 hours

—*Geographic Region Including Base of Operations:* ''Maryland'' (Base of Operations: Ocean City and Baltimore City, Maryland)

—*Vessel Length and Type:* 50′ sailing catamaran with fixed stub keels

The complete application is available for review identified in the DOT docket as MARAD–2018–0166 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the vessel name, state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov.,* keyword search MARAD–2018–0166 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Department of Transportation, Maritime Administration, Office of Legislation and Regulations, MAR–225, W24–220, 1200 New Jersey Avenue SE, Washington, DC 20590. Include a cover letter setting forth with specificity the basis for any such claim and, if possible, a summary of your submission that can be made available to the public.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121) * * *

Dated: November 28, 2018.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2018–26232 Filed 12–3–18; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2018–0176]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel VIANA 42′ Cruising Catamaran With Fixed Keels; Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirements of the coastwise trade laws to allow the carriage of no more than twelve passengers for hire on vessels, which are three years old or more. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before January 3, 2019.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2018–0176 by any one of the following methods:

• *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2018–0176 and follow the instructions for submitting comments.

• *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2018–0176, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–453, Washington, DC 20590. Telephone 202–366–9309, Email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel VIANA is:

—*Intended Commercial Use of Vessel:* ''Private Vessel Charters, Passengers Only''

—*Geographic Region Including Base of Operations:* ''Maine, New Hampshire, Massachusetts, Rhode Island, Connecticut, New York (excluding waters in New York Harbor), New Jersey, Pennsylvania, Delaware, Maryland, Virginia, North Carolina, South Carolina, Georgia, East Florida, California, Oregon, Washington, and Alaska (excluding waters in Southeastern Alaska).'' (Base of Operations: West Coast, Ca)

—*Vessel Length and Type:* 42′ cruising catamaran with fixed keels

The complete application is available for review identified in the DOT docket as MARAD–2018–0176 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the vessel name, state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov,* keyword search MARAD–2018–0176 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Department of Transportation, Maritime Administration, Office of Legislation and Regulations, MAR–225, W24–220, 1200 New Jersey Avenue SE, Washington, DC 20590. Include a cover letter setting forth with specificity the basis for any such claim and, if possible, a summary of your submission that can be made available to the public.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121) * * *

Dated: November 28, 2018.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2018–26242 Filed 12–3–18; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2018–0174]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel NEVER MONDAY 34′ Twin Engine Powerboat; Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirements of the coastwise trade laws to allow the carriage of no more than twelve passengers for hire on vessels, which are three years old or more. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before January 3, 2019.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2018–0174 by any one of the following methods:

• *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2018–0174 and follow the instructions for submitting comments.

• *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2018–0174, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–453, Washington, DC 20590. Telephone 202–366–9309, Email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel NEVER MONDAY is:

—*Intended Commercial Use of Vessel:* ''Charter Fishing out of Skagway, Alaska''

—*Geographic Region Including Base of Operations:* ''Alaska'' (Base of Operations: Skagway, Alaska)

—*Vessel Length and Type:* 34′ twin engine powerboat, probable place of build California but documentation insufficient by United States Coast Guard Standards.

The complete application is available for review identified in the DOT docket as MARAD–2018–0174 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the vessel name, state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov.,* keyword search MARAD–2018–0174 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Department of Transportation, Maritime Administration, Office of Legislation and Regulations, MAR–225, W24–220, 1200 New Jersey Avenue SE, Washington, DC 20590. Include a cover letter setting forth with specificity the basis for any such claim and, if possible, a summary of your submission that can be made available to the public.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121) * * *

Dated: November 28, 2018.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.

Secretary, Maritime Administration.

[FR Doc. 2018–26239 Filed 12–3–18; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2018–0170]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel MISS MARIE; Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirements of the coastwise trade laws to allow the carriage of no more than twelve passengers for hire on vessels, which are three years old or more. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before January 3, 2019.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2018–0170 by any one of the following methods:

• *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2018–0170 and follow the instructions for submitting comments.

• *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2018–0170, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include

your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–453, Washington, DC 20590. Telephone 202–366–9309, Email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel MISS MARIE is:

—*Intended Commercial Use of Vessel:* ''Uninspected vessel sport fishing charter service for 6 or less passengers (6 pack). Our business plan is to offer our customers inshore and offshore sport fishing (no selling of fish) on the south shore of Long Island NY (Nassau County).''

—*Geographic Region Including Base of Operations:* ''New York (excluding New York Harbor)'' (Base of Operations: Freeport, New York)

—*Vessel Length and Type:* 42′ downeast style fishing vessel

The complete application is available for review identified in the DOT docket as MARAD–2018–0170 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the vessel name, state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov.,* keyword search MARAD–2018–0170 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Department of Transportation, Maritime Administration, Office of Legislation and Regulations, MAR–225, W24–220, 1200 New Jersey Avenue SE, Washington, DC 20590. Include a cover letter setting forth with specificity the basis for any such claim and, if possible, a summary of your submission that can be made available to the public.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121) * * *

Dated: November 28, 2018.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2018–26238 Filed 12–3–18; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2018–0172]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel DIMINUENDO 43′ Fixed Keel Sloop Sailing Vessel; Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirements of the coastwise trade laws to allow the carriage of no more than twelve passengers for hire on vessels, which are three years old or more. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before January 3, 2019.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2018–0172 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2018–0172 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2018–0172, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information

provided. For detailed instructions on submitting comments, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–453, Washington, DC 20590. Telephone 202–366–9309, email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel DIMINUENDO is:

