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The Code of Federal Regulations is sold by the Superintendent of Documents.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 870

Commodity Credit Corporation

7 CFR Part 1427

[Doc. No. AMS–LRRS–21–0047]

Reorganization and Transfer of Regulations

AGENCY: Agricultural Marketing Service; Commodity Credit Corporation, USDA.

ACTION: Final rule.

SUMMARY: This rule transfers regulations pertaining to the Economic Adjustment Assistance for Textile Manufacturers program from the Commodity Credit Corporation (CCC) to the Agricultural Marketing Service (AMS) to reflect changes in the organizational structure and delegated authorities within the United States Department of Agriculture (USDA). This action is necessary to enable the AMS Administrator to issue, maintain, and revise as necessary regulations related to programs under the AMS Administrator's delegated authority.

DATES: Effective October 1, 2021.

FOR FURTHER INFORMATION CONTACT: Laurel May, Regulatory Analyst, Legislative and Regulatory Review Staff, Office of the Administrator, AMS, USDA; Telephone: (202) 384–2975, or Email: *Laurel.May@usda.gov.*

SUPPLEMENTARY INFORMATION: Congress directed the Secretary of Agriculture (Secretary) to provide economic adjustment assistance to domestic users of upland cotton under the Economic Adjustment Assistance to Users of Upland Cotton program in section 1207(c) of the Food, Conservation, and Energy Act of 2008 (Pub. L. 110–234; May 22, 2008). Under the program domestic users of upland cotton may qualify for financial assistance that can be used to acquire, construct, install, modernize, develop, convert, or expand land, plant, buildings, equipment, facilities, or machinery. Payments for such assistance are issued by CCC. Section 1203(b) of the Agriculture Improvement Act of 2018 (Pub. L. 115–334; December 20, 2018) renamed the program ''Economic Assistance Adjustment to Textile Mills'' (EAATM). Regulations implementing the EAATM are found at 7 CFR part 1427, in subpart C, in §§ 1427.100 to 1427.105.

In a memorandum dated July 1, 2019,[1] the Secretary redelegated authority to administer EAATM from the Farm Service Agency to the Agricultural Marketing Service (AMS). A final rule published October 15, 2020 (85 FR 65500), amended 7 CFR part 2 to reflect the redelegation. Amended § 2.79(a)(23) authorizes the AMS Administrator to administer the EAATM program (7 U.S.C. 9037(c)). The redelegation of authority necessitates the transfer of corresponding regulations to AMS, giving the AMS Administrator authority to issue, maintain, and revise the regulations pertaining to EAATM. This final rule completes the necessary transfer.

Overview of Changes

Currently, Title 7, Chapter XIV, part 1427 of the Code of Federal Regulations (CFR) contains the EAATM regulations (in §§ 1427.100 to 1427.105), under CCC administration. This final rule removes the EAATM regulations from 7 CFR part 1427 and adds them in a new part 870—Economic Adjustment Assistance to Textile Mills—to 7 CFR chapter VIII, Subchapter B. Currently Subchapter B is titled ''Regulations for Warehouses'' and contains part 869—Regulations for the United States Warehouse Act (USWA). This final rule revises the title for Subchapter B to read ''Fair Trade Practices'' to reflect the delegation of administrative authority for both USWA and EAATM activities to the AMS Administrator. The Deputy Administrator of AMS's Fair Trade Practices Program (FTPP) oversees USWA and EAATM activities for the Administrator. Finally, this rule makes a conforming change to the text of the EAATM regulations to reflect the program's revised name.

[1] Secretary's Memorandum 1076–030 (July 1, 2019), available at *https://www.ocio.usda.gov/document/secretarys-memorandum-1076-030.*

Classification

This final rule is administrative in nature and reflects changes in USDA's organization. Accordingly, pursuant to 5 U.S.C. 553, notice of proposed rulemaking and opportunity for comment are not required, and this rule may be made effective in fewer than 30 days after publication in the **Federal Register**. Therefore, this final rule is effective upon publication.

Additionally, this rule is exempt from the provisions of Executive Order 12866, as it is limited to agency management. This action is not a rule as defined by the Regulatory Flexibility Act, as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. 801 *et seq.,* and thus is exempt from the provisions of those Acts. This rule contains no information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Congressional Review Act (5 U.S.C. 801 *et seq.*) provides exemptions for rules ''of particular applicability;'' ''relating to agency management or personnel;'' or ''of agency organization, procedure, or practice that does not substantially affect the rights or obligations of non-agency parties.'' This action qualifies for this exemption.

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.

USDA has not identified any relevant Federal rules that duplicate, overlap, or conflict with this final rule.

List of Subjects

7 CFR Part 870

Cotton, Payments, Reporting and recordkeeping, Textile mills.

7 CFR Part 1427

Cotton, Cottonseeds, Loan programs-agriculture, Packaging and containers, Price support programs, Reporting and recordkeeping requirements, Surety bonds, Warehouses.

For the reasons stated in the preamble, as authorized by the Secretary's Memorandum implementing the Agriculture Improvement Act of 2018, dated July 1, 2019, the

Department of Agriculture amends 7 CFR chapters VIII and XIV as follows:

TITLE 7—AGRICULTURE

CHAPTER VIII—AGRICULTURAL MARKETING SERVICE (FEDERAL GRAIN INSPECTION SERVICE, FAIR TRADE PRACTICES PROGRAM), DEPARTMENT OF AGRICULTURE

Subchapter B—Fair Trade Practices

■ 1. Under the authority of 7 CFR 2.22(a)(1), revise the heading of subchapter B to read as set forth above.

■ 2. Add part 870 to read as follows:

PART 870—ECONOMIC ASSISTANCE ADJUSTMENT FOR TEXTILE MILLS

Sec.
870.1 Applicability.
870.3 Eligible upland cotton.
870.5 Eligible domestic users.
870.7 Upland cotton Domestic User Agreement.
870.9 Payment.

Authority: 7 U.S.C. 9037(c).

§ 870.1 Applicability.

(a) These regulations specify the terms and conditions under which the Commodity Credit Corporation (CCC) will make payments to eligible domestic users who have entered into an Upland Cotton Domestic User Agreement with CCC to participate in the upland cotton domestic user program.

(b) CCC will specify the forms to be used in administering the Economic Adjustment Assistance for Textile Mills program.

§ 870.3 Eligible upland cotton.

(a) For purposes of this subpart, eligible upland cotton is baled upland cotton, regardless of origin, that is opened by an eligible domestic user, and is either:

(1) Baled lint, including baled lint classified by USDA's Agricultural Marketing Service as Below Grade;

(2) Loose samples removed from upland cotton bales for classification purposes that have been rebaled;

(3) Semi-processed motes that are of a quality suitable, without further processing, for spinning, papermaking, or production of non-woven fabric; or

(4) Re-ginned (processed) motes.

(b) Eligible upland cotton must not be:

(1) Cotton for which a payment, under the provisions of this subpart, has been made available;

(2) Raw (unprocessed) motes, pills, linters, or other derivatives of the lint cleaning process; or

(3) Textile mill wastes.

§ 870.5 Eligible domestic users.

(a) For purposes of this subpart, a person regularly engaged in the business of opening bales of eligible upland cotton for the purpose of spinning, papermaking, or processing of non-woven cotton fabric in the United States, who has entered into an agreement with CCC to participate in the upland cotton user program, will be considered an eligible domestic user.

(b) Applications for payment under this subpart must contain documentation required by the provisions of the Upland Cotton Domestic User Agreement and other instructions that CCC issues.

§ 870.7 Upland cotton Domestic User Agreement.

(a) Payments specified in this subpart will be made available to eligible domestic users who have entered into an Upland Cotton Domestic User Agreement with CCC and who have complied with the terms and conditions in this subpart, the Upland Cotton Domestic User Agreement, and instructions issued by CCC.

(b) Upland Cotton Domestic User Agreements may be obtained from the Warehouse and Commodity Management Division, P.O. Box 419205, Stop 9148, Kansas City, MO 64141–6205. In order to participate in the program authorized by this subpart, domestic users must execute the Upland Cotton Domestic User Agreement and forward the original and one copy to KCCO.

§ 870.9 Payment.

(a) The payment rate for purposes of calculating payments as specified in this subpart is 3 cents per pound.

(b) Payments specified in this subpart will be determined by multiplying the payment rate, of 3 cents per pound, by

(1) In the case of baled upland cotton, whether lint, loose samples or reginned motes, but not semi-processed motes, the net weight of the cotton used (gross weight minus the weight of bagging and ties);

(2) In the case of unbaled reginned motes consumed, without rebaling, for an end use in a continuous manufacturing process, the weight of the reginned motes after final cleaning; and

(3) In the case of semi-processed motes which are of a quality suitable, without further processing, for spinning, papermaking, or manufacture of non-woven cotton fabric, 25 percent of the weight (gross weight minus the weight of bagging and ties, if baled) of the semi-processed motes; provided further, that with respect to semi-processed motes that are used prior to August 18, 2010, payment may be allowed by CCC in its sole discretion at 100 percent of the weight as determined appropriate for a transition of the program to the 25 percent factor.

(c) In all cases, the payment will be determined based on the amount of eligible upland cotton that an eligible domestic user consumed during the immediately preceding calendar month. For the purposes of this subpart, eligible upland cotton will be considered consumed by the domestic user on the date the bale is opened for consumption, or if not baled, the date consumed, without further processing, in a continuous manufacturing process.

(d) Payments specified in this subpart will be made available upon application for payment and submission of supporting documentation, as required by the CCC-issued provisions of the Upland Cotton Domestic User Agreement.

(e) All payments received by the eligible domestic user of upland cotton must be used for purposes specified in 7 U.S.C. 9037(c)(3), which include but are not limited to, acquisition, construction, installation, modernization, development, conversion, or expansion of land, plant, buildings, equipment, facilities, or machinery. Such capital expenditures must be directly attributable and certified as such by the user for the purpose of manufacturing upland cotton into eligible cotton products in the United States.

CHAPTER XIV—COMMODITY CREDIT CORPORATION, DEPARTMENT OF AGRICULTURE

PART 1427—COTTON

■ 3. The authority citation for part 1427 continues to read as follows:

Authority: 7 U.S.C. 7231–7237, 7931–7936, 9011, and 9031–40, 15 U.S.C. 714b and c.

Subpart C—[Removed and Reserved]

■ 4. Remove and reserve subpart C, consisting of §§ 1427.100 through 1427.105.

Mae Wu,

Deputy Under Secretary, Marketing and Regulatory Programs.

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NUCLEAR REGULATORY COMMISSION

10 CFR Part 72

[NRC–2021–0135]

RIN 3150–AK68

List of Approved Spent Fuel Storage Casks: Holtec International HI–STAR 100 Cask System, Certificate of Compliance No. 1008, Renewal of Initial Certificate and Amendment Nos. 1, 2, and 3

AGENCY: Nuclear Regulatory Commission.

ACTION: Direct final rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is amending its spent fuel storage regulations by revising the Holtec International HI–STAR 100 Cask System listing within the ''List of approved spent fuel storage casks'' to renew, for an additional 40 years, the initial certificate and Amendment Nos. 1, 2, and 3 of Certificate of Compliance No. 1008. The renewal of the initial certificate and Amendment Nos. 1, 2, and 3 revises the certificate of compliance's conditions and technical specifications to address aging management activities related to the structures, systems, and components of the dry storage system to ensure that these will maintain their intended functions during the period of extended storage operations.

DATES: This direct final rule is effective December 15, 2021, unless significant adverse comments are received by November 1, 2021. If this direct final rule is withdrawn as a result of such comments, timely notice of the withdrawal will be published in the **Federal Register**. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date. Comments received on this direct final rule will also be considered to be comments on a companion proposed rule published in the Proposed Rules section of this issue of the **Federal Register**.

ADDRESSES: Submit your comments, identified by Docket ID NRC–2021–0135, at *https://www.regulations.gov.* If your material cannot be submitted using *https://www.regulations.gov,* call or email the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

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: Kristina Banovac, Office of Nuclear Material Safety and Safeguards; telephone: 301–415–7116, email: *Kristina.Banovac@nrc.gov* and Vanessa Cox, Office of Nuclear Material Safety and Safeguards, telephone: 301–415–8342, email: *Vanessa.Cox@nrc.gov.* Both are staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

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I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2021–0135 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 *https://www.regulations.gov* and search for Docket ID NRC–2021–0135. Address questions about NRC dockets to Dawn Forder, telephone: 301–415–3407, email: *Dawn.Forder@nrc.gov.* For technical questions contact the individuals 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 *https://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.* For the convenience of the reader, instructions about obtaining materials referenced in this document are provided in the ''Availability of Documents'' section.
- Attention: The PDR, where you may examine and order copies of public documents, is currently closed. You may submit your request to the PDR via email at *pdr.resource@nrc.gov* or call 1–800–397–4209 between 8:00 a.m. and 4:00 p.m. (EST), Monday through Friday, except Federal holidays.

B. Submitting Comments

Please include Docket ID NRC–2021–0135 in your comment submission. The NRC requests that you submit comments through the Federal rulemaking website at *https://www.regulations.gov.* If your material cannot be submitted using *https://www.regulations.gov,* call or email the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

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 *https://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. Rulemaking Procedure

This rule is limited to the renewal of the initial certificate and Amendment Nos. 1, 2, and 3 to Certificate of Compliance No. 1008 and does not include other aspects of the Holtec International HI–STAR 100 Cask System design. The NRC is using the ''direct final rule procedure'' to issue this renewal because it represents a limited and routine change to an existing certificate of compliance that is expected to be non-controversial. Adequate protection of public health and safety continues to be reasonably assured. The amendment to the rule will become effective on December 15, 2021. However, if the NRC receives any significant adverse comment on this direct final rule by November 1, 2021, then the NRC will publish a document that withdraws this action and will subsequently address the comments received in a final rule as a response to

the companion proposed rule published in the Proposed Rules section of this issue of the **Federal Register**. Absent significant modifications to the proposed revisions requiring republication, the NRC will not initiate a second comment period on this action.

A significant adverse comment is a comment where the commenter explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. A comment is adverse and significant if:

(1) The comment opposes the rule and provides a reason sufficient to require a substantive response in a notice-and-comment process. For example, a substantive response is required when:

(a) The comment causes the NRC to reevaluate (or reconsider) its position or conduct additional analysis;

(b) The comment raises an issue serious enough to warrant a substantive response to clarify or complete the record; or

(c) The comment raises a relevant issue that was not previously addressed or considered by the NRC.

(2) The comment proposes a change or an addition to the rule, and it is apparent that the rule would be ineffective or unacceptable without incorporation of the change or addition.

(3) The comment causes the NRC to make a change (other than editorial) to the rule, certificate of compliance, or technical specifications.

III. Background

Section 218(a) of the Nuclear Waste Policy Act of 1982, as amended, requires that ''[t]he Secretary [of the Department of Energy] shall establish a demonstration program, in cooperation with the private sector, for the dry storage of spent nuclear fuel at civilian nuclear power reactor sites, with the objective of establishing one or more technologies that the [Nuclear Regulatory] Commission may, by rule, approve for use at the sites of civilian nuclear power reactors without, to the maximum extent practicable, the need for additional site-specific approvals by the Commission.'' Section 133 of the Nuclear Waste Policy Act states, in part, that ''[t]he Commission shall, by rule, establish procedures for the licensing of any technology approved by the Commission under Section 219(a) [sic: 218(a)] for use at the site of any civilian nuclear power reactor.''

To implement this mandate, the Commission approved dry storage of spent nuclear fuel in NRC-approved casks under a general license by publishing a final rule that added a new subpart K in part 72 of title 10 of the *Code of Federal Regulations* (10 CFR) entitled ''General License for Storage of Spent Fuel at Power Reactor Sites'' (55 FR 29181; July 18, 1990). This rule also established a new subpart L in 10 CFR part 72 entitled ''Approval of Spent Fuel Storage Casks,'' which contains procedures and criteria for obtaining NRC approval of spent fuel storage cask designs. The NRC subsequently issued a final rule on September 3, 1999 (64 FR 48259) that approved the HI–STAR 100 Cask System design and added it to the list of NRC-approved cask designs in § 72.214 as Certificate of Compliance No. 1008.

IV. Discussion of Changes

On December 7, 2018, Holtec International submitted a request to the NRC to renew, for an additional 40 years, the initial certificate and Amendment Nos. 1, 2, and 3 of Certificate of Compliance No. 1008 for the HI–STAR 100 Cask System. Holtec International supplemented its request on June 28, 2019, October 10, 2019, December 12, 2019, June 1, 2020, June 11, 2020, November 13, 2020, and November 24, 2020.

The renewal of the initial certificate and Amendment Nos. 1, 2, and 3 were conducted in accordance with the renewal provisions in § 72.240. This section of the NRC spent fuel storage regulations authorizes NRC staff to include any additional certificate conditions it deems necessary to ensure the safe operation of the cask during the certificate's renewal period. The NRC included three additional conditions to the renewal of the initial certificate of compliance and Amendment Nos. 1, 2, and 3:

- The submittal of an updated final safety analysis report (UFSAR) to address aging management activities resulting from the renewal of the certificate of compliance. This condition ensures that the UFSAR changes are made in a timely fashion to enable general licensees using the storage system during the period of extended operation to develop and implement necessary procedures.
- The requirement that general licensees initiating or using spent fuel dry storage operations with the HI–STAR 100 Cask System ensure that their evaluations are included in the reports required by § 72.212, ''Conditions of general license issued under § 72.210.'' These reports will include appropriate considerations for the period of extended operation, a review of the UFSAR changes resulting from the certificate of compliance renewal, and a review of the NRC safety evaluation report (SER) related to the certificate of compliance renewal.
- The requirement that future amendments and revisions to this certificate of compliance include evaluations of the impacts to aging management activities to ensure that they remain adequate for any changes to the structures, systems, and components (SSCs).

The NRC made one corresponding change to the technical specifications for the initial certificate of compliance and Amendment Nos. 1, 2, and 3 on the aging management program. The change added a new section, which ensures that general licensees using the storage system develop procedures to address aging management activities required in the period of extended operation.

As documented in the preliminary SER, the NRC performed a safety evaluation of the proposed certificate of compliance renewal request. The NRC determined that this renewal does not change the cask design or fabrication requirements in the proposed certificate of compliance renewal request. The NRC determined that the design of the cask would continue to maintain confinement, shielding, and criticality control in the event of each evaluated accident condition. In addition, any resulting occupational exposure or offsite dose rates from the renewal of the initial certificate of compliance and Amendment Nos. 1, 2, and 3 would remain well within the limits specified by 10 CFR part 20, ''Standards for Protection Against Radiation.'' Thus, the NRC found there will be no significant change in the types or amounts of any effluent released, no significant increase in the individual or cumulative radiation exposure, and no significant increase in the potential for or consequences from radiological accidents. In its SER for the renewal of the HI–STAR 100 Cask System, the NRC has determined that if the conditions specified in the certificate of compliance to implement these regulations are met, adequate protection of public health and safety will continue to be reasonably assured.

This direct final rule revises the HI–STAR 100 Cask System listing in § 72.214 by renewing, for 40 more years, the initial certificate and Amendment Nos. 1, 2, and 3 of Certificate of Compliance No. 1008. The renewal consists of the changes previously described, as set forth in the renewed initial certificate and amendments and their revised technical specifications. The revised technical specifications are identified in the SER.

V. Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995 (Pub. L. 104–113) requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. In this direct final rule, the NRC revises the Holtec International HI–STAR 100 Cask System Cask System design listed in § 72.214, ''List of approved spent fuel storage casks.'' This action does not constitute the establishment of a standard that contains generally applicable requirements.

VI. Agreement State Compatibility

Under the ''Agreement State Program Policy Statement'' approved by the Commission on October 2, 2017, and published in the **Federal Register** on October 18, 2017 (82 FR 48535), this rule is classified as Compatibility Category NRC—Areas of Exclusive NRC Regulatory Authority. The NRC program elements in this category are those that relate directly to areas of regulation reserved to the NRC by the Atomic Energy Act of 1954, as amended, or the provisions of 10 CFR chapter I. Therefore, compatibility is not required for program elements in this category. Although an Agreement State may not adopt program elements reserved to the NRC, and the Category ''NRC'' does not confer regulatory authority on the State, the State may wish to inform its licensees of certain requirements by means consistent with the particular State's administrative procedure laws.

VII. Plain Writing

The Plain Writing Act of 2010 (Pub. L. 111–274) requires Federal agencies to write documents in a clear, concise, and well-organized manner. The NRC has written this document to be consistent with the Plain Writing Act as well as the Presidential Memorandum, ''Plain Language in Government Writing,'' published June 10, 1998 (63 FR 31885).

VIII. Environmental Assessment and Finding of No Significant Impact

Under the National Environmental Policy Act of 1969, as amended, and the NRC's regulations in 10 CFR part 51, ''Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions,'' the NRC has determined that this direct final rule, if adopted, would not be a major Federal action significantly affecting the quality of the human environment and, therefore, an environmental impact statement is not required. The NRC has made a finding of no significant impact on the basis of this environmental assessment.

A. The Action

The action is to amend § 72.214 to revise the Holtec International HI–STAR 100 Cask System listing within the ''List of approved spent fuel storage casks'' to renew, for an additional 40 years, the initial certificate and Amendment Nos. 1, 2, and 3 of Certificate of Compliance No. 1008.

B. The Need for the Action

This direct final rule renews the initial certificate and Amendment Nos. 1, 2, and 3 of Certificate of Compliance No. 1008 for the Holtec International HI–STAR 100 Cask System design within the list of approved spent fuel storage casks to allow power reactor licensees to store spent fuel at reactor sites in casks with the approved modifications under a general license. Specifically, this rule extends the expiration date for the Holtec International HI–STAR 100 Cask System certificate for an additional 40 years, allowing a power reactor licensee to continue using it under general license provisions in an independent spent fuel storage installation to store spent fuel in dry casks in accordance with 10 CFR part 72.

C. Environmental Impacts of the Action

On July 18,1990 (55 FR 29181), the NRC issued an amendment to 10 CFR part 72 to provide for the storage of spent fuel under a general license in cask designs approved by the NRC. The potential environmental impact of using NRC-approved storage casks was analyzed in the environmental assessment for the 1990 final rule. The environmental assessment for the renewal of the initial certificate and Amendment Nos. 1, 2, and 3 of Certificate of Compliance No. 1008 tiers off of the environmental assessment for the July 18, 1990, final rule. Tiering on past environmental assessments is a standard process under the National Environmental Policy Act of 1969, as amended. As required by § 72.240, applications for renewal of a spent fuel storage certificate of compliance design are required to demonstrate that SSCs important to safety will continue to perform their intended function for the requested renewal term. As discussed in the NRC staff's SER for the renewal of the initial certificate and Amendment Nos. 1, 2, and 3, the NRC staff has approved conditions in the renewed initial certificate and Amendment Nos. 1, 2, and 3 requiring the general licensee to implement the aging management activities described in the renewal application and incorporated into the UFSAR. These conditions ensure that the Holtec International HI–STAR 100 Cask System will continue to perform its intended safety functions and provide reasonable assurance of adequate protection of public health and safety throughout the renewal period.

Incremental impacts from continued use of the HI–STAR 100 Cask System under a general license for an additional 40 years are not considered significant. When the general licensee follows all procedures and administrative controls, including the conditions established because of this renewal, no effluents are expected from the sealed dry cask systems. Activities associated with cask loading and decontamination may result in some small incremental liquid and gaseous effluents, but these activities will be conducted under 10 CFR parts 50 and 52 reactor operating licenses, and effluents will be controlled within existing reactor site technical specifications. Because reactor sites are relatively large, any incremental offsite doses due to direct radiation exposure from the spent fuel storage casks are expected to be small, and when combined with the contribution from reactor operations, well within the annual dose equivalent of 0.25 mSv (25 mrem) limit to the whole body specified in § 72.104. Incremental impacts on collective occupational exposures due to dry cask spent fuel storage are expected to be only a small fraction of the exposures from operation of the nuclear power station.

The HI–STAR 100 Cask System is designed to mitigate the effects of design basis accidents that could occur during storage. Design basis accidents account for human-induced events and the most severe natural phenomena reported for the site and surrounding area. Postulated accidents analyzed for an independent spent fuel storage installation include tornado winds and tornado-generated missiles, a design basis earthquake, a design basis flood, an accidental cask drop, lightning effects, fire, explosions, and other incidents.

During the promulgation of the amendments that added subpart K to 10 CFR part 72 (55 FR 29181; July 18, 1990), the NRC staff assessed the public health consequences of dry cask storage accidents and sabotage events. In the supporting analyses for these amendments, the NRC staff determined that a release from a dry cask storage system would be comparable in magnitude to a release from the same quantity of fuel in a spent fuel storage pool. As a result of these evaluations,

the NRC staff determined that, because of the physical characteristics of the storage casks and conditions of storage that include specific security provisions, the potential risk to public health and safety due to accidents or sabotage is very small.

Considering the specific design requirements for each accident or sabotage condition, the design of the cask would maintain confinement, shielding, and criticality control. If confinement, shielding, and criticality control are maintained, the environmental impacts from an accident would be insignificant.

There are no changes to cask design or fabrication requirements in the renewed initial certificate or Amendment Nos. 1, 2, and 3. Because there are no significant design or process changes, any resulting occupational exposure or offsite dose rates from the implementation of the renewal of the initial certificate and Amendment Nos. 1, 2, and 3 would remain well within the 10 CFR part 20 limits.

Decommissioning of dry cask spent fuel storage systems under a general license would be carried out as part of a power reactor's site decommissioning plan. In general, decommissioning would consist of removing the spent fuel from the site, decontaminating cask surfaces, and decontaminating and dismantling the independent spent fuel storage installation where the casks were deployed. Under normal and off-normal operating conditions, no residual contamination is expected to be left behind on supporting structures. The incremental impacts associated with decommissioning dry cask storage installations are expected to represent a small fraction of the impacts of decommissioning an entire nuclear power station.

In summary, the proposed changes will not result in any radiological or non-radiological environmental impacts that significantly differ from the environmental impacts evaluated in the environmental assessment supporting the July 18, 1990, final rule. Compliance with the requirements of 10 CFR parts 20 and 72 would provide reasonable assurance that adequate protection of public health and safety will continue. The NRC, in its SER for the renewal of the HI–STAR 100 Cask System, has determined if the conditions specified in the certificate of compliance to implement these regulations are met, adequate protection of public health and safety will continue to be reasonably assured.

Based on the previously stated assessments and its SER for the requested renewal of the HI–STAR 100 Cask System certificates, the NRC has determined that the expiration date of this system in 10 CFR 72.214 can be safely extended for an additional 40 years, and that commercial nuclear power reactor licensees can continue using the system during this period under a general license without significant impacts on the human environment.

D. Alternative to the Action

The alternative to this action is to deny approval of the renewal and not issue the direct final rule. Under this alternative, the NRC would either (1) require general licensees using the HI–STAR 100 Cask System to unload the spent fuel from these systems and either return it to a spent fuel pool or re-load it into a different dry storage cask system listed in § 72.214; or (2) require that users of the existing HI–STAR 100 Cask System request site-specific licensing proceedings to continue storage in these systems.

The environmental impacts of requiring the licensee to unload the spent fuel and either return it to the spent fuel pool or re-load it into another NRC-approved cask system would result in increased radiological doses to workers. These increased doses would be due primarily to direct radiation from the casks while the workers unloaded, transferred, and re-loaded the spent fuel. These activities would consist of transferring the dry storage canisters to a cask-handling building, opening the canister lid welds, returning the canister to a spent fuel pool or dry transfer facility, removing the fuel assemblies, and re-loading them, either into a spent fuel pool storage rack or another NRC-approved dry storage system. In addition to the increased occupational doses to workers, these activities may also result in additional liquid or gaseous effluents.

Alternatively, users of the dry cask storage system would need to apply for a site-specific license. Under this option for implementing the no-action alternative, interested licensees would have to prepare, and the NRC would have to review, each separate license application, thereby increasing the administrative burden upon the NRC and the costs to each licensee.

In summary, the no-action alternative would entail either (1) more environmental impacts than the preferred action from transferring the spent fuel now in the HI–STAR 100 Cask System; or (2) cost and administrative impacts from multiple licensing actions that, in aggregate, are likely to be the same as, or more likely greater than, the preferred action.

E. Alternative Use of Resources

Renewal of the initial certificate and Amendment Nos. 1, 2, and 3 to Certificate of Compliance No. 1008 would result in no irreversible commitment of resources.

F. Agencies and Persons Contacted

No agencies or persons outside the NRC were contacted in connection with the preparation of this environmental assessment.

G. Finding of No Significant Impact

The environmental impacts of the action have been reviewed under the requirements in the National Environmental Policy Act of 1969, as amended, and the NRC's regulations in subpart A of 10 CFR part 51, ''Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions.'' Based on the foregoing environmental assessment, the NRC concludes that this direct final rule, ''List of Approved Spent Fuel Storage Casks: Holtec International HI–STAR 100 Cask System, Certificate of Compliance No. 1008, Renewal of Initial Certificate and Amendment Nos. 1, 2, and 3,'' will not have a significant effect on the human environment. Therefore, the NRC has determined that an environmental impact statement is not necessary for this direct final rule.

IX. Paperwork Reduction Act Statement

This direct final rule does not contain any new or amended collections of information subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Existing collections of information were approved by the Office of Management and Budget, approval number 3150–0132.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid Office of Management and Budget control number.

X. Regulatory Flexibility Certification

Under the Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b)), the NRC certifies that this direct final rule will not, if issued, have a significant economic impact on a substantial number of small entities. This direct final rule affects only nuclear power plant licensees and Holtec International.

These entities do not fall within the scope of the definition of small entities set forth in the Regulatory Flexibility Act or the size standards established by the NRC (§ 2.810).

XI. Regulatory Analysis

On July 18, 1990 (55 FR 29181), the NRC issued an amendment to 10 CFR part 72 to provide for the storage of spent nuclear fuel under a general license in cask designs approved by the NRC. Any nuclear power reactor licensee can use NRC-approved cask designs to store spent nuclear fuel if (1) it notifies the NRC in advance; (2) the spent fuel is stored under the conditions specified in the cask's certificate of compliance; and (3) the conditions of the general license are met. A list of NRC-approved cask designs is contained in § 72.214. On September 3, 1999 (64 FR 48259), the NRC issued an amendment to 10 CFR part 72 that approved the HI–STAR 100 Cask System design by adding it to the list of NRC-approved cask designs in § 72.214 as Certificate of Compliance No. 1008.

On December 7, 2018, Holtec International requested a renewal of the initial certificate and Amendment Nos. 1, 2, and 3 of the HI–STAR 100 Cask System for an additional 40 years beyond the initial certificate term. Holtec International supplemented its request on June 28, 2019, October 10, 2019, December 12, 2019, June 1, 2020, June 11, 2020, November 13, 2020, and November 24, 2020. Because Holtec International filed its renewal application at least 30 days before the certificate expiration date of October 4, 2019, pursuant to the timely renewal provisions in § 72.240(b), the initial issuance of the certificate and Amendment Nos. 1, 2, and 3 of Certificate of Compliance No. 1008 did not expire.

The alternative to this action is to deny approval of the renewal of the initial certificate and Amendment Nos. 1, 2, and 3 of Certificate of Compliance No. 1008 and end this direct final rule. Under this alternative, the NRC would either (1) require general licensees using the HI–STAR 100 Cask System to unload spent fuel from these systems and return it to a spent fuel pool or re-load it into a different dry storage cask system listed in 10 CFR 72.214; or 2) require that users of the existing HI–STAR 100 Cask System request site-specific licensing proceedings to continue storage in these systems. Therefore, the no-action alternative would result in a significant burden on licensees and an additional inspection or licensing caseload on the NRC. In addition, the no-action alternative would entail either (1) more environmental impacts than the preferred action from transferring the spent fuel now in the HI–STAR 100 Cask System; or (2) cost and administrative impacts from multiple licensing actions that, in aggregate, are likely to be the same as, or more likely greater than, the preferred action.

Approval of this direct final rule is consistent with previous NRC actions. Further, as documented in the preliminary SER and environmental assessment, this direct final rule will have no adverse effect on public health and safety or the environment. This direct final rule has no significant identifiable impact or benefit on other government agencies. Based on this regulatory analysis, the NRC concludes that the requirements of this direct final rule are commensurate with the NRC's responsibilities for public health and safety and the common defense and security. No other available alternative is believed to be as satisfactory; therefore, this action is recommended.

XII. Backfitting and Issue Finality

The NRC has determined that the backfit rule (§ 72.62) does not apply to this direct final rule. Therefore, a backfit analysis is not required. This direct final rule revises Certificate of Compliance No. 1008 for the Holtec International HI–STAR 100 Cask System, as currently listed in § 72.214, to extend the expiration date of the initial certificate and Amendment Nos. 1, 2, and 3 by 40 years. The renewed initial certificate and Amendment Nos. 1, 2, and 3 consist of the changes previously described, as set forth in the renewed certificate of compliance and technical specifications.

Extending the effective date of the initial certificate and Amendment Nos. 1, 2, and 3 for 40 more years and requiring the implementation of aging management activities does not impose any modification or addition to the design of a cask system's SSCs, or to the procedures or organization required to operate the system during the initial 20-year storage period of the system, as authorized by the current certificate. General licensees that have loaded these casks, or that load these casks in the future under the specifications of the applicable certificate, may continue to store spent fuel in these systems for the initial 20-year storage period consistent with the original certificate. The aging management activities required to be implemented by this renewal are only required after the storage cask system's initial 20-year service period ends. As explained in the 2011 final rule that amended 10 CFR part 72 (76 FR 8872, Question I), the general licensee's authority to use a particular storage cask design under an approved certificate of compliance terminates 20 years after the date that the general licensee first loads the particular cask with spent fuel, unless the cask's certificate of compliance is renewed. Because this rulemaking renews the initial certificate and Amendment Nos. 1, 2, and 3, and renewal is a separate licensing action voluntarily implemented by vendors, the renewal of the initial certificate and Amendment Nos. 1, 2, and 3 is not an imposition of new or changed requirements from which these licensees would otherwise be protected by the backfitting provisions in § 72.62.

Even if renewal of the initial certificate and Amendment Nos. 1, 2, and 3 of Certificate of Compliance No. 1008 could be considered a backfit, Holtec International, as the holder of the certificate of compliance and vendor of the casks, is not protected by the backfitting provisions in § 72.62.

Unlike a vendor, general licensees using the existing systems subject to this renewal would be protected by the backfitting provisions in § 72.62 if the renewal constituted new or changed requirements applicable during the initial 20-year storage period. But, as previously explained, renewal of the initial certificate and Amendment Nos. 1, 2, and 3 of Certificate of Compliance No. 1008 does not impose such requirements. The general licensee using the initial certificate or Amendment Nos. 1, 2, or 3 of Certificate of Compliance No. 1008 may continue storing material in their respective cask systems for the initial 20-year storage period identified in the applicable certificate or amendment with no changes. If general licensees choose to continue to store spent fuel in HI–STAR 100 Cask Systems after the initial 20-year period, these general licensees will be required to implement aging management activities for any cask systems subject to a renewed certificate of compliance, but such continued use is voluntary.

For these reasons, renewing the initial certificate and Amendment Nos. 1, 2, and 3 of Certificate of Compliance No. 1008, and imposing the additional conditions previously discussed, does not constitute backfitting under § 72.62, or otherwise represent an inconsistency with the issue finality provisions applicable to combined licenses in 10 CFR part 52. Accordingly, the NRC has not prepared a backfit analysis for this rulemaking.

XIII. Congressional Review Act

This direct final rule is not a rule as defined in the Congressional Review Act.

XIV. Availability of Documents

The documents identified in the following table are available to interested persons as indicated.

Document	ADAMS accession No.
Holtec International HI–STAR 100 Storage System, Certificate of Compliance No. 1008 Renewal Application, dated December 7, 2018.	ML18345A178 (package).
Holtec International Response to the Request for Supplemental Information on the Renewal of the HI–STAR 100 Storage System, Certificate of Compliance No. 1008, dated June 28, 2019.	ML19184A232 (package).
Holtec International Submittal of Supplemental Information Related to Request for Supplemental Information on the Renewal of the HI–STAR 100 Storage System, Certificate of Compliance No. 1008, dated October 10, 2019.	ML19288A089 (package).
Holtec International HI–STAR 100 Storage System, Certificate of Compliance No. 1008 Renewal, Updated Non-Proprietary Documents, dated December 12, 2019.	ML19350A576.
Holtec International Response to the Request for Additional Information on the Renewal of the HI–STAR 100 Storage System, Certificate of Compliance No. 1008, dated June 1, 2020.	ML20153A768 (package).
Holtec International Response to the Request for Additional Information on the Renewal of the HI–STAR 100 Storage System, Certificate of Compliance No. 1008, dated June 11, 2020.	ML20163A713 (package).
Holtec International Response to the Request for Clarification of Additional Information on the Renewal of the HI–STAR 100 Storage System, Certificate of Compliance No. 1008, dated November 13, 2020.	ML20318A321 (package).
Holtec International Response to the Request for Clarification of Additional Information on the Renewal of the HI–STAR 100 Storage System, Certificate of Compliance No. 1008, Updated Attachment, dated November 24, 2020.	ML20329A321 (package).
User Need Memorandum for Rulemaking for Certificate of Compliance No. 1008 Renewal, Initial Issue, Amendment Numbers 1, 2, and 3 to HI–STAR 100 Cask System, dated June 28, 2021.	ML21168A352.
Proposed Certificate of Compliance No. 1008, Renewed Amendment No. 0	ML21168A353.
Proposed Technical Specifications (Appendix A) for Certificate of Compliance No. 1008, Renewed Amendment No. 0.	ML21168A354.
Proposed Technical Specifications (Appendix B) for Certificate of Compliance No. 1008, Renewed Amendment No. 0.	ML21168A355.
Proposed Certificate of Compliance No. 1008, Renewed Amendment No. 1	ML21168A356.
Proposed Technical Specifications (Appendix A) for Certificate of Compliance No. 1008, Renewed Amendment No. 1.	ML21168A357.
Proposed Technical Specifications (Appendix B) for Certificate of Compliance No. 1008, Renewed Amendment No. 1.	ML21168A358.
Proposed Certificate of Compliance No. 1008, Renewed Amendment No. 2	ML21168A359.
Proposed Technical Specifications (Appendix A) for Certificate of Compliance No. 1008, Renewed Amendment No. 2.	ML21168A360.
Proposed Technical Specifications (Appendix B) for Certificate of Compliance No. 1008, Renewed Amendment No. 2.	ML21168A361.
Proposed Certificate of Compliance No. 1008, Renewed Amendment No. 3	ML21168A362.
Proposed Technical Specifications (Appendix A) for Certificate of Compliance No. 1008, Renewed Amendment No. 3.	ML21168A363.
Proposed Technical Specifications (Appendix B) for Certificate of Compliance No. 1008, Renewed Amendment No. 3.	ML21168A364.
Preliminary Safety Evaluation Report for Renewed Certificate of Compliance No. 1008, Amendment Nos. 0, 1, 2, and 3.	ML21168A365.

The NRC may post materials related to this document, including public comments, on the Federal rulemaking website at *https://www.regulations.gov* under Docket ID NRC–2021–0135.