—*Intended Commercial Use of Vessel:* ''Crewed sailing charters and/or bareboat charters''

—*Geographic Region Including Base of Operations:* ''Washington State'' (Base of Operations: Squalicum Harbor Marina, Bellingham, WA)

—*Vessel Length and Type:* 43′ fixed keel sloop sailing vessel

The complete application is available for review identified in the DOT docket as MARAD–2018–0172 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the vessel name, state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov,* keyword search MARAD–2018–0172 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Department of Transportation, Maritime Administration, Office of Legislation and Regulations, MAR–225, W24–220, 1200 New Jersey Avenue SE, Washington, DC 20590. Include a cover letter setting forth with specificity the basis for any such claim and, if possible, a summary of your submission that can be made available to the public.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121) * * *

Dated: November 28, 2018.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2018–26234 Filed 12–3–18; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2018–0175]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel RIPPLE EFFECT II 46′ Sailing Catamaran; Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirements of the coastwise trade laws to allow the carriage of no more than twelve passengers for hire on vessels, which are three years old or more. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before January 3, 2019.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2018–0175 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2018–0175 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2018–0175, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590 between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey

Avenue SE, Room W23–453, Washington, DC 20590. Telephone 202–366–9309, Email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel RIPPLE EFFECT II is:

—*Intended Commercial Use of Vessel:* Eco boat tours and charters.
—*Geographic Region Including Base of Operations:* ''Florida'' (Base of Operations: Marineland, Florida).
—*Vessel Length and Type:* 46′ sailing catamaran.

The complete application is available for review identified in the DOT docket as MARAD–2018–0175 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the vessel name, state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov.,* keyword search MARAD–2018–0175 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Department of Transportation, Maritime Administration, Office of Legislation and Regulations, MAR–225, W24–220, 1200 New Jersey Avenue SE, Washington, DC 20590. Include a cover letter setting forth with specificity the basis for any such claim and, if possible, a summary of your submission that can be made available to the public.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121) * * *

Dated: November 28, 2018.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2018–26240 Filed 12–3–18; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2018–0169]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel MABUHAY; Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirements of the coastwise trade laws to allow the carriage of no more than twelve passengers for hire on vessels, which are three years old or more. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before January 3, 2019.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2018–0169 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2018–0169 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2018–0169, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–453, Washington, DC 20590. Telephone 202–366–9309, Email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel MABUHAY is:

—*Intended Commercial Use of Vessel:* ''Crewed recreational charter for day and overnight trips.''
—*Geographic Region Including Base of Operations:* ''California'' (Base of Operations: Long Beach, CA).
—*Vessel Length and Type:* 38.9′ Cabin Motor Vessel.

The complete application is available for review identified in the DOT docket as MARAD–2018–0169 at *http://*

www.regulations.gov. Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the vessel name, state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov.,* keyword search MARAD–2018–0169 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Department of Transportation, Maritime Administration, Office of Legislation and Regulations, MAR–225, W24–220, 1200 New Jersey Avenue SE, Washington, DC 20590. Include a cover letter setting forth with specificity the basis for any such claim and, if possible, a summary of your submission that can be made available to the public.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121) * * *

Dated: November 28, 2018.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2018–26237 Filed 12–3–18; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2018–0168]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel TORTOISE; Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirements of the coastwise trade laws to allow the carriage of no more than twelve passengers for hire on vessels, which are three years old or more. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before January 3, 2019.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2018–0168 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2018–0168 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2018–0168, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–453, Washington, DC 20590. Telephone 202–366–9309, email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel TORTOISE is:

—*Intended Commercial Use of Vessel:* ''Sightseeing cruises primarily along Coastal California''

—*Geographic Region Including Base of Operations:* ''California, Oregon, Washington State'' (Base of Operations: Chula Vista, California)

—*Vessel Length and Type:* 32′ Grand Banks power boat

The complete application is available for review identified in the DOT docket as MARAD–2018–0168 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the vessel name, state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov.,* keyword search MARAD–2018–0168 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Department of Transportation, Maritime Administration, Office of Legislation and Regulations, MAR–225, W24–220, 1200 New Jersey Avenue SE, Washington, DC 20590. Include a cover letter setting forth with specificity the basis for any such claim and, if possible, a summary of your submission that can be made available to the public.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121) * * *

Dated: November 28, 2018.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2018–26241 Filed 12–3–18; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2018–0171]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel LILIKOI; Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirements of the coastwise trade laws to allow the carriage of no more than twelve passengers for hire on vessels, which are three years old or more. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before January 3, 2019.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2018–0171 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2018–0171 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2018–0171, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–453, Washington, DC 20590. Telephone 202–366–9309, email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel LILIKOI is:

—*Intended Commercial Use of Vessel:* ''Sightseeing and Whale Watching Tours''

—*Geographic Region Including Base of Operations:* ''California'' (Base of Operations: San Diego, California)

—*Vessel Length and Type:* 36′ Islander fin keel sailboat

The complete application is available for review identified in the DOT docket as MARAD–2018–0171 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the vessel name, state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov.,* keyword search MARAD–2018–0171 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Department of Transportation, Maritime Administration, Office of Legislation and Regulations, MAR–225, W24–220, 1200 New Jersey Avenue SE, Washington, DC 20590. Include a cover letter setting forth with specificity the basis for any such claim and, if possible, a summary of your submission that can be made available to the public.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121) * * *

Dated: November 28, 2018.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2018–26235 Filed 12–3–18; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2018–0167]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel CHICANE; Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirements of the coastwise trade laws to allow the carriage of no more than twelve passengers for hire on vessels, which are three years old or more. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before January 3, 2019.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2018–0167 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2018–0167 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2018–0167, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–453, Washington, DC 20590. Telephone 202–366–9309, email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel CHICANE is:

—*Intended Commercial Use of Vessel:* Charter sailing with Mystic Seaport Museum visitors and supporters. Most likely day and short overnight trips in Long Island Sound and Block Island Sound, but with potential to visit other areas of the East Coast to engage museum supporters in other areas

—*Geographic Region Including Base of Operations:* ''Connecticut, Maine, New Hampshire, Massachusetts, Rhode Island, New York (excluding New York Harbor), New Jersey, Delaware, Pennsylvania, Maryland, Virginia, North Carolina, South Carolina, Georgia, Florida, Alabama, Mississippi, Louisiana, Texas, Puerto Rico'' (Base of Operations: Mystic Seaport Museum, Mystic, CT)

—*Vessel Length and Type:* 56′ cutter rigged sailing vessel

The complete application is available for review identified in the DOT docket as MARAD–2018–0167 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the vessel name, state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov.,* keyword search

MARAD–2018–0167 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Department of Transportation, Maritime Administration, Office of Legislation and Regulations, MAR–225, W24–220, 1200 New Jersey Avenue SE, Washington, DC 20590. Include a cover letter setting forth with specificity the basis for any such claim and, if possible, a summary of your submission that can be made available to the public.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121. * * *

Dated: November 28, 2018.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2018–26233 Filed 12–3–18; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

Agency Information Collection Activities; Information Collection Renewal; Comment Request; Leasing

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury.

ACTION: Notice and request for comment.

SUMMARY: The OCC, 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 a continuing information collection as required by the Paperwork Reduction Act of 1995 (PRA).

In accordance with the requirements of the PRA, the OCC may not conduct or sponsor, and respondents are not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number.

The OCC is soliciting comment concerning the renewal of its information collection titled, ''Leasing.''

DATES: Comments must be received by February 4, 2019.

ADDRESSES: Commenters are encouraged to submit comments by email, if possible. You may submit comments by any of the following methods:

- *Email: prainfo@occ.treas.gov.*
- *Mail:* Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, Attention: 1557–0206, 400 7th Street SW, Suite 3E–218, Washington, DC 20219.
- *Hand Delivery/Courier:* 400 7th Street SW, Suite 3E–218, Washington, DC 20219.
- *Fax:* (571) 465–4326.

Instructions: You must include ''OCC'' as the agency name and ''1557–0206'' in your comment. In general, the OCC publishes comments on *www.reginfo.gov* without change, including any business or personal information provided, such as name and address information, email addresses, or phone numbers. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

You may review comments and other related materials that pertain to this information collection beginning on the date of publication of the second notice for this collection [1] by any of the following methods:

- *Viewing Comments Electronically:* Go to *www.reginfo.gov.* Click on the ''Information Collection Review'' tab. Underneath the ''Currently under Review'' section heading, from the drop-down menu, select ''Department of Treasury'' and then click ''submit.'' This information collection can be located by searching by OMB control number ''1557–0206'' or ''Leasing.'' Upon finding the appropriate information collection, click on the related ''ICR Reference Number.'' On the next screen, select ''View Supporting Statement and Other Documents'' and then click on the link to any comment listed at the bottom of the screen.
- For assistance in navigating *www.reginfo.gov,* please contact the Regulatory Information Service Center at (202) 482–7340.
- *Viewing Comments Personally:* You may personally inspect comments at the OCC, 400 7th Street SW, Washington, DC. For security reasons, the OCC requires that visitors make an appointment to inspect comments. You may do so by calling (202) 649–6700 or, for persons who are deaf or hearing impaired, TTY, (202) 649–5597. Upon arrival, visitors will be required to present valid government-issued photo identification and submit to security screening in order to inspect comments.

FOR FURTHER INFORMATION CONTACT: Shaquita Merritt, Clearance Officer, (202) 649–5490 or, for persons who are deaf or hearing impaired, TTY, (202) 649–5597, Chief Counsel's Office, Office of the Comptroller of the Currency, 400 7th Street SW, Washington, DC 20219.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the OMB for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) to include agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of title 44 requires federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, the OCC is publishing notice of the collection of information set forth in this document.

[1] Following the close of the 60-day comment period for this notice, the OCC will publish a notice for 30 days of comment for this collection.

Title: Leasing.

OMB Control No.: 1557–0206.

Description: Under 12 CFR 23.4(c), national banks must liquidate or re-lease property that is no longer subject to lease (off-lease property) as soon as practicable and not later than five years from the date the bank acquires the legal right to possess or control the property. If a national bank wishes to extend the five-year holding period for up to an additional five years, it must obtain OCC approval. Section 23.4(c) requires a national bank seeking an extension to provide a clearly convincing demonstration as to why any additional holding period is necessary. In addition, a national bank must value off-lease property at the lower of current fair market value or book value promptly after the property becomes off-lease property.

Under 12 CFR 23.6, leases are subject to the lending limits prescribed by 12 U.S.C. 84, as implemented by 12 CFR part 32, or, if the lessee is an affiliate of the national bank, to the restrictions on transactions with affiliates prescribed by 12 U.S.C. 371c and 371c–1; Regulation W, 12 CFR part 223; and other limits or restrictions the OCC determines apply.