List of Subjects in 10 CFR Part 72

Administrative practice and procedure, Hazardous waste, Indians, Intergovernmental relations, Nuclear energy, Penalties, Radiation protection, Reporting and recordkeeping requirements, Security measures, Spent fuel, Whistleblowing.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; the Nuclear Waste Policy Act of 1982, as amended; and 5 U.S.C. 552 and 553; the NRC is adopting the following amendments to 10 CFR part 72:

PART 72—LICENSING REQUIREMENTS FOR THE INDEPENDENT STORAGE OF SPENT NUCLEAR FUEL, HIGH-LEVEL RADIOACTIVE WASTE, AND REACTOR-RELATED GREATER THAN CLASS C WASTE

■ 1. The authority citation for part 72 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 51, 53, 57, 62, 63, 65, 69, 81, 161, 182, 183, 184, 186, 187, 189, 223, 234, 274 (42 U.S.C. 2071, 2073, 2077, 2092, 2093, 2095, 2099, 2111, 2201, 2210e, 2232, 2233, 2234, 2236, 2237, 2238, 2273, 2282, 2021); Energy Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); National Environmental Policy Act of 1969 (42 U.S.C. 4332); Nuclear Waste Policy Act of 1982, secs. 117(a), 132, 133, 134, 135, 137, 141, 145(g), 148, 218(a) (42 U.S.C. 10137(a), 10152, 10153, 10154, 10155, 10157, 10161, 10165(g), 10168, 10198(a)); 44 U.S.C. 3504 note.

■ 2. In § 72.214, Certificate of Compliance No. 1008 is revised to read as follows:

§ 72.214 List of approved spent fuel storage casks.

* * * * *

Certificate Number: 1008.

Initial Certificate Effective Date: October 4, 1999, superseded by Renewed Initial Certificate, on December 15, 2021.

Amendment Number 1 Effective Date: December 26, 2000, superseded by Renewed Amendment Number 1, on December 15, 2021.

Amendment Number 2 Effective Date: May 29, 2001, superseded by Renewed

Amendment Number 2, on December 15, 2021.

Amendment Number 3 Effective Date: November 5, 2019, superseded by Renewed Amendment Number 3, on December 15, 2021.

SAR Submitted by: Holtec International.

SAR Title: Final Safety Analysis Report for the HI–STAR 100 Cask System.

Docket Number: 72–1008.

Certificate Expiration Date: October 4, 2019.

Renewed Certificate Expiration Date: October 4, 2059.

Model Number: HI–STAR 100 (MPC–24, MPC–32, MPC–68, MPC–68F).

* * * * *

Dated: September 15, 2021.

For the Nuclear Regulatory Commission.

Margaret M. Doane,

Executive Director for Operations.

[FR Doc. 2021–21427 Filed 9–30–21; 8:45 am]

BILLING CODE 7590–01–P

FARM CREDIT ADMINISTRATION

12 CFR Parts 614, 615, 620, and 628

RIN 3052–AD27

Regulatory Capital Rules: Tier 1/Tier 2 Framework

AGENCY: Farm Credit Administration.

ACTION: Final rule.

SUMMARY: The Farm Credit Administration (FCA or we) is adopting a final rule that amends the regulatory capital requirements for Farm Credit System (System or FCS) institutions. These amendments clarify certain provisions in the Tier 1/Tier 2 Capital Framework final rule that became effective in 2017 (2017 Capital Rule) and codify the guidance provided in FCA Bookletter—BL–068—Tier 1/Tier 2 Capital Framework Guidance. This final rule also includes revisions to the regulatory capital rules to reduce administrative burden for System institutions and the FCA. Lastly, to maintain comparability in our regulatory capital requirements, we are amending certain definitions pertaining to qualified financial contracts in conformity with changes adopted by the Federal banking regulatory agencies.

DATES: The regulation shall become effective January 1, 2022, or 30 days after publication in the **Federal Register** during which either or both houses of Congress are in session, whichever is later. Pursuant to 12 U.S.C. 2252(c)(1), FCA will publish notification of the effective date in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT:

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or

Legal information: Rebecca S. Orlich, *Orlichr@fca.gov,* Senior Counsel, or Jennifer A. Cohn, *Cohnj@fca.gov,* Senior Counsel, Office of General Counsel, Farm Credit Administration, McLean, VA 22102–5090, (703) 883–4020, TTY (703) 883–4056.

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I. Introduction

A. Objectives of the Final Rule

FCA's objectives in adopting this rule are to:

- Provide technical corrections, amendments and clarification to certain provisions in the Tier 1/Tier 2 Capital Framework; and
- Ensure the System's capital requirements maintain comparability with the standardized approach that the Federal banking regulatory agencies [1] have adopted (U.S. Rule) while accommodating the cooperative structure and the organization of the System.

B. Background

In 1916, Congress created the System to provide permanent, stable, affordable, and reliable sources of credit and related services to American agricultural and aquatic producers.[2] As of June 30, 2021, the System consists of 3 Farm Credit Banks, 1 agricultural credit bank, 66 agricultural credit associations, 1 Federal land credit association, service corporations, and the Federal Farm Credit Banks Funding Corporation (Funding Corporation). Farm Credit banks (including both the Farm Credit Banks and the agricultural credit bank) issue System-wide consolidated debt obligations in the capital markets through the Funding Corporation,[3] which enable the System to extend short-, intermediate-, and long-term credit and related services to farmers, ranchers, aquatic producers and harvesters, their cooperatives, rural utilities, exporters of agricultural commodities products, farm-related businesses, and certain rural homeowners.[4] The System's enabling statute is the Farm Credit Act of 1971, as amended (Act).[5]

FCA's Tier 1/Tier 2 Capital Framework, the 2017 Capital Rule, was published in the **Federal Register** in

[1] The Federal banking regulatory agencies are the Office of the Comptroller of the Currency (OCC), the Federal Deposit Insurance Corporation (FDIC), and the Board of Governors of the Federal Reserve (FRB). See 12 CFR 3.20(b)(1)(i) (OCC), 12 CFR 324.20(b)(1)(i) (FDIC); 12 CFR 217.20(b)(1)(i) (FRB).

[2] The Federal Agricultural Mortgage Corporation (Farmer Mac), which is also a System institution, has authority to operate secondary markets for agricultural real estate mortgage loans, rural housing mortgage loans, and rural utility cooperative loans. The FCA has a separate set of capital regulations that apply to Farmer Mac. This rulemaking does not affect Farmer Mac, and the use of the term ''System institution'' in this preamble and rule does not include Farmer Mac.

[3] The Funding Corporation was established pursuant to section 4.9 of the Farm Credit Act of 1971, as amended, and is owned by all Farm Credit banks.

[4] The agricultural credit bank lends to and provides other financial services to farmer-owned cooperatives, rural utilities (electric and telecommunications), and rural water and wastewater disposal systems. It also finances U.S. agricultural exports and imports and provides international banking services to cooperatives and other eligible borrowers. The agricultural credit bank operates a Farm Credit Bank subsidiary.

[5] 12 U.S.C. 2001–2279cc. The Act is available at *www.fca.gov* under ''Laws and regulations'' and ''Statutes.''

July 2016.[6] The objectives of the 2017 Capital Rule were:

- To modernize capital requirements while ensuring that institutions continue to hold enough regulatory capital to fulfill their mission as a Government-sponsored enterprise (GSE);
- To ensure that the System's capital requirements are comparable to the Basel III framework and the standardized approach in the U.S. Rule, but also to ensure that the rules take into account the cooperative structure and the organization of the System;
- To make System regulatory capital requirements more transparent; and
- To meet the requirements of section 939A of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 (Dodd-Frank Act).[7]

To date, FCA believes the 2017 Capital Rule has met, and continues to meet, these stated objectives.[8]

On December 22, 2016, the FCA Board adopted FCA Bookletter—BL–068—Tier 1/Tier 2 Capital Framework Guidance (Capital Bookletter).[9] The Capital Bookletter provided guidance to ensure System institutions had the necessary information to correctly implement the requirements of the 2017 Capital Rule. The Capital Bookletter included clarification and technical fixes on 18 separate items. The Capital Bookletter also stated our intention to incorporate some of these items into the regulation in a future rulemaking project.

C. Summary of the Proposed Rule

On September 10, 2020,[10] FCA published in the **Federal Register** a notice of proposed rulemaking seeking public comment on revisions to our regulatory capital requirements to incorporate some of the guidance in the Capital Bookletter, with various adjustments,[11] as well as other revisions, as follows:

- Eliminate the stand-alone capital requirements for Farm Credit Leasing Services Corporation (Farm Credit Leasing or FCL);
- Change the computation of the lending and leasing limit base in § 614.4351, by using total capital instead of permanent capital in the calculation [12] and eliminating the exceptional treatment of certain purchased stock in § 614.4351(a)(1);
- Simplify ''Safe Harbor'' provisions that determine when System institutions have ''deemed prior approval'' from FCA to distribute cash payments;
- Revise and clarify certain criteria that capital instruments must meet to be included in common equity tier 1 (CET1) and tier 2 capital;
- Further clarify when the holding period starts for certain Common Cooperative Equities included in CET1 or tier 2 capital; and
- Amend the requirement to adopt an annual board resolution with respect to prior approval requirements and the minimum holding periods for certain equities included in CET1 or tier 2 capital.

We additionally proposed technical revisions to:

- Amend the definitions of ''Collateral agreement,'' ''Eligible margin loan,'' ''Qualifying master netting agreement (QMNA),'' and ''Repo-style transaction'' to incorporate amendments made to these definitions in the U.S. Rule;
- Amend § 615.5220(a)(6) to replace references to parts 615 and 628 with a general reference to FCA regulations;
- Make certain amendments to § 620.5 to ensure institutions report financial information as we intended;
- Clarify the appropriate risk-weighting of cash and gold bullion held in a System institution's own vaults;
- Correct securitization formulas as provided in the Capital Bookletter;
- Specify the deductions and adjustments required for calculating the requirement in § 628.10 that at least 1.5 percent of the 4 percent tier 1 leverage ratio minimum must consist of unallocated retained earnings (URE) and URE equivalents;
- Revise the deductions required under existing § 628.22(a)(6) to include allocated equity investments in System service corporations;
- Add to the regulation certain guidance in the call report instructions on the treatment of accruals of patronage or dividend payables or receivables recorded prior to the governing board declaration or resolution;
- Clarify certain requirements for regulatory capital disclosures of System banks in §§ 620.3, 628.62(c), and 628.63(b)(4); and
- Clarify that institutions may retire minimum amounts of statutory borrower stock without prior approval from FCA so long as, after the retirement, the institution continues to comply with all minimum regulatory capital requirements. The proposal also provided clarification and guidance on continuously redeemable preferred stock (or ''H Stock''), responded to a letter received from the Farm Credit Council addressing various capital related topics, and sought comment on potential changes to FCA's existing permanent capital regulations.

D. General Summary of Comments Received

FCA received seven comment letters on the proposed rule.[13] The Farm Credit Council, a trade association representing System institutions, submitted a letter on behalf of its membership after soliciting comments from all institutions (System Comment Letter).[14] Two System banks [15] and three System associations [16] also submitted individual comment letters in support of the System Comment Letter. One System association, Compeer Financial, ACA (Compeer), raised additional concerns. The American Bankers Association (ABA), a trade association representing the U.S. banking industry, submitted the remaining comment letter.[17] We address the comments in the preamble sections that follow.

The System Comment Letter stated that the Farm Credit Council and its members ''generally support'' the proposed rule, including provisions that incorporate the Capital Bookletter and call report instructions, but that certain aspects of the proposal were

[6] 81 FR 49720 (July 28, 2016). The rule was effective January 1, 2017.

[7] Public Law 111–203, 124 Stat. 1376 (2010).

[8] For a comprehensive discussion of the 2017 Capital Rule, see 81 FR 49720 (July 28, 2016). FCA's capital requirements can be found at Parts 615 and 628 of FCA Regulations.

[9] A copy of the Capital Bookletter can be found at *www.fca.gov,* under ''Laws & Regulations'' and ''Bookletters.''

[10] See 85 FR 55786 (September 10, 2020).

[11] FCA adjusted some of the guidance provided in the Capital Bookletter to address concerns identified through ongoing monitoring and examination of the requirements of the 2017 Capital Rule. Specific elements of the Capital Bookletter as incorporated into the rule are detailed in the ''Substantive Revisions'' and the ''Clarifying and Other Revisions'' sections of this preamble.

[12] Total capital is defined at § 628.2. Permanent capital is defined at § 615.5201.

[13] The comment letters for the proposed rule are available at *www.fca.gov.* Once you are on the website, click the ''I want to . . .'' field near the top of the page; select ''find comments on a pending regulation'' from the drop down menu; and click ''Go;'' then select Capital—Tier 1/Tier 2 Capital Framework—Clean Up—NPRM.

[14] See Letter from Charles Dana, General Counsel, Farm Credit Council (November 6, 2020).

[15] See Letter from Thomas E. Halverson, President and Chief Executive Officer, CoBank, ACB (November 9, 2020); Letter from Barbara Kay Stille, Chief Administrative Officer and General Counsel, AgriBank, FCB (November 9, 2020).

[16] See Letter from Northwest Farm Credit Services, FLCA and PCA (November 6, 2020); Letter from Steve Zagar, Senior Vice President Chief Financial Officer, Farm Credit Mid-America, ACA (November 9, 2020); Letter from Jase Wagner, Chief Financial Officer (CFO), Compeer Financial, ACA (November 5, 2020).

[17] See Letter from Hu A. Benton, Vice President, Banking Policy, American Bankers Association (November 9, 2020).

''problematic.'' Many of the comments from System institutions reiterated recommendations they had previously communicated to FCA (in comments on the September 4, 2014, proposed rulemaking) [18] and requested changes that were beyond the scope of the proposal. The balance of the comments from System institutions were supportive of the proposed amendments or requested specific technical changes.

The ABA asserted that the proposed rule would increase risks to the safety and soundness of the System and increase competitive inequities between the System and commercial banks. The ABA also requested that we clarify certain matters we did not expressly address in the proposal. In some cases, the ABA's comments did not directly relate to the amendments we proposed.

In the preamble to the proposed rule, we discussed certain matters that were not the subject of the proposed rule,[19] and we also sought comments on potential changes to our permanent capital regulations to reduce regulatory burden. We may consider proposing specific changes to the permanent capital requirements and calculations in a future rulemaking.

As discussed in Section 2—Substantive Revisions to the Capital Rule and Section 3—Clarifying and Other Revisions to the Capital Rule, the final rule adopts the revisions we proposed with minor adjustments in response to comments received.

II. Substantive Revisions to the Capital Rule

A. Safe Harbor Deemed Prior Approval

Under existing § 628.20(f), System institutions are required to obtain prior approval from FCA before retiring equities included in tier 1 or tier 2 capital and making cash payments for dividends and patronage (collectively, cash distributions). Institutions have ''deemed prior approval'' from FCA for such distributions provided the conditions in § 628.20(f)(5) and (6) are satisfied (Safe Harbor). One of the conditions stipulates that, after any such cash payment, the dollar amount of CET1 capital must equal or exceed the dollar amount of CET1 on the *same date* in the previous calendar year.[20] Using the same date in the previous calendar year has made monitoring and enforcing this requirement difficult because regulatory capital numbers for System institutions are reported to FCA quarterly, rather than daily.

We proposed to simplify the Safe Harbor provisions of § 628.20(f) by replacing the requirement to use the exact calendar date of the cash distribution with a requirement to use the quarter-end date of the quarter in which the cash payment is made. A System institution would have ''deemed prior approval'' from FCA if, after making the cash distribution, the dollar amount of CET1 capital at the quarter-end equals or exceeds the dollar amount of CET1 capital on the same quarter-end in the previous calendar year. We provided two examples in the preamble to the proposed rule.[21] We stated that we do not believe the amendment as proposed would increase or decrease the amount of cash patronage System institutions would be able to pay when compared to the provision in the 2017 Capital Rule.

The ABA expressed concern that the proposal was ''liberalizing'' the provisions of the ''Safe Harbor Deemed Prior Approval'' in § 628.20(f)(5) and suggested that the Safe Harbor framework gives inadequate consideration to an institution's risk profile. The comments appear to be based in part on concerns regarding the proposal's omission of specific reference to capital distribution limitations already in the 2017 Capital Rule and unchanged by the proposal.

We disagree with the assertion that the proposal would ''liberalize'' the Safe Harbor. The proposed rule would change the date for determining compliance with the Safe Harbor provision in order to simplify the administration, enforcement, and monitoring of compliance with the Safe Harbor requirements. As we state above, we do not believe the proposal would increase or decrease the amount of cash patronage System institutions could pay when compared to the existing provision. The proposed changes would in no way ''liberalize'' the Safe Harbor or create any greater opportunity for capital distributions under the Safe Harbor.

In response to the ABA's concerns regarding the Safe Harbor giving inadequate consideration to an institution's risk profile, the commenter's assertion that the Safe Harbor permits ''cash payouts based only on maintaining the dollar amount of CET1 capital in a prior year'' is incorrect. As we stated in the preamble to the proposed rule, in order to make a cash distribution under the Safe Harbor, a System institution must remain in compliance with all regulatory capital requirements and any supervisory or enforcement actions after such distribution.[22] FCA's regulatory capital requirements are comparable to the U.S. Rule and include regulatory capital measures using both risk-adjusted and non-risk-adjusted computational methods.[23] Furthermore, FCA has comparable authorities to the Federal banking regulatory agencies to establish minimum capital ratios for an individual institution [24] as well as to place further restrictions on institutions' capital distributions as part of supervisory agreements and enforcement actions.[25] Lastly, cash distributions under the Safe Harbor are subject to the capital buffers in § 628.11, which reduce the amount of capital distributions an institution can make when its capital levels fall within the leverage buffer or capital conservation buffer ranges. These requirements are unaltered by the proposed or final rule.

Compeer requested that we expand the Safe Harbor to allow institutions to retire the allocated equities of a borrower, irrespective of compliance with minimum holding periods,[26] to offset losses when a borrower defaults on a loan. The commenter asserted that present hurdles to retiring equities in these scenarios (*i.e.,* requesting prior approval from FCA under § 628.20(f)) present an unnecessary administrative burden.

Compeer's requested revision is beyond the scope of the present rulemaking. We note, however, that as we stated in the preamble to the 2017 Capital Rule, equities are issued to capitalize the institution, not the loan. Accordingly, these equities should not be viewed or treated as compensating loan balances.[27] Furthermore, the preamble to the 2017 Capital Rule also explains in detail our position on the

[18] See 79 FR 52814 (September 4, 2014).

[19] In the proposed rule preamble, we discussed the exclusion of continuously redeemable preferred stock (H Stock) from tier 1 and tier 2 capital and also commented on issues raised in a 2016 letter we received from the Farm Credit Council. See 85 FR 57786, 55795 (September 10, 2020).

[20] See existing regulation § 628.20(f)(5)(ii). FCA considers the date of the cash distribution to be the date on which the institution's board passes a binding resolution declaring an amount it will make as a cash dividend or patronage refund. This either must be a specified dollar amount or must include language whereby a specific amount can be calculated.

[21] See 85 FR 55786, 55788 (September 10, 2020).

[22] See § 628.20(f)(5)(iii).

[23] Compare, for example, §§ 628.10 and 628.11 with the OCC's rules at 12 CFR 3.10 and 3.11.

[24] Section 4.3(a) of the Act (12 U.S.C. 2154) and 12 CFR 615.5350.

[25] Section 5.25 of the Act (12 U.S.C. 2261).

[26] To be included in regulatory capital, common cooperative equities (defined at § 628.2) must meet minimum holding periods as stipulated in § 628.20(b)(1)(xiv) and (d)(1)(xi). Minimum holding period requirements are further discussed below under Section II, C—Common Cooperative Equity Issuance Date.

[27] See 81 FR 49720, 49731 (July 28, 2016).

necessity for minimum holding periods to address the ''expectation criterion'' in the Basel III Framework and the U.S. Rule, maximizing comparability of our rule with the rules applicable to commercial banks.[28] We note that, under § 628.20(f)(6), System institutions may offset allocated equities against a loan in default if mandated by a court of competent jurisdiction or under § 615.5290 in connection with a restructuring plan.

The balance of comments received supported this proposed amendment, and we are adopting it as proposed.

B. Capital Bylaw or Board Resolution To Include Equities in Tier 1 and Tier 2 Capital

The 2017 Capital Rule stipulates conditions and criteria that must be met in order to include an instrument in an institution's regulatory capital.[29] Among these are the requirements for the institution's board of directors to affirm its commitment to adhere to the regulatory minimum redemption or revolvement periods; to obtain prior approval from FCA prior to redeeming, revolving, redesignating, cancelling or removing equities included in regulatory capital;[30] and to obtain prior approval from FCA for certain other actions that could impact the institution's capital quantity or quality.[31] Such affirmation must be set forth in the institution's capitalization bylaws or in a board resolution that the board must re-affirm annually. Where this requirement is satisfied by a board resolution, we proposed to reduce the administrative burden by no longer requiring an annual re-affirmation by the board. We proposed to replace the annual re-affirmation with a one-time requirement to adopt the board resolution and, in subsequent annual capital adequacy plans, to expressly acknowledge the continuing and binding effect of this resolution.

We proposed to move the existing requirements of § 615.5200(d) to a new section, § 628.21, and to revise them to provide that an institution's board must adopt either a capitalization bylaw requirement or a binding board resolution. New § 615.5200(b) would add to existing capital planning provisions a requirement that the capital adequacy plan must expressly acknowledge the continuing and binding effect of all board resolutions adopted pursuant to §§ 628.20(b)(1)(xiv), (c)(1)(xiv), and (d)(1)(xi) and 628.21. We proposed conforming changes as necessary to refer to new § 628.21 rather than § 615.5200(d).

We received no specific comments on this amendment and are adopting it as proposed.

C. Common Cooperative Equity Issuance Date

Common cooperative equities[32] included in CET1 capital have a minimum holding period of 7 years before redemption or revolvement, and common cooperative equities included in tier 2 capital have a minimum holding period of 5 years.[33] These holding periods also must be met for equities (other than the statutory borrower stock minimum) to be retireable under the Safe Harbor. To clarify when the minimum redemption and revolvement period starts for a common cooperative equity, we proposed to add a new definition, common cooperative equity issuance date, in § 628.2 and to make conforming changes to other sections of the regulations. Similar to our guidance in the Capital Bookletter, we proposed to define the common cooperative equity issuance date as the quarter-end in which an institution recognizes newly issued purchased stock in its financial statements and, for newly allocated equities, the quarter-end in which the institution's board has declared a patronage refund and the applicable accounting treatment has taken place. We provided examples of the proposed treatment in the proposed rule preamble.[34]

The System Comment Letter and Compeer requested that we eliminate altogether the minimum holding period requirements for allocated equities. The System made the same request and supporting arguments in comments on our 2014 Tier 1/Tier 2 proposed capital rule, and FCA responded to those comments in the final rule preamble to the 2017 Capital Rule.[35]

The System's request not only is beyond the scope of this rulemaking but also presents no new arguments that would persuade us to reevaluate the need for minimum holding periods. We discussed at length the stock-like attributes of allocated equities (as distinct from unallocated retained earnings) and the reasons for the minimum holding periods in the preamble to the 2017 Capital Rule.[36]

The System Comment Letter suggested we add the word ''calendar'' before ''quarter-end'' in the proposed definition of ''common cooperative equity issuance date'' to clarify that the issuance date would be the calendar quarter-end. We agree and have incorporated the suggestion into the final rule. FCA also fully acknowledges the legal stock issuance date may be different from the quarter-end date used for financial reporting and regulatory capital calculations. Beyond this minor change, we are adopting the new definition as proposed.

D. Farm Credit Leasing Services Corporation

The proposed rule would recognize the current ownership status of Farm Credit Leasing as a wholly-owned subsidiary of CoBank, ACB (CoBank) by removing FCL from the definition of ''System institution'' in §§ 615.5201 and 628.2 for the purposes of the regulatory capital requirements.[37] In so doing, FCA would no longer require FCL to meet minimum capital and related regulatory requirements under part 615, subpart H, and part 628 of our regulations on a stand-alone basis. As a wholly-owned subsidiary of CoBank, FCL is a business unit of the bank with profits and losses accrued to the bank, and its assets and liabilities are consolidated with the bank's assets and liabilities for financial and regulatory reporting purposes. To the extent the bank is adequately capitalized overall, CoBank's consolidation ensures FCL's assets are adequately capitalized. This amendment will reduce the administrative burden of separately applying the regulatory capital requirements to FCL and will not reduce the capital to be held against FCL and CoBank's combined assets. If

[28] See 81 FR 49720, 49732 (July 28, 2016).

[29] See existing regulations §§ 628.20 and 615.5200(d).

[30] By meeting the conditions for ''deemed prior approval'' under regulation § 628.20(f)(5) and (6), an institution effectively obtains FCA prior approval for a given capital distribution.

[31] Existing § 615.5200(d)(3) requires boards to obtain prior approval before redesignating unallocated retained earnings (URE) equivalents as redeemable equities; removing equities from regulatory capital (other than through repurchase, cancellation, redemption, or revolvement); or redesignating equities from one regulatory capital component to another. Section 615.5200(d)(4) requires that URE equivalents shall not be revolved, except under very limited circumstances (*i.e.,* upon dissolution or liquidation).

[32] Common cooperative equities are defined in § 628.2.

[33] As established in § 628.20(b)(1)(xiv)(A) and (d)(1)(xi)(A).

[34] See 85 FR 55786, 55789 (September 10, 2020).

[35] See 81 FR 49720, 49732 (July 28, 2016). The proposed rule is at 79 FR 52814 (September 4, 2014).

[36] See 81 FR 49720, 49726–49730 (July 28, 2016).

[37] Farm Credit Leasing is a service corporation chartered under section 4.25 of the Act. A service corporation is an institution of the System that is established by System banks or associations and chartered by FCA, and it is subject to FCA regulation and examination. See title IV, subpart E of the Act.

FCL's ownership status were to change in the future, we will reassess whether to separately apply our regulatory capital requirements.[38]

Commenters supported this change, and we are adopting it as proposed.

E. Lending and Leasing Limit Base Calculation

Since adopting the 2017 Capital Rule, FCA has relied on tier 1 and tier 2 capital, not on permanent capital, to evaluate the safety and soundness of System institutions. In order to better align the lending and leasing limit base with FCA's supervisory focus on tier 1 and tier 2 capital, we proposed to shift the base of the lending and leasing limit from permanent capital[39] to total capital as defined and adjusted in §§ 628.20–628.22 and to continue to include otherwise eligible third-party capital that must be excluded under § 628.23. We further proposed to align the treatment of investments in other System institutions under the lending and leasing limit base with the treatment under regulatory capital calculations by eliminating the exceptional treatment of stock purchased in connection with a loan participation under § 614.4351(a)(1).[40] We estimated that the impacts to lending limits at System institutions resulting from these changes would be small.[41] The System Comment Letter supported the change to the use of total capital as the lending limit base and noted that most institutions have internal lending limit policies that are lower than the lending limit base in the regulation. We received no other comments and are adopting the amendment as proposed.

F. Qualified Financial Contract (QFC) Related Definitions

In 2017, the Federal banking regulatory agencies adopted rules establishing certain restrictions and requirements for the financial contracts (QFC Rules) of global systemically important banking institutions (GSIBs).[42] We provided details on the background and impetus for these regulatory changes in the preamble to the proposed rule.[43] The QFC Rules prompted related definitional changes in the U.S. Rule to ensure regulated entities continued to benefit from recognition of the risk-mitigating effects of netting and financial collateral on certain financial transactions. This recognition likely results in reduced capital requirements for those transactions.

To incorporate amendments made to the U.S. Rule[44] and to ensure System institutions would also continue to benefit from recognition of the risk-mitigating effects of netting and financial collateral, we proposed changes to the definitions of ''Collateral agreement,'' ''Eligible margin loan,'' ''Qualifying master netting agreement (QMNA),'' and ''Repo-style transaction.'' The proposed changes to QMNA would also harmonize that definition with the definition of ''Eligible master netting agreement'' as used in FCA's Margin and Capital requirements for Covered Swap Entities regulation.[45] The System Comment Letter supported these revisions, and we are adopting them as proposed.

G. Common Equity Tier 1 Capital Eligibility Requirements

Consistent with the Basel III regulatory capital framework[46] and the U.S. Rule, we proposed to add the term ''paid-in'' to the eligibility criteria for CET1 capital in § 628.20(b)(1)(i). Basel III defines ''paid-in'' capital as capital that (1) has been received with finality by the institution, (2) is reliably valued, (3) is fully under the institution's control, and (4) does not directly or indirectly expose the institution to the credit risk of the investor.[47]

As discussed in the preamble to the proposed rule, we proposed this amendment to the eligibility criteria for CET1 capital after re-evaluating the attributes of System allocated equities, which we have subsequently determined meet the Basel definition of ''paid-in.''[48] We further discussed our reexamination of the attributes of allocated equities and the financing of statutorily required borrower stock at System institutions.[49] The System Comment Letter supported our recognition of allocated equities as meeting the definition of ''paid-in'' and expressed no concern with the additional criteria for an instrument's inclusion in CET1 capital.[50] We are adopting the revision as proposed.

We also proposed a conforming change in § 628.20(d)(1)(i) to clarify that all instruments included in tier 2 capital must be issued and paid-in. We received no comments on this proposed change and are adopting it as proposed.

Lastly, we proposed clarifying, non-substantive changes to § 628.20(b)(1)(i) and (b)(1)(ii), both to align our language more closely with the language in the U.S. Rule and to emphasize a difference between the rules' prioritization of a capital instrument holder's claim on the residual assets of an institution in a receivership, insolvency, liquidation, or similar proceeding. We received no comments on these proposed revisions and are adopting them as proposed.

III. Clarifying and Other Revisions to the Capital Rule

A. Capitalization Bylaw Adjustment

Section 615.5220(a)(6) requires a System institution to include in its capitalization bylaws a provision stating that equities other than those protected under Section 4.9A of the Act are retireable at the sole discretion of the board, provided minimum capital adequacy standards established in subpart H of part 615 and part 628 are

[38] The definitions of ''System institution'' under §§ 615.5201 and 628.2 provide that we may include ''any other institution chartered by the FCA that we determine should be included for purposes of this subpart.''

[39] The existing lending and leasing limit base (which this final rule is changing) is a System institution's permanent capital with adjustments applicable to the institution in accordance with § 615.5207, and with two additional adjustments in § 614.4351(a) that apply only to the lending and leasing limit base.

[40] The 2017 Capital Rule requires System institutions to deduct their investments in other System institutions from regulatory capital calculations. Existing § 614.4351(a)(1) directs a System institution to include its investment in another System institution in its lending limit base where the investment resulted from stock purchased in connection with a loan participation. This is, in effect, the exact opposite of the regulatory capital requirements in the 2017 Capital Rule.

[41] See 85 FR 55786, 55790 (September 10, 2020), footnotes 29 and 30.

[42] See 82 FR 56630 (November 29, 2017) (OCC); 82 FR 50228 (October 30, 2017) (FDIC); and 82 FR 42882 (September 12, 2017) (FRB).

[43] See 85 FR 55786, 55790–55791 (September 10, 2020).

[44] As we have previously stated, FCA seeks to achieve comparability between our regulatory capital rules and those of the Federal banking regulatory agencies. Among other benefits, comparability of rules increases transparency for investors in the capital markets.

[45] See § 624.2.

[46] See Basel Committee on Banking Supervision (BCBS), Basel III: A Global Regulatory Framework for More Resilient Banks and Banking Systems, December 2010 (as revised June 2011).

[47] See BCBS, Basel III Definition of capital—Frequently Asked Questions, September 2017 (update of FAQs published in December 2011).

[48] See 85 FR 55786, 55791–55792 (September 10, 2020).

[49] Id.

[50] As discussed under Section III, E—Unallocated Retained Earnings and Equivalents Deductions and Adjustments, the System Comment Letter draws a connection between our determination that allocated equities are ''paid-in,'' as defined by the Basel Committee, and arguments in the letter requesting the elimination of the URE and URE equivalents requirements in FCA's capital rules. Our determination that allocated equities fully meet the Basel III definition of paid-in capital does not have any connection to our URE and URE equivalents requirements.

met. We proposed to amend this section by replacing the reference to parts 615 and 628 with a general reference to FCA's capital adequacy standards. This would satisfy the requirement to refer to parts 615 and 628 and would include all existing capital requirements of the FCA as well as any future capital requirements that we may adopt in other parts of our regulations.

As we noted in the proposal,[51] changes to bylaws to conform to this regulatory requirement should not change any substantive rights of the System institution or its member-borrowers.[52] System institutions that have already amended their capitalization bylaws to include a reference to parts 615 and 628 do not need to amend their capitalization bylaws to comply with this revision.

We received no comments on this amendment and are adopting it as proposed.

B. Annual Report to Shareholders Corrections

We proposed technical revisions to § 620.5, which lists the required contents of a System institution's annual report to shareholders, to ensure institutions report financial data as we intended. First, we proposed to move the requirement that System associations report their tier 1 leverage ratio in each annual report for each of the last 5 fiscal years from § 620.5(f)(4)(iv) to § 620.5(f)(3)(v), as we had originally intended. In addition, we proposed to amend the requirement in § 620.5(f)(4) that institutions report core surplus, total surplus, and the net collateral ratio (banks only) in a comparative columnar form for each fiscal year ending in 2012 through 2016. This requirement resulted in System institutions reporting capital ratios beyond the 5-year requirement established in § 620.5(f), which was not our intention. Accordingly, we proposed to require these disclosures in each annual report through 2021, but only as long as these ratios are part of the previous 5 fiscal years for which disclosures are required. We received no comments on these revisions and are adopting them as proposed.

C. Appropriate Risk-Weighting of Cash and Gold Bullion

We proposed to delete provisions in § 628.32(l)(1) pertaining to the risk weighting of cash that were redundant and potentially confusing. Specifically, existing § 628.32(l)(1) states that System institutions must assign a 0-percent risk weight to cash held in accounts at a depository institution, which created potential confusion pertaining to the proper risk weight for deposits that exceed the limit of FDIC deposit insurance coverage (currently set at $250,000). In addition, existing § 628.32(l)(1) also states that System institutions must assign a 0-percent risk weight to cash held in accounts at a Federal Reserve Bank. As the risk weighting of cash on deposit with a U.S. depository institution or at the Federal Reserve Bank is adequately and more accurately addressed in § 628.32(a)(1)(i)(A) and (B) and (d)(1), we proposed eliminating the duplicative and potentially confusing provisions in § 628.32(l)(1). We received no comments on these revisions and are adopting them as proposed.

We additionally proposed to revise § 628.32(l)(1) to add a provision assigning a 0-percent risk weight to gold bullion held in a System institution's own vaults, consistent with the risk weight assigned to gold bullion held in the vaults of a depository institution. We received no comments on this revision and are adopting it as proposed.

D. Securitization Formulas

Consistent with corrections previously provided in the Capital Bookletter, we proposed to correct 3 formulas used in the simplified supervisory formula approach (SSFA) to risk-weighting securitizations under § 628.43(d), and one formula used in the simple risk-weight approach (SRWA) for risk-weighting equity exposures under § 628.52. These formulas were printed incorrectly in the **Federal Register** version of the 2017 Capital Rule. We received no comments on these corrections and are finalizing them as proposed.

E. Unallocated Retained Earnings and Equivalents Deductions and Adjustments

Under § 628.10, at least 1.5 percent of the 4 percent tier 1 leverage ratio minimum must consist of URE and URE equivalents (UREE). As the 2017 Capital Rule did not specify how to calculate this requirement, we proposed to prescribe the calculation methodology. Specifically, we proposed to incorporate the guidance in the Capital Bookletter requiring the deductions in § 628.22(a) from the numerator and the deductions used in calculating the tier 1 leverage ratio from the denominator.[53] We also proposed to require that institutions deduct from the numerator any purchased equity investments that must be deducted under the corresponding deduction approach in § 628.22(c). The use of differing deductions for the computation of the tier 1 leverage ratio and the URE and UREE measure, which is a component of the tier 1 leverage ratio, resulted in the URE and UREE measure, when calculated on a stand-alone basis, exceeding the tier 1 leverage ratio at many System institutions.[54] This was not our intent. The System Comment Letter generally supported our proposed revisions, and we are adopting them as proposed.

In addition, we are adopting technical conforming amendments in § 628.10(c)(4) to incorporate adjustments required under proposed § 628.22(b)[55] into the computation of both the tier 1 leverage ratio and the URE and UREE measure. More specifically, we are amending the calculation of average total consolidated assets described in § 628.10(c)(4)(i) to include the deduction or adjustment required by § 628.22(b). Furthermore, we are amending the calculation of the URE and UREE measure described in § 628.10(c)(4)(ii) to include the deduction or adjustment required by § 628.22(b). These conforming changes are consistent with existing call report instructions,[56] are technical in nature, and are necessary to maintain consistency in the deductions for the computation of the tier 1 leverage ratio and the URE and UREE measure, consistent with the intent of the proposed rule.

[51] See 85 FR 55786, 55792 (September 10, 2020).

[52] If the change is non-substantive and does not alter, reduce, or increase the rights of any member-borrowers, a System institution's board may choose to make a conforming change to the capitalization bylaws to include a general reference to regulatory capital adequacy standards without a vote by its member-borrowers, provided that such bylaws allow for technical amendments without a shareholder vote.

[53] See Capital Bookletter, Item 4.

[54] Section 628.10(c)(4) requires the amounts deducted under §§ 628.22(a) and (c) and 628.23 to be deducted from tier 1 capital when calculating the tier 1 leverage ratio. However, the deductions under §§ 628.22(c) and 628.23 were not applied to the numerator when calculating the URE and UREE requirement as they do not increase the URE of a System institution. Although we are amending the rule to incorporate deductions under new § 628.22(b) and existing § 628.22(c), we did not find it necessary to require the deductions under § 628.23 when calculating the URE and UREE measure because third-party stock is not a component of URE, UREE, or CET1 capital.

[55] Proposed § 628.22(b) is discussed below under Section III, G—Adjustments for Accruing Patronage and Dividends.

[56] See the call report instructions for Uniform Call Report schedule RC–R.4, item 3, and schedule RC–R.5, item 1.c. The call report instructions are available at *https://ww3.fca.gov/fcsinfo/CRS/CallReportFiles/UCR%20Report%20Instructions.pdf.*

The System Comment Letter advocated that FCA reconsider the necessity of requirements to hold a minimum level of URE. Consistent with its comments on our 2014 proposed Capital Rule, the System Comment Letter asserted that the minimum URE requirement establishes URE as higher quality capital relative to other System capital components, results in nearly 3 percent of URE held against each dollar of new loans made by associations, violates the cooperative principle of user-ownership, and undermines the cooperative principle of user-control.[57] In addition, the System Comment Letter asserted that a minimum URE requirement is not consistent with the Basel III Framework and thus decreases the comparability of FCA's capital requirements to those of the U.S. Rule.

The System Comment Letter and AgriBank, FCB (AgriBank), also requested that we consider changes to the definition of UREE in § 628.2 if we retain the URE requirement.