Twelve U.S.C. 24 contains two separate provisions authorizing a national bank to acquire personal property for purposes of lease financing. 12 U.S.C. 24 (Seventh) authorizes leases of personal property (Section 24 (Seventh) Leases) if the lease is a conforming lease as defined in 12 CFR 23.2(d)(2) and represents a noncancelable obligation of the lessee (*i.e.,* the lease serves as the functional equivalent of a loan). See 12 CFR 23.20. A national bank also may acquire personal property for purposes of lease financing under the authority of 12 U.S.C. 24 (Tenth). Section 23.5 requires that if a national bank enters into both types of leases, its records must distinguish between the two types of leases. This information is required to establish that the national bank is complying with the limitations and requirements applicable to the two separate types of leases.

Type of Review: Regular.

Affected Public: Businesses or other for-profit.

Estimated Number of Respondents: 229.

Frequency of Response: On occasion.

Estimated Total Annual Burden: 562.

Comments submitted in response to this notice will be summarized and included in the submission to OMB. Comments are requested on:

(a) Whether the information collections are necessary for the proper performance of the OCC's functions, including whether the information has practical utility;

(b) The accuracy of the OCC's estimates of the burden of the information collections, including the validity of the methodology and assumptions used;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected;

(d) Ways to minimize the burden of information collections on respondents, including through the use of automated collection techniques or other forms of information technology; and

(e) Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: November 28, 2018.

Theodore J. Dowd,

Deputy Chief Counsel, Office of the Comptroller of the Currency.

[FR Doc. 2018–26252 Filed 12–3–18; 8:45 am]

BILLING CODE 4810–33–P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

Agency Information Collection Activities; Information Collection Renewal; Comment Request; Funding and Liquidity Risk Management

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury.

ACTION: Notice and request for comment.

SUMMARY: The OCC, 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 a continuing information collection as required by the Paperwork Reduction Act of 1995 (PRA).

In accordance with the requirements of the PRA, the OCC may not conduct or sponsor, and respondents are not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number.

The OCC is soliciting comment concerning renewal of its information collection titled, ''Funding and Liquidity Risk Management.''

DATES: Comments must be received by February 4, 2019.

ADDRESSES: Commenters are encouraged to submit comments by email, if possible. You may submit comments by any of the following methods:

- *Email: prainfo@occ.treas.gov.*
- *Mail:* Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, Attention: 1557–0244, 400 7th Street SW, Suite 3E–218, Washington, DC 20219.
- *Hand Delivery/Courier:* 400 7th Street SW, Suite 3E–218, Washington, DC 20219.
- *Fax:* (571) 465–4326.

Instructions: You must include ''OCC'' as the agency name and ''1557–0244'' in your comment. In general, the OCC will publish comments on *www.reginfo.gov* without change, including any business or personal information provided, such as name and address information, email addresses, or phone numbers. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

You may review comments and other related materials that pertain to this information collection beginning on the date of publication of the second notice for this collection [1] by any of the following methods:

- *Viewing Comments Electronically:* Go to *www.reginfo.gov.* Click on the ''Information Collection Review'' tab. Underneath the ''Currently under Review'' section heading, from the drop-down menu, select ''Department of Treasury'' and then click ''submit.'' This information collection can be located by searching by OMB control number ''1557–0244'' or ''Funding and Liquidity Risk Management.'' Upon finding the appropriate information collection, click on the related ''ICR Reference Number.'' On the next screen, select ''View Supporting Statement and Other Documents'' and then click on the link to any comment listed at the bottom of the screen.
- For assistance in navigating *www.reginfo.gov,* please contact the Regulatory Information Service Center at (202) 482–7340.
- *Viewing Comments Personally:* You may personally inspect comments at the OCC, 400 7th Street SW, Washington, DC. For security reasons, the OCC requires that visitors make an appointment to inspect comments. You may do so by calling (202) 649–6700 or, for persons who are deaf or hearing impaired, TTY, (202) 649–5597. Upon arrival, visitors will be required to present valid government-issued photo identification and submit to security screening in order to inspect comments.

[1] Following the close of the 60-day comment period for this notice, the OCC will publish a notice for 30 days of comment for this collection.

FOR FURTHER INFORMATION CONTACT: Shaquita Merritt, Clearance Officer, (202) 649–5490 or, for persons who are deaf or hearing impaired, TTY, (202) 649–5597, Chief Counsel's Office, Office of the Comptroller of the Currency, 400 7th Street SW, Suite 3E–218, Washington, DC 20219.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from OMB for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) to include agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of title 44 requires federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, the OCC is publishing notice of the collection of information set forth in this document.

Title: Funding and Liquidity Risk Management.

OMB Control No.: 1557–0244.

Description: The Interagency Policy Statement on Funding and Liquidity Risk Management [2] (Policy Statement) summarizes the principles of sound liquidity risk management that the federal banking agencies have issued in the past [3] and, where appropriate, harmonizes these principles with the international statement issued by the Basel Committee on Banking Supervision titled ''Principles for Sound Liquidity Risk Management and Supervision.'' [4] The Policy Statement describes supervisory expectations for all depository institutions including banks, savings associations, and credit unions.