Under the existing definition, nonqualified allocated equities not subject to redemption or revolvement are included in the definition of UREE and count towards an institution's minimum URE and UREE requirement, provided that certain additional stipulations are met.[58] Such equities *allocated to other System institutions* are expressly excluded. The commenters assert that, because of the deductions and eliminations for computing regulatory capital under FCA's 2017 Capital Rule, equities allocated by a System bank to an association satisfy the objectives for URE and UREE as previously outlined by FCA.[59]

The request to reconsider application of the minimum URE and UREE requirements or to change the definition of UREE is beyond the scope of the proposal. We explained at length our position on the significance of URE and UREE to System capitalization in the preamble to the 2017 Capital Rule.[60]

We note that the System Comment Letter and AgriBank drew a connection between our interpretation that allocated equities are ''paid-in'', as defined by Basel, and their argument for the elimination of the URE and UREE requirements. The interpretation that allocated equities meet the Basel definition of paid-in capital, as discussed in the proposal,[61] does not diminish the importance of the URE and UREE requirements.[62]

The minimum URE and UREE requirement as presently calculated protects association members against association losses, associations against bank losses, and the System against financial contagion. Financial contagion in this context would include impacts to earnings measures that are relevant to System investors and FCA's evaluations of the safety and soundness of System institutions. In addition to our previously stated position, we note that URE at a System bank ensures the bank can act as a source of strength and provide assistance to district associations or other banks if needed, and it also insulates a bank's affiliated associations from losses in other districts in the event of a joint and several liability call.

F. Service Corporation Deductions and Adjustments

Existing § 628.22(a)(6) requires a System institution to deduct any allocated equity investment in another System institution. We proposed to expand the deduction requirement to include allocated equity investments in a System service corporation.[63] The System Comment Letter indicated that System institutions are unaware of any service corporations that allocate equities and provided no further comment on the amendment proposed. Accordingly, we are adopting the revision as proposed.

As we noted in the preamble to the proposed rule, in November 2016 the Farm Credit Council sent a letter[64] to FCA requesting that institutions be permitted to risk-weight their investments in System service corporations at 100 percent instead of having to deduct the investments from CET1 capital in their regulatory capital calculations. The Farm Credit Council further requested FCA to establish regulatory capital treatments for unincorporated business entities (UBEs) based on the specific nature of the entity in question. We responded to this request in the preamble to the proposed rule, declining to revise the requirement to deduct equity investments in service corporations from regulatory capital and noting that we retain the authority to consider the appropriate capital treatment of UBEs on a case-by-case basis.

The System Comment Letter requested that we reconsider our position on service corporation investments. The System believes the requirement to deduct investments in System service corporations is inconsistent with the level of risk in the investments and state that the deduction requirement discourages the formation of organizations that provide an efficient means for cooperation among System institutions in providing services to their stockholders. The System further noted that all service corporations are subject to chartering requirements and that FCA can establish the individual capital requirements of a service corporation on a case-by-case basis.

We are not convinced of the need to change our previously communicated position. As we stated in the preamble to the proposed rule, we believe that investments in service corporations are committed to support the risks at the service corporation and must be available to meet the service corporation's capital needs.[65] This position and our resulting regulatory capital treatment of investments in service corporations are consistent with our treatment of all intra-System investments. The System accurately points out that FCA can establish

[57] The Farm Credit Council made similar comments in response to the 2017 Capital Rule, as we summarized in the rule's preamble. See 81 FR 49720, 49733–49735 (July 28, 2016).

[58] To include nonqualified allocated equities in UREE, an institution's board must designate the equities as UREE at issuance and undertake in its capitalization bylaws or a board resolution (1.) not to change the designation without FCA prior approval, (2.) not to exercise discretion to revolve the equities except under dissolution or liquidation, and (3.) not offset the equities against a loan in default except as required by a court of competent jurisdiction, or if required under § 615.5290 in connection with a restructuring.

[59] URE and UREE provide a cushion from losses for both third-party and common cooperative equities and protect against interconnected risk between System banks and associations. See 79 FR 52814 (September 4, 2014).

[60] See 81 FR 49720, 49732–49735 (July 28, 2016).

[61] See 81 FR 55786, 55791 (September 10, 2020).

[62] As noted in the System Comment Letter, Basel III recognizes two broad categories of CET1 capital: Retained earnings and paid-in capital instruments. Consistent with that view, our capital rules acknowledge and draw distinction between these two types of CET1 capital (§ 628.20(b)(1) and (2)). Our interpretation that common cooperative equities are ''paid-in'' as defined by Basel does not eliminate the distinction between these two types of high-quality capital. Equities allocated by one System institution to another are at risk at both institutions and present a risk of financial contagion as a result of the interconnection that gives rise to their existence. Unallocated retained earnings and equivalents (as presently defined) do not present the same contagion risk.

[63] System institution is defined in existing § 628.2 as ''a System bank, an association of the Farm Credit System, . . . and any other institution chartered by the FCA that the FCA determines should be considered a System institution for the purposes of this part.'' The FCA has not made any determinations to include other institutions in this definition.

[64] Letter dated November 22, 2016, from Charles Dana, General Counsel, Farm Credit Council to Gary K. Van Meter, Director, Office of Regulatory Policy. This letter was received after the 2017 Capital Rule had been adopted by the FCA Board and communicated a request to change certain provisions of the 2017 Capital Rule, as discussed in this section.

[65] See 85 FR 55786, 55795 (September 10, 2020).

individual capital requirements for service corporations as part of the chartering process. We believe the more prudent default treatment is deduction rather than risk weighting. We would consider risk weighting on a case-by-case basis as the exception.

G. Adjustments for Accruing Patronage and Dividends

We proposed to amend the regulatory capital adjustment and deduction requirements under § 628.22 by incorporating in proposed § 628.22(b) the existing call report instructions directing System institutions to reverse the accrual of patronage or dividend payables or receivables that occur prior to a board declaration resolution.[66] As discussed in the proposed rule preamble, FCA believes it is important to reflect regulatory capital on the basis of related contractual obligations. Some options for the treatment of patronage and dividend accruals under GAAP may not be consistent with this regulatory capital requirement.[67] FCA looks to the date an institution's board of directors passes a binding resolution declaring an amount it will pay in patronage or dividends[68] to establish when the legal obligation exists and should be reflected in regulatory capital computations. We received no comments on this amendment and are adopting it as proposed.

H. Bank Disclosures

We proposed clarifying amendments to the requirement under § 628.63(b)(4) that banks disclose a reconciliation of their regulatory capital elements to their balance sheets in any audited consolidated financial statements. Specifically, we proposed to add the word ''applicable'' before ''audited'' to clarify that reconciliation requirements apply only to current period financial statements that have been audited.[69] We further proposed that System banks be required to complete this reconciliation of regulatory capital elements using both point-in-time and three-month average daily balance regulatory capital values as our regulatory capital requirements are based on a three-month average daily balance.[70] Financial statements are generally prepared using point-in-time information.

The System Comment Letter questioned the value added by completing the required reconciliation on both a point-in-time and a three-month average daily balance basis. The commenters noted that Basel III Pillar 3 disclosure requirements are based on a tieback to audited financial statements, which are prepared on a point-in-time basis. They further noted that the addition of the three-month average reconciliation was unnecessary and potentially confusing.

We are persuaded that completing the reconciliation on a point-in-time basis satisfies the Basel III Pillar 3 disclosure requirement for a reconciliation of regulatory capital to GAAP capital. We acknowledge that requiring a reconciliation on two separate bases would have added another administrative requirement. We have decided instead to revise § 628.63(b)(4) to require only a reconciliation on a point-in-time basis, together with a statement that compliance with the minimum capital requirements in subpart B of part 628 is determined using average daily balances for the most recent 3 months.

To address potential conflicts between the requirements of §§ 620.3 and 628.62(c), we proposed to revise § 620.3 to state that, unless otherwise determined by FCA, the use of the authorized limited disclosure in § 628.62(c) does not create an incomplete disclosure. We also proposed to revise § 620.3 to permit institutions to modify the required statement that the information provided is true, accurate, and complete to explain that the completeness of the disclosure was determined in consideration of § 628.62(c). We received no comments on this amendment and are adopting it as proposed.

Lastly, we proposed to remove and reserve § 628.63(b)(3), which required disclosure of the computation of regulatory capital ratios during the transition period, because the provision is no longer applicable. We received no comments on this amendment and are adopting it as proposed.

I. Retirement of Statutory Borrower Stock

Under existing § 628.20(b)(1)(xiv)(B), System institutions may redeem the minimum statutory borrower stock described in § 628.20(b)(1)(x) without prior FCA approval and without satisfying the minimum holding period for common cooperative equities included in CET1 capital. In order to eliminate any possible misinterpretation that an institution could retire statutory borrower stock if the institution were not meeting its regulatory capital requirements, we proposed to add a provision to § 628.20(b)(1)(xiv)(B) to clarify that institutions may redeem statutory borrower stock only provided that, after such redemption, the institution continues to comply with all minimum regulatory capital requirements.

The System Comment Letter and Compeer requested that we reconsider the regulatory provisions for redemptions of statutory minimum borrower stock because of the administrative burden they create for small-balance loans at some institutions (those with balances of $50,000 or less). As we clarified in the preamble to the proposed rule, under the existing provisions of § 628.20(b)(1)(xiv)(B), for any statutory borrower stock exceeding $1,000 or 2 percent of the loan amount, *whichever is less,* the minimum holding periods for inclusion in regulatory capital apply.[71] We also clarified in the preamble that the 2 percent of the loan amount is determined relative to the originated loan amount. Commenters stated that, under this structure, some System institutions must undertake a ''burdensome process'' to track the holding period for stock that is $1,000 or less but greater than 2 percent of the loan balance. The commenters further noted that the amounts of capital retained as a result of this requirement are de minimis in terms of any institution's total capital.

We are persuaded that the burden of tracking and managing these de minimis amounts of statutory minimum borrower stock in accordance with existing requirements is not justified by the safety and soundness benefits of the nominal amounts of capital retained. Accordingly, we are amending the provisions of § 628.20(b)(1)(xiv)(B) to reflect that an amount of the statutory borrower stock as described in section 4.3A of the Act, not to exceed $1,000, may be redeemed without a minimum period outstanding after issuance and without the prior approval of the FCA. This amendment eliminates the burden of tracking de minimis amounts of statutory borrower stock that are less than $1,000 but exceed 2 percent of the loan balance. More specifically, System institutions may redeem *up to* $1,000 of statutory borrower stock irrespective of

[66] See existing Call Report instructions for Schedule RC–R.4, Line item 3 at *https://www.fca.gov/bank-oversight/fcs-call-reports.*

[67] See 85 FR 55786, 55787–55788 (September 10, 2020).

[68] The declaration must include an amount to be paid or include language by which an amount could be calculated.

[69] Under FCA regulations, only the annual report to shareholders prepared at yearend must be audited. See § 620.5(j)(1).

[70] See § 628.10(a).

[71] See 85 FR 55786, 55794 (September 10, 2020). Of note, under § 628.20(b)(1)(x) and (d)(1)(viii), any statutory borrower stock in excess of the statutory minimum that is funded through loan proceeds from the System institution is includable only in tier 2 capital.

the proportional relationship of the stock investment and the originated loan amount. We are making conforming changes to § 628.20(b)(1)(x) and (d)(1)(viii)(C) to incorporate this change.

The ABA commented that it appreciated our clarification but asserted that the proposal would still leave FCS institutions subject to very lax requirements concerning stock redemptions compared to those applicable to commercial banks. We note that the proposed amendment eliciting this comment does not reduce restrictions on stock redemptions for System institutions. As discussed in the preamble to the proposed rule, the proposed amendment is merely a technical clarification for the avoidance of doubt.[72]

As stated in the preamble to the 2017 Capital Rule, one of our objectives was to ensure the System's capital requirements are comparable to the Basel III framework and the standardized approach under the U.S. Rule, taking into consideration the cooperative structure and the organization of the System.[73] Accordingly, while most requirements of our rule are similar or identical to requirements in the U.S. Rule, the cooperative structure and the organization of System institutions necessitated modification of other requirements. A piecemeal comparison of various elements of the two rules will not yield an accurate appraisal of the regulatory outcome of our requirements as compared to the U.S. Rule.

As the ABA points out, when restrictions on stock redemptions are considered in isolation of other rule requirements, commercial banks are subject to more restrictions than System institutions. For example, to retire stock, national banks must obtain the approval of shareholders owning two thirds of the shares in each affected class, as well as prior approval from the OCC.[74] By contrast, System institutions may redeem common cooperative equities without obtaining FCA or shareholder prior approval, provided certain conditions are met.[75] We acknowledged and discussed this difference in the preamble to the 2017 Capital Rule.[76] However, the requirements for stock redemptions should not be evaluated in isolation of the remaining restrictions on distributions in FCA's capital rules.

First, FCA's Safe Harbor for stock redemptions applies only to common cooperative equities; all other capital instruments including preferred stock and subordinated debt cannot be redeemed or retired prior to their maturity without express prior approval from the FCA Board.[77] Second, the most flexible treatment of stock redemptions under FCA's existing capital rules, which is the focus of the ABA's comments, is applicable only to minimum statutory borrower stock.[78] This capital element comprises less than 1 percent of the System's total capital base.[79] All other common cooperative equities included in regulatory capital are subject to further restrictions including minimum holding periods before they can be redeemed without obtaining prior approval from FCA.[80] A third consideration is that a significant portion of allocated equities in the System has been designated as unallocated retained earnings equivalents,[81] a type of common cooperative equity that cannot be redeemed without obtaining prior approval from the FCA Board.[82]

Finally and most importantly, as previously discussed in the preamble to the 2017 Capital Rule, the redemptions we allow must be considered in the context of our overall limitations on capital distributions.[83] Under the provisions of FCA's Safe Harbor Deemed Prior Approval,[84] all capital distributions by a System institution, including redemptions of common cooperative equities, dividends, and cash patronage, are limited to no more than the year-over-year dollar increase in CET1 capital for any given 12-month period. All other factors held constant, this in effect limits System institutions to distributing no more than the current year's net income. By contrast, national banks have statutory authority to distribute cash dividends in amounts up to current year's net income plus the retained net income for the two previous years.[85] As we noted in the preamble to the 2017 Capital Rule, we believe that our Safe Harbor for equities is appropriately comparable to Basel III and the U.S. Rule because the Safe Harbor's broader application to total cash dividend payments, cash patronage payments, and equity redemptions or revolvements is tempered by an overall limit that is more restrictive than commercial banks' safe harbor to pay cash dividends.[86]

IV. Abbreviations

BCBS Basel Committee on Banking Supervision
CFR Code of Federal Regulations
CFTC Commodity Futures Trading Commission
EMNA Eligible Master Netting Agreement
FCA Farm Credit Administration
FDIC Federal Deposit Insurance Corporation
FDI Act Federal Deposit Insurance Corporation Improvement Act of 1991
FFIEC Federal Financial Institutions Examination Council
FR Federal Register
FRB Board of Governors of the Federal Reserve System
GAAP Generally Accepted Accounting Principles (U.S.)
GSE Government-Sponsored Enterprise
GSIB Global Systemically Important Bank
OCC Office of the Comptroller of the Currency
QFC Qualified Financial Contract
QMNA Qualified Master Netting Agreement
SEC Securities and Exchange Commission
SFA Supervisory Formula Approach
SRWA Simple Risk-Weight Approach
SSFA Simplified Supervisory Formula Approach
UBE Unincorporated Business Entity
URE Unallocated Retained Earnings
UREE Unallocated Retained Earnings Equivalents
U.S.C. United States Code

[72] 85 FR 55786, 55794 (September 10, 2020).

[73] See objectives in 81 FR 49720 (July 28, 2016).

[74] 12 U.S.C. 59.

[75] Under § 628.20(f)(5), institutions may retire common cooperative equities included in CET1 capital a minimum of 7 years after the issuance date, and they may retire common cooperative equities included in tier 2 capital a minimum of 5 years after the issuance date. In the case of common cooperative equities included in CET1, after such retirements the dollar amount of CET1 capital outstanding must equal or exceed the dollar amount outstanding one year earlier. Under § 628.20(b)(1)(xiv)(B), statutory minimum borrower stock may be retired without a minimum period outstanding after issuance and without the prior approval of FCA.

[76] See 81 FR 49720, 49731 (July 28, 2016).

[77] See § 628.20(c)(1)(vi) and (d)(1)(X).

[78] Statutory minimum borrower stock is stock acquired by System borrowers to satisfy requirements under Section 4.3A of the Act. It is equal to the lesser of $1,000 or 2 percent of the loan.

[79] As of June 30, 2021, System entities reported combined total regulatory capital of $65.8 billion, of which $0.39 billion or 0.6 percent was comprised of statutory minimum borrower stock that is already eligible to be redeemed without a minimum holding period under existing regulatory requirements. This rulemaking does not change the requirements governing redemption of this stock.

[80] See § 628.20(f)(5).

[81] As defined in § 628.2, unallocated retained earnings (URE) equivalents include nonqualified allocated equities designated as URE equivalents at issuance that a System institution undertakes not to revolve except upon dissolution or liquidation. Under new § 628.21, System institutions are required to obtain prior FCA approval before re-designating URE equivalents as equities that the institution has discretion to redeem.

[82] As of March 31, 2021, System entities reported a combined total regulatory capital of $65.8 billion, of which $19.2 billion (29 percent) was comprised of allocated common cooperative equities. Of the $19.1 billion in allocated common cooperative equities, $11.9 billion (62 percent) were designated as unallocated retained earnings equivalents.

[83] See 81 FR 49720, 49731 (July 28, 2016).

[84] § 628.20(f)(5).

[85] 12 U.S.C. 60.

[86] See 81 FR 49720, 49731 (July 28, 2016).

V. Regulatory Analysis

A. Regulatory Flexibility Act

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

B. Congressional Review Act

Under the provisions of the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Management and Budget's Office of Information and Regulatory Affairs has determined that this final rule is not a ''major rule'' as the term is defined at 5 U.S.C. 804(2).

List of Subjects

12 CFR Part 614

Agriculture, Banks, Banking, Foreign trade, Reporting and recordkeeping requirements, Rural areas.

12 CFR Part 615

Accounting, Agriculture, Banks, Banking, Government securities, Investments, Rural areas.

12 CFR Part 620

Accounting, Agriculture, Banks, Banking, Reporting and recordkeeping requirements, Rural areas.

12 CFR Part 628

Accounting, Agriculture, Banks, Banking, Capital, Government securities, Investments, Rural areas.

For the reasons stated in the preamble, the Farm Credit Administration amends parts 614, 615, 620, and 628 of chapter VI, title 12 of the Code of Federal Regulations as follows:

PART 614—LOAN POLICIES AND OPERATIONS

■ 1. The authority citation for part 614 is revised to read as follows:

Authority: Secs. 1.3, 1.5, 1.6, 1.7, 1.9, 1.10, 1.11, 2.0, 2.2, 2.3, 2.4, 2.10, 2.12, 2.13, 2.15, 3.0, 3.1, 3.3, 3.7, 3.8, 3.10, 3.20, 3.28, 4.12, 4.12A, 4.13B, 4.14, 4.14A, 4.14D, 4.14E, 4.18, 4.18A, 4.19, 4.25, 4.26, 4.27, 4.28, 4.36, 4.37, 5.9, 5.10, 5.17, 7.0, 7.2, 7.6, 7.8, 7.12, 7.13, 8.0, 8.5 of the Farm Credit Act (12 U.S.C. 2011, 2013, 2014, 2015, 2017, 2018, 2019, 2071, 2073, 2074, 2075, 2091, 2093, 2094, 2097, 2121, 2122, 2124, 2128, 2129, 2131, 2141, 2149, 2183, 2184, 2201, 2202, 2202a, 2202d, 2202e, 2206, 2206a, 2207, 2211, 2212, 2213, 2214, 2219a, 2219b, 2243, 2244, 2252, 2279a, 2279a–2, 2279b, 2279c–1, 2279f, 2279f–1, 2279aa, 2279aa–5); 12 U.S.C. 2121 note; 42 U.S.C. 4012a, 4104a, 4104b, 4106, and 4128.

■ 2. Amend § 614.4351 by revising paragraph (a) to read as follows:

§ 614.4351 Computation of lending and leasing limit base.

(a) *Lending and leasing limit base.* An institution's lending and leasing limit base is composed of the total capital (tier 1 and tier 2) of the institution, as defined in § 628.2 of this chapter, with adjustments applicable to the institution provided for in § 628.22 of this chapter, and with the following further adjustments:

(1) [Reserved]

(2) Eligible third-party capital that is required to be excluded from total capital under § 628.23 of this chapter may be included in the lending limit base.

* * * * *

PART 615—FUNDING AND FISCAL AFFAIRS, LOAN POLICIES AND OPERATIONS, AND FUNDING OPERATIONS

■ 3. The authority citation for part 615 is revised to read as follows:

Authority: Secs. 1.5, 1.7, 1.10, 1.11, 1.12, 2.2, 2.3, 2.4, 2.5, 2.12, 3.1, 3.7, 3.11, 3.25, 4.3, 4.3A, 4.9, 4.14B, 4.25, 5.9, 5.17, 8.0, 8.3, 8.4, 8.6, 8.8, 8.10, 8.12 of the Farm Credit Act (12 U.S.C. 2013, 2015, 2018, 2019, 2020, 2073, 2074, 2075, 2076, 2093, 2122, 2128, 2132, 2146, 2154, 2154a, 2160, 2202b, 2211, 2243, 2252, 2279aa, 2279aa-3, 2279aa–4, 2279aa–6, 2279aa–8, 2279aa–10, 2279aa–12); 12 U.S.C. 2154 note; 15 U.S.C. 78o–7 note.

■ 4. Revise § 615.5200 to read as follows:

§ 615.5200 Capital planning.

(a) The Board of Directors of each System institution shall determine the amount of regulatory capital needed to assure the System institution's continued financial viability and to provide for growth necessary to meet the needs of its borrowers. The minimum capital standards specified in this part and part 628 of this chapter are not meant to be adopted as the optimal capital level in the System institution's capital adequacy plan. Rather, the standards are intended to serve as minimum levels of capital that each System institution must maintain to protect against the credit and other general risks inherent in its operations.

(b) Each Board of Directors shall establish, adopt, and maintain a formal written capital adequacy plan as a part of the financial plan required by § 618.8440 of this chapter. The plan shall include the capital targets that are necessary to achieve the System institution's capital adequacy goals as well as the minimum permanent capital, common equity tier 1 (CET1) capital, tier 1 capital, total capital, and tier 1 leverage ratios (including the unallocated retained earnings (URE) and URE equivalents minimum) standards. The plan shall expressly acknowledge the continuing and binding effect of all board resolutions adopted in accordance with § 628.20(b)(1)(xiv), (c)(1)(xiv), and (d)(1)(xi) of this chapter, and with § 628.21 of this chapter. The plan shall address any projected dividend payments, patronage payments, equity retirements, or other action that may decrease the System institution's capital or the components thereof for which minimum amounts are required by this part and part 628 of this chapter. The plan shall set forth the circumstances and minimum timeframes in which equities may be redeemed or revolved consistent with the System institution's applicable bylaws or board of directors' resolutions.

(c) In addition to factors that must be considered in meeting the minimum standards, the board of directors shall also consider at least the following factors in developing the capital adequacy plan:

(1) Capability of management and the board of directors (the assessment of which may be a part of the assessments required in paragraphs (b)(2)(ii) and (b)(7)(i) of § 618.8440 of this chapter);

(2) Quality of operating policies, procedures, and internal controls;

(3) Quality and quantity of earnings;

(4) Asset quality and the adequacy of the allowance for losses to absorb potential loss within the loan and lease portfolios;

(5) Sufficiency of liquid funds;

(6) Needs of a System institution's customer base; and

(7) Any other risk-oriented activities, such as funding and interest rate risks, potential obligations under joint and several liability, contingent and off-balance-sheet liabilities or other conditions warranting additional capital.

■ 5. Amend § 615.5201 by revising the definition of ''System institution'' to read as follows:

§ 615.5201 Definitions.

* * * * *

System institution means a System bank, an association of the Farm Credit System, and their successors, and any other institution chartered by the Farm Credit Administration (FCA) that the FCA determines should be considered a

System institution for the purposes of this subpart.

* * * * *

■ 6. Amend § 615.5220 by revising paragraph (a)(6) to read as follows:

§ 615.5220 Capitalization bylaws.

(a) * * *

(6) The manner in which equities will be retired, including a provision stating that equities other than those protected under section 4.9A of the Act are retireable at the sole discretion of the board, provided minimum capital adequacy standards established by the Farm Credit Administration, and the capital requirements established by the board of directors of the System institution, are met;

* * * * *

PART 620—DISCLOSURE TO SHAREHOLDERS

■ 7. The authority citation for part 620 continues to read as follows:

Authority: Secs. 4.3, 4.3A, 4.19, 5.9, 5.17, 5.19 of the Farm Credit Act (12 U.S.C. 2154, 2154a, 2207, 2243, 2252, 2254); sec. 424 of Pub. L. 100–233, 101 Stat. 1568, 1656; sec. 514 of Pub. L. 102–552, 106 Stat. 4102.

■ 8. Amend § 620.3 by adding a sentence at the ends of paragraphs (a) and (c)(3) to read as follows:

§ 620.3 Accuracy of reports and assessment of internal control over financial reporting.

(a) * * * Unless otherwise determined by the Farm Credit Administration (FCA), the appropriate use of the limited disclosure authorized by § 628.62(c) of this chapter does not create an incomplete disclosure.

* * * * *

(c) * * *

(3) * * * If the report contains the limited disclosure authorized by § 628.62(c) of this chapter, the statement may be modified to explain that the completeness of the report was determined in consideration of § 628.62(c).

* * * * *

■ 9. Amend § 620.5 by adding paragraph (f)(3)(v) and revising paragraph (f)(4) to read as follows:

§ 620.5 Contents of the annual report to shareholders.

* * * * *

(f) * * *

(3) * * *

(v) Tier 1 leverage ratio.

(4) *For all banks (on a bank only basis) and for all associations.* The following ratios shall be disclosed in comparative columnar form in each annual report through fiscal year end 2021, only as long as these ratios are part of the previous 5 fiscal years of financial data required under paragraphs (f)(2) and (3) of this section:

(i) Core surplus ratio.

(ii) Total surplus ratio.

(iii) For banks only, net collateral ratio.

* * * * *

PART 628—CAPITAL ADEQUACY OF SYSTEM INSTITUTIONS

■ 10. The authority citation for part 628 is revised to read as follows:

Authority: Secs. 1.5, 1.7, 1.10, 1.11, 1.12, 2.2, 2.3, 2.4, 2.5, 2.12, 3.1, 3.7, 3.11, 3.25, 4.3, 4.3A, 4.9, 4.14B, 4.25, 5.9, 5.17, 8.0, 8.3, 8.4, 8.6, 8.8, 8.10, 8.12 of the Farm Credit Act (12 U.S.C. 2013, 2015, 2018, 2019, 2020, 2073, 2074, 2075, 2076, 2093, 2122, 2128, 2132, 2146, 2154, 2154a, 2160, 2202b, 2211, 2243, 2252, 2279aa, 2279aa–3, 2279aa–4, 2279aa–6, 2279aa–8, 2279aa–10, 2279aa–12); 12 U.S.C. 2154 note; 15 U.S.C. 78o–7 note.

■ 11. Amend § 628.2 by:

■ a. Revising the definition of ''Collateral agreement'';

■ b. Adding in alphabetical order a definition for ''Common cooperative equity issuance date''; and

■ c. Revising the definitions of ''Eligible margin loan'', ''Qualifying master netting agreement'', ''Repo-style transaction'', and ''System institution''.

The revisions and addition read as follows:

§ 628.2 Definitions.

* * * * *

Collateral agreement means a legal contract that specifies the time when, and circumstances under which, a counterparty is required to pledge collateral to a System institution for a single financial contract or for all financial contracts in a netting set and confers upon the System institution a perfected, first-priority security interest (notwithstanding the prior security interest of any custodial agent), or the legal equivalent thereof, in the collateral posted by the counterparty under the agreement. This security interest must provide the System institution with a right to close-out the financial positions and liquidate the collateral upon an event of default of, or failure to perform by, the counterparty under the collateral agreement. A contract would not satisfy this requirement if the System institution's exercise of rights under the agreement may be stayed or avoided:

(1) Under applicable law in the relevant jurisdictions, other than:

(i) In receivership, conservatorship, or resolution under the Federal Deposit Insurance Act, Title II of the Dodd-Frank Act, or under any similar insolvency law applicable to Government-sponsored enterprises (GSEs), or laws of foreign jurisdictions that are substantially similar to the U.S. laws referenced in this paragraph (1)(i) in order to facilitate the orderly resolution of the defaulting counterparty;

(ii) Where the agreement is subject by its terms to, or incorporates, any of the laws referenced in paragraph (1)(i) of this definition; or

(2) Other than to the extent necessary for the counterparty to comply with the requirements of part 47, subpart I of part 252, or part 382 of this title, as applicable.

* * * * *

Common cooperative equity issuance date means the date in which the holding period for purchased stock (excluding statutory minimum borrower stock and third-party stock) and allocated equities start:

(1) For allocated equities, the calendar quarter-ending in which:

(i) The System institution's Board of Directors has passed a resolution declaring a patronage refund; and

(ii) The System institution has completed the applicable accounting treatment by segregating the new allocated equities from its unallocated retained earnings.

(2) For purchased stock (excluding statutory minimum borrower stock and third-party stock), the calendar quarter-ending in which the stock is acquired by the holder and recognized on the institution's balance sheet.

* * * * *

Eligible margin loan means:

(1) An extension of credit where:

(i) The extension of credit is collateralized exclusively by liquid and readily marketable debt or equity securities, or gold;

(ii) The collateral is marked-to-fair value daily, and the transaction is subject to daily margin maintenance requirements; and

(iii) The extension of credit is conducted under an agreement that provides the System institution the right to accelerate and terminate the extension of credit and to liquidate or set-off collateral promptly upon an event of default, including upon an event of receivership, insolvency, liquidation, conservatorship, or similar proceeding, of the counterparty, provided that, in any such case:

(A) Any exercise of rights under the agreement will not be stayed or avoided under applicable law in the relevant jurisdictions, other than:

(*1*) In receivership, conservatorship, or resolution under the Federal Deposit

Insurance Act, Title II of the Dodd-Frank Act, or under any similar insolvency law applicable to GSEs,[2] or laws of foreign jurisdictions that are substantially similar to the U.S. laws referenced in this paragraph (1)(iii)(A)(*1*) in order to facilitate the orderly resolution of the defaulting counterparty; or

(*2*) Where the agreement is subject by its terms to, or incorporates, any of the laws referenced in paragraph (1)(iii)(A)(*1*) of this definition; and

(B) The agreement may limit the right to accelerate, terminate, and close-out on a net basis all transactions under the agreement and to liquidate or set-off collateral promptly upon an event of default of the counterparty to the extent necessary for the counterparty to comply with the requirements of part 47, subpart I of part 252, or part 382 of this title, as applicable.

(2) In order to recognize an exposure as an eligible margin loan for purposes of this subpart, a System institution must comply with the requirements of § 628.3(b) with respect to that exposure.

* * * * *

Qualifying master netting agreement means a written, legally enforceable agreement provided that:

(1) The agreement creates a single legal obligation for all individual transactions covered by the agreement upon an event of default following any stay permitted by paragraph (2) of this definition, including upon an event of receivership, conservatorship, insolvency, liquidation, or similar proceeding, of the counterparty;

(2) The agreement provides the System institution the right to accelerate, terminate, and close-out on a net basis all transactions under the agreement and to liquidate or set-off collateral promptly upon an event of default, including upon an event of receivership, conservatorship, insolvency, liquidation, or similar proceeding, of the counterparty, provided that, in any such case:

(i) Any exercise of rights under the agreement will not be stayed or avoided under applicable law in the relevant jurisdictions, other than:

(A) In receivership, conservatorship, or resolution under the Federal Deposit Insurance Act, Title II of the Dodd-Frank Act, or under any similar insolvency law applicable to GSEs, or laws of foreign jurisdictions that are substantially similar to the U.S. laws referenced in this paragraph (2)(i)(A) in order to facilitate the orderly resolution of the defaulting counterparty; or

(B) Where the agreement is subject by its terms to, or incorporates, any of the laws referenced in paragraph (2)(i)(A) of this definition; and

(ii) The agreement may limit the right to accelerate, terminate, and close-out on a net basis all transactions under the agreement and to liquidate or set-off collateral promptly upon an event of default of the counterparty to the extent necessary for the counterparty to comply with the requirements of part 47, subpart I of part 252, or part 382 of this title, as applicable;

(3) The agreement does not contain a walkaway clause (that is, a provision that permits a non-defaulting counterparty to make a lower payment than it otherwise would make under the agreement, or no payment at all, to a defaulter or the estate of a defaulter, even if the defaulter or the estate of the defaulter is a net creditor under the agreement); and

(4) In order to recognize an agreement as a qualifying master netting agreement for purposes of this subpart, a System institution must comply with the requirements of § 628.3(d) with respect to that agreement.

Repo-style transaction means a repurchase or reverse repurchase transaction, or a securities borrowing or securities lending transaction, including a transaction in which the System institution acts as agent for a customer and indemnifies the customer against loss, provided that:

(1) The transaction is based solely on liquid and readily marketable securities, cash, or gold;

(2) The transaction is marked-to-fair value daily and subject to daily margin maintenance requirements;

(3)(i) The transaction is a ''securities contract'' or ''repurchase agreement'' under section 555 or 559, respectively, of the Bankruptcy Code (11 U.S.C. 555 or 559), a qualified financial contract under section 11(e)(8) of the Federal Deposit Insurance Act, or a netting contract between or among financial institutions under sections 401–407 of the Federal Deposit Insurance Corporation Improvement Act or the Federal Reserve's Regulation EE (12 CFR part 231); or

(ii) If the transaction does not meet the criteria set forth in paragraph (3)(i) of this definition, then either:

(A) The transaction is executed under an agreement that provides the System institution the right to accelerate, terminate, and close-out the transaction on a net basis and to liquidate or set-off collateral promptly upon an event of default, including upon an event of receivership, insolvency, liquidation, or similar proceeding, of the counterparty, provided that, in any such case:

(*1*) Any exercise of rights under the agreement will not be stayed or avoided under applicable law in the relevant jurisdictions, other than:

(*i*) In receivership, conservatorship, or resolution under the Federal Deposit Insurance Act, Title II of the Dodd-Frank Act, or under any similar insolvency law applicable to GSEs, or laws of foreign jurisdictions that are substantially similar to the U.S. laws referenced in this paragraph (3)(ii)(A)(*1*)(*i*) in order to facilitate the orderly resolution of the defaulting counterparty;

(*ii*) Where the agreement is subject by its terms to, or incorporates, any of the laws referenced in paragraph (3)(ii)(A)(*1*)(*i*) of this definition; and

(*2*) The agreement may limit the right to accelerate, terminate, and close-out on a net basis all transactions under the agreement and to liquidate or set-off collateral promptly upon an event of default of the counterparty to the extent necessary for the counterparty to comply with the requirements of part 47, subpart I of part 252, or part 382 of this title, as applicable; or

(B) The transaction is:

(*1*) Either overnight or unconditionally cancelable at any time by the System institution; and

(*2*) Executed under an agreement that provides the System institution the right to accelerate, terminate, and close-out the transaction on a net basis and to liquidate or set-off collateral promptly upon an event of counterparty default; and

(4) In order to recognize an exposure as a repo-style transaction for purposes of this subpart, a System institution must comply with the requirements of § 628.3(e) with respect to that exposure.

* * * * *

System institution means a System bank, an association of the Farm Credit System, and their successors, and any other institution chartered by the Farm Credit Administration (FCA) that the FCA determines should be considered a System institution for the purposes of this subpart.

* * * * *

■ 12. Amend § 628.10 by revising paragraph (c)(4) to read as follows:

§ 628.10 Minimum capital requirements.

* * * * *

[2] This requirement is met where all transactions under the agreement are (i) executed under U.S. law and (ii) constitute ''securities contracts'' under section 555 of the Bankruptcy Code (11 U.S.C. 555), qualified financial contracts under section 11(e)(8) of the Federal Deposit Insurance Act, or netting contracts between or among financial institutions under sections 401–407 of the Federal Deposit Insurance Corporation Improvement Act or the Federal Reserve Board's Regulation EE (12 CFR part 231).

(c) * * *

(4) *Tier 1 leverage ratio.* (i) A System institution's leverage ratio is the ratio of the institution's tier 1 capital to the institution's average total consolidated assets as reported on the institution's Call Report net of deductions and adjustments from tier 1 capital under §§ 628.22(a), (b), and (c) and 628.23.

(ii) To calculate the measure of URE and URE equivalents described in paragraph (b)(4) of this section, a System institution must adjust URE and URE equivalents to reflect all the deductions and adjustments required under § 628.22(a), (b), and (c), and must use the denominator of the tier 1 leverage ratio.

* * * * *

■ 13. Amend § 628.20 by revising paragraphs (b)(1)(i), (ii), (x), and (xiv), (c)(1)(xiv), (d)(1)(i), (d)(1)(viii)(C), (d)(1)(xi), and (f)(5)(ii) to read as follows:

§ 628.20 Capital components and eligibility criteria for tier 1 and tier 2 capital instruments.

* * * * *

(b) * * *

(1) * * *

(i) The instrument is paid-in, issued directly by the System institution, and represents the most subordinated claim in a receivership, insolvency, liquidation, or similar proceeding of the System institution;

(ii) The holder of the instrument is entitled to a claim on the residual assets of the System institution after all senior claims have been satisfied in a receivership, insolvency, liquidation, or similar proceeding;

* * * * *

(x) The System institution, or an entity that the System institution controls, did not purchase or directly or indirectly fund the purchase of the instrument, except that where there is an obligation for a member of the institution to hold an instrument in order to receive a loan or service from the System institution, an amount of that loan equal to no more than $1,000 of the borrower stock requirement under section 4.3A of the Act will not be considered as a direct or indirect funding where:

(A) The purpose of the loan is not the purchase of capital instruments of the System institution providing the loan; and

(B) The purchase or acquisition of one or more member equities of the institution is necessary in order for the beneficiary of the loan to become a member of the System institution;

* * * * *

(xiv) The System institution's capitalization bylaws, or a resolution adopted by its board of directors under § 628.21, provides that the institution:

(A) Establishes a minimum redemption or revolvement period of 7 years for equities included in CET1; and

(B) Shall not redeem, revolve, cancel, or remove any equities included in CET1 without prior approval of the FCA under paragraph (f) of this section, except that the statutory borrower stock described in paragraph (b)(1)(x) of this section, not to exceed $1,000, may be redeemed without a minimum period outstanding after issuance and without the prior approval of the FCA, as long as after the redemption, the System institution continues to comply with all minimum regulatory capital requirements.

* * * * *

(c) * * *

(1) * * *

(xiv) The System institution's capitalization bylaws, or a resolution adopted by its board of directors under § 628.21, provides that the institution:

(A) Establishes a minimum redemption or no-call period of 5 years for equities included in additional tier 1; and

(B) Shall not redeem, revolve, cancel, or remove any equities included in additional tier 1 capital without prior approval of the FCA under paragraph (f) of this section.

* * * * *

(d) * * *

(1) * * *

(i) The instrument is issued and paid-in;

* * * * *

(viii) * * *

(C) The capital instruments are in excess of $1,000.

* * * * *

(xi) The System institution's capitalization bylaws, or a resolution adopted by its board of directors under § 628.21, provides that the institution:

(A) Establishes a minimum call, redemption or revolvement period of 5 years for equities included in tier 2 capital; and

(B) Shall not call, redeem, revolve, cancel, or remove any equities included in tier 2 capital without prior approval of the FCA under paragraph (f) of this section.

* * * * *

(f) * * *

(5) * * *

(ii) After such cash payments have been declared and defined by resolution of the board, the dollar amount of the System institution's CET1 capital at quarter-end equals or exceeds the dollar amount of CET1 capital on the same quarter-end in the previous calendar year; and

* * * * *

■ 14. Add § 628.21 to read as follows:

§ 628.21 Capital bylaw or board resolution to include equities in tier 1 and tier 2 capital.

In order to include otherwise eligible purchased and allocated equities in tier 1 capital and tier 2 capital, the System institution must adopt a capitalization bylaw, or its board of directors must adopt a binding resolution, which resolution must be acknowledged by the board on an annual basis in the capital adequacy plan described in § 615.5200, in which the institution undertakes the following, as applicable:

(a) The institution shall obtain prior FCA approval under § 628.20(f) before:

(1) Redeeming or revolving the equities included in common equity tier 1 (CET1) capital;

(2) Redeeming or calling the equities included in additional tier 1 capital; and

(3) Redeeming, revolving, or calling instruments included in tier 2 capital other than limited life preferred stock or subordinated debt on the maturity date.

(b) The equities shall have a minimum redemption or revolvement period as follows:

(1) 7 years for equities included in CET1 capital, except that the statutory borrower stock described in § 628.20(b)(1)(x) may be redeemed without a minimum holding period and that equities designated as unallocated retained earnings (URE) equivalents cannot be revolved without submitting a written request to the FCA for prior approval;

(2) a minimum no-call, repurchase, or redemption period of 5 years for additional tier 1 capital; and

(3) a minimum no-call, repurchase, redemption, or revolvement period of 5 years for tier 2 capital.

(c) The institution shall submit to FCA a written request for prior approval before:

(1) Redesignating URE equivalents as equities that the institution may exercise its discretion to redeem other than upon dissolution or liquidation;

(2) Removing equities or other instruments from CET1, additional tier 1, or tier 2 capital other than through repurchase, cancellation, redemption or revolvement; and

(3) Redesignating equities included in one component of regulatory capital (CET1 capital, additional tier 1 capital, or tier 2 capital) for inclusion in another component of regulatory capital.

(d) The institution shall not exercise its discretion to revolve URE

equivalents except upon dissolution or liquidation and shall not offset URE equivalents against a loan in default except as required under final order of a court of competent jurisdiction or if required under § 615.5290 in connection with a restructuring under part 617 of this chapter.

(e) The minimum redemption and revolvement period (holding period) for purchased and allocated equities starts on the common cooperative equity issuance date, as defined in § 628.2.

■ 15. Amend § 628.22 by revising paragraph (a)(6) and adding paragraph (b) to read as follows:

§ 628.22 Regulatory capital adjustments and deductions.

* * * * *

(a) * * *

(6) The System institution's allocated equity investment in another System institution or service corporation; and

* * * * *

(b) *Regulatory adjustments to CET1 capital.* (1) Any accrual of a patronage or dividend payable or receivable recognized in the financial statements prior to a related board declaration or resolution must be reversed to or from unallocated retained earnings for purposes of calculating CET1 capital.

(2) [Reserved]

* * * * *

■ 16. Amend § 628.32 by revising paragraph (l)(1) to read as follows:

§ 628.32 General risk weights.

* * * * *

(l) * * *

(1) A System institution must assign a 0-percent risk weight to cash owned and held in all offices of the System institution or in transit; to gold bullion held in the System institution's own vaults or held in a depository institution's vaults on an allocated basis, to the extent the gold bullion assets are offset by gold bullion liabilities; and to exposures that arise from the settlement of cash transactions (such as equities, fixed income, spot foreign exchange (FX), and spot commodities) with a central counterparty where there is no assumption of ongoing counterparty credit risk by the central counterparty after settlement of the trade.

* * * * *

■ 17. Amend § 628.43 by revising paragraphs (d)(1) and (2) to read as follows:

§ 628.43 Simplified supervisory formula approach (SSFA) and the gross-up approach.

* * * * *

(d) * * *

(1) The System institution must define the following parameters:

$K_A = (1 - W) \times K_G + (0.5 \times W)$

(2) Then the System institution must calculate K_{SSFA} according to the following equation:

$$K_{SSFA} = \frac{e^{au} - e^{al}}{a(u-l)}$$

Where:

$$a = -\frac{1}{p \times K_A},$$

$$u = D - K_A,$$

$$l = \max(A - K_A, 0), \text{ and}$$

$$e = 2.71828, \text{ the base of the natural logarithm}$$

* * * * *

■ 18. Amend § 628.52 by revising paragraph (c)(2)(ii) to read as follows:

§ 628.52 Simple risk-weight approach (SRWA).

* * * * *

(c) * * *

(2) * * *

(ii) Under the variability-reduction method of measuring effectiveness:

$$E = 1 - \frac{\sum_{t=1}^{T}\left(X_t - X_{t-1}\right)^2}{\sum_{t=1}^{T}\left(A_t - A_{t-1}\right)^2}$$

Where:

$X_t = A_t - B_t$;

A_t = the value at time t of one exposure in a hedge pair; and

Bt = the value at time t of the other exposure in a hedge pair.

* * * * *

■ 19. Amend § 628.63 by:

■ a. Removing and reserving paragraph (b)(3);

■ b. Revising paragraph (b)(4).

The revision reads as follows:

§ 628.63 Disclosures.

* * * * *

(b) * * *

(4) A reconciliation of regulatory capital elements using month-end balances as they relate to its balance sheet in any applicable audited consolidated financial statements. The reconciliation must include a statement that compliance with the regulatory capital requirements outlined in subpart B of this part is determined using average daily balances for the most recent 3 months.

* * * * *

Dated: September 16, 2021.

Dale Aultman,

Secretary, Farm Credit Administration Board.

[FR Doc. 2021–20433 Filed 9–30–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2021–0235; Airspace Docket No. 21–AGL–18]

RIN 2120–AA66

Revocation of Class E Airspace: Port Huron, MI

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule, withdrawal.

SUMMARY: The FAA published the same final action twice, on September 1, 2021, and again on September 9, 2021. The FAA is withdrawing the first publication.

DATES: Effective October 1, 2021, FR Doc. 2021–18759, published at 86 FR 48905 (September 1, 2021), is withdrawn.

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

FOR FURTHER INFORMATION CONTACT: Rebecca Shelby, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5857.

SUPPLEMENTARY INFORMATION:

History

The FAA published FR Doc. 2021–18759 (86 FR 48905) on September 1, 2021, with an effective date of October 7, 2021. This docket did not allow sufficient time to accomplish charting, and the FAA re-published the same document as FR Doc. 2021–19275 (86 FR 50453) on September 9, 2021, with a later effective date of December 2, 2021, without withdrawing the first document. The FAA is withdrawing the first document.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Withdrawal

■ Accordingly, pursuant to the authority delegated to me, the final rule published in the **Federal Register** on September 1, 2021, (86 FR 48905) FR Doc. 2021–18759 is hereby withdrawn.

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.

Issued in Fort Worth, Texas, on September 24, 2021.

Martin A. Skinner,

Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2021–21227 Filed 9–30–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2021–0159; Airspace Docket No. 21–ACE–6]

RIN 2120–AA66

Amendment of Class E Airspace; Scott City, KS

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule, withdrawal.

SUMMARY: The FAA published the same final action twice, on August 31, 2021, and again on September 8, 2021. The FAA is withdrawing the first publication.

DATES: Effective October 1, 2021, FR Doc. 2021–18708, published at 86 FR 48496 (August 31, 2021), is withdrawn.

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

FOR FURTHER INFORMATION CONTACT: Rebecca Shelby, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5857.

SUPPLEMENTARY INFORMATION:

History

The FAA published FR Doc. 2021–18708 (86 FR 48496) on August 31, 2021, with an effective date of October 7, 2021. This docket did not allow sufficient time to accomplish charting, and the FAA re-published the same document as FR Doc. 2021–19278 (86 FR 50247) on September 8, 2021, with a later effective date of December 2, 2021, without withdrawing the first document. The FAA is withdrawing the first document.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Withdrawal

■ Accordingly, pursuant to the authority delegated to me, the final rule published in the **Federal Register** on August 31, 2021, (86 FR 48496) FR Doc. 2021–18708 is hereby withdrawn.

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.

Issued in Fort Worth, Texas, on September 24, 2021.

Martin A. Skinner,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2021–21225 Filed 9–30–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2021–0277; Airspace Docket No. 21–AGL–19]

RIN 2120–AA66

Revocation of Class E Airspace: Standish, MI

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule, withdrawal.

SUMMARY: The FAA published the same final action twice, on August 31, 2021, and again on September 8, 2021. The FAA is withdrawing the first publication.

DATES: Effective October 1, 2021, FR Doc. 2021–18709, published at 86 FR 48494 (August 31, 2021), is withdrawn.

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

FOR FURTHER INFORMATION CONTACT: Rebecca Shelby, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5857.

SUPPLEMENTARY INFORMATION:

History

The FAA published FR Doc. 2021–18709 (86 FR 48494) on August 31, 2021, with an effective date of October 7, 2021. This docket did not allow sufficient time to accomplish charting, and the FAA re-published the same document as FR Doc. 2021–19276 (86 FR 50248) on September 8, 2021, with a later effective date of December 2, 2021, without withdrawing the first document. The FAA is withdrawing the first document.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Withdrawal

Accordingly, pursuant to the authority delegated to me, the final rule published in the **Federal Register** on August 31, 2021, (86 FR 48494) FR Doc. 2021–18709 is hereby withdrawn.

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.

Issued in Fort Worth, Texas, on September 24, 2021.

Martin A. Skinner,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2021–21232 Filed 9–30–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2021–0278; Airspace Docket No. 21–ACE–10]

RIN 2120–AA66

Amendment of Class E Airspace; Pocahontas, IA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule, withdrawal.

SUMMARY: The FAA published the same final action twice, on August 31, 2021, and again on September 7, 2021. The FAA is withdrawing the first publication.

DATES: Effective October 1, 2021, FR Doc. 2021–18707, published at 86 FR 48493 (August 31, 2021), is withdrawn.

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

FOR FURTHER INFORMATION CONTACT: Rebecca Shelby, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5857.

SUPPLEMENTARY INFORMATION:

History

The FAA published FR Doc. 2021–18707 (86 FR 48493) on August 31, 2021, with an effective date of October 7, 2021. This docket did not allow sufficient time to accomplish charting, and the FAA re-published the same document as FR Doc. 2021–19235 (86 FR 49918) on September 7, 2021, with a later effective date of December 2, 2021, without withdrawing the first document. The FAA is withdrawing the first document.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Withdrawal

■ Accordingly, pursuant to the authority delegated to me, the final rule published in the **Federal Register** on August 31, 2021, (86 FR 48493) FR Doc. 2021–18707 is hereby withdrawn.

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.

Issued in Fort Worth, Texas, on September 24, 2021.

Martin A. Skinner,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2021–21226 Filed 9–30–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2021–0066; Airspace Docket No. 21–ANE–1]

RIN 2120–AA66

Amendment of Class E Airspace; Bangor, ME

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends Class E airspace extending upward from 700 feet above the surface in Bangor, ME by establishing airspace for Eastern Maine Medical Center Heliport, to accommodate new area navigation (RNAV) global positioning system (GPS) standard instrument approach procedures (SIAPs) serving this heliport. Also, this action amends the existing Class E airspace extending upward from 700 feet above the surface at Bangor International Airport by omitting the Bangor VORTAC from the airport description.

DATES: Effective 0901 UTC, December 2, 2021. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

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

inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order JO 7400.11F at NARA, email *fr.inspection@nara.gov* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

FOR FURTHER INFORMATION CONTACT: John Fornito, Operations Support Group, Eastern Service Center, Federal Aviation Administration, 1701 Columbia Ave., College Park, GA 30337; Telephone (404) 305–6364.

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 the Class E airspace extending upward from 700 feet above the surface in Bangor, ME, to support IFR operations in the area.

History

The FAA published a notice of proposed rulemaking in the **Federal Register** (86 FR 38419, July 21, 2021) for Docket No. FAA–2021–0066 to amend Class E airspace extending upward from 700 feet above the surface at Bangor, ME, by establishing airspace for Eastern Maine Medical Center Heliport, and removing the Bangor VORTAC from the Bangor International Airport descriptor, as it is no longer used.

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 JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in the Order.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic routes, and reporting points.

The Rule

The FAA is amending 14 CFR part 71 by amending the Class E airspace extending upward from 700 feet above the surface in Bangor, ME, by establishing controlled airspace for Eastern Maine Medical Center Heliport to accommodate new RNAV standard instrument approach procedures serving this heliport. Also, this action amends Class E airspace extending upward from 700 feet above the surface for Bangor International Airport, omitting the Bangor VORTAC, as well as removing the extension to the north, reducing the radius to 8.4 miles (previously 10 miles), and amending the extension to the southeast to a 134° bearing from the airport, extending from the 8.4-mile radius to 15.5-miles southeast of the airport (previously 136° bearing extending from the 10-mile radius to 16.7 miles southeast of the airport). Controlled airspace is necessary for the safety and management of instrument flight rules (IFR) operations in the area.

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

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. 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 minimal. Since this is a routine matter that only affects air traffic procedures an air navigation, it is certified that this rule, when promulgated, does 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 JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

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

* * * * *

ANE ME E5 Bangor, ME [Amended]

Bangor International Airport, ME
(Lat. 44°48′27″ N, long. 68°49′41″ W)

Eastern Maine Medical Center Heliport, ME,
(Lat. 44°48′30″ N, long. 68°45′08″ W)

That airspace extending upward from 700 feet above the surface within an 8.4-mile radius of Bangor International Airport, and within 4-miles each side of the 134° bearing from the airport, extending from the 8.4-mile radius to 15.5-miles southeast of the airport, and that airspace within a 6-mile radius of Eastern Maine Medical Center Heliport.

Issued in College Park, Georgia, on September 27, 2021.

Andreese C. Davis,

Manager, Airspace & Procedures Team South, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2021–21348 Filed 9–30–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

25 CFR Part 90

[212A2100DD/AAKC001030/A0A501010.999900]

RIN 1076–AF58

Election of Officers of the Osage Minerals Council

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Final rule.

SUMMARY: The Bureau of Indian Affairs (BIA) is finalizing revisions to its regulations governing elections of the Osage Nation. These revisions update and limit the Secretary's role to the task of compiling a list of voters for Osage Minerals Council elections. These changes reaffirm the inherent sovereign rights of the Osage Nation to determine its membership and form of government.

DATES: This rule is effective on November 1, 2021.

FOR FURTHER INFORMATION CONTACT: Elizabeth Appel, Office of Regulatory Affairs & Collaborative Action, telephone (202) 273–4680, *elizabeth.appel@bia.gov.*

SUPPLEMENTARY INFORMATION:

I. Statutory Authority
II. History of the Rule
III. Overview of Rule
IV. Changes From Proposed Rule to Final Rule
V. Procedural Requirements
A. Regulatory Planning and Review (E.O. 12866, 13563, and 13771)
B. Regulatory Flexibility Act
C. Small Business Regulatory Enforcement and Fairness Act
D. Unfunded Mandates Reform Act of 1995
E. Takings (E.O. 12630)
F. Federalism (E.O. 13132)
G. Civil Justice Reform (E.O. 12988)
H. Paperwork Reduction Act
I. National Environmental Policy Act (NEPA)
J. Consultation With Indian Tribes (E.O. 13175)
K. Energy Effects (E.O. 13211)

I. Statutory Authority

BIA is finalizing this rule under the authority of the Act of June 28, 1906, Public Law 59–321, 34 Stat. 539, as amended by the Act of December 3, 2004, Public Law 108–431, 118 Stat. 2609.

II. History of the Rule

The Department of the Interior provided testimony in support of the legislation proposed by the Osage Nation when the Nation sought to exercise its inherent sovereign rights. Thereafter, the United States Congress reaffirmed in 2004 the Nation's rights to determine its membership and form of government. The following discussion sets forth a brief historical account of the relationship between the Osage Nation and the Federal government.

In 1906, the Congress enacted the Osage Allotment Act, which is unique among Federal Indian laws in that it restricted the Osage Nation from defining its own membership rules, and prescribes a particular form of government, which the Nation could not change without seeking amendment or clarification of Federal law. In 2002, the 31st Osage Tribal Council, formed pursuant to the Osage Allotment Act, actively began seeking a legislative remedy to address the restrictions contained in the Osage Allotment Act.

On July 25, 2003, Congressman Frank Lucas (R–OK) introduced H.R. 2912, a bill reaffirming the rights of the Osage Nation to form its own membership rules and tribal government, provided that no rights to any shares in the mineral estate of the Nation's reservation are diminished. The bill also directs the Secretary of the Interior to assist the Nation in holding appropriate elections and referenda at the request of the Nation.

H.R. 2912 was referred to the Committee on Resources. On March 15, 2004, that Committee held a hearing on the bill in Tulsa, Oklahoma. Osage Nation officials, a BIA representative, and Osage people testified in favor of the bill. On May 5, 2004, the bill was favorably reported to the House of Representatives by unanimous consent. See H. Rpt. 108–502. On June 1, 2004, the House of Representatives passed the bill and then sent it to the Senate, and it was referred to the Committee on Indian Affairs.

On July 14, 2004, the Committee on Indian Affairs favorably reported H.R. 2912 to the Senate with a ''do pass'' recommendation. President Bush signed H.R. 2912 into law on December 3, 2004, and became Public Law 108–431, 118 Stat. 2609.

The Commission began conducting town hall meetings in April 2005. Meetings were conducted in all Osage communities and other geographic areas with large concentrations of Osages. This was followed by a written survey mailed to all Osages with a Certificate of Degree of Indian Blood (CDIB) card. Input from the meetings and data obtained from the survey results were compiled to formulate key questions put forward to the Osage people for a vote in a referendum in November 2005.

The results from the referendum were used to draft an Osage Constitution, which was ratified on March 11, 2006, in a second referendum vote. The Osage Nation adopted a new constitutional form of government reorganized from a Tribal Council system into a tripartite system, which now includes an executive, legislative and judicial branch with a separation of powers between the three branches.

This was followed on June 5, 2006, by the election of a Principal Chief and Assistant Principal Chief, Osage Nation Congress, and Osage Minerals Council. At the request of the Nation, the BIA provided technical assistance in conducting the election in accordance with Public Law 108–431, 118 Stat. 2609. With the elections completed, all elected officials were sworn into their respective offices on July 3, 2006. Upon the swearing in of these elected officials, governmental authority passed from the Osage Tribal Council to the Osage Nation Constitutional Government. Thereafter, the Osage Tribe of Indians of Oklahoma became the Osage Nation.

In 2008, the BIA formally acknowledged the name change of the Tribe from the Osage Tribe of Indians of Oklahoma to the Osage Nation and published the change in the **Federal Register** in the list of Indian Entities Recognized and Eligible to Receive Services from the United States Bureau of Indian Affairs. (See, 73 FR 18553, April 4, 2008). Further communication between the Nation and the BIA eventually resulted in an agreement to begin an informal negotiated rulemaking process. In February 2010, representatives from the Osage Nation, the BIA Eastern Oklahoma Region, Osage Agency, the BIA Eastern Oklahoma Region, Eastern Oklahoma Regional Office, the Tulsa Field Solicitor's Office, and the BIA Central Office convened to form a joint regulation negotiation team. The team completed new and revised regulations to cover 25 CFR parts 90, 91, 117, and 158. The June 2010 Election resulted in a change of administration of the Osage Nation, thereby, starting the process over again with a new vision from Osage Nation. The Osage Nation formed a new team in 2019 and they have reviewed and revised regulations to cover 25 CFR part 90. The team will continue working on parts 91, 117, and 158.

III. Overview of Rule

This rule governs BIA's role in providing information to the Osage Minerals Council Election Board for purposes of notice. The existing 25 CFR part 90 is the authority for the release of otherwise potentially confidential

information to the Osage Minerals Council Election Board. The alternative to these amendments would deprive the Osage Nation of the information it needs to accurately identify Osage voters. Amendments to this part focus on the BIA's procedures in compiling a complete annuitant list with addresses and headright interests to the Osage Minerals Council Election Board for purposes of identifying Osage voters.

This rule deletes most provisions of part 90 in their entirety because of the enactment of the Public Law 108–431, 118 Stat. 2609, and subsequent adoption of the Constitution of the Osage Nation. Thus, the remaining purpose of this part is the authority for BIA to provide a list to the Osage Minerals Council Election Board of eligible headright interest owners in the manner requested by the Osage Nation. The Department may not generally release this information but this part provides authority for the release solely to the Osage Minerals Council Election Board for purposes of conducting elections for the Osage Minerals Council. The Privacy Act does not prohibit disclosure of the headright interests of eligible Osage voters for this purpose. The Department may provide the list of eligible headright interest owners as a routine use under the Privacy Act.

In response to the Constitution of the Osage Nation, the BIA significantly reduced its role in the elections of the Osage Nation as of June 2006. The only remaining portion in part 90 describes the current role of the BIA in the Osage Minerals Council election process.

The following distribution table indicates where each of the current regulatory sections in 25 CFR part 90 is located in the new 25 CFR part 90.

Current 25 CFR §	New 25 CFR §	Title	Description of change
N/A	90.100	What role does BIA play in the Osage Minerals Council elections?	Consolidated current §§ 90.21 and 90.35 into one new section.
90.1	N/A	General, Definitions	Deleted.
90.2	N/A	General, Statutory provisions	Deleted.
90.21	N/A	Eligibility, General	Revised and incorporated into the new § 90.100.
90.30	N/A	Elections, Nominating conventions and petitions.	Deleted.
90.31	N/A	Elections, Applicability	Deleted.
90.32	N/A	Elections, Election Board	Deleted.
90.33	N/A	Elections, Watchers and challengers	Deleted.
90.34	N/A	None (Apparently omitted).	
90.35	N/A	Elections, List of voters	Revised and redesignated as § 90.100 (see first row).
90.36	N/A	Elections, Disputes on eligibility of voters	Deleted.
90.37	N/A	Elections, Election Notices	Deleted.
90.38	N/A	Elections, Opening and closing of poll	Deleted.
90.39	N/A	Elections, Voters to announce name and residence.	Deleted.
90.40	N/A	Elections, Ballots	Deleted.
90.41	N/A	Elections, Absentee voting	Deleted.
90.42	N/A	Elections, Absentee ballots	Deleted.
90.43	N/A	Elections, Canvass of election returns	Deleted.
90.44	N/A	Elections, Statement of supervisor	Deleted.
90.46	N/A	Elections, Notification of election of tribal officers.	Deleted.
90.47	N/A	Elections, Contesting elections	Deleted.
90.48	N/A	Elections, Notice of Contest	Deleted.
90.49	N/A	Elections, Expenses of elections	Deleted.

IV. Changes From Proposed Rule to Final Rule

On December 4, 2020 (85 FR 78300), the BIA published a proposed rule to update Federal regulations related specifically to the Osage Nation so that the regulations align with the Osage Nation's new form of government and address outdated regulations. The proposed rule was developed through a consensus-oriented process conducted between the BIA and the Osage Nation.

During the public comment period on the proposed rule, the BIA received two comments: One from an individual in support of the rule, the other from the Osage Minerals Council expressing general support for the proposed rule but requesting a change in the nomenclature of the titles and entities that conduct the elections to reflect the sovereign authority of the Osage Nation and the Osage Minerals Council to change that nomenclature. Specifically, the Osage Minerals Council requested that ''supervisor of the Osage Minerals Council Election Board'' be changed to the ''Osage Minerals Council's designee charged with carrying out Osage Minerals Council elections.'' The final rule makes this change.

The Osage Nation also requested clarification that the list of names the Osage Agency Superintendent provides be based on the quarterly annuity roll at the Osage Agency as of the last quarterly payment ''of the last full quarter'' immediately preceding the date of the election. To clarify which quarterly annuity roll is intended as the basis for the list, the final rule specifies that it will be the March quarterly annuity payment. Elections are held in June so the voters list would reflect the March annuity payment. This revision avoids the potential for misinterpretation of which quarter's annuity roll is intended.

V. Procedural Requirements

A. Regulatory Planning and Review (E.O. 12866, 13563, and 13771)

Executive Order (E.O.) 12866 provides that the Office of Information and Regulatory Affairs (OIRA) at the Office of Management and Budget (OMB) will review all significant rules. OIRA has determined that this rule is not significant.

E.O. 13563 reaffirms the principles of E.O. 12866 while calling for improvements in the Nation's regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. The E.O. directs agencies to consider

regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. E.O. 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. We have developed this rule in a manner consistent with these requirements.

B. The Regulatory Flexibility Act

The Department of the Interior certifies that this rule will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

C. Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. Because this rule is exclusively confined to the Federal Government, Osage Indians, and the Osage Nation, this rule:

(a) Does not have an annual effect on the economy of $100 million or more.

(b) Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions.

(c) Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises.

D. Unfunded Mandates Reform Act of 1995

This rule does not impose an unfunded mandate on State, local, or Tribal governments or the private sector of more than $100 million per year. The rule does not have a monetarily significant or unique effect on State, local, or Tribal governments or the private sector. A statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1531 *et seq.*) is not required.

E. Takings (E.O. 12630)

This rule does not affect a taking of private property or otherwise have taking implications under Executive Order 12630 because this rule does not affect individual property rights protected by the Fifth Amendment or involve a compensable ''taking.'' A takings implication assessment is not required.

F. Federalism (E.O. 13132)

Under the criteria in section 1 of Executive Order 13132, this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement. A federalism summary impact statement is not required.

G. Civil Justice Reform (E.O. 12988)

This rule complies with the requirements of Executive Order 12988. Specifically, this rule: (a) Meets the criteria of section 3(a) requiring that all regulations be reviewed to eliminate errors and ambiguity and be written to minimize litigation; and (b) Meets the criteria of section 3(b)(2) requiring that all regulations be written in clear language and contain clear legal standards.

H. Consultation With Indian Tribes (E.O. 13175)

The Department of the Interior strives to strengthen its government-to-government relationship with federally recognized Indian Tribes through a commitment to consultation with these Indian Tribes and recognition of their right to self-governance and Tribal sovereignty. We have evaluated this rule under the Department's consultation policy and under the criteria in Executive Order 13175 and have determined that it has substantial direct effects on one federally recognized Indian Tribe because the rule directly addresses the Osage Nation. The Department consulted with the Osage Nation on this rule. This rulemaking is a result of a consensus-oriented process conducted between the Department of the Interior and the Osage Nation to identify a rulemaking strategy to address issues and concerns contained in the regulations related specifically to the Osage Nation, which no longer align with the Nation's form of government. The purpose of this rulemaking is to allow the Department of the Interior to better meet its fiduciary trust responsibilities and to carry out the policies established by the Congress to strengthen Tribal sovereignty with regard to elections of Osage Nation officers.

I. Paperwork Reduction Act

This rule does not contain information collection requirements, and a submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) is not required. We may not conduct or sponsor and you are not required to respond to a collection of information unless it displays a currently valid OMB control number.

J. National Environmental Policy Act

This rule does not constitute a major Federal action significantly affecting the quality of the human environment. A detailed statement under the National Environmental Policy Act of 1969 (NEPA) is not required because this is an administrative and procedural regulation. (For further information see 43 CFR 46.210(i)). We have also determined that the rule does not involve any of the extraordinary circumstances listed in 43 CFR 46.215 that would require further analysis under NEPA.

K. Effects on the Energy Supply (E.O. 13211)

This rule is not a significant energy action under the definition in Executive Order 13211. A Statement of Energy Effects is not required.

List of Subjects in 25 CFR Part 90

Elections, Indians—tribal government.

■ For the reasons given in the preamble, the Department of the Interior revises 25 CFR part 90 to read as follows:

PART 90—ELECTIONS OF OSAGE MINERALS COUNCIL

Sec.
90.100 What role does the Bureau of Indian Affairs (BIA) play in the Osage Minerals Council's elections?
90.101 [Reserved]

Authority: 5 U.S.C. 301; 25 U.S.C. 2, 9; Sec. 9, Pub. L. 59–321, 34 Stat. 539; Pub. L. 108–431, 118 Stat. 2609, 118 Stat. 2609.

§ 90.100 What role does the Bureau of India Affairs (BIA) play in the Osage Minerals Council's elections?

(a) The Superintendent of the Osage Agency must compile, at the request of the Chair of the Osage Minerals Council, a list of the voters of Osage descent who will be 18 years of age or over on the election day designated by the Osage Minerals Council and whose names appear on the March quarterly annuity roll at the Osage Agency as of the March quarterly payment immediately preceding the date of the election. Such list must set forth only the name and last known address of each voter.

(b) For purposes of calculating votes, the Superintendent must furnish to the Osage Minerals Council designee charged with carrying out Osage Minerals Council elections a separate list containing the name and last known address of each eligible voter and including the voter's headright interest shown on the last March quarterly annuity roll.

§ 90.101 [Reserved]

Bryan Newland,

Assistant Secretary—Indian Affairs.

[FR Doc. 2021–21385 Filed 9–30–21; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9922]

RIN 1545–BP21; 1545–BP22

Guidance Related to the Allocation and Apportionment of Deductions and Foreign Taxes, Foreign Tax Redeterminations, Foreign Tax Credit Disallowance Under Section 965(g), Consolidated Groups, Hybrid Arrangements and Certain Payments Under Section 951A; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correcting amendments.

SUMMARY: This document contains corrections to the final regulations (Treasury Decision 9922) that were published in the **Federal Register** on Thursday, November 12, 2020. Treasury Decision 9922 provided guidance relating to the allocation and apportionment of deductions and creditable foreign taxes, the definition of financial services income, foreign tax redeterminations, availability of foreign tax credits under the transition tax, the application of the foreign tax credit limitation to consolidated groups, adjustments to hybrid deduction accounts to take into account certain inclusions in income by a United States shareholder, conduit financing arrangements involving hybrid instruments, and the treatment of certain payments under the global intangible low-taxed income provisions.

DATES: Effective on October 1, 2021, and applicable as of November 12, 2020.

FOR FURTHER INFORMATION CONTACT: Concerning §§ 1.861–8 and 1.861–17, Jeffrey P. Cowan, (202) 317–4924; concerning §§ 1.861–20, 1.904–4, and 1.904–6, Suzanne M. Walsh, (202) 317–4908; concerning § 1.881–3, Richard F. Owens, (202) 317–6501; concerning § 1.904(g)-3, Jeffrey L. Parry, (202) 317 4916; concerning § 1.905–4T, Corina Braun, (202) 317–5004 (not toll-free numbers).

Background

The final regulations (TD 9922) that are the subject of this correction are issued under sections 861, 881, 904, and 905 of the Internal Revenue Code.

Need for Correction

As published on Thursday, November 12, 2020 (85 FR 71998), the final regulations (TD 9922) contain errors that need to be corrected.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Correction of Publication

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

PART 1—INCOME TAXES

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

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

■ **Par. 2.** Section 1.861–8 is amended by revising the last sentence of paragraph (e)(5)(ii) and the first and second sentences of paragraph (e)(8)(ii) to read as follows:

§ 1.861–8 Computation of taxable income from sources within the United States and from other sources and activities.

* * * * *

(e) * * *

(5) * * *

(ii) * * * The deductions are apportioned among the statutory and residual groupings on the basis of the relative values (as determined under the asset method in § 1.861–9 for purposes of allocating and apportioning the taxpayer's interest expense) of the assets that were involved in the event or (if the taxpayer no longer owns the assets involved in the event) the assets that are used to produce or sell products or services in the relevant class in each grouping; such values are determined in the year the deductions are allowed.

* * * * *

(8) * * *

(ii) * * * A net operating loss taken as a deduction in computing taxable income for a particular taxable year as allowed under section 172 is allocated and apportioned to statutory and residual groupings by reference to the statutory and residual groupings of the components of the net operating loss (as determined under paragraph (e)(8)(i) of this section) that is deducted in the taxable year. Except as provided under the rules for an operative section, if the full net operating loss carryover is not taken as a deduction in a taxable year, the partial net operating loss deduction is treated as ratably comprising the components of a net operating loss. * * *

* * * * *

■ **Par. 3.** Section 1.861–17 is amended in paragraph (d)(4)(iv), by revising the first sentence and adding a sentence at the end of the paragraph to read as follows:

§ 1.861–17 Allocation and apportionment of research and experimental expenditures.

* * * * *

(d) * * *

(4) * * *

(iv) * * * If the controlled party has entered into a cost sharing arrangement, in accordance with the provisions of § 1.482–7, with the taxpayer for the purpose of developing intangible property, then ordinarily the controlled party is not reasonably expected to acquire rights in intangible property that would arise from the taxpayer's share of the R&E expenditures with respect to the cost shared intangibles as defined in § 1.482–7(j)(1)(i); acquire products in which such intangible property is embedded or used in connection with the manufacture or sale of such products; or receive services that incorporate or directly or indirectly benefit from such intangible property. * * * However, the rule in this paragraph (d)(4)(iv) does not apply, and the controlled party's sales are taken into account, to the extent the taxpayer licenses, or has licensed, to the controlled party intangible property resulting from a cost sharing arrangement with the controlled party.

* * * * *

■ **Par. 4.** Section 1.861–20 is amended by revising the first sentence of paragraph (d)(3)(i)(B)(*2*) to read as follows:

§ 1.861–20 Allocation and apportionment of foreign income taxes.

* * * * *

(d) * * *

(3) * * *

(i) * * *

(B) * * *

(*2*) * * * The foreign dividend amount is, to the extent of the U.S. dividend amount, assigned to the same statutory and residual grouping (or ratably to the groupings) to which a distribution of the U.S. dividend amount is assigned under Federal income tax law. * * *

* * * * *

§ 1.881–3 [Amended]

■ **Par. 5.** For each entry in § 1.881–3 in the ''Paragraph Heading'' column, remove the language in ''Remove'' column and add in its place the

language in the ''Add'' column as set forth below:

Paragraph heading	Remove	Add
Paragraph (e)(5)	*Example 4* ..	*Example 5*
Paragraph (e)(6)	*Example 5* ..	*Example 6*
Paragraph (e)(7)	*Example 6* ..	*Example 7*
Paragraph (e)(8)	*Example 7* ..	*Example 8*
Paragraph (e)(9)	*Example 8* ..	*Example 9*
Paragraph (e)(10)	*Example 9* ..	*Example 10*
Paragraph (e)(11)	*Example 10*	*Example 11*
Paragraph (e)(12)	*Example 11*	*Example 12*
Paragraph (e)(13)	*Example 12*	*Example 13*
Paragraph (e)(14)	*Example 13*	*Example 14*
Paragraph (e)(15)	*Example 14*	*Example 15*
Paragraph (e)(16)	*Example 15*	*Example 16*
Paragraph (e)(17)	*Example 16*	*Example 17*
Paragraph (e)(18)	*Example 17*	*Example 18*
Paragraph (e)(19)	*Example 18*	*Example 19*
Paragraph (e)(20)	*Example 19*	*Example 20*
Paragraph (e)(21)	*Example 20*	*Example 21*
Paragraph (e)(22)	*Example 21*	*Example 22*
Paragraph (e)(23)	*Example 22*	*Example 23*
Paragraph (e)(24)	*Example 23*	*Example 24*
Paragraph (e)(25)	*Example 24*	*Example 25*
Paragraph (e)(26)	*Example 25*	*Example 26*
Paragraph (e)(27)	*Example 26*	*Example 27*

§ 1.904–4 [Amended]

■ **Par. 6.** Section 1.904–4 is amended by removing the language ''and (3)'' from paragraph (q)(1).

■ **Par. 7.** Section 1.904–6 is amended by revising the first and second sentences of paragraph (f) to read as follows:

§ 1.904–6 Allocation and apportionment of foreign income taxes.

* * * * *

(f) * * * Some or all of the foreign gross income of a United States shareholder of a controlled foreign corporation, or of a U.S. person that owns the United States shareholder (the ''U.S. owner''), that is attributable to foreign law inclusion regime income with respect to a foreign law CFC described in § 1.861–20(d)(3)(iii) or foreign law pass-through income from a reverse hybrid described in § 1.861–20(d)(3)(i)(C) is assigned to the section 951A category if, were the controlled foreign corporation the taxpayer that recognizes the foreign gross income, the foreign gross income would be assigned to the controlled foreign corporation's tested income group (as defined in § 1.960–1(b)(33)) within the general category to which an inclusion under section 951A is attributable. The amount of the United States shareholder's, or the U.S. owner's, foreign gross income that is assigned to the section 951A category (or a specified separate category associated with the section 951A category) is based on the inclusion percentage (as defined in § 1.960–2(c)(2)) of the United States shareholder. * * *

* * * * *

■ **Par. 8.** Section 1.904(g)–3 is amended by revising paragraphs (b)(2) and (3) to read as follows:

§ 1.904 (g)–3 Ordering rules for the allocation of net operating losses, net capital losses, U.S. source losses, and separate limitation losses, and for the recapture of separate limitation losses, overall foreign losses, and overall domestic losses.

* * * * *

(b) * * *

(2) *Full net operating loss deduction.* If the full net operating loss (that remains after carryovers to other taxable years) is deducted in computing the taxable income in a particular year (carryover year), so that there is no remaining net operating loss that can be carried to other taxable years, U.S. source losses and foreign source losses in separate categories that comprise the net operating loss shall be combined with the U.S. source income or loss and the foreign source income or loss in the same separate categories in the carryover year.

(3) *Partial net operating loss deduction.* If the full net operating loss (that remains after carryovers to other taxable years) is not deducted in computing the taxable income in a carryover year, so that there is remaining loss that can be carried to other taxable years, the following rules apply:

(i) Any U.S. source loss (not to exceed the amount of the net operating loss carryover deducted in computing the taxable income in the carryover year (the net operating loss deduction)) shall be carried over to the extent of any U.S. source income in the carryover year.

(ii) If the net operating loss deduction exceeds the U.S. source loss carryover determined under paragraph (b)(3)(i) of this section, then separate limitation losses that are part of the net operating loss shall be tentatively carried over to the extent of separate limitation income in the same separate category in the carryover year. If the sum of the potential separate limitation loss carryovers determined under the preceding sentence exceeds the amount of the net operating loss deduction reduced by any U.S. source loss carried over under paragraph (b)(3)(i) of this section, then the potential separate limitation loss carryovers shall be reduced pro rata so that their sum equals such amount.

(iii) If the net operating loss deduction exceeds the sum of the U.S. and separate limitation loss carryovers determined under paragraphs (b)(3)(i) and (ii) of this section, then a proportionate part of the remaining loss from each separate category shall be carried over to the extent of such excess and combined with the foreign source loss, if any, in the same separate categories in the carryover year.

(iv) If the net operating loss deduction exceeds the sum of all the loss carryovers determined under paragraphs (b)(3)(i), (ii), and (iii) of this section, then any U.S. source loss not carried over under paragraph (b)(3)(i) of this section shall be carried over to the extent of such excess and combined with the U.S. source loss, if any, in the carryover year.

* * * * *

§ 1.905–4T [Removed]

■ **Par. 9.** Section 1.905–4T is removed.

Oluwafunmilayo A. Taylor,

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

[FR Doc. 2021–21175 Filed 9–30–21; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF JUSTICE

28 CFR Part 16

[CPCLO Order No. 009–2021]

Privacy Act of 1974; Implementation

AGENCY: Office of Legal Policy, United States Department of Justice.

ACTION: Final rule.