Section 14 of the Policy Statement provides that financial institutions should consider liquidity costs, benefits, and risks in strategic planning and budgeting processes. Significant business activities should be evaluated for liquidity risk exposure as well as profitability. More complex and sophisticated financial institutions should incorporate liquidity costs, benefits, and risks in the internal product pricing, performance measurement, and new product approval process for all material business lines, products, and activities. Incorporating the cost of liquidity into these functions should align the risk-taking incentives of individual business lines with the liquidity risk exposure their activities create for the institution as a whole. The quantification and attribution of liquidity risks should be explicit and transparent at the line management level, and should include consideration of how liquidity would be affected under stressed conditions.

Section 20 of the Policy Statement states that liquidity risk reports should provide aggregate information with sufficient supporting detail to enable management to assess the sensitivity of the institution to changes in market conditions, its own financial performance, and other important risk factors. Institutions also should report on the use and availability of government support, such as lending and guarantee programs, and implications on liquidity positions, particularly since these programs are generally temporary or reserved as a source for contingent funding.

Type of Review: Regular.

Affected Public: Businesses or other for-profit.

Estimated Number of Respondents: 1,171.

Frequency of Response: On occasion.

Estimated Total Burden Hours: 84,464 hours.

Comments: Comments submitted in response to this notice will be summarized and included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on:

(a) Whether the information collections are necessary for the proper performance of the functions of the OCC, including whether the information has practical utility;

(b) The accuracy of the OCC's estimate of the information collection burden;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected;

(d) Ways to minimize the burden of information collections on respondents, including through the use of automated collection techniques or other forms of information technology; and

(e) Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of the services necessary to provide the required information.

Dated: November 28, 2018.

Theodore J. Dowd,

Deputy Chief Counsel, Office of the Comptroller of the Currency.

[FR Doc. 2018–26251 Filed 12–3–18; 8:45 am]

BILLING CODE 4810–33–P

[2] 75 FR 13656 (Mar. 22, 2010).

[3] For national banks and federal savings associations, see the *Comptroller's Handbook on Liquidity*. For state member banks and bank holding companies, see the Federal Reserve's *Commercial Bank Examination Manual* (section 4020), *Bank Holding Company Supervision Manual* (section 4010), and *Trading and Capital Markets Activities Manual* (section 2030). For state non-member banks, see the FDIC's *Revised Examination Guidance for Liquidity and Funds Management* (Trans. No. 2002–01) (Nov. 19, 2001), and Financial Institution Letter 84–2008, *Liquidity Risk Management* (August 2008). For federally insured credit unions, see Letter to Credit Unions No. 02–CU–05, Examination Program Liquidity Questionnaire (March 2002).

[4] Basel Committee on Banking Supervision, ''Principles for Sound Liquidity Risk Management and Supervision,'' September 2008. See *www.bis.org/publ/bcbs144.htm*. Federally insured credit unions are not directly referenced in the principles issued by the Basel Committee.

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Actions.

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of one or more persons that have been placed on OFAC's Specially Designated Nationals and Blocked Persons List based on OFAC's determination that one or more applicable legal criteria were satisfied. All property and interests in property subject to U.S. jurisdiction of these persons are blocked, and U.S. persons are generally prohibited from engaging in transactions with them.

DATES: See **SUPPLEMENTARY INFORMATION** section for applicable date(s).

FOR FURTHER INFORMATION CONTACT: *OFAC:* Associate Director for Global Targeting, tel.: 202–622–2420; Assistant Director for Licensing, tel.: 202–622–2480; Assistant Director for Regulatory Affairs, tel.: 202–622–4855; Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490; or the Department of the Treasury's Office of the General Counsel: Office of the Chief Counsel (Foreign Assets Control), tel.: 202–622–2410.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The Specially Designated Nationals and Blocked Persons List and additional information concerning OFAC sanctions programs are available on OFAC's website (*www.treasury.gov/ofac*).

Notice of OFAC Actions

On November 28, 2018, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following persons are

blocked under the relevant sanctions authority listed below.

Individuals:

1. GHORBANIYAN, Mohammad (a.k.a. GHORBANIAN, Mohammad; a.k.a. ''EnExchanger''; a.k.a. ''Ensaniyat''; a.k.a. ''Ensaniyat_Exchanger''), Iran; DOB 09 Mar 1987; POB Tehran, Iran; nationality Iran; website *www.enexchanger.com;* Email Address *EnExchanger@gmail.com;* alt. Email Address *Ensaniyat1365@gmail.com;* Additional Sanctions Information—Subject to Secondary Sanctions; Gender Male; Digital Currency Address—XBT 1AjZPMsnmpd K2Rv9KQNfMurTXinscVro9V; Identification Number 008–046347–9 (Iran); Birth Certificate Number 32270 (Iran) (individual) [CYBER2].

2. KHORASHADIZADEH, Ali (a.k.a. ''Iranvisacart''; a.k.a. ''Mastercartaria''), Iran; DOB 21 Sep 1979; POB Tehran, Iran; nationality Iran; Email Address *iranvisacart@yahoo.com;* alt. Email Address *mastercartaria@yahoo.com;* alt. Email Address *alikhorashadi@yahoo.com;* alt. Email Address *toppglasses@gmail.com;* alt. Email Address *iranian_boy5@yahoo.com;* Additional Sanctions Information—Subject to Secondary Sanctions; Gender Male; Digital Currency Address—XBT 149w62rY42aZBox 8fGcmqNsXUzSStKeq8C; Passport T14553558 (Iran) issued 28 Oct 2008 expires 29 Oct 2013 (individual) [CYBER2].