SUMMARY: The United States Department of Justice (DOJ or Department), is finalizing with changes its Privacy Act exemption regulations for the system of records titled, ''Judicial Nominations Files,'' JUSTICE/OLP–002, which were published as a notice of proposed rulemaking (NPRM) on July 23, 2021. Specifically, the Department's regulations will exempt the records maintained in JUSTICE/OLP–002 from one or more provisions of the Privacy Act.

DATES: This final rule is effective November 1, 2021.

FOR FURTHER INFORMATION CONTACT: Matrina Matthews, Executive Officer, Office of Legal Policy, U.S. Department of Justice, 950 Pennsylvania Avenue NW, Room 4234, Washington, DC 20530–0001; telephone: (202) 616–0040; email: *matrina.matthews@usdoj.gov.*

SUPPLEMENTARY INFORMATION:

Background

On July 14, 2021, the Office of Legal Policy (OLP) published in the **Federal Register** a System of Records Notice (SORN) for an OLP system of records titled, ''Judicial Nominations Files,'' JUSTICE/OLP–002. 86 FR 37192. On July 23, 2021, the Department published

a notice of proposed rulemaking (NPRM) proposing to exempt records maintained in JUSTICE/OLP–002 from certain provisions of the Privacy Act pursuant to 5 U.S.C. 552a(k), and inviting public comment on the proposed exemptions. 86 FR 38955. The comment period was open through August 13, 2021, for the SORN and through August 23, 2021, for the NPRM. The Department received no comments on the proposed rule. After providing the opportunity for public comment, exemptions necessary to protect the ability of OLP to do its judicial nomination functions have been codified in this final rule as proposed in the NPRM.

The exemptions are necessary because certain classified information may be maintained in JUSTICE/OLP–002, including but not limited to, records related to a potential nominee that maintained a previous or current position with access to classified information and/or assigned to a national security sensitive position. Moreover, given the law enforcement information that may be discovered as part of the nomination investigation and/or evaluations, certain investigatory materials for law enforcement purposes may be maintained in this system of records. In addition, investigatory material may also be used in determining suitability, eligibility, or qualification decisions, and such information may require exemption to the extent that the disclosure of such material would reveal the identity of a source who furnished information to the Department under an express promise that the identity of the source would be held in confidence. Finally, the Department also utilizes various examination materials to determine individual qualifications for appointment, which if disclosed, could compromise the objectivity or fairness of the Department's examination and vetting process.

Response to Public Comments

In its Judicial Nominations Files SORN, published on July 14, 2021, and its Judicial Nominations Files NPRM, published on July 23, 2021, the Department invited public comment. The comment period for the SORN closed on August 13, 2021, and the comment period for the NPRM closed on August 23, 2021. The Department received no comments. Because no comments were submitted, and because OLP continues to assert the rationales in support of the exemptions as stated in the NPRM, the Department adopts in this final rule the exemptions and rationales proposed in the NPRM.

Executive Orders 12866 and 13563—Regulatory Review

This regulation has been drafted and reviewed in accordance with Executive Order 12866, ''Regulatory Planning and Review'' section 1(b), Principles of Regulation, and Executive Order 13563 ''Improving Regulation and Regulatory Review'' section 1(b), General Principles of Regulation.

The Department of Justice has determined that this rule is not a ''significant regulatory action'' under Executive Order 12866, section 3(f), and accordingly this rule has not been reviewed by the Office of Information and Regulatory Affairs within the Office of Management and Budget pursuant to Executive Order 12866.

Regulatory Flexibility Act

This regulation will only impact Privacy Act-protected records, which are personal and generally do not apply to an individual's entrepreneurial capacity, subject to limited exceptions. Accordingly, the Chief Privacy and Civil Liberties Officer, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this regulation and by approving it certifies that this regulation will not have a significant economic impact on a substantial number of small entities.

Executive Order 13132—Federalism

This regulation will not have substantial direct effects on the States, on the relationship between the National Government and the States, or on distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132, it is determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Executive Order 12988—Civil Justice Reform

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13175—Consultation and Coordination With Indian Tribal Governments

This regulation will have no implications for Indian Tribal governments. More specifically, it does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. Therefore, the consultation requirements of Executive Order 13175 do not apply.

Unfunded Mandates Reform Act of 1995

This regulation will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000, as adjusted for inflation, or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Congressional Review Act

This rule is not a major rule as defined by 5 U.S.C. 804 of the Congressional Review Act.

Paperwork Reduction Act

This rule imposes no information collection or recordkeeping requirements.

List of Subjects in 28 CFR Part 16

Administrative practices and procedures, Courts, Freedom of information, Privacy Act.

Pursuant to the authority vested in the Attorney General by 5 U.S.C. 552a and delegated to me by Attorney General Order 2940–2008, the Department of Justice amends 28 CFR part 16 as follows:

PART 16—PRODUCTION OR DISCLOSURE OF MATERIAL OR INFORMATION

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

Authority: 5 U.S.C. 301, 552, 552a, 553; 28 U.S.C. 509, 510, 534; 31 U.S.C. 3717.

Subpart E—Exemption of Records Systems Under the Privacy Act

■ 2. Revise § 16.73 to read as follows:

§ 16.73 Exemption of Office of Legal Policy Systems.

(a) The Judicial Nominations Files (JUSTICE/OLP–002) system of records is exempt from subsections (c)(3); (d); (e)(1), (e)(4)(G), (H), and (I); and (f) of the Privacy Act, pursuant to 5 U.S.C. 552a(k)(1), (k)(2), (k)(5), and (k)(6). The exemptions in this paragraph (a) apply only to the extent that information in this system of records is subject to an exemption, pursuant to 5 U.S.C. 552a(k). Where compliance would not appear to

interfere with or adversely affect the Office of Legal Policy's (OLP's) processes, OLP may waive the applicable exemption.

(b) Exemptions from the particular subsections in paragraph (a) of this section are justified for the following reasons:

(1) From subsection (c)(3), the requirement that an accounting be made available to the named subject of a record, because release of disclosure accountings could alert the subject of an investigation and/or evaluation to the extent of an investigation and/or evaluation. Such a disclosure could also reveal investigative interests by not only OLP, but also other recipient agencies or components. Since release of such information to the subjects of an investigation would provide them with significant information concerning the nature of the investigation and/or evaluation, release could result in the destruction of documentary evidence, improper influencing of witnesses, endangerment of the physical safety of confidential sources, witnesses, and law enforcement personnel, the fabrication of testimony, and other activities that could impede or compromise the investigation and/or evaluation. In addition, providing the individual an accounting for each disclosure could result in the release of properly classified information which would compromise the national defense or disrupt foreign policy.

(2) From subsection (d), the access and amendment provisions, because many persons are contacted who, without an assurance of anonymity, refuse to provide information concerning the subject of an investigation and/or evaluation. Access could reveal the identity of the source of the information and constitute a breach of the promised confidentiality on the part of the Department. Such breaches ultimately would restrict the free flow of information vital to the determination of a candidate's qualifications and suitability, among other determinations. The Department also relies on certain examination materials to assess and evaluate an individual's qualifications for an applicable position. Access and/or amendment to such material could reveal information about the examination and vetting process and could compromise its objectivity and/or fairness. Access and/or amendment to such material could also inappropriately advantage future candidates with knowledge of the examination materials. Finally, providing the individual access or amendment rights could result in the release of properly classified information which would compromise the national defense or disrupt foreign policy.

(3) From subsection (e)(1), because in the collection of information for investigative and evaluative purposes, it is impossible to determine in advance what exact information may be of assistance in determining the qualifications and suitability of the subject of an investigation and/or evaluation. Information which may seem irrelevant, when combined with other seemingly irrelevant information, can on occasion provide a composite picture of a candidate which assists in determining whether that candidate should be nominated for appointment. Relevance and necessity are questions of judgment and timing, and it is only after the information is evaluated that the relevance and necessity of such information can be established. In interviewing individuals or obtaining other forms of information during OLP processes, information may be supplied to OLP which relates to matters incidental to the primary purpose of OLP's processes, but also relate to matters under the investigative jurisdiction of another agency. Such information cannot readily be segregated.

(4) From subsections (e)(4)(G) and (H), and subsection (f), because this system is exempt from the access and amendment provisions of subsection (d).

(c) The General Files System of the Office of Legal Policy (JUSTICE/OLP–003) system of records is exempt from subsections 552a(c)(3) and (4); (d); (e)(1), (2) and (3), (e)(4)(G) and (H), and (e)(5); and (g) of the Privacy Act, pursuant to 5 U.S.C. 552a(j)(2), (k)(1), (k)(2) and (k)(5). The exemptions in this paragraph (c) apply only to the extent that information in this system is subject to exemption pursuant to 5 U.S.C. 552(j), (k). Where compliance would not appear to interfere with or adversely affect OLP's processes, the applicable exemption may be waived by OLP.

(d) Exemptions from the particular subsections in paragraph (c) of this section are justified for the following reasons:

(1) From subsection (c)(3) because making available to a record subject the accounting of disclosures from records concerning him/her would reveal investigative interest on the part of the Department as well as the recipient agency. This would permit record subjects to impede the investigation, *e.g.,* destroy evidence, intimidate potential witnesses, or flee the area to avoid inquiries or apprehension by law enforcement personnel.

(2) From subsection (c)(4) because this system is exempt from the access provisions of subsection (d) pursuant to subsections (j) and (k) of the Privacy Act.

(3) From subsection (d) because the records contained in this system relate to official Federal investigations. Individual access to these records might compromise ongoing investigations, reveal confidential informants, or constitute unwarranted invasions of the personal privacy of third parties who are involved in a certain investigation. Amendment of records would interfere with ongoing criminal law enforcement proceedings and impose an impossible administrative burden by requiring criminal investigations to be continuously reinvestigated.

(4) From subsections (e)(1) and (5) because in the course of law enforcement investigations, information may occasionally be obtained or introduced the accuracy of which is unclear or which is not strictly relevant or necessary to a specific investigation. In the interests of effective law enforcement, it is appropriate to retain all information since it may aid in establishing patterns of criminal activity. Moreover, it would impede the specific investigation process if it were necessary to assure the relevance, accuracy, timeliness and completeness of all information obtained.

(5) From subsections (e)(2) because in a law enforcement investigation the requirement that information be collected to the greatest extent possible from the subject individual would present a serious impediment to law enforcement in that the subject of the investigation would be informed of the existence of the investigation and would therefore be able to avoid detection, apprehension, or legal obligations and duties.

(6) From subsection (e)(3) because to comply with the requirements of this subsection during the course of an investigation could impede the information gathering process, thus hampering the investigation.

(7) From subsections (e)(4)(G) and (H) because this system is exempt from the access provisions of subsection (d) pursuant to subsections (j) and (k) of the Privacy Act.

(8) From subsection (g) because this system is exempt from the access and amendment provisions of subsection (d) pursuant to subsections (j) and (k) of the Privacy Act.

Dated: September 23, 2021.

Peter A. Winn,

Acting Chief Privacy and Civil Liberties Officer, United States Department of Justice.

[FR Doc. 2021–21340 Filed 9–30–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 323

[Docket ID: DOD–2019–OS–0110]

RIN 0790–AK69

Defense Logistics Agency Privacy Program

AGENCY: Defense Logistics Agency, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: This final rule removes DoD's regulation concerning the Defense Logistics Agency Privacy Program. On April 11, 2019, the Department of Defense published a revised DoD-level Privacy Program rule, which contains the necessary information for an agency-wide privacy program regulation under the Privacy Act and now serves as the single Privacy Program rule for the Department. That revised Privacy Program rule also includes all DoD component exemption rules. Therefore, this part is now unnecessary and may be removed from the CFR.

DATES: This rule is effective on October 1, 2021.

FOR FURTHER INFORMATION CONTACT: Lew Oleinick at 703–767–6194.

SUPPLEMENTARY INFORMATION: DoD now has a single DoD-level Privacy Program rule at 32 CFR part 310 (84 FR 14728) that contains all the codified information required for the Department. The Defense Logistics Agency Program regulation at 32 CFR part 323, last updated on July 9, 2015 (80 FR 39381), is no longer required and can be removed.

It has been determined that publication of this CFR part removal for public comment is impracticable, unnecessary, and contrary to public interest since it is based on the removal of policies and procedures that are either now reflected in another CFR part, 32 CFR part 310, or are publicly available on the Department's website. To the extent that the Defense Logistics Agency internal guidance concerning the implementation of the Privacy Act within the Defense Logistics Agency is necessary, it will be issued in an internal document.

This rule is one of 20 separate component Privacy rules. With the finalization of the DoD-level Privacy rule at 32 CFR part 310, the Department is eliminating the need for this separate component Privacy rule and reducing costs to the public as explained in the preamble of the DoD-level Privacy rule published on April 11, 2019, at 84 FR 14728.

This rule is not significant under Executive Order 12866, ''Regulatory Planning and Review.''

List of Subjects in 32 CFR Part 323

Privacy.

PART 323—[REMOVED]

■ Accordingly, by the authority of 5 U.S.C. 301, 32 CFR part 323 is removed.

Dated: September 27, 2021.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2021–21344 Filed 9–30–21; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2021–0201]

RIN 1625–AA00

Safety Zone; Columbia River Outfall Project, Columbia River, Vancouver, WA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for certain navigable waters of the Columbia River. This action is necessary to provide for the safety of life on these navigable waters near Knapp, WA, at Columbia River Mile 95.8. This regulation prohibits persons and vessels from being in the safety zone unless authorized by the Captain of the Port Sector Columbia River or a designated representative.

DATES: This rule is effective from 12:01 a.m. on October 1, 2021 through 11:59 p.m. on March 15, 2022.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2021–0201 in the search box and click ''Search.'' Next, in the Document Type column, select ''Supporting & Related Material.''

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email LCDR Sean Morrison, Waterways Management Division, Marine Safety Unit Portland, U.S. Coast Guard; telephone 503–240–9319, email *D13-SMB-MSUPortlandWWM@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

On November 18, 2020, the Discovery Clean Water Alliance notified the Coast Guard that it would begin construction on the Phase 5A Project: Columbia River Outfall and Effluent Pipeline from 12:01 a.m. on October 1, 2021 through 11:59 p.m. on March 15, 2022, to remove and replace existing pipeline. The construction project includes the removal and replacement of an existing navigation marker (3-pile dolphin), installation of a 48″ pipeline in the riverbed outside the navigation channel, and removal of an existing 30″ pipeline from the riverbed. The scope of work may include the need to construct temporary pile-supported work platforms, or dredge, to access shallow water areas. Lighted barges will be used in deeper water. The Captain of the Port Sector Columbia River (COTP) has determined that potential hazards associated with the construction project would be a safety concern for anyone within the designated area of the Columbia River Outfall and Effluent Pipeline construction project. In response, on August 28, 2021 the Coast Guard published a notice of proposed rulemaking (NPRM) titled Safety Zone; Columbia River Outfall Project, Columbia River, Vancouver, WA (86 FR 47611). There we stated why we issued the NPRM, and invited comments on our proposed regulatory action related to this safety zone. During the comment period that ended September 10, 2021 we received no comments.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable because immediate action is needed to respond to the potential safety hazards associated with the Columbia River Outfall Projects.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The COTP has determined that potential hazards associated with construction project would be a safety concern for anyone within the designated area of the Columbia River Outfall Project. The purpose of this rule is to ensure safety of vessels and the navigable waters in the safety zone during the scheduled construction period.

IV. Discussion of Comments, Changes, and the Rule

As noted above, we received no comments on our NPRM published August 28, 2021. There are no changes in the regulatory text of this rule from the proposed rule in the NPRM.

This rule establishes a safety zone from October 1, 2021, through March 15, 2022. The safety zone will cover all navigable waters of the Columbia River, surface to bottom, encompassed by a line connecting the following points beginning at the shoreline at 45°43′57.0″ N, 122°45′21.0″ W, west to 45°43′58.0″ N, 122°45′33.0″ W, south to 45°43′39.0″ N, 122°45′35.0″ W, thence east to 45°43′39.0″ N, 122°45′21″ W, and along the shoreline back to the beginning point. The duration of the zone is intended to ensure the safety of vessels and these navigable waters while the pipeline construction project is underway. No vessel or person would be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative. A designated representative means any Coast Guard commissioned, warrant, or petty officer who has been authorized by the COTP to act on his behalf, or a Federal, State, and local officer designated by or assisting the COTP in the enforcement of the safety zone. Vessel operators desiring to enter or operate with the safety zone would contact the COTP's on-scene designated representative by calling (503) 209–2468 or the Sector Columbia River Command Center on Channel 16 VHF–FM. Those in the safety zone would comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This rule has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on size, location, duration, and time-of-year of the safety zone. Vessel traffic would be able to safely transit around this safety zone which would impact a small designated area of the Columbia River during the construction project. Moreover, the Coast Guard would issue a Notice to Mariners about the zone, and the rule would allow vessels to seek permission to enter the zone.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard received no comments from the Small Business Administration on this rulemaking. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

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

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST

5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone lasting 166 days that would prohibit vessel traffic to transit the area during construction operations. It is categorically excluded from further review under paragraph L60 of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

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

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: 46 U.S.C. 70034, 70051; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1, Revision No. 01.2.

■ 2. Add § 165.T13–0201 to read as follows:

§ 165.T13–0201 Safety Zones: Safety Zone; Columbia River Outfall and Effluent Pipeline Construction Project, Columbia River, Vancouver, WA.

(a) *Location.* The following area is a safety zone: All navigable waters of the Columbia River, surface to bottom, encompassed by a line connecting the following points beginning at the shoreline at 45°43′57.0″ N/122°45′21.0″ W, west to 45°43′58.0″ N/122°45′33.0″ W, south to 45°43′39.0″ N/122°45′35.0″ W, thence east to 45°43′39.0″ N/122°45′21″ W, and along the shoreline back to the beginning point.

(b) *Definitions.* As used in this section, *designated representative* means any Coast Guard commissioned, warrant, or petty officer who has been authorized by the Captain of the Port Sector Columbia River (COTP) to act on his behalf, or a Federal, State, and local officer designated by or assisting the Captain of the Port Sector Columbia River in the enforcement of the safety zone.

(c) *Regulations.* (1) Under the general safety zone regulations in subpart C of this part, you may not enter the safety zone described in paragraph (a) of this section unless authorized by the COTP or the COTP's designated representative.

(2) Vessel operators desiring to enter or operate with the safety zone may contact the COTP's on-scene designated representative by calling (503) 209–2468 or the Sector Columbia River Command Center on Channel 16 VHF–FM. Those in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

(d) *Enforcement period.* This section will be enforced from 12:01 a.m. on October 1, 2021, through 11:59 p.m.on March 15, 2022. It will be subject to enforcement this entire period unless the COTP or a designated representative determines it is no longer needed. The Coast Guard will inform mariners of any change to this period of enforcement via Notice to Mariners.

Dated: September 28, 2021.

M.S. Jackson,

Captain, U.S. Coast Guard, Captain of the Port Sector Columbia River.

[FR Doc. 2021–21458 Filed 9–30–21; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2020–0129; FRL–8975–02–R4]

Air Plan Approval; AL; NO_X SIP Call and Removal of CAIR; Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; correction.

SUMMARY: The Environmental Protection Agency (EPA) published a final rule in the **Federal Register** on July 7, 2021, entitled ''Air Plan Approval; AL; NO_X SIP Call and Removal of CAIR.'' The July 7, 2021 rule, which became effective on August 6, 2021, contained an error in the amendatory instructions for the regulatory text. This correction does not change any final action taken by EPA in the July 7, 2021, final rule but makes a correction to final regulations.

DATES: This action is effective October 1, 2021.

ADDRESSES: EPA has established a docket for this action under Docket Identification No. EPA–R04–OAR–2020–0129, FRL–10025–80-Region 4. All documents in the docket are listed on the *www.regulations.gov* website. Although listed in the index, some information may not be 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 and Radiation 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: Andres Febres, Air Regulatory Management Section, Air Planning and Implementation Branch, Air and Radiation Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. The telephone number is (404) 562–8966. Mr. Febres can also be reached via electronic mail at *febres-martinez.andres@epa.gov.*

SUPPLEMENTARY INFORMATION: On July 7, 2021 (86 FR 35610), EPA published a final rule in the **Federal Register** entitled ''Air Plan Approval; AL; NO_X SIP Call and Removal of CAIR'' which became effective on August 6, 2021. The final rule approved the addition of regulations to Alabama's State Implementation Plan (SIP) to maintain compliance with their nitrogen oxides (NO_X) SIP Call obligations for large non-electricity generating units (non-EGUs), the repeal of the State's regulations previously sunsetted regarding the NOx Budget Trading Program, and the repeal of the State's Clean Air Interstate Rule (CAIR) regulations.[1] Additionally, the

[1] *See* 86 FR 35610 (July 7, 2021) for information on the NO_X SIP Call, NO_X Budget Trading Program, and CAIR.

final rule conditionally approved state regulations into the SIP that establish monitoring and reporting requirements for units subject to the NO_X SIP Call, including alternative monitoring options for certain sources.

However, the rule contained two errors in the instructions regarding amendments to the table titled ''EPA-Approved Alabama Regulations'' found at 40 CFR 52.50(c). *See* 86 FR at 35614. Because of the errors in the amendatory instructions, the Office of the Federal Register was not able to incorporate some of the changes and placed an editorial note at the bottom of 40 CFR 52.50. Although the rational for incorporating these changes remains the same as presented in the July 7, 2021, rule, EPA is now correcting the CFR to appropriately display the approved rules in the South Carolina SIP.

List of Subjects in 40 CFR Part 52

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

Dated: September 9, 2021.

John Blevins,

Acting Regional Administrator, Region 4.

For the reasons set out in the preamble, the EPA corrects 40 CFR part 52 by making the following correcting amendment:

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. In Section 52.50 amend the table in paragraph (c) by revising the entries for sections:

■ a. 335–3–5–.06 through 335–3–5–.08;

■ b. 335–3–5–.11 through 335–3–5–.14;

■ c. 335–3–8–.07 through 335–3–8–.14;

■ d. 335–3–8–.16 through 335–3–8–.18;

■ e. 335–3–8–.20 and 335–3–8–.21;

■ f. 335–3–8–.23 through 335–3–8–.27; and

■ g. 335–3–8–.29, 335–3–8–.30, and 335–3–8–.33.

The revisions read as follows:

§ 52.50 Identification of plan.

* * * * *

(c) * * *

EPA-APPROVED ALABAMA REGULATIONS

State citation	Title/subject	State effective date	EPA approval date	Explanation
*	*	*	*	*
Chapter No. 335–3–5 Control of Sulfur Compound Emissions				
*	*	*	*	*
Section 335–3–5–.06 ...	TR SO_2 Trading Program—Purpose and Definitions.	11/24/2015	8/31/2016, 81 FR 59869.	
Section 335–3–5–.07 ...	TR SO_2 Trading Program—Applicability ...	11/24/2015	8/31/2016, 81 FR 59869.	
Section 335–3–5–.08 ...	TR SO_2 Trading Program—Retired Unit Exemption.	11/24/2015	8/31/2016, 81 FR 59869.	
*	*	*	*	*
Section 335–3–5–.11 ...	Administrative Appeal Procedures	11/24/2015	8/31/2016, 81 FR 59869.	
Section 335–3–5–.12 ...	SO_2 Trading Budgets and Variability Limits.	11/24/2015	8/31/2016, 81 FR 59869.	
Section 335–3–5–.13 ...	TR SO_2 Allowance Allocations	12/7/2018	3/12/2020, 85 FR 14418.	
Section 335–3–5–.14 ...	Authorization of Designated Representative and Alternate Designated Representative.	11/24/2015	8/31/2016, 81 FR 59869.	
*	*	*	*	*
Chapter No. 335–3–8 Control of Nitrogen Oxides Emissions				
*	*	*	*	*
Section 335–3–8–.07 ...	TR NO_X Annual Trading Program—Purpose and Definitions.	11/24/2015	8/31/2016, 81 FR 59869.	
Section 335–3–8–.08 ...	TR NO_X Annual Trading Program—Applicability.	11/24/2015	8/31/2016, 81 FR 59869.	
Section 335–3–8–.09 ...	TR NO_X Annual Trading Program—Retired Unit Exemption.	11/24/2015	8/31/2016, 81 FR 59869.	
Section 335–3–8–.10 ...	TR NO_X Annual Trading Program—Standard Requirements.	11/24/2015	8/31/2016, 81 FR 59869.	
Section 335–3–8–.11 ...	TR NO_X Annual Trading Program—Computation of Time.	11/24/2015	8/31/2016, 81 FR 59869.	
Section 335–3–8–.12 ...	Administrative Appeal Procedures	11/24/2015	8/31/2016, 81 FR 59869.	
Section 335–3–8–.13 ...	NO_X Annual Trading Budgets and Variability Limits.	11/24/2015	8/31/2016, 81 FR 59869.	
Section 335–3–8–.14 ...	TR NO_X Annual Allowance Allocations	12/7/2018	3/12/2020, 85 FR 14418.	
Section 335–3–8–.16 ...	Authorization of Designated Representative and Alternate Designated Representative.	11/24/2015	8/31/2016, 81 FR 59869.	

EPA-APPROVED ALABAMA REGULATIONS—Continued

State citation	Title/subject	State effective date	EPA approval date	Explanation
Section 335–3–8–.17 ...	Responsibilities of Designated Representative and Alternate Designated Representative.	11/24/2015	8/31/2016, 81 FR 59869.	
Section 335–3–8–.18 ...	Changing Designated Representative and Alternate Designated Representative; Changes in Owners and Operators; Changes in Units at the Source.	11/24/2015	8/31/2016, 81 FR 59869.	
*	* *	*	*	* *
Section 335–3–8–.20 ...	Objections Concerning Designated Representative and Alternate Designated Representative.	11/24/2015	8/31/2016, 81 FR 59869.	
Section 335–3–8–.21 ...	Delegation by Designated Representative and Alternate Designated Representative.	11/24/2015	8/31/2016, 81 FR 59869.	
Section 335–3–8–.23 ...	Establishment of Compliance Accounts, Assurance Accounts, and General Accounts.	11/24/2015	8/31/2016, 81 FR 59869.	
Section 335–3–8–.24 ...	Recordation of TR NO_X Annual Allowance Allocations and Auction Results.	11/24/2015	8/31/2016, 81 FR 59869.	
Section 335–3–8–.25 ...	Submission of TR NO_X Annual Allowance Transfers.	11/24/2015	8/31/2016, 81 FR 59869.	
Section 335–3–8–.26 ...	Recordation of TR NO_X Annual Allowance Transfers.	11/24/2015	8/31/2016, 81 FR 59869.	
Section 335–3–8–.27 ...	Compliance with TR NO_X Annual Emissions Limitation.	11/24/2015	8/31/2016, 81 FR 59869.	
*	* *	*	*	* *
Section 335–3–8–.29 ...	Banking	11/24/2015	8/31/2016, 81 FR 59869.	
Section 335–3–8–.30 ...	Account Error	11/24/2015	8/31/2016, 81 FR 59869.	
*	* *	*	*	* *
Section 335–3–8–.33 ...	General Monitoring, Recordkeeping, and Reporting Requirements.	11/24/2015	8/31/2016, 81 FR 59869.	
*	* *	*	*	* *

* * * * *

[FR Doc. 2021–20072 Filed 9–30–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R02–OAR–2020–0466; FRL–9004–02–R2]

Approval of Air Quality Implementation Plans; New York; Part 212, Process Operations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving a revision to the New York State Implementation Plan (SIP) concerning process operations. The effect of this revision is to streamline and update provisions, align those provisions with permitting regulations, and provide regulatory certainty for the regulated community.

DATES: This final rule is effective on November 1, 2021.

ADDRESSES: The EPA has established a docket for this action under Docket ID Number EPA–R02–OAR–2020–0466. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available electronically through *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Nicholas Ferreira, Air Programs Branch, Environmental Protection Agency, Region 2, 290 Broadway, 25th Floor, New York, New York 10007–1866, (212) 637–3127, or by email at *ferreira.nicholas@epa.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. What is the background for this action?
II. What comments were received in response to the EPA's proposed action?
III. What action is the EPA taking?
IV. Incorporation by reference.
V. Statutory and Executive order reviews.

I. What is the background for this action?

On July 1, 2021 (86 FR 35042), the EPA published a notice of proposed rulemaking that proposed to approve a revision to the State Implementation Plan (SIP) submitted by the State of New York on February 5, 2019, and supplemented on March 25, 2021, for purposes of revising Title 6 of the New York Codes, Rules and Regulations (6 NYCRR) Part 212, ''General Process Emission Sources.'' The EPA is also approving attendant revisions to Part 200, ''General Provisions,'' Subpart 200.1, ''Definitions.''

The revisions to Part 212, which is now entitled, ''Process Operations,'' apply to process emission sources and/or emission points associated with a

process operation. The changes to Part 212 include establishing consistent terminology between Part 212, Part 200, and Part 201, ''Permits and Registrations''; establishing a Toxic Best Available Control Technology (T–BACT) standard for toxic air contaminants; clarifying the interaction between Part 212 and the National Emission Standards for Hazardous Air Pollutants (NESHAPs); offering a streamlined approach for demonstrating compliance with regulatory standards for air contaminants by adopting a mass emission rate option; replacing the current Part 212 control requirement, which provides the New York State Department of Environmental Conservation (NYSDEC) Commissioner with discretion to establish the degree of required air cleaning upon performance of air dispersion modeling analyses in order to demonstrate compliance with the NYSDEC Guideline Concentrations or National Ambient Air Quality Standards (NAAQS); controlling High Toxicity Air Contaminants (HTACs) to the greatest extent possible; and generally reorganizing and clarifying Part 212. These revisions streamline and update provisions, align those provisions with permitting regulations, and provide regulatory certainty for the regulated community.

New York's March 25, 2021 comprehensive supplemental submittal also included Part 201 Operating Permit Program requirements; however, the EPA will be acting on these revisions under a separate action.

The specific details of New York's SIP submittals and the rationale for the EPA's approval action are explained in the EPA's proposed rulemaking and are not restated in this final action. For this detailed information, the reader is referred to the EPA's July 1, 2021 proposed rulemaking. *See* 86 FR 35042.

II. What comments were received in response to the EPA's proposed action?

The EPA did not receive any comments on the July 1, 2021 proposed approval of Title 6 of the New York Codes, Rules and Regulations, Part 212, ''Process Operations'' and Part 200, ''General Provisions,'' Subpart 200.1, ''Definitions.''

III. What action is the EPA taking?

The EPA is approving the revisions to the State Implementation Plan (SIP) submitted by the State of New York on February 5, 2019, and supplemented on March 25, 2021, for purposes of revising Title 6 of the New York Codes, Rules and Regulations (6 NYCRR) Part 212, ''Process Operations''. The EPA is also approving attendant revisions to Part 200, ''General Provisions,'' Subpart 200.1, ''Definitions.''

IV. Incorporation by Reference

In this rule, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with the requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference of 6 NYCRR Part 212, ''Process Operations'' and Part 200, ''General Provisions,'' Subpart 200.1, ''Definitions,'' as described in the amendments to 40 CFR part 52 set forth below. The EPA has made, and will continue to make, these materials generally available through *www.regulations.gov* and at the EPA Region 2 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 the EPA for inclusion in the New York State Implementation Plan, have been incorporated by reference by the EPA into that plan, are fully federally enforceable under sections 110 and 113 of the Clean Air Act, 42 U.S.C. 7401 *et seq.,* as of the effective date of the final rulemaking of the EPA's approval, and will be incorporated by reference in the next update to the SIP compilation.[1]

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, the 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 that meets 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);
- 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 the 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 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 November 30, 2021. Filing a petition for reconsideration by the Administrator of

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

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* Clean Air Act section 307(b)(2)).

List of Subjects in 40 CFR Part 52

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

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

Dated: September 27, 2021.

Walter Mugdan,

Acting Regional Administrator, Region 2.

Part 52, 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 HH—New York

■ 2. In § 52.1670, in the table in paragraph (c), revise the entries ''Title 6, Part 200, Subpart 200.1'' and ''Title 6, Part 212'' to read as follows:

§ 52.1670 Identification of plan.

* * * * *

(c) * * *

EPA–APPROVED NEW YORK STATE REGULATIONS AND LAWS

State citation	Title/subject	State effective date	EPA approval date	Comments
Title 6, Part 200, Subpart 200.1.	General Provisions, Definitions.	2/25/2021	10/1/2021	• EPA is approving definitions that are not already federally enforceable. • EPA approval finalized at [insert **Federal Register** citation].
*	*	*	*	* * *
Title 6, Part 212	Process Operations	2/25/2021	10/1/2021	• EPA approval finalized at [insert **Federal Register** citation].
*	*	*	*	* * *

* * * * *

[FR Doc. 2021–21370 Filed 9–30–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R02–OAR–2021–0263; FRL–8943–02–R2]

Approval of Air Quality Implementation Plans; New York; 2011 Periodic Emission Inventory SIP for the Ozone Nonattainment Areas

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving a State Implementation Plan (SIP) revision submitted by the New York State Department of Environmental Conservation (NYSDEC). The SIP revision consists of the following: 2011 calendar year ozone precursor emission inventory for volatile organic compounds (VOCs), oxides of nitrogen (NO_X), and carbon monoxide (CO) for the New York portion of the New York-Northern New Jersey-Long Island, Connecticut NY-NJ-CT area (New York Metropolitan Area, or NYMA) classified as serious ozone nonattainment for the 2008 8-hour ozone National Ambient Air Quality Standards (NAAQS or standard); and the Jamestown (Chautauqua County) ozone nonattainment area classified as marginal for the 2008 8-hour ozone standard. In addition, the SIP revision also consists of the 2011 calendar year statewide periodic emission inventory for volatile organic compounds, oxides of nitrogen, and carbon monoxide. This action is being taken in accordance with the Clean Air Act (CAA).

DATES: This final rule is effective on November 1, 2021.

ADDRESSES: EPA has established a docket for this action under Docket ID Number EPA–R02–OAR–OAR–2021–0263. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* confidential business information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through *https://www.regulations.gov,* or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information.

FOR FURTHER INFORMATION CONTACT: Ysabel Banon, Air Programs Branch, Environmental Protection Agency, Region 2 Office, 290 Broadway, 25th Floor, New York, New York 10007–1866, (212) 637–3382, or by email at *banon.ysabel@epa.gov.*

SUPPLEMENTARY INFORMATION: The **SUPPLEMENTARY INFORMATION** section is arranged as follows:

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 July 1, 2021 (86 FR 35030), the EPA published a notice of proposed rulemaking (NPRM) for the New York State Implementation Plan submitted on November 13, 2017. The NPRM proposed approval of the 2011 calendar year ozone season daily and annual ozone precursor emission inventory for carbon monoxide (CO), oxides of nitrogen (NO_X), and volatile organic compounds (VOCs) for the New York portion of New York-New Jersey-Long Island NY-NJ-CT (NYMA) serious

nonattainment area; and for the Jamestown, NY marginal nonattainment area. In addition, the NPRM proposed approval of the 2011 calendar year ozone emission inventory that was developed statewide for New York.

The pollutants included in the inventory are annual emissions for CO, NO_X, and VOC. These submittals were made, in part to meet requirements for serious areas for the 2008 ozone national ambient air quality standard (NAAQS). Other specific requirements of New York's SIP revisions for the 2008 ozone NAAQS and the rationale for the EPA's proposed action are explained in the NPRM and will not be restated here.

II. Response to Comments

The EPA did not receive any comments on the July 1, 2021 NPRM.

III. Final Action

The EPA is approving revisions to the New York SIP which pertains to the following: 2011 calendar year ozone season daily and annual ozone precursor emission inventories for CO, NO_X, and VOC for the NYMA portion of New York-New Jersey-Long Island NY-NJ-CT serious nonattainment area, and for the Jamestown marginal nonattainment area. In addition, the EPA is approving the 2011 calendar year ozone emissions inventory that was developed statewide for New York. The pollutants included in the inventory are annual emissions for CO, NO_X, and VOC.

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, the 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));
- 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 the 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 the 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 November 30, 2021. 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, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: September 27, 2021.

Walter Mugdan,

Acting Regional Administrator, EPA Region 2.

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 HH—New York

■ 2. Section 52.1670 is amended in paragraph (e) by adding the entries ''2011 base year emissions inventory,'' ''2011 VOC, NO_X and CO ozone summer season and annual emission inventory,'' and ''2011 VOC, NO_X and CO ozone summer season and annual emission inventory'' to the end of the table to read as follows:

§ 52.1670 Identification of plan.

* * * * *

(e) * * *

EPA—APPROVED NEW YORK NONREGULATORY AND QUASI-REGULATORY PROVISIONS

Action/SIP element	Applicable geographic or nonattainment area	New York submittal date	EPA approval date	Explanation
*	* *	‘‘‘*	*	* *
2011 base year emissions inventory.	State-wide	11/13/2017	10/1/2021, [insert **Federal Register** citation].	• Full approval. •The inventory contains point, nonpoint, nonroad, on-road and biogenic source data.
2011 VOC, NO_X and CO ozone summer season and annual emission inventory..	New York portion of the New York-Northern New Jersey-Long Island NY-NJ-CT 8-hour serious ozone nonattainment area.	11/13/2017	10/1/2021, [insert **Federal Register** citation].	• Full approval. •The inventory contains point, nonpoint, nonroad, on-road and biogenic source data.
2011 VOC, NO_X and CO ozone summer season and annual emission inventory..	Jamestown 8-hour marginal ozone nonattainment area.	11/13/2017	10/1/2021, [insert **Federal Register** citation].	• Full approval. •The inventory contains point, nonpoint, nonroad, on-road and biogenic source data.

[FR Doc. 2021–21346 Filed 9–30–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 70

[EPA–R04–OAR–2020–0461; FRL–8976–02–R4]

Air Plan Approval and Operating Permit Program; KY; Public, Affected State, and EPA Review

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving changes to the Kentucky State Implementation Plan (SIP) and the Kentucky Title V Operating Permit Program (Title V) submitted by the Commonwealth of Kentucky, through the Energy and Environment Cabinet (Cabinet) on August 12, 2020, and March 29, 2021. These revisions address the public notice rule provisions for the New Source Review (NSR), Federally Enforceable State Operating Permits (FESOP), and Title V programs of the Clean Air Act (CAA or Act) by providing for electronic notice (‘‘e-notice’’) and removing the mandatory requirement to provide public notice of a draft air permit in a newspaper. EPA is approving these changes as they are consistent with the Clean Air Act (CAA or Act) and implementing Federal regulations.

DATES: This rule is effective November 1, 2021.