Designated pursuant to section 1(a)(iii)(B) of Executive Order 13694 of April 1, 2015, ''Blocking the Property of Certain Persons Engaging in Significant Malicious Cyber-Enabled Activities,'' as amended, (E.O. 13694) for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of an activity described in section 1(a)(ii) of E.O. 13694, namely the SamSam ransomware attacks.

Dated: November 28, 2018.

Andrea Gacki,

Director, Office of Foreign Assets Control.

[FR Doc. 2018–26216 Filed 12–3–18; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Extension of Information Collection Request Submitted for Public Comment; Comment Request for Tests for Determining Whether an Obligation is Principally Secured

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 public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. Currently, the IRS is soliciting comments concerning modifications of commercial mortgage loans held by a real estate mortgage investment conduit.

DATES: Written comments should be received on or before February 4, 2019 to be assured of consideration.

ADDRESSES: Direct all written comments to Carolyn Brown, Internal Revenue Service, Room 6236, 1111 Constitution Avenue NW, Washington, DC 20224. Requests for additional information or copies of the regulations should be directed to R. Joseph Durbala, at Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW, Washington DC 20224, or through the internet, at *RJoseph.Durbala@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Obligations principally secured by an interest in real property.

OMB Number: 1545–2110.

Form Number: TD 9463.

Abstract: This collection covers final regulations under section 1.860G–2 that expand the list of permitted loan modifications to include certain modifications that are often made to commercial mortgages. The collection of information in this regulation is in section 1.860G–2(b)(7). To establish that the 80-percent test is met at the time of modification, the servicer must obtain an appraisal or some other form of commercially reasonable valuation (the appraisal requirement). This information is required to show that modifications to mortgages permitted will not cause the modified mortgage to cease to be a qualified mortgage.

Current Actions: There is no change to the burden previously approved.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 375.

Estimated Time Per Respondent: 8 hrs.

Estimated Total Annual Burden Hours: 3,000.

The following paragraph applies to all 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 if 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.

Desired Focus of Comments: The Internal Revenue Service (IRS) is particularly interested in comments that:

- 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 using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* by permitting electronic submissions of responses.

Comments submitted in response to this notice will be summarized and/or included in the ICR for OMB approval of the extension of the information collection; they will also become a matter of public record.

Approved: November 27, 2018.

R. Joseph Durbala,

IRS Tax Analyst.

[FR Doc. 2018–26258 Filed 12–3–18; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Extension of Information Collection Request Submitted for Public Comment; Comment Request for Disclosure of Returns and Return Information to Designee of Taxpayer

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 public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction

Act of 1995. Currently, the IRS is soliciting comments concerning the disclosure of returns and return information to a designee of a taxpayer.

DATES: Written comments should be received on or before February 4, 2019 to be assured of consideration.

ADDRESSES: Direct all written comments to Carolyn Brown, Internal Revenue Service, Room 6236, 1111 Constitution Avenue NW, Washington, DC 20224. Requests for additional information or copies of the regulations should be directed to R. Joseph Durbala, at Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW, Washington DC 20224, or through the internet, at *RJoseph.Durbala@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Disclosure of Returns and Return Information to Designee of Taxpayer.

OMB Number: 1545–1816.

Regulation Project Number: TD 9054, as amended by TD 9618.

Abstract: Under section 6103(a), returns and return information are confidential unless disclosure is otherwise authorized by the Code. Section 6103(c), as amended in 1996 by section 1207 of the Taxpayer Bill of Rights II, Public Law 104–168 (110 Stat. 1452), authorizes the IRS to disclose returns and return information to such person or persons as the taxpayer may designate in a request for or consent to disclosure, or to any other person at the taxpayer's request to the extent necessary to comply with a request for information or assistance made by the taxpayer to such other person. Disclosure is permitted subject to such requirements and conditions as may be prescribed by regulations. With the amendment in 1996, Congress eliminated the longstanding requirement that disclosures to designees of the taxpayer must be pursuant to the written request or consent of the taxpayer.

Current Actions: There is no change to the burden previously approved.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals or households, business or other not-for-profit institutions, farms, and Federal, state, local or tribal governments.

Estimated Number of Respondents: 4,000.

Estimated Time per Respondent: 12 min.

Estimated Total Annual Burden Hours: 800.

The following paragraph applies to all 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 if 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.

Desired Focus of Comments: The Internal Revenue Service (IRS) is particularly interested in comments that:

- 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 using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* by permitting electronic submissions of responses.

Comments submitted in response to this notice will be summarized and/or included in the ICR for OMB approval of the extension of the information collection; they will also become a matter of public record.

Approved: November 27, 2018.

R. Joseph Durbala,

IRS Tax Analyst.

[FR Doc. 2018–26259 Filed 12–3–18; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Extension of Information Collection Request Submitted for Public Comment; Comment Request for Form 8918

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 public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. Currently, the IRS is soliciting comments concerning the disclosure of reportable transactions.

DATES: Written comments should be received on or before February 4, 2019 to be assured of consideration.

ADDRESSES: Direct all written comments to Carolyn Brown, Internal Revenue Service, Room 6236, 1111 Constitution Avenue NW, Washington, DC 20224. Requests for additional information or copies of the regulations should be directed to R. Joseph Durbala, at Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW, Washington DC 20224, or through the internet, at *RJoseph.Durbala@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Disclosure of reportable transactions.

OMB Number: 1545–0865.

Form Number: 8918.