ADDRESSES: EPA has established a docket for this action under Docket Identification No. EPA–R04–OAR–2020–0461. All documents in the docket are listed on the *www.regulations.gov* website. Although listed in the index, some information may not be 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 and Radiation 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: Sarah LaRocca, Air Regulatory Management Section, Air Planning and Implementation Branch, Air and Radiation Division, Region 4, U.S. Environmental Protection Agency, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. The telephone number is (404) 562–8994. Ms. LaRocca can also be reached via electronic mail at *larocca.sarah@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

EPA is approving changes to 401 Kentucky Administrative Regulation (KAR) 52:100, *Public, affected state, and U.S. EPA review,* of the Kentucky SIP and Title V program, submitted by the Commonwealth on August 12, 2020, and March 29, 2021. The August 12, 2020, and March 29, 2021, SIP and Title V program revisions seek to establish a revised method of publication of public notices for public hearings and public comment periods, establish a revised method of notification of the opportunity to be placed on a mailing list of permit actions, change how documents related to permit proceedings will be available for public inspection, and make minor changes to 401 KAR 52:100 that do not alter the meaning of the regulation. The SIP revisions, which address public notice rule provisions for the NSR and FESOP programs, updates the current SIP-approved version of 401 KAR 52:100 (Version 1) to Version 2. The Title V revision updates the approved version of 401 KAR 52:100 originally approved in the Kentucky Title V program to Version 2 as well.[1]

II. Analysis of Kentucky's Submission

On October 5, 2016, EPA finalized revised public notice provisions for the NSR, Title V, and Outer Continental Shelf permitting programs of the CAA. *See* 81 FR 71613 (October 18, 2016). These rule revisions removed the mandatory requirement to provide public notice of permitting actions through publication in a newspaper and allow for internet e-notice as an option for permitting authorities implementing their own EPA-approved SIP rules and Title V rules, such as Kentucky's EPA-approved permitting programs. Permitting authorities are not required to adopt e-notice. Nothing in the revised

[1] EPA fully approved Kentucky's Title V permitting program in 2001. *See* 66 FR 54955 (October 31, 2001).

rules prevents a permitting authority with an EPA-approved permitting program from continuing to use newspaper notification and/or from supplementing e-notice with newspaper notification and/or additional means of notification. For the noticing of draft permits issued by permitting authorities with EPA-approved programs, the rule requires the permitting authority to use ''a consistent noticing method'' for all permit notices under the specific permitting program. When e-notice is provided, EPA's rule requires electronic access (e-access) to the draft permit for the duration of the public comment period.

A full description of the e-notice and e-access provisions are contained in EPA's October 18, 2016 rulemaking document. *See* 81 FR 71613.

The SIP and Title V permit programs are revised through changes to 401 KAR 52:100, *Public, affected state, and U.S. EPA review,* which establishes the procedures used by the Cabinet to provide for the review of federally-enforceable permits by the public, affected states, and EPA. Specifically, 401 KAR 52:100 applies to permit actions established in 401 KAR 52.020, *Title V Permits* and 401 KAR 52.030, *Federally-enforceable permits for non-major sources.* In addition, the public participation provisions of Kentucky's major source NSR permitting programs at 401 KAR 51:017, *Prevention of significant deterioration of air quality* (PSD), and 401 KAR 51:052, *Review of new sources in or impacting upon nonattainment areas* (addressing nonattainment new source review (NNSR)) cross reference the public notice procedures of 401 KAR 52:100.

In a notice of proposed rulemaking (NPRM) published on May 28, 2021 (86 FR 28740), EPA proposed to approve Kentucky's SIP and Title V program revisions provided on August 12, 2020, and March 29, 2021. The NPRM provides additional detail regarding the background and rationale for EPA's action. Comments on the NPRM were due on or before June 28, 2021. EPA did not receive any comments on the NPRM.

III. 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 401 KAR 52:100, *Public, affected state, and U.S. EPA review,* Version 2, State effective June 2, 2020, into the Kentucky SIP. The incorporation includes minor textual changes and establishes a revised means of publication for public notices for public hearing, public comment periods, and the opportunity to join mailing lists, and a revised means to inspect documents related to permit proceedings. 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 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.[2]

IV. Final Action

EPA is approving the changes to the 401 KAR 52:100 *Public, affected state, and U.S. EPA review,* of the Kentucky SIP and Title V program, as submitted on August 12, 2020, and March 29, 2021, as these changes are consistent with the CAA and implementing Federal regulations.

V. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve SIP and Title V submissions that comply with the provisions of the Act and applicable Federal regulations. *See* 42 U.S.C. 7410(k) and 7661a(d); 40 CFR 52.02(a) and 70.4(e). Thus, in reviewing SIP and Title V 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);
- 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 Kentucky SIP and Title V program are 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 rules do not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will they 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 November 30, 2021. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the

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

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

40 CFR Part 52

Environmental protection, Administrative practice and procedure, Air pollution control, Incorporation by reference, Intergovernmental relations, Reporting and recordkeeping requirements.

40 CFR Part 70

Environmental protection, Administrative practice and procedure, Air pollution control, Incorporation by reference, Intergovernmental relations, Operating permits, Reporting and recordkeeping requirements.

Dated: September 22, 2021.

John Blevins,

Acting Regional Administrator, Region 4.

For the reasons stated in the preamble, the EPA amends 40 CFR parts 52 and 70 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 S—Kentucky

■ 2. In § 52.920(c), Table 1 is amended under ''Chapter 52 Permits, Registrations, and Prohibitory Rules'' by revising the entry for ''401 KAR 52:100'' to read as follows:

§ 52.920 Identification of plan.

* * * * *

(c) * * *

TABLE 1—EPA-APPROVED KENTUCKY REGULATIONS

State citation	Title/subject	State effective date	EPA approval date	Explanation
*	*	*	*	*
Chapter 52 Permits, Registrations, and Prohibitory Rules				
*	*	*	*	*
401 KAR 52:100	Public, affected state, and U.S. EPA review.	6/2/2020	10/1/2021, [Insert citation of publication].	
*	*	*	*	*

* * * * *

PART 70—STATE OPERATING PERMIT PROGRAMS

■ 3. The authority citation for part 70 continues to read as follows:

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

■ 4. Amend appendix A to part 70 by adding paragraph (c) under the heading ''Kentucky'' to read as follows:

Appendix A to Part 70—Approval Status of State and Local Operating Permits Programs

* * * * *

Kentucky

* * * * *

(c) Revisions to 401 Kentucky Administrative Regulation 52:100, submitted on March 29, 2021, with a State effective date of June 2, 2020, to allow for electronic noticing of operating permits, are approved on October 1, 2021.

* * * * *

[FR Doc. 2021–21048 Filed 9–30–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 262, 264 and 265

[EPA–HQ–RCRA–2015–0147; FRL 8562–01–OLEM]

Conforming Changes to Canada-Specific Hazardous Waste Import-Export Recovery and Disposal Operation Codes

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA or the Agency) is making conforming changes to regulations related to twelve hazardous waste import-export recovery and disposal operations used in hazardous waste export and import notices submitted to EPA by U.S. exporters and importers, and in movement documents that accompany export and import shipments. The changes to regulations related to these twelve recovery and disposal operations are needed to reflect changes to regulations related to Canadian import-export recovery and disposal operations that Canada promulgated in the Canada Gazette Part II on March 17, 2021 and that become effective in Canada on October 31, 2021. Additionally, as the changes in today's rule are being made solely to conform to Canada's regulatory changes to Canada-specific operation codes and descriptions, this is a final rulemaking and no public comment is being solicited.

DATES: This rule is effective on October 31, 2021.

FOR FURTHER INFORMATION CONTACT: Laura Coughlan, Materials Recovery and Waste Management Division, Office of Resource Conservation and Recovery (5304P), Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; telephone number: (703) 308–0005; email address: *coughlan.laura@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Why is EPA issuing a final rule?

Section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553(b)(3)(B), provides that when an agency for good cause finds that notice and public procedures are impracticable, unnecessary, or contrary to the public interest, the agency may

issue a final rule without providing notice and an opportunity for public comment.

The EPA is issuing this final rule solely because Environment and Climate Change Canada's revisions to its import-export recovery and disposal code numbers and descriptions become effective on October 31, 2021. The EPA must revise twelve of its import-export recovery and disposal code numbers and descriptions in 40 CFR 262.81 to reflect the revised Canadian regulatory definitions so that export and import notices and subsequent movement documents exchanged between Canada and the United States on or after October 31, 2021, do not contain conflicting information. Consequently, the EPA has determined that there is good cause for making the conforming changes in this final rule without prior proposal and opportunity for comment, because notice and public comment would have no impact on the need to parallel as closely as possible the Canadian regulatory revisions that triggered this final rule.

With respect to the effective date, EPA finds that it has good cause for the October 31, 2021 effective date under section 553(d) of the Administrative Procedure Act (APA), 5 U.S.C. 553(d), and section 3010(b) of RCRA, 42 U.S.C. 6930(b). EPA has good cause because this rule must be effective on October 31, 2021 to match the effective date for the Canadian regulatory changes. The purpose of section 553(d) of the APA is to ''give affected parties a reasonable time to adjust their behavior before the final rule takes effect.'' *Omnipoint Corp.* v. *FCC,* 78 F.3d 620, 630 (D.C. Cir. 1996); see also *United States* v. *Gavrilovic,* 551 F.2d 1099, 1104 (8th Cir. 1977) (quoting legislative history). Notwithstanding this purpose, section 553(d) authorizes an Agency to establish an effective date for a rule that is sooner than 30 days from its publication, ''as otherwise provided by the agency for good cause found and published with the rule.'' Similarly, whether the regulated community needs a period of time to come into compliance is relevant to the application of RCRA section 3010(b).

With respect to the effective date, U.S. exporters and U.S. importers will have sufficient time to comply with this rule. They must use EPA's Waste Import Export Tracking System (WIETS) to create and submit their notices to the Agency, and WIETS will reflect the changes in the recovery and disposal operation lists for exporters and importers to use in notices submitted to EPA on or after October 31, 2021, so the regulated community will not need to change how they use the system. As explained above, EPA has good cause for this effective date because this rule must be effective on October 31, 2021 in order to match the effective date for the Canadian regulatory changes. For these reasons, the EPA has concluded that the regulated community will have sufficient time to comply with this rule and that good cause exists for making the changes in this final rule effective October 31, 2021.

General Information

A. List of Acronyms Used in This Action

Acronym Meaning
CFR Code of Federal Regulations
EPA United States Environmental Protection Agency
FR Federal Register
HSWA Hazardous and Solid Waste Amendments
ICR Information Collection Request
NAICS North American Industrial Classification System
NTTAA National Technology Transfer and Advancement Act
OLEM Office of Land and Emergency Management
OMB Office of Management and Budget
RCRA Resource Conservation and Recovery Act
RFA Regulatory Flexibility Act
UMRA Unfunded Mandates Reform Act
WIETS Waste Import Export Tracking System

B. Does this action apply to me?

These revisions to the regulations related to twelve recovery and disposal codes used by exporters and importers in this action generally affect two groups: (1) All persons who export or import (or arrange for the export or import of) hazardous waste for recycling or disposal, including those hazardous wastes subject to the alternate management standards for (a) universal waste for recycling or disposal, (b) spent lead-acid batteries (SLABs) being shipped for reclamation, (c) industrial ethyl alcohol being shipped for reclamation, (d) hazardous waste samples of more than 25 kilograms being shipped for waste characterization or treatability studies, and (e) hazardous recyclable materials being shipped for precious metal recovery; and (2) all persons who export or arrange for the export of conditionally excluded cathode ray tubes being shipped for recycling or conditionally excluded hazardous secondary materials being shipped for recycling. Potentially affected entities may include, but are not limited to:

NAICS code	NAICS description
211	Oil and Gas Extraction.
212	Mining (except Oil and Gas).
213	Support Activities for Mining.
311	Food Manufacturing.
324	Petroleum and Coal Products Manufacturing.
325	Chemical Manufacturing.
326	Plastics and Rubber Products Manufacturing.
327	Nonmetallic Mineral Product Manufacturing.
331	Primary Metal Manufacturing.
332	Fabricated Metal Product Manufacturing.
333	Machinery Manufacturing.
334	Computer and Electronic Product Manufacturing.
335	Electrical Equipment, Appliance, and Component Manufacturing.
336	Transportation Equipment Manufacturing.
339	Miscellaneous Manufacturing.
423	Merchant Wholesalers, Durable Goods.
424	Merchant Wholesalers, Nondurable Goods.
441	Motor Vehicle and Parts Dealers.
562	Waste Management and Remediation Services.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. This table lists the types of entities that EPA is now aware could potentially be regulated by this action. Other types of entities not listed in the table could also be regulated. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

C. How can I get additional information, including copies of this document or other related information?

To obtain electronic copies of this document and other related information that are available electronically, please visit *www.epa.gov/hwgenerators.*

II. Background

A. What action is the Agency taking?

This action makes conforming changes to regulations related to twelve (12) hazardous waste import-export recovery and disposal operations used in hazardous waste export and import notices submitted to EPA by U.S. exporters and importers, and in movement documents that must accompany such shipments. Changes in these regulations related to twelve recovery and disposal operations are needed to reflect changes to regulations related to Canadian import-export recovery and disposal operations that Canada promulgated in the Canada Gazette Part II on March 17, 2021 (''Cross-border Movement of Hazardous Waste and Hazardous Recyclable Material Regulations,'' Canada Gazette Part II, volume 155, number 6, pp. 324–543) and that will become effective on

October 31, 2021. The changes to the regulations related to the twelve import-export disposal and recovery operations will ensure that the disposal and recovery operation codes listed in U.S export notices proposing exports to Canada facilities and subsequent movement documents will continue to reflect the accurate Canadian code numbers and description of the operations, enabling matching to the information listed in the Canadian import notices and movement documents.

The current and revised regulatory text for the twelve affected disposal and recovery operations are as follows:

Current regulatory definition	Revised regulatory definition
(13) D13 Blending or mixing, prior to any of operations D1 through D12	(13) D13 Interim blending or mixing, before an operation that bears any of the disposal operations D1 to D12.
(14) D14 Repackaging, prior to any of operations D1 through D13	(14) D14 Interim repackaging, before an operation that bears any of the disposal operations D1 to D12.
(15) D15 (or DC17 for transboundary movements with Canada only) Interim Storage, prior to any of operations D1 through D12.	(15) D15 Interim storage, before an operation that bears any of the disposal operations D1 to D12.
(16) DC15 Release, including the venting of compressed or liquified gases, or treatment, other than by any of operations D1 to D12 (for transboundary movements with Canada only).	(16) DC1 Release, including the venting of compressed or liquified gases, or treatment, other than by any of disposal operation codes D1 to D12. (for transboundary movements with Canada only).
(17) DC16 Testing of a new technology to dispose of a hazardous waste (for transboundary movements with Canada only).	(17) DC2 Testing of a new technology to dispose of a hazardous waste (for transboundary movements with Canada only).
(11) R11 Uses of residual materials obtained from any of the operations numbered R1 through R10 or RC14 (for transboundary shipments with Canada only).	(11) R11 Use of residual materials obtained from any of the recovery operation codes numbered R1 through R10 or RC1.
(12) R12 Exchange of wastes for submission to any of the operations numbered R1 through R11 or RC14 (for transboundary shipments with Canada only).	(12) R12 Interim exchange of wastes before recycling using any of the recovery operation codes numbered R1 through R11 or RC1.
(13) R13 Accumulation of material intended for any operation numbered R1 through R12 or RC14 (for transboundary shipments with Canada only).	(13) R13 Interim accumulation of wastes before recycling using any of the recovery operation codes numbered R1 through R11 or RC1.
(14) RC14 Recovery or regeneration of a substance or use or re-use of a recyclable material, other than by any of operations R1 to R10 (for transboundary shipments with Canada only).	(14) RC1 Recovery or regeneration of a substance or use or re-use of a recyclable material, other than by any of operations R1 to R10 (for transboundary shipments with Canada only).
(15) RC15 Testing of a new technology to recycle a hazardous recyclable material (for transboundary shipments with Canada only).	(15) RC2 Testing of a new technology to recycle a hazardous recyclable material (for transboundary shipments with Canada only).
(16) RC16 Interim storage prior to any of operations R1 to R11 or RC14 (for transboundary shipments with Canada only).	(16) RC3 Interim storage prior to any of operations R1 to R11 or RC1 (for transboundary shipments with Canada only).

These revised codes and descriptions will be automatically available for exporters and importers to use in EPA's WIETS on October 31, 2021 when they create export or import notices to submit to EPA. Exporters and importers shipping hazardous waste between the U.S. and Canada generally comply with the movement document requirements in 40 CFR 262.83(d) and 40 CFR 262.84(d) respectively, by relying on the use of a Canadian movement document that will be required to reflect the modified recovery and disposal operation code numbers for consents issued by either the EPA or Environment and Climate Change Canada based on notices submitted on or after October 31, 2021 due to the Canadian regulatory revisions.

B. What is the Agency's authority for taking this action?

The EPA is issuing this document under its authority in sections 1002, 2002(a), 3001–3004, and 3017 of the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act (RCRA), and as amended by the Hazardous and Solid Waste Amendments, 42 U.S.C. 6901 *et seq.,* 6912, 6921–6924, and 6938.

III. State Authorization

A. Applicability of Rules in Authorized States

Under section 3006 of RCRA, EPA may authorize qualified States to administer their own hazardous waste programs in lieu of the federal program within the State. Following authorization, EPA retains enforcement authority under sections 3008, 3013, and 7003 of RCRA, although authorized States have primary enforcement responsibility. The standards and requirements for State authorization are found at 40 CFR part 271.

Prior to enactment of the Hazardous and Solid Waste Amendments of 1984 (HSWA), a State with final RCRA authorization administered its hazardous waste program entirely in lieu of EPA administering the federal program in that State. The federal requirements no longer applied in the authorized State, and EPA could not issue permits for any facilities in that State, since only the State was authorized to issue RCRA permits. When new, more stringent federal requirements were promulgated, the State was obligated to enact equivalent authorities within specified time frames. However, the new federal requirements did not take effect in an authorized State until the State adopted the federal requirements as State law.

In contrast, under RCRA section 3006(g) (42 U.S.C. 6926(g)), which was added by HSWA, new requirements and prohibitions imposed under HSWA authority take effect in authorized States at the same time that they take effect in unauthorized States. The EPA is directed by the statute to implement these requirements and prohibitions in authorized States, including the issuance of permits, until the State is granted authorization to do so. While States must still adopt HSWA related provisions as State law to retain final authorization, EPA implements the HSWA provisions in authorized States until the States do so.

Authorized States are required to modify their programs only when EPA enacts federal requirements that are more stringent or broader in scope than existing federal requirements. RCRA section 3009 allows the States to impose standards more stringent than those in the federal program (see also 40 CFR 271.1). Therefore, authorized States may, but are not required to, adopt federal regulations, both HSWA and non HSWA, that are considered less

stringent than previous federal regulations.

B. Effect on State Authorization

Because of the federal government's special role in matters of foreign policy, EPA does not authorize States to administer Federal import/export functions in any section of the RCRA hazardous waste regulations. This approach of having Federal, rather than State, administering of the import/export functions promotes national coordination, uniformity and the expeditious transmission of information between the United States and foreign countries.

Although States do not receive authorization to administer the Federal government's import/export functions in 40 CFR part 262 subpart H, or the import/export relation functions in any other section of the RCRA hazardous waste regulations, State programs are still required to adopt the provisions in this rule to maintain their equivalency with the Federal program (see 40 CFR 271.10(e)). The States that have already adopted 40 CFR part 262 subpart H, 40 CFR part 264, and 40 CFR part 265 must adopt the revisions to those provisions in this final rule. When a State adopts the import/export provisions in this final rule, they must not replace Federal or international references or terms with State references or terms.

The provisions of this rule will take effect in all States on the effective date of the rule, since these import and export requirements will be administered by the Federal government as a foreign policy matter and will not be administered by States.

IV. Do any of the statutory and Executive Order reviews apply to this action?

This final rule changes the regulations related to code numbers and descriptions for twelve hazardous waste import-export recovery and disposal operations used in hazardous waste export and import notices and subsequent movement documents to reflect changes to regulations related to Canadian import-export recovery and disposal operations that Canada promulgated in the Canada Gazette Part II on March 17, 2021 and that become effective on October 31, 2021. This action is not a ''significant regulatory action'' and is therefore not subject to OMB review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Additionally, this action is not a significant regulatory action and does not impose any new information collection burden under the Paperwork Reduction Act. The changes made to the regulations because of this action merely revise certain recovery and disposal operations that are listed in export and import notices and related movement documents. They impose no new reporting requirements on regulated parties. Because this action is not subject to notice and comment requirements under the Administrative Procedure Act or any other statute, it is not subject to the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) or Sections 202 and 205 of the Unfunded Mandates Reform Act of 1999 (UMRA) (Pub. L. 104–4). In addition, this action does not significantly or uniquely affect small governments. This action does not create new binding legal requirements that substantially and directly affect Tribes under Executive Order 13175 (65 FR 67249, November 9, 2000). This action does not have significant Federalism implications under Executive Order 13132 (64 FR 43255, August 10, 1999). Because this final rule has been exempted from review under Executive Order 12866, this final rule 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 final rule does not contain any new 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). This action does not involve technical standards; thus, the requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply.

The Congressional Review Act (CRA), 5 U.S.C. 801 *et seq.,* generally provides that before certain actions may take effect, the agency promulgating the action must submit a report, which includes a copy of the action, to each House of the Congress and to the Comptroller General of the United States. This final action is subject to the CRA, and the EPA will submit a rule report to each House of Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by U.S.C. 804(2).

List of Subjects

40 CFR Part 262

Environmental protection, Exports, Hazardous materials transportation, Hazardous waste, Imports, Labeling, Packaging and containers, Reporting and recordkeeping requirements.

40 CFR Part 264

Environmental protection, Hazardous waste, Imports, Packaging and containers, Reporting and recordkeeping requirements.

40 CFR Part 265

Environmental protection, Hazardous waste, Imports, Packaging and containers, Reporting and recordkeeping requirements.

Dated: September 28, 2021.

Barry N. Breen,

Acting Assistant Administrator, Office of Land and Emergency Management.

For the reasons stated in the preamble, EPA amends title 40, chapter 1 of the Code of Federal Regulations as follows:

PART 262—STANDARDS APPLICABLE TO GENERATORS OF HAZARDOUS WASTE

■ 1. The authority citation for part 262 continues to read as follows:

Authority: 42 U.S.C 6906, 6912, 6922–6925, 6937, 6938 and 6939g.

■ 2. Amend § 262.81 by:

■ a. In the definition of ''Disposal operations'' revising paragraphs (13) through (17); and

■ b. In the definition of''Recovery operations'', revising paragraphs (11) through (16).

The revisions read as follows:

§ 262.81 Definitions.

* * * * *

Disposal operations * * *

* * * * *

(13) D13 Interim blending or mixing, before an operation that bears any of the disposal operations D1 to D12.

(14) D14 Interim repackaging, before an operation that bears any of the disposal operations D1 to D12.

(15) D15 Interim storage, before an operation that bears any of the disposal operations D1 to D12.

(16) DC1 Release, including the venting of compressed or liquified gases, or treatment, other than by any of disposal operation codes D1 to D12. (for transboundary movements with Canada only).

(17) DC2 Testing of a new technology to dispose of a hazardous

waste (for transboundary movements with Canada only).

* * * * *

Recovery operations * * *

* * * * *

(11) R11 Use of residual materials obtained from any of the recovery operation codes numbered R1 through R10 or RC1.

(12) R12 Interim exchange of wastes before recycling using any of the recovery operation codes numbered R1 through R11 or RC1.

(13) R13 Interim accumulation of wastes before recycling using any of the recovery operation codes numbered R1 through R11 or RC1.

(14) RC1 Recovery or regeneration of a substance or use or re-use of a recyclable material, other than by any of operations R1 to R10 (for transboundary shipments with Canada only).

(15) RC2 Testing of a new technology to recycle a hazardous recyclable material (for transboundary shipments with Canada only).

(16) RC3 Interim storage prior to any of operations R1 to R11 or RC1 (for transboundary shipments with Canada only).

* * * * *

■ 3. Amend § 262.83 by revising paragraphs (b)(3) and (f)(6) to read as follows:

§ 262.83 Exports of hazardous waste.

* * * * *

(b) * * *

(3) Notifications listing interim recycling operations or interim disposal operations. If the foreign receiving facility listed in paragraph (b)(1)(ii) of this section will engage in any of the interim recovery operations R12 or R13 or interim disposal operations D13 through D15, or in the case of transboundary movements with Canada, any of the interim recovery operations R12, R13, or RC3, or interim disposal operations D13 to D14, or D15, the notification submitted according to paragraph (b)(1) of this section must also include the final foreign recovery or disposal facility name, address, telephone, fax numbers, email address, technologies employed, and which of the applicable recovery or disposal operations R1 through R11 and D1 through D12, or in the case of transboundary movements with Canada, which of the applicable recovery or disposal operations R1 through R11, RC1 to RC2, D1 through D12, and DC1 to DC2 will be employed at the final foreign recovery or disposal facility. The recovery and disposal operations in this paragraph are defined in § 262.81.

* * * * *

(f) * * *

(6) Contracts must specify that the foreign importer or the foreign receiving facility that performed interim recycling operations R12, R13, or RC3, or interim disposal operations D13 through D15, (recovery and disposal operations defined in 40 CFR 262.81) as appropriate, will:

(i) Provide the notification required in paragraph (f)(3)(ii) of this section prior to any re-export of the hazardous wastes to a final foreign recovery or disposal facility in a third country; and

(ii) Promptly send copies of the confirmation of recovery or disposal that it receives from the final foreign recovery or disposal facility within one year of shipment delivery to the final foreign recovery or disposal facility that performed one of recovery operations R1 through R11, or RC1, or one of disposal operations D1 through D12, DC1 or DC2 to the competent authority of the country of import. For contracts that will be in effect on or after the electronic import-export reporting compliance date, the contracts must additionally specify that the foreign facility send copies to EPA at the same time using the allowable method listed in paragraph (b)(1) of this section on or after that date.

* * * * *

■ 4. Amend § 262.84 by revising paragraphs (b)(2), (f)(5), (g)(2), (h)(2)(iii) to read as follows:

§ 262.84 Imports of hazardous waste.

* * * * *

(b) * * *

(2) Notifications listing interim recycling operations or interim disposal operations. If the receiving facility listed in paragraph (b)(1)(ii) of this section will engage in any of the interim recovery operations R12, R13, or RC3 or interim disposal operations D13 through D15, the notification submitted according to paragraph (b)(1) of this section must also include the final recovery or disposal facility name, address, telephone, fax numbers, email address, technologies employed, and which of the applicable recovery or disposal operations R1 through R11, RC1, and D1 through D12, will be employed at the final recovery or disposal facility. The recovery and disposal operations in this paragraph are defined in § 262.81.

* * * * *

(f) * * *

(5) Contracts must specify that the importer or the receiving facility that performed interim recycling operations R12, R13, or RC3, or interim disposal operations D13 through D15, as appropriate, will provide the notification required in § 262.83(b)(7) prior to the re-export of hazardous wastes. The recovery and disposal operations in this paragraph are defined in § 262.81.

* * * * *

(g) * * *

(2) If the receiving facility performed any of recovery operations R12, R13, or RC3, or disposal operations D13 through D15, the receiving facility shall promptly send copies of the confirmation of recovery or disposal that it receives from the final recovery or disposal facility within one year of shipment delivery to the final recovery or disposal facility that performed one of recovery operations R1 through R11, or RC1 to RC2, or one of disposal operations D1 through D12, or DC1 to DC2, to the competent authority of the country of export, and for confirmations received on or after the electronic import-export reporting compliance date, to EPA electronically using EPA's Waste Import Export Tracking System (WIETS), or its successor system. The recovery and disposal operations in this paragraph are defined in § 262.81.

* * * * *

(h) * * *

(2) * * *

(iii) For the receiving facility that performed any of recovery operations R12, R13, or RC3, or disposal operations D13 through D15 (recovery and disposal operations defined in § 262.81), a copy of each confirmation of recovery or disposal that the final recovery or disposal facility sent to it for at least three (3) years from the date that the final recovery or disposal facility completed processing the waste shipment; and

* * * * *

PART 264—STANDARDS FOR OWNERS AND OPERATORS OF HAZARDOUS WASTE TREATMENT, STORAGE, AND DISPOSAL FACILITIES

■ 5. The authority citation for part 264 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6924, and 6925.

■ 6. Revise § 264.12(a)(4)(ii) to read as follows:

§ 264.12 Required notices.

(a) * * *

(4) * * *

(ii) If the facility performed any of recovery operations R12, R13, or RC3, or disposal operations D13 through D15, promptly send copies of the confirmation of recovery or disposal

that it receives from the final recovery or disposal facility within one year of shipment delivery to the final recovery or disposal facility that performed one of recovery operations R1 through R11, or RC1, or one of disposal operations D1 through D12, or DC1 to DC2, to the competent authority of the country of export that controls the shipment as an export of hazardous waste, and on or after the electronic import-export reporting compliance date, to EPA electronically using EPA's Waste Import Export Tracking System (WIETS), or its successor system. The recovery and disposal operations in this paragraph are defined in 40 CFR 262.81.

* * * * *

PART 265—INTERIM STATUS STANDARDS FOR OWNERS AND OPERATORS OF HAZARDOUS WASTE TREATMENT, STORAGE, AND DISPOSAL FACILITIES

■ 7. The authority citation for part 265 continues to read as follows:

Authority: 42 U.S.C. 6905, 6906, 6912, 6922, 6923, 6924, 6925, 6935, 6936, and 6937.

■ 8. Revise § 265.12(a)(4)(ii) to read as follows:

§ 265.12 Required notices.

(a) * * *

(4) * * *

(ii) If the facility performed any of recovery operations R12, R13, or RC3, or disposal operations D13 through D15, promptly send copies of the confirmation of recovery or disposal that it receives from the final recovery or disposal facility within one year of shipment delivery to the final recovery or disposal facility that performed one of recovery operations R1 through R11, or RC1, or one of disposal operations D1 through D12, or DC1 to DC2, to the competent authority of the country of export that controls the shipment as an export of hazardous waste, and on or after the electronic import-export reporting compliance date, to EPA electronically using EPA's Waste Import Export Tracking System (WIETS), or its successor system. The recovery and disposal operations in this paragraph are defined in 40 CFR 262.81.

[FR Doc. 2021–21417 Filed 9–30–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 716

[EPA–HQ–OPPT–2020–0474; FRL–8204–02–OCSPP]

RIN 2070–AB11

Health and Safety Data Reporting; Addition of 20 High-Priority Substances and 30 Organohalogen Flame Retardants; Extension of Submission Deadline

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; extension of submission deadline.

SUMMARY: EPA is amending the deadline for reporting pursuant to the Toxic Substances Control Act (TSCA) Health and Safety Data Reporting rule, which requires manufacturers (including importers) of 50 specified chemical substances to report certain lists and copies of unpublished health and safety studies to EPA. Specifically, EPA will be amending the deadline from September 27, 2021 to December 1, 2021 for 20 of the 50 chemical substances and to January 25, 2022 for 30 of the 50 chemical substances. The Health and Safety Data Reporting Rule, promulgated pursuant to TSCA section 8(d), requires manufacturers (including importers) of certain chemical substances to submit lists and copies of certain unpublished health and safety studies to EPA.

DATES: This final rule is effective October 1, 2021.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPPT–2020–0474, is available at *https://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.

Please note that due to the public health concerns related to COVID–19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on the EPA/DC and docket access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT:

For technical information contact: Virginia Lee, Data Collections Branch, Data Gathering and Analysis Division (7410M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 564–4142; email address: *lee.virginia@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. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you manufacture (defined by statute to include import) any of the chemical substances that are listed in 40 CFR 716.120(d) of the regulatory text of this document. 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: Chemical manufacturers (including importers), (NAICS codes 325 and 324110), *e.g.,* persons who manufacture (defined by statute to include import) one or more of the subject chemical substances.

B. What action is the Agency taking?

EPA promulgated a final rule in the **Federal Register** of June 29, 2021 (86 FR 34147) (FRL–10020–38) to require manufacturers (including importers) of 50 specified chemical substances to report certain lists and copies of unpublished health and safety studies to EPA. The chemical substances subject to this rule are listed in this document and consist of the 20 designated by EPA as high-priority substances and the 30 organohalogen flame retardants being evaluated for risks by the Consumer Product Safety Commission (CPSC) under the Federal Hazardous Substances Act (FHSA), The Agency.is extending the submission deadline established in that final rule from September 27, 2021 to December 1, 2021 for the following chemicals:

- Ethylene Dibromide
- 1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta [g]-2-benzopyran (HHCB)
- Tris(2-chloroethyl) phosphate (TCEP)
- Phthalic Anhydride
- p- Dichlorobenzene
- o-Dichlorobenzene
- Phosphoric acid, triphenyl ester (TPP)
- Di-ethylhexyl phthalate (DEHP)
- 1,2-Dichloroethane
- trans-1,2-Dichloroethylene
- 1,1,2-Trichloroethane
- 1,2-Dichloropropane

- 1,1-Dichloroethane
- 1,3-Butadiene
- Formaldehyde
- Dibutyl phthalate (DBP)
- Butyl benzyl phthalate (BBP)
- Di-isobutyl phthalate
- Dicyclohexyl phthalate
- 4,4′-(1-Methylethylidene)bis[2, 6-dibromophenol] (TBBPA)

EPA is also extending the deadline established in the June 29, 2021 final rule from September 27, 2021 to January 25, 2022 for the following chemicals:

- Bis(2-ethylhexyl) tetrabromophthalate
- Bis(hexachlorocyclopentadieno) cyclooctane
- 1,2-Bis(2,4,6-tribromophenoxy)ethane
- 1,1′-Ethane-1,2-diylbis(pentabromobenzene)
- 2-Ethylhexyl-2,3,4,5-tetrabromobenzoate
- 2-(2-Hydroxyethoxy)ethyl 2-hydroxypropyl 3,4,5,6-tetrabromophthalate
- 2,2′-[(1-Methylethylidene)bis[(2,6-dibromo-4,1-phenylene) oxymethylene]]bis[oxirane]
- Mixture of chlorinated linear alkanes C14–17 with 45–52% chlorine
- N,N-Ethylene-bis(tetrabromophthalimide)
- Pentabromochlorocyclohexane
- (Pentabromophenyl)methyl acrylate
- Pentabromotoluene
- Perbromo-1,4-diphenoxybenzene
- Phosphonic acid, (2-chloroethyl)-, bis(2-chloroethyl) ester
- Phosphoric acid, 2,2-bis(chloromethyl)-1,3-propanediyl tetrakis(2-chloroethyl) ester
- Propanoic acid, 2-bromo-, methyl ester
- Tetrabromobisphenol A-bis(2,3-dibromopropyl ether)
- Tetrabromobisphenol A-bis(2-hydroxyethyl) ether
- Tetrabromobisphenol A diallyl ether
- Tetrabromobisphenol A dimethyl ether
- 2,4,6-Tribromoaniline
- 1,3,5-Tribromo-2-(prop-2-en-1-yloxy)benzene
- Tris(2-chloroethyl)phosphite
- Tris(1-chloro-2-propyl)phosphate
- Tris(2-chloro-1-propyl)phosphate
- Tris(2,3-dibromopropyl)phosphate
- 1,3,5-Tris(2,3-dibromopropyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione
- Tris(1,3-dichloro-2-propyl)phosphate
- Tris(tribromoneopentyl)phosphate
- 2,4,6-Tris-(2,4,6-tribromophenoxy)-1,3,5-triazine

C. Why is the Agency taking this action?

The Agency is taking this action to provide additional time for the regulated community to familiarize themselves with new TSCA Health and Safety Data Reporting requirements. EPA has not added chemicals to the TSCA section 8(d) rule in a manner that would affect a large group of stakeholders since 2006, for the orphan High Production Volume chemicals. With respect to the timing of this action, the need for the Agency to extend the deadline arose, in part, as a result of receiving a sizable number of requests to extend the reporting deadline. Additionally, the Agency recognizes that complications exist for certain entities subject to this rule resulting from the COVID–19 pandemic, which can present challenges to accessing records that may only be available in hard copy formats (*e.g.,* microfiche).

EPA therefore believes it is appropriate to extend the reporting period to allow the regulated community additional time for data reporting. EPA is making available a historic question and answer document about reporting under TSCA 8(d) and additional content on its web page for the rulemaking (available at *https://www.epa.gov/chemicals-under-tsca/health-and-safety-data-reporting-addition-20-high-priority-substances-and-30*), providing reporting entities additional time to review these materials and prepare any necessary submissions to improve reporting quality for this rule.

EPA's timeline for risk evaluations under TSCA section 6 necessitates that data received via the TSCA section 8(d) action be received in time for use in risk evaluations for chemical substances that have been designated as high-priority substances. Thus, EPA is limiting the deadline extension to December 1, 2021 for these chemical substances. Receiving TSCA section 8(d) submissions on these high-priority substances by December 1, 2021 will ensure that such information will be received in time for use in risk evaluations on these chemical substances. For the remaining organohalogen flame retardants subject to the rule, EPA is extending the deadline to January 25, 2022.

D. What is the Agency's authority for taking this action?

EPA promulgated the Health and Safety Data Reporting rule under TSCA section 8(d) (15 U.S.C. 2607(d)), and it is codified at 40 CFR part 716. EPA is using this TSCA section 8(d) rule in accordance with 40 CFR 716.105 to gather information on chemical substances. Under section 553(b)(B) of the Administrative Procedure Act (APA), 5 U.S.C. 553(b)(B), an agency may issue a final rule without providing notice and an opportunity for public comment if it for good cause finds that notice and public procedures are impracticable, unnecessary, or contrary to the public interest. In this instance, the Agency finds that notice and public comment procedures are unnecessary because this is merely an extension of the reporting period that does not alter the substantive TSCA section 8(d) reporting requirements in any way and are impracticable because there is insufficient time for notice and comment on an extension to the deadline prior to the reporting deadline, and EPA only became aware of the need for the extension upon receiving numerous requests recently. The Agency believes the extension will not result in a significant delay in the processing and availability of information to EPA for TSCA section 6 risk evaluations or to Consumer Product Safety Commission's (CPSC) evaluation for risks under the Federal Hazardous Substances Act (FHSA). Receiving TSCA section 8(d) submissions pursuant to these deadlines (*i.e.,* December 1, 2021 for the high-priority substances and January 25, 2022 for the Organohalogen Flame Retardants) will ensure that such information will be received in time for use in these respective activities (*i.e.,* evaluations pursuant to TSCA and FHSA). Further, any impact on the regulated community is expected to be beneficial to the public interest given that the extension provides additional time to submit complete and accurate unpublished health and safety studies to EPA.

This final rule is effective immediately upon publication. Section 553(d)(1) of the Administrative Procedure Act, 5 U.S.C. 553(d)(1), provides that final rules shall not become effective until 30 days after publication in the **Federal Register** ''except . . . a substantive rule which grants or recognizes an exemption or relieves a restriction.'' The purpose of this provision is to ''give affected parties a reasonable time to adjust their behavior before the final rule takes effect.'' *Omnipoint Corp.* v. *Fed. Commc'n Comm'n,* 78 F.3d 620, 630 (D.C. Cir. 1996); *see also United States* v. *Gavrilovic,* 551 F.2d 1099, 1104 (8th Cir. 1977) (quoting legislative history). However, when the agency grants or recognizes an exemption or relieves a restriction, affected parties do not need a reasonable time to adjust because the effect is not adverse. EPA has determined that this rule relieves a restriction because it provides manufacturers (including importers) additional time to comply with the Health and Safety Data Reporting rule.

II. Statutory and Executive Order Reviews

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

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

The Office of Management and Budget (OMB) has exempted actions under TSCA section 8(d) related to the Health and Safety Data Reporting rule from the requirements of Executive Order 12866 (58 FR 51735, October 4, 1993). As such, this final rule was not reviewed by OMB under Executive Orders 12866 and 13563 (76 FR 3821, January 21, 2011).

B. Paperwork Reduction Act (PRA)

This action does not contain any new or revised information collections subject to OMB approval under the PRA, 44 U.S.C. 3501 *et seq.* Information collection activities contained in the TSCA 8(d) rule are already approved by the Office of Management and Budget (OMB) under OMB Control No. 2070–0004.

C. Regulatory Flexibility Act (RFA)

This action is not subject to the RFA, 5 U.S.C. 601 *et seq.* The RFA applies only to rules subject to notice and comment rulemaking requirements under the APA, 5 U.S.C. 553, or any other statute. This rule is not subject to notice and comment requirements under the APA because the Agency has invoked the APA ''good cause'' exemption.

D. Unfunded Mandates Reform Act (UMRA)

This action will not impose any enforceable duty or contain any unfunded mandate as described under Title II of UMRA, 2 U.S.C. 1531–1538 *et seq.*

E. Executive Order 13132: Federalism

This action does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000). It will not have substantial direct effects on tribal governments, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes. Thus, E.O. 13175 does not apply to this action.

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

EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997) as applying only to those regulatory actions that concern environmental health or safety risks that the Agency 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 a covered regulatory action because it is not ''economically significant'' under Executive Order 12866 and it does not concern an environmental health risk or safety risk. Although this action would not establish an environmental standard intended to mitigate health or safety risks, the information that would be submitted to EPA in accordance with this rule would be used to inform the Agency's decision-making process regarding chemical substances to which children may be disproportionately exposed. This information may also assist the Agency and others in determining whether the chemical substances covered in this proposed rule present potential risks, which would allow the Agency and others to take appropriate action to investigate and mitigate those risks.

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

This action is not a ''significant energy action'' as defined in Executive Order 13211 (66 FR 28355, May 22, 2001) because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy and has not otherwise been designated by the Administrator of OMB's Office of Information and Regulatory Affairs as a ''significant energy action.''

I. National Technology Transfer and Advancement Act (NTTAA)

Because this action does not involve any technical standards, NTTAA section 12(d), 15 U.S.C. 272 note, does not apply to this action.

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

This action does not entail special considerations of environmental justice related issues as delineated by Executive Order 12898 (59 FR 7629, February 16, 1994). However, the Agency believes that the information collected through this rule will inform the TSCA risk evaluations that are planned for these chemicals and will thereby enable the Agency to better protect human health and the environment, including in low-income and minority communities.

K. Congressional Review Act (CRA)

This action is subject to the CRA (5 U.S.C. 801 *et seq.*), and EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 716

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

Dated: September 23, 2021.

Michal Freedhoff,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

PART 716—HEALTH AND SAFETY DATA REPORTING

■ 1. The authority citation for part 716 continues to read as follows:

Authority: 15 U.S.C. 2607(d).

■ 2. In § 716.120(d), amend the table by revising all the entries under the headings ''High-Priority Substances'' and ''Organohalogen flame retardants'' to read as follows:

§ 716.120 Substances and listed mixtures to which this subpart applies.

* * * * *

(d) * * *

Category	CASRN	Special exemptions	Effective date	Sunset date
* * * *	*	*	*	
High-Priority Substances:				
1,3-Butadiene	106–99–0	§ 716.21(a)(9)	7/29/21	12/01/21
Butyl benzyl phthalate (BBP)—1,2-Benzene-dicarboxylic acid, 1-butyl 2(phenylmethyl) ester	85–68–7	§ 716.21(a)(9)	7/29/21	12/01/21
Dibutyl phthalate (DBP) (1,2-Benzene-dicarboxylic acid, 1,2-dibutyl ester)	84–74–2	§ 716.21(a)(9)	7/29/21	12/01/21
o-Dichlorobenzene	95–50–1	§ 716.21(a)(9)	7/29/21	12/01/21
p-Dichlorobenzene	106–46–7	§ 716.21(a)(9)	7/29/21	12/01/21
1,1-Dichloroethane	75–34–3	§ 716.21(a)(9)	7/29/21	12/01/21
1,2-Dichloroethane	107–06–2	§ 716.21(a)(9)	7/29/21	12/01/21
Trans-1,2-Dichloroethylene	156–60–5	§ 716.21(a)(9)	7/29/21	12/01/21
1,2-Dichloropropane	78–87–5	§ 716.21(a)(9)	7/29/21	12/01/21
Dicyclohexyl phthalate	84–61–7	§ 716.21(a)(9)	7/29/21	12/01/21
Di-ethylhexyl phthalate (DEHP)—(1,2-Benzene-dicarboxylic acid, 1,2-bis(2-ethylhexyl) ester)	117–81–7	§ 716.21(a)(9)	7/29/21	12/01/21
Di-isobutyl phthalate (DIBP)—(1,2-Benzene-dicarboxylic acid, 1,2-bis-(2methylpropyl) ester)	84–69–5	§ 716.21(a)(9)	7/29/21	12/01/21
Ethylene dibromide	106–93–4	§ 716.21(a)(9)	7/29/21	12/01/21
Formaldehyde	50–00–0	§ 716.21(a)(9)	7/29/21	12/01/21
1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta [g]-2-benzopyran (HHCB)	1222–05–5	§ 716.21(a)(9)	7/29/21	12/01/21
4,4′-(1-Methylethylidene)bis[2,6-dibromophenol] (TBBPA)	79–94–7	§ 716.21(a)(9)	7/29/21	12/01/21
Phosphoric acid, triphenyl ester (TPP)	115–86–6	§ 716.21(a)(9)	7/29/21	12/01/21
Phthalic anhydride	85–44–9	§ 716.21(a)(9)	7/29/21	12/01/21
1,1,2-Trichloroethane	79–00–5	§ 716.21(a)(9)	7/29/21	12/01/21
Tris(2-chloroethyl) phosphate (TCEP)	115–96–8	§ 716.21(a)(9)	7/29/21	12/01/21
* * * *	*	*	*	
Organohalogen flame retardants:				
Bis(2-ethylhexyl) tetrabromophthalate	26040–51–7	§ 716.21(a)(10)	7/29/21	1/25/22
Bis(hexachlorocyclopentadieno) cyclooctane	13560–89–9	§ 716.21(a)(10)	7/29/21	1/25/22
1,2-Bis(2,4,6-tribromophenoxy)ethane	37853–59–1	§ 716.21(a)(10)	7/29/21	1/25/22
1,1′-Ethane-1,2-diylbis(pentabromobenzene)	84852–53–9	§ 716.21(a)(10)	7/29/21	1/25/22
2-Ethylhexyl-2,3,4,5-tetrabromobenzoate	183658–27–7	§ 716.21(a)(10)	7/29/21	1/25/22
2-(2-Hydroxyethoxy)ethyl 2-hydroxypropyl 3,4,5,6-tetrabromophthalate	20566–35–2	§ 716.21(a)(10)	7/29/21	1/25/22
2,2′-[(1-Methylethylidene)bis[(2,6-dibromo-4,1-phenylene)oxymethylene]]bis[oxirane]	3072–84–2	§ 716.21(a)(10)	7/29/21	1/25/22
Mixture of chlorinated linear alkanes C14–17 with 45–52% chlorine	85535–85–9	§ 716.21(a)(10)	7/29/21	1/25/22
N,N-Ethylene-bis(tetrabromophthalimide)	32588–76–4	§ 716.21(a)(10)	7/29/21	1/25/22
Pentabromochlorocyclohexane	87–84–3	§ 716.21(a)(10)	7/29/21	1/25/22
(Pentabromophenyl)methyl acrylate	59447–55–1	§ 716.21(a)(10)	7/29/21	1/25/22
Pentabromotoluene	87–83–2	§ 716.21(a)(10)	7/29/21	1/25/22
Perbromo-1,4-diphenoxybenzene	58965–66–5	§ 716.21(a)(10)	7/29/21	1/25/22
Phosphonic acid, (2-chloroethyl)-, bis(2-chloroethyl) ester	6294–34–4	§ 716.21(a)(10)	7/29/21	1/25/22
Phosphoric acid, 2,2-bis(chloromethyl)-1,3-propanediyl tetrakis(2-chloroethyl) ester	38051–10–4	§ 716.21(a)(10)	7/29/21	1/25/22
Propanoic acid, 2-bromo-, methyl ester	5445–17–0	§ 716.21(a)(10)	7/29/21	1/25/22
Tetrabromobisphenol A-bis(2,3-dibromopropyl ether)	21850–44–2	§ 716.21(a)(10)	7/29/21	1/25/22
Tetrabromobisphenol A bis(2-hydroxyethyl) ether	4162–45–2	§ 716.21(a)(10)	7/29/21	1/25/22
Tetrabromobisphenol A diallyl ether	25327–89–3	§ 716.21(a)(10)	7/29/21	1/25/22
Tetrabromobisphenol A dimethyl ether	37853–61–5	§ 716.21(a)(10)	7/29/21	1/25/22
2,4,6-Tribromoaniline	147–82–0	§ 716.21(a)(10)	7/29/21	1/25/22
1,3,5-Tribromo-2-(prop-2-en-1-yloxy)benzene	3278–89–5	§ 716.21(a)(10)	7/29/21	1/25/22
Tris(2-chloroethyl)phosphite	140–08–9	§ 716.21(a)(10)	7/29/21	1/25/22
Tris(1-chloro-2-propyl)phosphate	13674–84–5	§ 716.21(a)(10)	7/29/21	1/25/22
Tris(2-chloro-1-propyl)phosphate	6145–73–9	§ 716.21(a)(10)	7/29/21	1/25/22
Tris(2,3-dibromopropyl)phosphate	126–72–7	§ 716.21(a)(10)	7/29/21	1/25/22
1,3,5-Tris(2,3-dibromopropyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione	52434–90–9	§ 716.21(a)(10)	7/29/21	1/25/22
Tris(1,3-dichloro-2-propyl)phosphate	13674–87–8	§ 716.21(a)(10)	7/29/21	1/25/22
Tris(tribromoneopentyl)phosphate	19186–97–1	§ 716.21(a)(10)	7/29/21	1/25/22
2,4,6-Tris-(2,4,6-tribromophenoxy)-1,3,5-triazine	25713–60–4	§ 716.21(a)(10)	7/29/21	1/25/22
* * * *	*	*	*	

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 51c

RIN 0906–AB30

Implementation of Executive Order on Access to Affordable Life-Saving Medications; Rescission of Regulation

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Final rule; rescission of regulations.

SUMMARY: HHS is rescinding the final rule entitled ''Implementation of Executive Order on Access to Affordable Life-Saving Medications,'' published in the December 23, 2020, **Federal Register** (2020 Rule). HHS is rescinding the 2020 Rule due to the excessive administrative costs and burdens that implementation would have imposed on health centers. In particular, the 2020 Rule required health centers to create and maintain new practices necessary to determine patients' eligibility to receive certain drugs at or below the discounted price paid by the health center or subgrantees plus a minimal administration fee. HHS finds the 2020 Rule's implementation would have resulted in reduced resources available to support critical services to health center patients—including those who use insulin and injectable epinephrine. HHS's consideration of the 2020 Rule's impact was informed, in part, by the demands on health centers resulting from the COVID–19 pandemic. As Executive Order 13937 remains in effect, HHS is exploring non-regulatory options to implement the Executive Order.

DATES: This rule is effective November 1, 2021.

FOR FURTHER INFORMATION CONTACT: Jennifer Joseph, Director, Office of Policy and Program Development, Bureau of Primary Health Care, Health Resources and Services Administration, 5600 Fishers Lane, Rockville, Maryland 20857; email: *jjoseph@hrsa.gov;* telephone: 301–594–4300; fax: 301–594–4997.

SUPPLEMENTARY INFORMATION:

I. Public Participation

On June 16, 2021, HHS published a Notice of Proposed Rulemaking (2021 NPRM) in the **Federal Register** (86 FR 32008) to rescind the ''Implementation of Executive Order on Access to Affordable Life-Saving Medications'' rule. The 2021 NPRM provided for a 30-day comment period, and HHS received 332 comments. HHS carefully considered all comments in developing this rule, as outlined in Section VI below, and presents a summary of all significant comments and HHS responses.

II. Background

HHS published the subject NPRM in the **Federal Register** on September 28, 2020 (85 FR 60748), and the 2020 Rule on December 23, 2020 (85 FR 83822). The 2020 Rule established a new requirement directing all health centers receiving grants under section 330(e) of the Public Health Service Act (42 U.S.C. 254b(e)) that participate in the 340B Program (42 U.S.C. 256b), to the extent that they plan to make insulin and/or injectable epinephrine available to their patients, to provide assurances that they have established practices to provide these drugs at or below the discounted price paid by the health center or subgrantees under the 340B Program (plus a minimal administration fee) to health center patients with low incomes, as determined by the Secretary, who have a high cost sharing requirement for either insulin or injectable epinephrine; have a high unmet deductible; or who have no health insurance.

On June 16, 2021, after a careful reassessment of the comments submitted in response to the proposed rule published at 85 FR 60748 (September 28, 2020) and consideration of the comments received on the proposed rule to delay the effective date published at 86 FR 13872 (March 11, 2021), HHS published the 2021 NPRM to rescind the 2020 Rule. The 2021 NPRM cited significant concerns regarding health centers needing to divert vital resources to implement the 2020 Rule. The 2021 NPRM requested comment on the administrative burden and costs to comply with the 2020 Rule and thus maintain eligibility for future Health Center Program grants. The 2021 NPRM also requested comment on whether a rescission would assist health centers in continuing to provide primary care services to medically underserved and vulnerable populations. HHS noted the administrative burdens associated with the 2020 Rule, particularly in light of health centers' continuing role in ensuring equitable access to COVID–19 vaccination and maintaining the capacity to provide primary and preventive care that addresses the ongoing and evolving needs of hard-to-reach and disproportionately affected populations. HHS also noted that the 2020 Rule would carry increased administrative costs and administrative burden and would result in reduced resources being available to support services to health center patients. In addition, most comments submitted previously noted that, in many cases, health centers already voluntarily provided medications at reduced prices to their patients.

The 2021 NPRM comment period ended on July 16, 2021. After review and consideration of all submitted comments, HHS has concluded that the 2020 Rule created excessive administrative burden for health centers, which in turn would have resulted in reduced resources for health center patient services. HHS has determined that the overall impacts of the administrative burden outweigh benefits to patients from the reduction in prices of insulin and injectable epinephrine. Therefore, HHS is issuing this final rule rescinding the 2020 Rule, which was published at 85 FR 83822.

The 2020 Rule became effective on July 20, 2021, prior to publication of this rescission. Due to the timing of Health Center Program funding, grants awarded in Fiscal Year 2022 would be the first opportunity for HRSA to impose the requirements of the ''Implementation of Executive Order on Access to Affordable Life-Saving Medications'' rule, and so the requirements have not yet been implemented.

III. Statutory Authority

The statement of authority for 42 CFR part 51c cites to sections 330 (42 U.S.C. 254b) and 215 of the Public Health Service Act, (42 U.S.C. 216), respectively.

IV. Overview of This Rule

HHS is rescinding the 2020 Rule and therefore deleting the associated revision to the regulations codified at 42 CFR 51c.303(w). 42 CFR 51c.303(w) stated: ''To the extent that an applicant for funding under Section 330(e) of the Public Health Service Act (42 U.S.C. 254b(e)) has indicated that it plans to distribute, either directly, or through a written agreement, drugs purchased through the 340B Drug Pricing Program (42 U.S.C. 256b), and to the extent that such applicant plans to make insulin and/or injectable epinephrine available to its patients, the applicant shall provide an assurance that it has established practices to provide insulin and injectable epinephrine at or below the discounted price paid by the health center grantee or subgrantee under the 340B Drug Pricing Program (plus a

minimal administration fee) to health center patients with low incomes, as determined by the Secretary, who have a high cost sharing requirement for either insulin or injectable epinephrine; have a high unmet deductible; or have no health insurance.''

This final rule also states that the program term established by the ''Implementation of Executive Order on Access to Affordable Life-Saving Medications'' rule will not be included on any Notices of Award issued to health centers receiving grant funds under section 330(e) of the Public Health Service Act. Due to the timing of Health Center Program funding, placement of that program term on health center awards would have first been applied to funds awarded in Fiscal Year 2022. As HHS has issued this final rule prior to the issuance of such awards, this program term has not been placed on Health Center Program awards.

This final rule does not revoke Executive Order 13937, which may only be revoked by executive order. As Executive Order 13937 remains in effect, HHS is exploring non-regulatory options to implement the Executive Order.

V. Rationale for Rescission

HHS is rescinding the 2020 Rule because the overall impact of the additional administrative costs and burden that the 2020 Rule would have placed on health centers would have harmed health centers and the patients they serve.

In implementing the requirement of the 2020 Rule, health centers would have had to absorb significant additional costs in financial resources, time, and ongoing support staff to create and maintain new reporting, monitoring, technical and administrative re-engineering, staff training, and workflow re-designs to assess eligibility based on the numerous different categories set forth in the 2020 Rule for patients to receive insulin and injectable epinephrine.

The 2020 Rule would have significantly increased the administrative burden on health centers because it would have required health centers to track and monitor in real time: (1) Whether patients were receiving insulin or injectable epinephrine through a 340B pharmacy, (2) whether patients' incomes met the threshold in the 2020 Rule (which is different from the standard used for the Health Center Program sliding fee discount schedule and therefore would have had to be calculated separately), and (3) whether patients had a high unmet deductible each time they filled their prescriptions—which may have been further complicated due to medical billing and claims processing delays or whether they had a high deductible or high cost-sharing requirement as part of their insurance plan. These burdens would have also required that health centers work with their contract pharmacies to implement these new requirements, which would have created extra administrative costs. HHS has determined that, under the 2020 Rule, health centers and pharmacies would have found it challenging to ascertain in real time a patient's eligibility for discounted pricing under the 2020 Rule based on whether or not that patient continued to have a high unmet deductible, as defined in the 2020 Rule, particularly due to delays in medical billing and claims processing.

HHS also notes that the 2020 Rule codified a new definition, applicable only to these two classes of drugs, for ''individuals with low income,'' to include those individuals with incomes at or below 350 percent of the amount identified in the Federal Poverty Guidelines (FPG). This new definition contrasted with the Health Center Program's sliding fee discount schedule requirement for Health Center Program grantees applicable to individuals with incomes at or below 200 percent of the FPG, pursuant to 42 CFR 51c.303(f). Under this subsection, health centers must establish a sliding fee discount schedule for services provided to patients with incomes between 100 and 200 percent of the FPG, with a full discount to individuals and families with annual incomes at or below 100 percent of those set forth in the FPG. Health centers also may collect nominal fees for services from individuals and families at or below 100 percent of the FPG, and no sliding fee discount may be provided to individuals and families with annual incomes greater than 200 percent of the FPG. Health centers must also demonstrate to HHS that they maintain and apply such sliding fee discount schedules to the provision of health services, which requires them to establish and maintain processes for identifying patient income levels for billing purposes consistent with these requirements.

In its decision to rescind the 2020 Rule, HHS notes the concerns expressed by the vast majority of commenters that the ''low income'' definition of 350 percent of the FPG, applicable to patients receiving these two classes of drugs, would have created significant administrative challenges for health centers. HHS is issuing this rule in recognition that the 2020 Rule would have resulted in additional administrative burden and costs, resulting in a diversion of resources from needed patient care, especially during the COVID–19 pandemic, in order to cover such increased administrative costs.

As commenters have noted, the rule would have forced health centers to construct two different eligibility systems. As the 2020 Rule's definition of ''low income'' is inconsistent with standards applied in the Health Center Program and in other comparable federal programs with an income eligibility threshold, this would have imposed new administrative burdens on health centers to implement. Furthermore, the 2020 Rule would require health center staff, who are not clinicians, to ask patients at the time of screening if they use insulin or injectable epinephrine, which may raise concerns related to the sharing of protected health information if not conducted in a confidential setting.

Rescinding the 2020 Rule prevents unnecessary costs to health centers that are on the front lines of fighting COVID–19 and providing care to millions of Americans. The 2020 Rule would have resulted in increased administrative costs and administrative burden and reduced resources available to support critical services to health center patients, including those who use insulin or injectable epinephrine and who receive other services from health centers.

VI. Public Comments and Responses

HRSA received a total of 332 comments from the public, including: Health centers, associations and organizations representing health centers, a health center controlled network, individual health center staff and clinical professionals, individuals and organizations concerned with the high cost of insulin or injectable epinephrine, an association representing pharmacies, an association representing hospitals participating in the 340B Program, a health insurance issuer, a health innovation and research non-profit organization, a pharmaceutical manufacturer, and an association representing pharmaceutical manufacturers.

The vast majority of comments (318) favored rescission of the 2020 Rule. There were 12 comments opposing rescission of the 2020 Rule and supporting its implementation. Two remaining comments did not explicitly support or oppose the rescission of the 2020 Rule.

All comments were considered in developing this final rule. This section

presents a summary of all major issues raised by commenters, grouped by subject, as well as responses to the comments. Commenters used the terms ''Federally Qualified Health Centers (FQHCs)'' and ''health centers'' interchangeably. This final rule only applies to health centers funded under Section 330(e) of the Public Health Service Act, and not to other FQHCs. For consistency, this final rule uses ''health center'' throughout.

1. Support for Rescission

Approximately 318 commenters supported rescission of the 2020 Rule. Commenters cited a number of reasons for their support, which are summarized below.

Comment: Approximately 316 commenters expressed concern that the net impact of implementing the 2020 Rule would be a reduction in access to care for underserved populations. These commenters described the anticipated administrative burden and cost for health centers to implement the rule and noted that these costs would reduce resources available to provide essential primary care services to patients.

A subset of these commenters (61) detailed the specific administrative burdens and costs that would result if the 2020 Rule were implemented, including:

- Determining in real time whether a patient has a high remaining deductible. The remaining deductible amount can be inaccurate as it may change as a result of pending and delayed medical bills;
- Adjusting the charge for qualifying patients for every form of insulin and injectable epinephrine every quarter, when the 340B price changes; and
- Keeping pharmacy partners/contractors informed and ensuring their compliance with new charges and eligibility rules.

Another subset of commenters (59) also noted that HRSA estimated it would require one full-time equivalent (FTE) staff member per health center to implement the 2020 Rule, resources the commenters stated would be better spent increasing access in other ways. For example, commenters stated that one FTE would have greater impact on patient pharmaceutical access by focusing efforts such as helping patients apply to pharmaceutical manufacturers' Patient Assistance Programs and for enabling services to connect patients to other services in the community.

Response: HHS agrees with these commenters' concerns regarding reduced access to care resulting from the additional burden required of health centers to implement the 2020 Rule. Specifically, the 2020 Rule would necessitate some health centers redirecting resources that might have otherwise gone to support patient care to support additional staff to ascertain whether a high unmet deductible has been met in real time.

Comment: Approximately 305 commenters noted that the 2020 Rule's definition of ''low income'' as persons below 350 percent of the FPG was inconsistent with other federal programs. These commenters further stated that having different definitions across programs increases administrative burden of implementing the 2020 Rule.

A subset of these commenters (58) outlined specific issues that these differing ''low income'' definitions would cause for health centers implementing the 2020 Rule:

- Health centers would need to establish new policies and procedures for eligibility determinations;
- Eligibility workers would need to ask all patients if they use insulin or injectable epinephrine to appropriately screen them, which would require patients to share protected health information with non-clinicians;
- The higher income threshold would reduce health center savings on these medications, reducing revenue that could be used to support patient services for all patients; and
- A higher income threshold would reduce the cost that health centers could charge insurers for insulin and injectable epinephrine, effectively transferring savings from the health centers to insurers. The commenters explained that this is because insurance contracts generally prohibit health centers from billing insurers more than their ''usual and customary'' rate for each specific drug, and if the 2020 Rule were not rescinded, it would be very difficult for health centers to argue that the 340B price is not their usual and customary, as very few cash patients would not qualify for the 340B price.

Response: HHS agrees with these commenters' concerns that the definition of ''low income'' in the 2020 Rule increases the administrative burden of implementing this rule. For example, the 2020 Rule's inconsistency with current health center requirements would require health centers to create new policies, procedures, and workflows to ensure that eligible patients would be charged the 340B price or less for insulin and injectable epinephrine. Additionally, HHS shares commenters' concerns regarding the sharing of protected health information with non-clinicians.

Comment: Approximately 300 commenters expressed concern that implementation of the 2020 Rule would divert health center resources away from the COVID–19 pandemic response.

A subset of these commenters (57) further noted that health centers are making meaningful contributions to COVID–19 testing, treatment, and vaccination, and that these contributions are very resource-intensive. These commenters stated that reducing burden by rescinding the 2020 Rule would allow this vital work to continue.

Response: HHS appreciates the role health centers continue to play in the response to the COVID–19 pandemic. HHS shares commenters' concerns about the potential for implementation of the 2020 Rule to divert resources away from health centers' ongoing critical role in the COVID–19 pandemic response, stabilization, and recovery.

Comment: Approximately 301 commenters stated that implementing the 2020 Rule would only improve medication access for a small population of patients, and health center services would be drastically reduced for all health center patients given the increase in administrative costs and loss of 340B savings.

A subset of these commenters (59) noted that the 2020 Rule would have no impact on the overall price of the covered medications outside of the 340B Program; those prices are set by manufacturers and would not be changed by this rule. Further, these commenters stated that 90 percent of diabetic patients in the United States are not health center patients, and therefore the 2020 Rule would not impact what the majority of diabetic patients pay for insulin. Commenters also stated that health center patients with diabetes are already likely to qualify for discounted pricing through health centers.

Response: HHS appreciates the detail provided by commenters in support of their conclusion that the 2020 Rule would not meaningfully impact medication access for health center patients or individuals who are not health center patients. HHS agrees that the 2020 Rule would be unlikely to impact the underlying price of these two medications. HHS also agrees that the 2020 Rule would likely improve medication access for only a small population of health center patients.

Comment: One commenter, an association of chain drug stores, stated that the 2020 Rule would place undue burdens on 340B-covered entities as well as their contract pharmacies. The commenter also stated that the 2020 Rule had not sufficiently resolved

several concerns, including concerns regarding the need for specific guidance to 340B-covered entities for determining the patient's deductible at the pharmacy point-of-sale and communicating patient eligibility to contract pharmacies and additional clarity with respect to administration fees. The commenter argued that because these concerns were not addressed in the 2020 Rule, the proper course of action would be for HRSA to rescind the 2020 Rule.

Response: HHS acknowledges that the 2020 Rule would result in significant administrative burden on health centers, which may be passed on to the pharmacies with which they contract to provide access to medications.

Comment: One commenter, a health insurance issuer, stated support for rescinding the 2020 Rule. The commenter also stated that as HHS considers alternative approaches to implementation of Executive Order 13937, it should prioritize options that can be implemented with minimal administrative burden to the parties involved in the 340B Program, including health centers, their private sector partners, and patients served. The commenter further stated that any alternative approaches should ensure that HRSA maintains a regularly updated directory of health centers, require health centers to adjudicate 340B claims of patients who have health insurance, and require pharmacy providers to adhere to 340B claim stamping using the National Council for Prescription Drugs Programs submission clarification code.

Response: HHS acknowledges the comment and support for minimizing administrative burden. Alternative methods for implementation of Executive Order 13937 are beyond the scope of this rulemaking.

2. Opposition to Proposed Rescission

Twelve commenters opposed the proposed rescission of the 2020 Rule. Commenters cited a number of reasons for their opposition, which are summarized below.

Comment: Six commenters opposed HHS's proposed rescission of the 2020 Rule noting the importance of insulin and the additional costs that could be imposed on the health system if patients were not taking the necessary amounts of insulin to avoid additional complications.

Response: HHS shares commenters' concerns about the additional health care costs that can result from a lack of access to timely and appropriate primary health care. The fundamental purpose of the Health Center Program is to ensure access to care for underserved and vulnerable populations; Section 330 of the Public Health Service Act requires health centers to provide comprehensive primary health care to patients without regard to the patient's ability to pay. HHS is concerned that the increased costs due to the extra administrative burden placed on health centers to comply with the 2020 Rule would lead to fewer resources available to help provide comprehensive primary health care to as many health center patients as possible and that decrease in resources would result in the cost of the 2020 Rule outweighing its benefit.

Comment: Five commenters opposed HHS's proposed rescission of the 2020 Rule noting that the cost of monthly medications poses a financial burden to patients which can be life-threatening, especially for underserved populations who depend on lower medication costs. These commenters further stated that HHS should consider the cost to patients and not just the financial burden on healthcare systems. A subset of these commenters (3) stated that if medication costs increase, these patients will likely stop taking their medication or be forced to choose between food, rent, or medication. Another subset of these commenters (2) opposed HHS's proposed rescission of the 2020 Rule noting that human life is of greater value than costs to institutions, and that the increased burden on health centers does not justify taking away affordable medications from underserved populations.

Response: HHS is concerned that the increased costs due to the extra administrative burden placed on health centers to comply with the 2020 Rule would lead to the availability of fewer resources to help provide comprehensive primary health care to as many health center patients as possible and that decrease in resources would result in the cost of the 2020 Rule outweighing its benefit. HHS believes the 2020 Rule would improve medication access for only a small percentage of health center patients while not meaningfully impacting medication access for the majority of health center patients.

Comment: Four commenters opposed HHS's proposed rescission of the 2020 Rule noting that they disagree with HHS's reasoning for rescinding the 2020 Rule. The commenters stated that administrative burden and administrative costs do not justify limiting access to lifesaving medications to low income patients who do not have insurance or otherwise cannot afford their medications.

Response: HHS is concerned that the increased costs due to the extra administrative burden placed on health centers to comply with the 2020 Rule would lead to fewer resources available to help provide comprehensive primary health care to as many health center patients as possible and that decreased resources would result in the cost of the 2020 Rule outweighing its benefit. Executive Order 13937 remains in effect and HHS is exploring alternative approaches to address the high costs of prescription drugs, such as insulin or injectable epinephrine.

Comment: Two commenters opposed HHS's proposed rescission of the 2020 Rule noting that health care institutions (including health centers) can address increasing costs of providing essential programs, including during the COVID–19 pandemic, without HHS rescinding this rule. Comments included suggested alternative health center cost cutting methods such as allocating resources, improving workflows, and using employee retention strategies.

Response: HHS is rescinding the 2020 Rule to maximize resources health centers have to provide access to high quality, comprehensive primary health care in the most efficient way and to as many health center patients as possible. HHS believes the 2020 Rule would improve medication access for only a small percentage of health center patients. Examining other cost cutting measures to decrease the burden on health centers is beyond the scope of this proposed rulemaking.

Comment: Two commenters opposed HHS's proposed rescission of the 2020 Rule noting that it would benefit numerous health center patients through greater access to affordable insulin and it should be kept for that reason. One of those commenters further noted that, unlike patients under 200 percent of the FPG who already receive significant discounts from health centers and would be less impacted by the 2020 Rule, patients between 200 and 350 percent of the FPG would greatly benefit from this rule going into effect.

Response: While the 2020 Rule would likely provide benefits to a small number of health center patients with diabetes and severe allergic reactions, HHS is concerned that the increased costs due to the extra administrative burden placed on health centers to comply with the 2020 Rule would lead to fewer resources available to provide comprehensive primary health care to as many health center patients as possible. As Executive Order 13937 remains in effect, HHS is exploring non-regulatory options to implement the Executive Order.

Comment: One commenter opposed HHS's proposed rescission of the 2020

Rule noting that HHS should not place a charge on American families to pay for administrative costs at health centers, nor administrative costs caused by the COVID–19 pandemic.

Response: HHS appreciates this comment and is committed to maximizing resources for health centers to provide comprehensive primary health care to health center patients without regard for patients' ability to pay.

Comment: One commenter opposed HHS's proposed rescission of the 2020 Rule noting that it would allow health centers to divert resources to other services at the expense of the community's health needs during the COVID–19 pandemic, specifically, access to the lifesaving medications of insulin and injectable epinephrine.

Response: HHS is concerned that the increased costs due to the extra administrative burden placed on health centers to comply with the 2020 Rule would lead to fewer resources available to provide comprehensive primary health care to as many health center patients as possible, including those who use insulin or injectable epinephrine, and that decrease in resources would result in the cost of the 2020 Rule outweighing its benefit. In addition, as noted in the 2020 Rule, in many cases, health centers already voluntarily provide medications, including insulin and injectable epinephrine, to their patients at reduced prices.

Comment: One commenter, a pharmaceutical manufacturer, opposed HHS's proposed rescission of the 2020 Rule noting that most of its insulin products are available to covered entities for pennies and rescinding the 2020 Rule would make covered entity patients pay more for the medications. The commenter also noted that covered entity patients in most cases could receive larger discounts from the company's own discount programs for medications.

Response: Nothing in this rule rescinding the 2020 Rule prohibits health center patients from accessing pharmaceutical company and charity discount programs to find the most affordable medications, including for insulin or injectable epinephrine.

Comment: One commenter, a pharmaceutical manufacturer, opposed HHS's proposed rescission of the 2020 Rule, noting that it provides insulin to several charitable organizations including its own foundation, which provide insulin for free for qualifying patients at or below 400 percent of FPG and covered entities should be held to the same standard. Additionally, this commenter noted that it participates in a number of programs that allow patients, regardless of their income, to purchase insulin at no more than $35 a month.

Response: HHS commends those who are working to ensure underserved patients are able to access discounted medications. As noted above, HHS is concerned that the increased costs due to the extra administrative burden placed on health centers to comply with the 2020 Rule would lead to fewer resources available to provide comprehensive primary health care to as many health center patients as possible, including those who use insulin or injectable epinephrine.

Comment: One commenter, a pharmaceutical manufacturer, opposed HHS's proposed rescission of the 2020 Rule, noting that grantees that are covered entities under the 340B Program should not be able to charge large markups on drugs purchased through the 340B Program to uninsured or underinsured individuals to fund their operations.

Response: With regard to the commenter's concern regarding the general requirements of the 340B Program, those requirements, including charges for drugs purchased through the 340B Program by covered entities, are beyond the scope of this rulemaking.

Comment: One commenter, a pharmaceutical manufacturer, opposed HHS's proposed rescission of the 2020 Rule, noting that the commenter is able to verify income and insurance information with minimal burden and that six covered entities have worked with the commenter to provide insulin to their patients for pennies, demonstrating that the 2020 Rule would not be overly burdensome.

Response: HHS has concerns that under the 2020 Rule's definition of ''high unmet deductible,'' health centers and pharmacies with which they contract may find it challenging to ascertain in real time a patient's eligibility for pricing based on whether or not the patient continues to have a ''high unmet deductible'' that meets the 2020 Rule's definition of the term. The 2020 Rule defined ''high unmet deductible'' as ''the amount a patient owes toward their high deductible at any time during a plan year in which the portion of the patient's high deductible for the plan year that has not yet been met exceeds 20 percent of the deductible.'' Determining whether a patient's plan year spending toward their deductible meets this definition has the potential to be particularly challenging due to medical billing and claims processing delays. For these and other reasons, HHS believes the administrative burden and costs the 2020 Rule places on health centers outweigh the benefits.

3. General Comments

Comment: One commenter, an association of pharmaceutical manufacturers, while not opposing rescission of the 2020 Rule, noted that the 340B Program has grown exponentially in recent years without a commensurate benefit to the underserved patients.

Response: The growth of the 340B Program is beyond the scope of this rulemaking.

Comment: One commenter stated that the 340B Program is essential to the well-being of all patients that receive care at health centers and asked that the 340B Program be kept in place.

Response: HHS acknowledges the importance of the 340B Program to patients served by health centers. This rulemaking does not change the 340B Program.

4. Request To Revoke Executive Order 13937

Comment: Approximately 300 commenters urged revocation of the ''Executive Order on Access to Affordable Lifesaving Medications,'' on which the 2020 Rule was based. These commenters expressed many concerns with the underlying Executive Order and requested that it be revoked.

Response: Revoking Executive Order 13937, ''Access to Affordable Lifesaving Medications'' is beyond the authority of HHS and outside the scope of this final rule.

5. Miscellaneous

Other commenters raised a variety of issues that HHS determined did not pertain to the rescission of the 2020 Rule. This rulemaking does not address those issues as they are outside of its scope.

VII. Regulatory Impact Analysis (RIA)

HHS has examined the effects 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 8, 2011), the Regulatory Flexibility Act (Pub. L. 96–354, September 19, 1980), the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132 on Federalism (August 4, 1999).

Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and

benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in Executive Order 12866, emphasizing the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year), and a ''significant'' regulatory action is subject to review by the Office of Management and Budget (OMB). HRSA estimates that, on average, each health center would have needed to hire one additional full-time equivalent (FTE) eligibility assistance worker at approximately $50,000 to support necessary additional administrative processes, totaling approximately $68,750,000 across health centers.

As stated in the RIA for the 2020 Rule, HRSA determined that the 2020 Rule was not economically significant, given that the administrative burden of $68.7 million described above fell below the ''economically significant'' threshold of $100 million. HRSA relies on that same analysis now, finding that rescission of that rule will have an economic impact of the same amount, $68,750,000, in administrative savings to health centers, and that such amount is below the ''economically significant'' threshold of $100 million. As Executive Order 13937 remains in effect, HHS is exploring non-regulatory options for implementation.

HHS welcomed but did not receive comments on whether the proposed rescission of the 2020 Rule is a ''significant regulatory action'' under Section 3(f) of Executive Order 12866.

The Regulatory Flexibility Act (RFA)

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) and the Small Business Regulatory Enforcement and Fairness Act of 1996, which amended the RFA, require HHS to analyze options for regulatory relief of small businesses. If a rule has a significant economic effect on a substantial number of small entities, the Secretary must specifically consider the economic effect of the rule on small entities and analyze regulatory options that could lessen the impact of the rule. As we did in the ''Implementation of Executive Order on Access to Affordable Life-Saving Medications'' rule, HHS will use an RFA threshold of at least a 3 percent impact on at least 5 percent of small entities.

For purposes of the RFA, HHS considers all health care providers to be small entities either by meeting the Small Business Administration (SBA) size standard for a small business, or by being a nonprofit organization that is not dominant in its market. The current SBA size standard for health care providers ranges from annual receipts of $8 million to $41.5 million. As of September 31, 2020, the Health Center Program provides grant funding under section 330(e) of the Public Health Service Act to 1,315 organizations to provide health care to medically underserved communities. HHS has determined, and the Secretary certifies, that this rule will not have a significant impact on the operations of a substantial number of small health centers; therefore, we are not preparing an analysis of impact for purposes of the RFA. HHS estimates the economic impact on small entities as a result of rescinding the 2020 Rule will be minimal. HHS welcomed but did not receive comments concerning the economic impact of the proposed rescission of the ''Implementation of Executive Order on Access to Affordable Life-Saving Medications'' rule on health centers for the purposes of the RFA.

Unfunded Mandates Reform Act

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $158 million, using the most current (2020) Implicit Price Deflator for the Gross Domestic Product. As stated in the RIA for the 2020 Rule, HRSA determined that the administrative burden of $68.75 million described above fell below the Unfunded Mandates Reform Act's threshold of $158 million. HRSA relies on that same analysis now, finding that rescission of that rule will have an economic impact of the same amount, $68.75 million in administrative savings to health centers, and that such amount is below the threshold of $158 million.

Executive Order 13132—Federalism

HHS has reviewed this rule in accordance with Executive Order 13132 regarding federalism and has determined that it does not have ''federalism implications.'' This rule will not ''have substantial direct effects on the States, or on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This rule will not adversely affect the following family elements: Family safety, family stability, marital commitment; parental rights in the education, nurture, and supervision of their children; family functioning, disposable income or poverty; or the behavior and personal responsibility of youth, as determined under section 654(c) of the Treasury and General Government Appropriations Act of 1999.