Abstract: Internal Revenue Code (IRC) 6111 requires a sub-set of promoters called ''material advisors'' to disclose information about the promotion of certain types of transactions called ''reportable transactions.'' Material advisors to any reportable transaction must disclose certain information about the reportable transaction by filing a Form 8918 with the IRS. Material advisors who file a Form 8918 will receive a reportable transaction number from the IRS. Material advisors must provide the reportable transaction number to all taxpayers and material advisors for whom the material advisor acts as a material advisor.

Current Actions: There is no change to the burden previously approved.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 350.

Estimated Time Per Respondent: 14 hrs., 33 min.

Estimated Total Annual Burden Hours: 5,096.

The following paragraph applies to all 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 if 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.

Desired Focus of Comments: The Internal Revenue Service (IRS) is particularly interested in comments that:

- 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 using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* by permitting electronic submissions of responses.

Comments submitted in response to this notice will be summarized and/or included in the ICR for OMB approval of the extension of the information collection; they will also become a matter of public record.

Approved: November 27, 2018.

R. Joseph Durbala,

IRS Tax Analyst.

[FR Doc. 2018–26256 Filed 12–3–18; 8:45 am]

BILLING CODE 4830–01–P

FEDERAL REGISTER

Vol. 83 Tuesday,

No. 233 December 4, 2018

Part II

The President

Memorandum of November 5, 2018—Delegation of Authority Contained in Condition 23 of the Resolution of Advice and Consent to Ratification of the Chemical Weapons Convention

Federal Register
Vol. 83, No. 233
Tuesday, December 4, 2018

Presidential Documents

Title 3—

The President

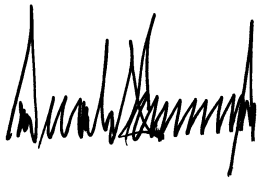
Memorandum of November 5, 2018

Delegation of Authority Contained in Condition 23 of the Resolution of Advice and Consent to Ratification of the Chemical Weapons Convention

Memorandum for the Secretary of State

By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 301 of title 3, United States Code, I hereby delegate to the Secretary of State, in coordination with departments and agencies through the National Security Presidential Memorandum–4 process, the authority to carry out the functions assigned to the President by Condition 23 of the United States Senate's Resolution of Advice and Consent to Ratification of the Convention on the Prohibition of the Development, Production, Stockpiling, and Use of Chemical Weapons and on their Destruction.

You are authorized and directed to publish this memorandum in the *Federal Register*.



THE WHITE HOUSE,
Washington, November 5, 2018

[FR Doc. 2018–26528
Filed 12–3–18; 11:15 am]
Billing code 4710–10–P

FEDERAL REGISTER

Vol. 83 Tuesday,

No. 233 December 4, 2018

Part III

The President

Proclamation 9828—National Impaired Driving Prevention Month, 2018
Proclamation 9829—World AIDS Day, 2018
Executive Order 13852—Providing for the Closing of Executive Departments and Agencies of the Federal Government on December 5, 2018

Federal Register
Vol. 83, No. 233
Tuesday, December 4, 2018

Presidential Documents

Title 3—

The President

Proclamation 9828 of November 30, 2018

National Impaired Driving Prevention Month, 2018

By the President of the United States of America

A Proclamation

During National Impaired Driving Prevention Month, we recommit ourselves to the fight against impaired driving. Every day, lives are needlessly lost and irreparably altered by collisions involving drugs or alcohol. These horrible tragedies are avoidable, and each of us must make responsible decisions to prevent them and keep our communities safe.

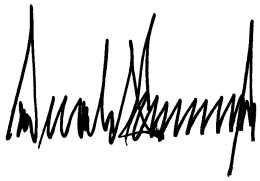
Operating a vehicle while under the influence of alcohol, illicit drugs, or certain medications can have devastating consequences. In 2017, more than 10,000 people died in alcohol-related crashes in the United States, accounting for 29 percent of all traffic fatalities. Drunk or drugged drivers experience diminished judgment and decreased motor coordination and reaction time, putting at grave risk passengers, pedestrians, and other drivers.

My Administration is committed to raising public awareness about the dangers of impaired driving, and to supporting innovative ways of reducing related fatalities. This month in particular, we recognize the public safety professionals and law enforcement officers who work to protect our communities by removing dangerously impaired drivers from the road. We also express our great appreciation for the emergency responders across America who save lives through rescue operations on our roads on a daily basis. We continue our efforts to eliminate outdated regulations that unnecessarily hamper the ability of American companies to help reduce instances of impaired driving through innovations such as ride hailing services and Advanced Vehicle Technology. Additionally, we are providing treatment for those suffering from alcohol and substance abuse, improving data collection and toxicology practices, and ensuring that our law enforcement professionals receive vital resources to help prevent impaired driving and to respond to the tragedies it causes.

Every American can take a few simple steps to make our roads safer. We hope every driver commits to making responsible and safe decisions when driving, including driving sober, finding a designated driver, and keeping loved ones from getting behind the wheel while impaired. By educating our communities on the importance of driving sober, we can help avoid loss of life, debilitating injuries, and unbearable heartache. We must act to protect our loved ones and eliminate fatalities that prevent our fellow Americans from enjoying full and happy lives.

NOW, THEREFORE, I, DONALD J. TRUMP, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim December 2018 as National Impaired Driving Prevention Month. I urge all Americans to make responsible decisions and take appropriate measures to prevent impaired driving.

IN WITNESS WHEREOF, I have hereunto set my hand this thirtieth day of November, in the year of our Lord two thousand eighteen, and of the Independence of the United States of America the two hundred and forty-third.



[FR Doc. 2018–26540
Filed 12–3–18; 2:00 pm]
Billing code 3295–F9–P

Presidential Documents

Proclamation 9829 of November 30, 2018

World AIDS Day, 2018

By the President of the United States of America

A Proclamation

For more than three decades, our Nation and the world have confronted the challenges posed by the human immunodeficiency virus (HIV) and acquired immunodeficiency syndrome (AIDS). Today, thanks to lifesaving medications, an HIV/AIDS diagnosis does not have to be a death sentence. On World AIDS Day, we remember the 35 million lives that have sadly been cut short by this terrible disease, and we renew our pledge to stand with those living with it until it is eliminated from our communities.

Medical advancements and procedures have transformed HIV from a disease that meant nearly certain death into a generally manageable, chronic condition. Antiretroviral drugs and therapies help control the virus so that people with HIV can experience healthy and productive lives with reduced risk of transmitting it to others. With these long-sought solutions now at our disposal, we have the ability to help alleviate the pain and needless suffering of our fellow Americans living with HIV, their family and friends, and the millions of others around the world living with this disease.

Our efforts to connect those affected by this disease with high-quality healthcare are dramatically improving many lives. The 2017 National HIV/AIDS Strategy (NHAS) progress report indicates a significant increase of Americans living with HIV. These people are now able to suppress the virus with medication. But we cannot rest on this progress. In recent years, opioids and other injected drugs have caused HIV outbreaks in communities rarely affected before the outbreak of the epidemic. We must continue to work to eliminate the stigma that surrounds HIV so that no one is afraid to learn their HIV status, treat their condition if HIV infected, and prevent infection if they are at risk.

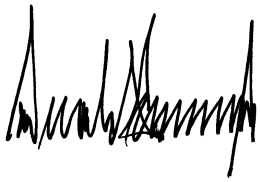
My Administration remains steadfastly focused on achieving the NHAS goals for 2020. These goals are within our reach, but achieving them will require continued coordinated work with local and State governments, faith-based and charitable organizations, and many others. One such critical component of our domestic public health response is the Ryan White HIV/AIDS Program. Working with cities, counties, States, and local community-based programs, this program provides a comprehensive system of HIV care, lifesaving medications, and essential support services to more than half a million low-income people in the United States each year.

We also remain committed to collaborating with both national and international stakeholders through the U.S. President's Emergency Plan for AIDS Relief (PEPFAR). For 15 years, PEPFAR has devoted American resources to critical HIV prevention, treatment, and care to some of the world's most vulnerable populations, helping to save more than 17 million lives. PEPFAR has continued to support a rapid acceleration of HIV prevention by using data to increase program performance, mobilize domestic resources, and support local partners for sustainable implementation. Through this program, we are supporting lifesaving HIV treatment for more than 14 million people and have enabled more than 2 million babies of HIV-infected mothers to be born HIV-free.

With American leadership, the HIV/AIDS pandemic has shifted from crisis toward control. Hope and life are prospering where death and despair once prevailed. A generation that could have been lost is instead thriving and building a brighter future. For the first time in modern history, we have the ability to sustainably control an epidemic, despite the absence of a vaccine or cure, and create a future of flourishing, stable communities in the United States and around the globe.

NOW, THEREFORE, I, DONALD J. TRUMP, President of the United States of America, by virtue of the authority vested in me by the Constitution and laws of the United States, do hereby proclaim December 1, 2018, as World AIDS Day. I urge the Governors of the States and the Commonwealth of Puerto Rico, officials of the other territories subject to the jurisdiction of the United States, and American people to join me in appropriate activities to remember those who have lost their lives to AIDS and to provide support and compassion to those living with HIV.

IN WITNESS WHEREOF, I have hereunto set my hand this thirtieth day of November, in the year of our Lord two thousand eighteen, and of the Independence of the United States of America the two hundred and forty-third.



[FR Doc. 2018–26543
Filed 12–3–18; 2:00 pm]
Billing code 3295–F9–P

Presidential Documents

Executive Order 13852 of December 1, 2018

Providing for the Closing of Executive Departments and Agencies of the Federal Government on December 5, 2018

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. All executive departments and agencies of the Federal Government shall be closed on December 5, 2018, as a mark of respect for George Herbert Walker Bush, the forty-first President of the United States.

Sec. 2. The heads of executive departments and agencies may determine that certain offices and installations of their organizations, or parts thereof, must remain open and that certain employees must report for duty on December 5, 2018, for reasons of national security, defense, or other public need.

Sec. 3. December 5, 2018, shall be considered as falling within the scope of Executive Order 11582 of February 11, 1971, and of 5 U.S.C. 5546 and 6103(b) and other similar statutes insofar as they relate to the pay and leave of employees of the United States.

Sec. 4. The Director of the Office of Personnel Management shall take such actions as may be necessary to implement this order.

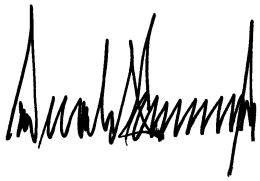
Sec. 5. *General Provisions.* (a) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(b) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.



THE WHITE HOUSE,
December 1, 2018.

[FR Doc. 2018–26552
Filed 12–3–18; 2:00 pm]
Billing code 3295–F9–P

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Tuesday, December 4, 2018

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