Paperwork Reduction Act of 1995

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) requires that OMB approve all collections of information by a federal agency from the public before they can be implemented. This rule is projected to have no impact on current reporting and recordkeeping burden for health centers. This rule will result in no new reporting burdens. HHS welcomed but did not receive comments that this rule would result in new reporting burdens for health centers.

Dated: September 28, 2021.

Xavier Becerra,

Secretary, Department of Health and Human Services.

List of Subjects in 42 CFR Part 51c

Grant programs—Health, Health care, Health facilities, Reporting and recordkeeping requirements.

Accordingly, by the authority vested in me as the Secretary of Health and Human Services, and for the reasons set forth in the preamble, 42 Code of Federal Regulations part 51c is amended as follows:

PART 51c—GRANTS FOR COMMUNITY HEALTH CENTERS

■ 1. The authority citation for part 51c is revised to read as follows:

Authority: Sec. 330, Public Health Service Act, 89 Stat. 342, (42 U.S.C. 254b); sec. 215, Public Health Service Act, 58 Stat. 690, (42 U.S.C. 216).

§ 51c.303 [Amended]

■ 2. Amend § 51c.303 by removing paragraph (w).

[FR Doc. 2021–21457 Filed 9–30–21; 8:45 am]

BILLING CODE 4165–15–P

NATIONAL SCIENCE FOUNDATION

45 CFR Part 670

RIN 3145–AA63

Conservation of Antarctic Animals and Plants; Correction

AGENCY: National Science Foundation.

ACTION: Final rule; correction.

SUMMARY: This document corrects the Regulation Identification Number that appeared in a final rule published in the **Federal Register** on May 25, 2021, regarding changes to changes to Annex II to the Protocol on Environmental Protection to the Antarctic Treaty (Protocol) agreed to by the Antarctic Treaty Consultative Parties.

DATES: This final rule correction is effective October 1, 2021.

FOR FURTHER INFORMATION CONTACT: Bijan Gilanshah, Assistant General Counsel, Office of the General Counsel, at 703–292–8060, National Science Foundation, 2415 Eisenhower Avenue, W 18200, Alexandria, VA 22314.

SUPPLEMENTARY INFORMATION:

Correction

In final rule FR Doc. 2021–10807, beginning on page 27985 in the issue of May 25, 2021, make the following correction: On page 27985, in the third column, the Regulation Identifier Number is corrected to read ''RIN 3145–AA63.''

Dated: September 28, 2021.

Suzanne H. Plimpton,

Reports Clearance Officer, National Science Foundation.

[FR Doc. 2021–21365 Filed 9–30–21; 8:45 am]

BILLING CODE 7555–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 25, 63 and 73

[IB Docket No. 21–265; FCC 21–87; FR ID 39973]

Mandatory Electronic Filing of Applications and Reports Administered by the International Bureau

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document, the Commission requires that any remaining applications and reports administered by the International Bureau and filed on paper or through an alternative filing process be filed only electronically through the Commission's International Bureau Filing System. Specifically, the Commission modifies its rules to mandate the electronic filings of applications for permits to deliver programs to foreign stations, applications for International High Frequency Broadcast Stations, and quarterly reports filed by U.S.-authorized carriers that are affiliates of foreign carriers with market power on the foreign end of a U.S.-international route, and to remove a duplicate paper filing requirement for satellite cost-recovery declarations.

DATES: Effective October 1, 2021.

FOR FURTHER INFORMATION CONTACT: Jocelyn Jezierny, Telecommunications and Analysis Division, International Bureau, *Jocelyn.Jezierny@fcc.gov,* 202–418–0272.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Order, FCC 21–87, adopted and released on July 13, 2021. The full text of this document is available at *https://docs.fcc.gov/public/attachments/FCC-21-87A1.pdf.* To request materials in accessible formats for people with disabilities, send an email to *FCC504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (TTY).

Final Regulatory Flexibility Analysis

Because these rule changes are being adopted without notice and comment, the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.,* does not apply to this Order.

Paperwork Reduction Act

This Order does not contain new or substantively modified information collections subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13, 44 U.S.C. 3501–3520. Specifically, the changes to existing information collections, including mandatory electronic filing for Section 325(c) Applications, IHF Applications, and Dominant Carrier Section 63.10(c) Quarterly Reports are non-substantive. Because these changes are non-substantive, there is also no new or modified information collection burden for small business concerns with fewer than 25 employees pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4).

After the adoption and release of this Order, the Commission submitted the changes to the Office of Management and Budget (OMB) and received the OMB approvals. The Commission also received emergency approval from OMB for certain requirements that were inadvertently omitted from existing information collections. The relevant OMB Control numbers are 3060–0678, 3060–0686, 3060–1035, 3060–1133, and 3060–1290.

Congressional Review Act

The Commission will not send a copy of this Order to Congress and the Government Accountability Office pursuant to 5 U.S.C. 801(a)(1)(A), because the adopted rules are rules of agency organization, procedure, or practice that do not substantially affect the rights or obligations of non-agency parties.

Synopsis

I. Introduction

1. Over the past decades, the Commission has made significant progress to upgrade and modernize its licensing systems and filing procedures.[1] Today, we continue these efforts and require that any remaining applications and reports administered by the International Bureau and filed on paper or through an alternative filing process be filed only electronically through the Commission's International

[1] *See, e.g., International Bureau Announces a Change in the Procedure for Filing Coordination Notifications for Earth Stations on Vessels Operating in the C-Band,* Public Notice, DA 11–132, 26 FCC Rcd 564 (IB 2011) (requiring coordination notification for Earth Stations on Vessels operating in the C-band to be filed electronically via the International Bureau Filing System (IBFS)); *Completing the Transition to Electronic Filing, Licenses and Authorizations, and Correspondence in the Wireless Radio Services,* Order, 35 FCC 10781 (2020) (*2020 Wireless Radio Order*) (requiring electronic filing of certain applications for licenses in the Wireless Radio Services); *Amendment of Certain of the Commission's Part 1 Rules of Practice and Procedure and Part 0 Rules of Commission Organization,* Order, 29 FCC Rcd 14955 (2014) (requiring electronic filing of certain applications under sections 214(a) and 251(c)(5) of the Communications Act of 1934, as amended (Act)).

Bureau Filing System (IBFS).[2] Specifically, we modify our rules to mandate the electronic filings of Section 325(c) Applications,[3] applications for International High Frequency Broadcast (IHF) Stations (IHF Applications),[4] and Dominant Carrier Section 63.10(c) Quarterly Reports,[5] and to remove a duplicate paper filing requirement for satellite cost-recovery declarations.[6] These mandatory electronic filing requirements will reduce costs and administrative burdens, result in greater efficiencies, facilitate faster and more efficient communications, and improve transparency to the public.

A. Background

2. *Electronic and Paper Filings.* The Commission has been committed to streamlining its processes by mandating the electronic filing of applications and other filings related to telecommunications services over the past several decades.[7] Today, the majority of applications and other filings are filed electronically with the Commission.[8] Applications and other filings for which an electronic form is not available and/or is not yet required to be filed electronically by rule must be filed by paper or by modified electronic filing.[9] Currently, for international licenses, authorizations, or other filings that are processed by the International Bureau, almost all applications must be filed electronically through IBFS, including all applications for international and satellite services for which an IBFS form is available.[10] The exceptions to mandatory electronic filing in IBFS, however, remain for Section 325(c) Applications,[11] IHF Applications,[12] and Dominant Carrier Section 63.10(c) Quarterly Reports.[13] Section 325(c) and IHF Applications are submitted through a modified electronic filing process that involves filing a non-docketed pleading through the Commission's Electronic Comment Filing System (ECFS).[14] For Dominant Carrier Section 63.10(c) Quarterly Reports, certain authorization holders are required to mail a paper copy to the Commission within ninety (90) days from the end of each calendar quarter.[15] Section 25.111(d) also requires a paper copy of satellite cost-recovery declarations to be submitted in addition to the version filed electronically.[16]

II. Discussion

3. Given the well-established benefits of electronic filing, in this Order we amend our rules to require the electronic filing of Section 325(c) Applications, IHF Applications, and Dominant Carrier Section 63.10(c) Quarterly Reports in IBFS, which will reduce the overall burden associated with these filings and increase significantly the efficiency of our administrative processes.[17] We modify our rules involving procedural filing of Section 325(c) Applications and IHF Applications, and require electronic filing of these applications in IBFS and remove a duplicate paper filing requirement for satellite cost-recovery declarations. We also eliminate paper filing of Dominant Carrier Section 63.10(c) Quarterly Reports and require their submission in IBFS within ninety (90) days after the end of each calendar quarter. Finally, we set a process for any changes to take effect.

A. Mandatory Electronic Filing

4. As part of the Commission's continuing efforts to modernize its IBFS, electronic forms will be available for Section 325(c) Applications, IHF Applications, and Dominant Carrier Section 63.10(c) Quarterly Reports. Accordingly, we require such filings to be submitted to the Commission electronically in IBFS, subject to the transition period set forth below. We have long-recognized the benefits of mandatory electronic filing, including reducing regulatory burdens and environmental waste while streamlining the filing process.[18] As the Commission explained in its *2005 IBFS Order,* electronic filing eliminates delays from mail delivery and does not require Commission staff to convert the filings into electronic format.[19] Electronic

[2] *See* Federal Communications Commission, International Bureau Filing System (IBFS), *http://licensing.fcc.gov/myibfs/* (IBFS Filing System).

[3] 47 CFR 73.3545.

[4] 47 CFR 73.702; 73.761, 73.3533; 73.3539–73.3540.

[5] 47 CFR 63.10(c)(2)–(4).

[6] 47 CFR 25.111(d).

[7] *See Mandatory Electronic Filing for International Telecommunications Services and Other International Filings,* Report and Order, 20 FCC Rcd 9292 (2005) (*2005 IBFS Order*); *International Bureau Filing System* (IBFS), Order, 19 FCC Rcd 4575 (2004); *2020 Wireless Radio Order.*

[8] *See* 47 CFR 1.767(n)(1), 1.768(j), 25.110, 25.111, 25.113, 25.115, 25.116, 25.119, 25.137, 25.172, 63.11(j), 63.18(r), 63.19(d), 63.20(a), 63.21(j), 63.24(h), 63.25(e), 63.701(j).

[9] *See International Bureau Reminds Interested Parties That Section 325(C) Applications for Permit to Deliver Programs to Foreign Stations And International High Frequency Applications Can Be Submitted Electronically as Non-Docketed Filings,* Public Notice, DA 14–1838 (rel. Dec. 16, 2014) (*325(c) and IHF Electronic Filing Notice);* International and Satellite Services Fee Filing Guide at 6 (effective September 4, 2018) (*2018 IB Fee Filing Guide*) (''The Bureau offers a choice of paper filing and/or modified electronic filing on the remaining international telecommunications, international high frequency broadcast (IHF), and Section 325(c) (325) applications pending the availability of OMB approved electronic forms.'').

[10] *See 2005 IBFS Order.* A list of forms that are available for electronic filing can be found on the FCC web page and through the IBFS homepage. *See* Federal Communications Commission, Licensing & Databases, Forms, *https://www.fcc.gov/licensing-databases/forms;* IBFS Filing System; *see also* 47 CFR 1.10000–1.10018.

[11] 47 U.S.C. 325(c) (''No person shall be permitted to locate, use, or maintain a radio broadcast studio or other place or apparatus from which or whereby sound waves are converted into electrical energy, or mechanical or physical reproduction of sound waves produced, and caused to be transmitted or delivered to a radio station in a foreign country for the purpose of being broadcast from any radio station there having a power output of sufficient intensity and/or being so located geographically that its emissions may be received consistently in the United States, without first obtaining a permit from the Commission upon proper application therefore''); 47 CFR 73.3545.

[12] An International Broadcast Station, also known as High Frequency Broadcasting (IHF) or Shortwave Broadcasting, employs frequencies allocated to the Broadcasting Service between 5,950 and 26,100 kHz. The transmissions of an IHF station, which are licensed only to non-governmental entities, are intended to be received directly by the general public in foreign countries. 47 U.S.C. 307; 47 CFR 73.701, 73.702.

[13] Section 63.10(c) of the Commission's rules sets forth competitive safeguards that the Commission applies to U.S.-authorized carriers that are affiliates of foreign carriers with market power on the foreign end of a U.S.-international route as a condition of the U.S. carriers' section 214 authorization(s) to provide U.S.-international service on the route. 47 CFR 63.10(c)(2)–(4).

[14] *See 325(c) and IHF Electronic Filing Notice; 2018 IB Fee Filing Guide;* Electronic Comment Filing System, Non-Docketed Filing, *https://www.fcc.gov/ecfs/filings/nodocket.* Once the non-docketed ECFS submissions are received, they are uploaded into IBFS by the Commission's staff.

[15] 47 CFR 63.10(c)(2)–(4). While similar reporting requirements, such as those for cable landing licensees affiliated with a carrier with market power in a cable's destination market, mandate the electronic filing of those reports, the reporting requirements under section 63.10(c) contain no such obligation. *Compare* 47 CFR 1.767(l) *with* 47 CFR 63.10(c).

[16] 47 CFR 25.111(d).

[17] Because these modifications requiring mandatory electronic filing are procedural in nature and do not substantively change the information required to be filed with the Commission, the notice and comment requirements of the Administrative Procedure Act do not apply. 5 U.S.C. 553(b)(3)(A); *Promoting Expanded Opportunities for Radio Experimentation and Market Trials Under Part 5 of the Commission's Rules and Streamlining Other Related Rules; 2006 Biennial Review of Telecommunications Regulations—Part 2 Administered by the Office of Engineering and Technology (OET),* Report and Order, 28 FCC Rcd 758, 818, para. 164 (2013) (*2013 Radio Experimentation Order*) (rule change clarifying that informal objections to certain applications should be filed electronically); *Amendment of Part 5 of the Commission's Rules to Require Electronic Filing of Applications for Experimental Radio Licenses and Authorizations,* Order, 18 FCC Rcd 16966, 16967, paras. 4, 6 (2003) (*2003 Amendment of Part 5 Order*) (adopting requirement to electronically file certain applications); *JEM Broadcasting Co. Inc.* v. *FCC,* 22 F.3d 320, 326 (D.C. Cir. 1994).

[18] *2020 Wireless Radio Order,* 35 FCC at 10784, para. 8; *2005 IBFS Order,* 20 FCC Rcd at 9294–95, paras. 5–7.

[19] *2005 IBFS Order,* 20 FCC Rcd at 9294, para. 5.

filing also reduces time needed to process applications and can allow the Commission to more quickly place applications on public notice.[20] Filers also benefit from electronic filing because an electronic filing system can automatically notify users of critical errors or omissions in their filings,[21] and electronic filing creates a digital record of users' submissions to the Commission and establishes proof of delivery.[22] The Commission benefits from a reduced workload because the data fields on electronic forms are automatically populated.[23] Other interested parties benefit as well because electronic filings are transmitted nearly instantaneously, making the filings available to the other interested parties around the same time that they become available to the Commission.[24]

5. For Section 325(c) Applications and IHF Applications, we eliminate the paper mailing and modified electronic filing requirements through ECFS and require applicants to file electronically in IBFS when the electronic forms are available.[25] The changes we adopt herein will improve the filing process and expedite review of the applications in an orderly manner as IBFS will automatically identify initial filing deficiencies in the electronic forms and route the filed applications to appropriate Commission staff without delay, thereby facilitating timely review. Additionally, any properly filed amendments, renewals, transfers, assignments, surrenders, notifications of limitation or discontinuance of operations, notifications of broadcast service resumption, equipment tests, program tests, post-season reports, pre-season operation notifications, or modifications, will be linked to other relevant applications or filings and similarly routed to the relevant Commission staff, decreasing processing time and administrative cost serving the public interest.[26]

6. For Dominant Carrier Section 63.10(c) Quarterly Reports, we eliminate the paper filing option and require carriers to submit these reports electronically in IBFS within ninety (90) days after the end of each calendar quarter.[27] This change will provide a number of benefits to carriers and Commission staff, including cost savings, convenience, and speed. As the Commission noted in the *2020 Wireless Radio Order,* ''[e]lectronic filing reduces paper, printing, and delivery expenses,'' and is more convenient as users can submit their filings ''nearly 24 hours a day, 7 days a week . . . .'' [28] Further, the electronic filing of Dominant Carrier Section 63.10(c) Quarterly Reports will eliminate the delay of waiting for these filings to be delivered to the Commission, processed, and provided to the relevant Commission staff. Carriers will receive confirmation of their filing from the system, and Commission staff will no longer need to manually digitize these quarterly reports, reducing burdens and decreasing costs to carriers and the Commission.

7. With the actions taken herein, we take another key step to modernize our filings processes, enable cost savings, increase convenience, and decrease processing time and complete the process of mandating that all International Bureau forms and filings must be submitted electronically in IBFS.

B. Conforming Amendments

8. *Section 63.10.* Section 63.10(d) specifies the number of copies and where to file each quarterly report. However, it misstates the relevant provisions of section 63.10(c)(2)–(4) identifying these quarterly reports. To correct the error, we revise paragraph (d) to remove the erroneous reference to section 63.10(c)(3)–(5) and replace this portion of the rule with the correct reference to section 63.10(c)(2)–(4), as well as to reflect the new electronic filing requirement for these reports.[29]

C. Paper Copies of Satellite ITU Cost-Recovery Declarations

9. The Commission's part 25 rules governing satellite services contain one paper filing requirement. Before the Commission will submit a satellite network filing to the International Telecommunication Union (ITU), the party requesting the filing must submit a signed declaration of unconditional acceptance of all consequent ITU cost-recovery responsibility.[30] This cost-recovery declaration ensures that the ITU filing charges are paid by the operator, not the United States as notifying administration.[31] The cost-recovery declaration must be filed electronically in IBFS. A paper copy must also be mailed to the Satellite Division of the International Bureau. Our experience has shown that this duplicate, paper copy is unnecessary to ensure that cost-recovery responsibility is properly assumed by the requesting party. We therefore modify our rules and remove the paper filing requirement.

D. Transition and Other Issues

10. We direct the International Bureau to release any relevant public notices announcing the availability of electronic filing for Section 325(c) Applications, IHF Applications, and Dominant Carrier Section 63.10(c) Quarterly Reports as the rules and forms become effective and available in IBFS. Until the International Bureau announces the availability of electronic filing, the current filing processes will continue to apply.

11. *Waiver Requests.* There may be limited instances where electronic filing rather than paper filing may be unduly burdensome or create a hardship for some potential applicants. For such cases, we will permit applicants and filers to file a request for waiver of our

[20] *Id.* at 9294–95, para 7.

[21] *Id.* at 9294, para 6.

[22] *2020 Wireless Radio Order,* 35 FCC Rcd at 10788, para. 23.

[23] *2005 IBFS Order,* 20 FCC Rcd at 9294–95, para 7.

[24] *2020 Wireless Radio Order,* 35 FCC Rcd at 10788, para. 23.

[25] 47 CFR 73.3533(a)(2), 73.3545.

[26] 47 CFR 73.3540(c)–(d), 73.702, 73.713(a), 73.732, 73.759(c)(2), 73.761, 73.762, 73.3539(a).

[27] *See* Appx. A.

[28] *2020 Wireless Radio Order,* 25 FCC Rcd at 10788, para. 23. In 2020, the Commission received a total of 73 reports: 20 reports in the first quarter, 19 reports in the second quarter, 20 reports in the third quarter, and 14 reports in the fourth quarter. The data derived from these reports continue to be important resource for the Commission.

[29] These amendments, referring to how the quarterly reports should be filed, are procedural rules, thus the notice and comment requirements of the Administrative Procedure Act do not apply. 5 U.S.C. 553(b)(3)(A). We also find there is good cause to forego a notice-and-comment period in this instance given that notice and comment is unnecessary and contrary to the public interest to make the modifications to section 63.10(d), as discussed herein. 5 U.S.C. 553(b)(3)(B). Here, we correct a typographical error with respect to cross-references contained in the rule paragraph and eliminate a requirement that will be rendered obsolete by the adoption of an electronic filing requirement and find that following a notice and comment process would needlessly prolong an obvious inaccuracy in the rules, reference an obsolete requirement, and fail to yield any of the public interest benefits that notice and comment procedures are designed to produce. *See, e.g., Allocation and Service Rules for the 1675–1680 MHz Band,* Notice of Proposed Rulemaking and Order, 34 FCC Rcd 3552, 3572, para. 55 (2019) (finding for good cause that notice and comment procedures are unnecessary to correct and update incorrect cross-references in various rule paragraphs).

[30] 47 CFR 25.111(d); *see also Comprehensive Review of Licensing and Operating Rules for Satellite Services,* Report and Order, 28 FCC Rcd 12403, 12425–26, paras. 61–65, 12479–80, Appx. B (2013); *Implementation of ITU Cost Recovery Charges for Satellite Network Filings,* Public Notice, 16 FCC Rcd 18732 (IB 2001).

[31] *See generally* ITU Council Decision 482 (modified 2020) at 4, *decides* 9 (providing that the invoice for ITU cost-recovery charges will be sent to the notifying administration or, at the request of that administration, to the satellite network operator in question), *https://www.itu.int/md/S20-CL-C-0070/en.*

electronic filing requirements under limited circumstances for good cause shown, pursuant to section 1.3 of our rules.[32] To qualify for a waiver, the applicant must plead with particularity the facts and circumstances warranting relief.[33] For example, the applicant must set forth the specific reasons why electronic filing would constitute an unreasonable burden or expense, including the special circumstances at hand that justify a waiver and how a waiver would serve the public interest. We expect the number of waiver requests to be small, and we will not routinely grant waivers of our mandatory filing requirement.

12. *Confidential Filings.* Applicants or other filers that seek to file confidentially or to preserve the confidentiality of a piece of information in a filing may request such treatment under section 0.459 of the Commission's rules.[34]

III. Procedural Matters

13. *Regulatory Flexibility Analysis.* Because these rule changes are being adopted without notice and comment, the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.,* does not apply.[35]

14. *Paperwork Reduction Act.* This Order does not contain new or substantively modified information collections subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13 (44 U.S.C. 3501–3520). Specifically, the changes to existing information collections, including mandatory electronic filing for Section 325(c) Applications, IHF Applications, and Dominant Carrier Section 63.10(c) Quarterly Reports are non-substantive.[36] Because these changes are non-substantive, there is also no new or modified information collection burden for small business concerns with fewer than 25 employees pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4).

15. *Congressional Review Act.* The Commission will not send a copy of this Order to Congress and the Government Accountability Office pursuant to 5 U.S.C. 801(a)(1)(A), because the adopted rules are rules of agency organization, procedure, or practice that do not substantially affect the rights or obligations of non-agency parties.[37]

IV. Ordering Clauses

13. Accordingly, *it is ordered* that pursuant to Sections 1, 4(i), 214, 218, 301, 303, 307, 308(b), and 325(c) of the Communications Act of 1934, as amended, 47 U.S.C. 151, 154(i), 214, 218, 301, 303, 307, 308(b), 325(c), this Order is *hereby adopted.*

14. *It is further ordered* that pursuant to Sections 1, 4(i), 214, 218, 301, 303, 307, 308(b) and 325(c) of the Communications Act of 1934, as amended, 47 U.S.C. 151, 154(i), 214, 218, 301, 303, 307, 308(b), 325(c), the rules discussed herein *are adopted* and Parts 63 and 73 of the Commission's rules, 47 CFR 63 and 73 *are amended as set forth in* Appendix A.

15. *It is further ordered* that this Order, including the revisions to Title 47 of the Code of Federal Regulations shown in Appendix A, *shall be effective* upon publication in the **Federal Register**.[38]

List of Subjects in 47 CFR Parts 25, 63, and 73

Broadcast Stations, Communications, Communications common carriers, Radio, Reporting and recordkeeping requirements, Satellites, Telecommunications.

Federal Communications Commission.

Marlene Dortch,

Secretary.

Final Rules

For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR parts 25, 63 and 73 as follows:

PART 25—SATELLITE COMMUNICATIONS

■ 1. The authority citation for part 25 continues to read as follows:

Authority: 47 U.S.C. 154, 301, 302, 303, 307, 309, 310, 319, 332, 605, and 721, unless otherwise noted.

■ 2. Amend § 25.111 by revising the second sentence of paragraph (d) to read as follows:

§ 25.111 Additional information, ITU filings, and ITU cost recovery.

* * * * *

(d) * * * Applicants and licensees must file the declaration electronically in the application file in the International Bureau Filing System (IBFS). * * *

* * * * *

PART 63—EXTENSION OF LINES, NEW LINES, AND DISCONTINUANCE, REDUCTION, OUTAGE AND IMPAIRMENT OF SERVICE BY COMMON CARRIERS; AND GRANTS OF RECOGNIZED PRIVATE OPERATING AGENCY STATUS

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

Authority: 47 U.S.C. 151, 154(i), 154(j), 160, 201–205, 214, 218, 403, 571, unless otherwise noted.

■ 4. Amend § 63.10 by revising paragraph (d) to read as follows:

§ 63.10 Regulatory classification of U.S. international carriers.

* * * * *

(d) A carrier classified as dominant under this section shall file electronically each report required by paragraphs (c)(2), (c)(3), and (c)(4) of this section in the International Bureau Filing System (IBFS). Each report filed in IBFS shall clearly identify the report as responsive to the appropriate paragraph of § 63.10(c).

* * * * *

PART 73—RADIO BROADCAST SERVICES

■ 5. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 155, 301, 303, 307, 309, 310, 334, 336, 339.

* * * * *

Subpart F—International Broadcast Stations

■ 6. Amend § 73.702 by revising paragraphs (a), (b), (c), (d), (e), (h)(2), (i)

[32] 47 CFR 1.3.

[33] The Commission may waive its policies or rules upon a showing of good cause and may take into account, on an individual basis, considerations of hardship, equity, or more effective implementation of overall policy. *See WAIT Radio* v. *FCC,* 418 F.2d 1153, 1159 (D.C. Cir. 1969); *see also Ne. Cellular Tel. Co.* v. *FCC,* 897 F.2d 1164, 1166 (D.C. Cir. 1990). Waiver of the Commission's policies or rules is appropriate only if both: (i) Special circumstances warrant a deviation from the general rule; and (ii) such deviation will serve the public interest. *See Network IP, LLC* v. *FCC,* 548 F.3d 116, 127 (D.C. Cir. 2008).

[34] 47 CFR 0.459.

[35] *See* 5 U.S.C. 601(2) (definition of ''rule''), 604(a) (requiring a final regulatory flexibility analysis when an agency promulgates a final rule ''after being required . . . to publish a general notice of proposed rulemaking'').

[36] After the adoption and release of this Order, the Commission submitted the changes to the Office of Management and Budget (OMB) and received the OMB approvals. The Commission also received emergency approval from OMB for certain requirements that were inadvertently omitted from existing information collections. The relevant OMB Control numbers are 3060–0678, 3060–0686, 3060–1035, 3060–1133, and 3060–1290.

[37] *See* 5 U.S.C. 804(3)(C).

[38] The rule changes adopted in this Order and contained in Appendix A constitute procedural rules and are not subject to the effective date provisions of the Administrative Procedure Act. 47 CFR 1.427(b) (rules of procedure may be made effective without regard to the 30-day **Federal Register** publication requirement). The Administrative Procedure Act's requirement that rules must be published in the **Federal Register** at least 30 days before their effective date, subject to certain exceptions, applies only to ''substantive rules.'' *See* 5 U.S.C. 553(d).

introductory text, Note 4 to paragraph (i), (j), and (m) to read as follows:

§ 73.702 Assignment and use of frequencies.

(a) Frequencies will be assigned by the Commission prior to the start of each season to authorized international broadcasting stations for use during the season at specified hours and for transmission to specified zones or areas of reception, with specified power and antenna bearing. Six months prior to the start of each season, licensees and permittees shall by informal written request, submitted to the Commission electronically in the International Bureau Filing System (IBFS), indicate for the season the frequency or frequencies desired for transmission to each zone or area of reception specified in the license or permit, the specific hours during which it desires to transmit to such zones or areas on each frequency, and the power, antenna gain, and antenna bearing it desires to use. Requests will be honored to the extent that interference and propagation conditions permit and that they are otherwise in accordance with the provisions of this section.

(b) After necessary processing of the requests required by paragraph (a) of this section, the Commission will notify each licensee and permittee of the frequencies, hours of use thereof to specified zones or areas of reception, power, and antenna bearing which it intends to authorize for the season in question. After receipt of such notification, the licensee or permittee shall, in writing, not later than two months before the start of the season in question, electronically inform the Commission in IBFS either that it plans to operate in accordance with the authorization which the Commission intends to issue, or that it plans to operate in another manner. If the licensee or permittee indicates that it plans to operate in another manner, it shall furnish explanatory details.

(c) If after submitting the request required under the provisions of paragraph (a) of this section, but before receipt of the Commission's notification referred to in paragraph (b) of this section, the licensee or permittee submits a request for changes of its original request electronically in IBFS such requests will be accepted for consideration only if accompanied by statements showing good cause therefor and will be honored only if conditions permit. If the information required to be submitted by the licensee or permittee under the provisions of paragraph (b) of this section indicates that operation in another manner is contemplated, and the explanatory details contain a request for change in the originally proposed manner of operation, such requests will be accepted for consideration only if accompanied by statements showing good cause therefor and will be honored only if conditions permit. If after the licensee or permittee submits the information required under the provisions of paragraph (b) of this section, but before the start of the season in question, the licensee or permittee submits electronically in IBFS a request for changes in its manner of operation for the season in question, the request will be accepted for consideration only if accompanied by statements showing good cause therefor and will be honored only if conditions permit. If after the start of a season the licensee or permittee submits a request for changes in the manner of operation as authorized, the request will be considered only if accompanied by statements showing good cause therefor, and will be honored only if conditions permit.

(d) The provisions of paragraphs (a), (b), and (c) of the section shall apply to licensees, to permittees operating under program test authority, and to permittees who anticipate applying for and receiving program test authority for operation during the specified season.

Note: Permittees who during the process of construction wish to engage in equipment tests shall by informal written request, submitted to the Commission electronically in IBFS not less than 30 days before they desire to begin such testing, indicate the frequencies they desire to use for testing and the hours they desire to use those frequencies. No equipment testing shall occur until the Commission has authorized frequencies and hours for such testing. Such authorizations shall be only for one season, and if it is desired to continue equipment testing in a following season, new requests for frequencies and hours must be submitted at least 30 days before it is desired to begin testing in the following season.

(e) Within 14 days after the end of each season, a report shall be filed with the Commission electronically in IBFS by each licensee or permittee operating under program test authority who has been issued a seasonal schedule for that season. The report shall state whether the licensee or permittee has operated the number of frequency-hours authorized by the seasonal schedule to each of the zones or areas of reception specified in the schedule. If such operation has not occurred, a detailed explanation of that fact shall also be submitted which includes specific dates, frequency-hours not used, and reasons for the failure to operate as authorized. The report shall also contain information that has been received by the licensee or permittee as to reception or interference, and conclusions with regard to propagation characteristics of frequencies that were assigned for the season in question.

* * * * *

(h) * * *

(2) During the hours of 0800–1600 UTC (Coordinated Universal Time) antenna gain with reference to an isotropic radiator in any easterly direction that would intersect any area in Region 2 shall not exceed 2.15 dBi, except in the case where a transmitter power of less than 100 kW is used. In this case, antenna gain on restricted azimuths shall not exceed that which is determined in accordance with equation below. Stations desiring to operate in this band must submit sufficient antenna performance information electronically in IBFS to ensure compliance with these restrictions. Permitted gain for transmitter powers less than 100 kW:

Where:

$$\mathrm{Gi} = 2.15 + 10\ \log\left(\frac{100}{\mathrm{Pa}}\right)\ \mathrm{dBi}$$

Gi = maximum gain permitted with reference to an isotropic radiator. Pa = Transmitter power employed in kW.

(i) Frequencies requested for assignment must be as near as practicable to the optimum working frequency (unless otherwise justified) for the zone or area of reception for the period and path of transmission, and should be chosen so that a given frequency will provide the largest period of reliable transmission to the selected zone or area of reception. Moreover, at the zone or area of reception frequencies shall provide protection to the transmissions of other broadcasting stations which, in the opinion of the Commission, have priority of assignment.

* * * * *

Note 4: Seasonal requests for frequency-hours will be only for transmissions to zones or areas of reception specified in the basic instrument of authorization. Changes in such zones or areas will be made only on separate application for modification of such instruments made electronically in IBFS.

(j) Not more than one frequency will be assigned for use at any one time for any one program transmission except in instances where a program is intended for reception in more than one zone or area of reception and the intended zones or areas cannot be served by a single frequency: Provided, however, That on a showing of good cause made electronically in IBFS a licensee may be authorized to operate on more than one frequency at any one time to transmit any

one program to a single zone or area of reception.

* * * * *

(m) The total maximum number of frequency-hours which will be authorized to all licensees of international broadcasting stations during any one day for any season is 100. The number of frequency-hours allocated to any licensee will depend on past usage, availability, and need. If for a forthcoming season the total of the requests for daily frequency-hours of all licensees exceeds 100, all licensees will be notified and each licensee that makes an adequate showing electronically in IBFS that good cause exists for not having its requested number of frequency-hours reduced and that operation of its station without such reduction would be consistent with the public interest may be authorized the frequency-hours requested.

■ 7. Amend § 73.713 by revising paragraph (a) to read as follows:

§ 73.713 Program Tests.

(a) Upon completion of construction of an international broadcasting station in accordance with the terms of the construction permit, the technical provisions of the application therefor, and the rules and regulations and the applicable engineering standards, and when an application for station license has been filed showing the station to be in satisfactory operating condition, the permittee may request authority to conduct program tests. Such request shall be electronically filed with the FCC in the International Bureau Filing System (IBFS) at least 10 days prior to the date on which it is desired to begin such operation. All data necessary to show compliance with the terms and conditions of the construction permit must be filed with the license application.

* * * * *

■ 8. Revise § 73.732 to read as follows:

§ 73.732 Authorizations.

Authorizations issued to international broadcasting stations by the Commission will be authorizations to permit the construction or use of a particular transmitting equipment combination and related antenna systems for international broadcasting, and to permit broadcasting to zones or areas of reception specified on the instrument of authorization. The authorizations will not specify the frequencies to be used or the hours of use. Requests for frequencies and hours of use will be made by electronic filing in the International Bureau Filing System (IBFS) as provided in § 73.702. Seasonal schedules, when issued pursuant to the provisions of § 73.702, will become attachments to and part of the instrument of authorization, replacing any such prior attachments.

■ 9. Amend § 73.759 by revising paragraph (c)(2) to read as follows:

§ 73.759 Auxiliary transmitters.

* * * * *

(c) * * *

(2) The transmission of regular programs during maintenance or modification work on the main transmitter, necessitating discontinuance of its operation for a period not to exceed 5 days. (This includes the equipment changes which may be made without authority as set forth elsewhere in the rules and regulations or as authorized by the Commission by letter or by construction permit. Where such operation is required for periods in excess of 5 days, request therefor shall be made electronically in the International Bureau Filing System (IBFS) in accordance with § 73.3542 of this chapter.)

* * * * *

■ 10. Revise § 73.761 to read as follows:

§ 73.761 Modification of transmission systems.

Specific authority, upon electronic filing of a formal application (FCC Form 309) therefor in the International Bureau Filing System (IBFS), is required for any of the following changes:

(a) Change involving an increase or decrease in the power rating of the transmitters.

(b) A replacement of the transmitters as a whole.

(c) Change in the location of the transmitting antenna.

(d) Change in the power delivered to the antenna.

(e) Change in frequency control and/or modulation system.

(f) Change in direction or gain of antenna system.

(g) Other changes, not specified above in this section, may be made at any time without the authority of the Commission: Provided, That the Commission shall be immediately notified electronically in IBFS thereof and such changes shall be shown in the next application for renewal of license.

■ 11. Amend § 73.762 by revising paragraphs (b) and (c) to read as follows:

§ 73.762 Time of operation.

* * * * *

(b) In the event that causes beyond a licensee's control make it impossible to adhere to the seasonal schedule or to continue operating, the station may limit or discontinue operation for a period of not more than 10 days, without further authority from the FCC. However, in such cases, the FCC shall be immediately notified by electronic filing in the International Bureau Filing System (IBFS) of such limitation or discontinuance of operation and shall subsequently be notified by electronic filing in IBFS when the station resumes regular operation.

(c) In the event that causes beyond a licensee's control make it impossible to adhere to the seasonal schedule or to continue operating for a temporary period of more than 10 days, the station may not limit or discontinue operation until it requests and receives specific authority to do so from the FCC by electronic filing in IBFS. When the station subsequently resumes regular operation after such limited operation or discontinuance of operation, it shall notify the FCC in Washington, DC by electronic filing in IBFS. The license of a broadcasting station that fails to transmit broadcast signals for any consecutive 12-month period expires as a matter of law at the end of that period, notwithstanding any provision, term, or condition of the license to the contrary.

Subpart H—Rules Applicable to All Broadcast Stations

■ 12. Amend § 73.3533 by revising paragraph (a)(2) to read as follows:

§ 73.3533 Application for construction permit or modification of construction permit.

(a) * * *

(2) FCC Form 309, ''Application for Authority to Construct or Make Changes in an Existing International or Experimental Broadcast Stations.'' For International Broadcast Stations, applications shall be filed electronically in the International Bureau Filing System (IBFS).

* * * * *

■ 13. Amend § 73.3539 by revising paragraph (a) to read as follows:

§ 73.3539 Application for renewal of license.

(a) Unless otherwise directed by the FCC, an application for renewal of license shall be filed not later than the first day of the fourth full calendar month prior to the expiration date of the license sought to be renewed, except that applications for renewal of license of an experimental broadcast station shall be filed not later than the first day of the second full calendar month prior to the expiration date of the license sought to be renewed. If any deadline prescribed in this paragraph falls on a

nonbusiness day, the cutoff shall be the close of business of the first full business day thereafter. For International Broadcast Stations, applications shall be filed electronically in the International Bureau Filing System (IBFS).

* * * * *

■ 14. Amend § 73.3540 by revising paragraphs (c) and (d) to read as follows:

§ 73.3540 Application for voluntary assignment or transfer of control.

* * * * *

(c) Application for consent to the assignment of construction permit or license must be filed on FCC Form 314 ''Assignment of license'' or FCC Form 316 ''Short form'' (See paragraph (f) of this section). For International Broadcast Stations, the application shall be filed electronically in the International Bureau Filing System (IBFS).

(d) Application for consent to the transfer of control of a corporation holding a construction permit or license must be filed on FCC Form 315 ''Transfer of Control'' or FCC Form 316 ''Short form'' (see paragraph (f) of this section). For International Broadcast Stations, applications shall be filed electronically in IBFS.

* * * * *

■ 15. Revise § 73.3545 to read as follows:

§ 73.3545 Application for permit to deliver programs to foreign stations.

Application under section 325(c) of the Communications Act for authority to locate, use, or maintain a broadcast studio in connection with a foreign station consistently received in the United States, should be made on FCC Form 308, ''Application for Permit to Deliver Programs to Foreign Broadcast Stations.'' An informal application may be used by applicants holding an AM, FM or TV broadcast station license or construction permit. Informal applications must, however, contain a description of the nature and character of the programming proposed, together with other information requested on Page 4 of Form 308. All applications must be filed electronically in the International Bureau Filing System (IBFS).

[FR Doc. 2021–17394 Filed 9–30–21; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF VETERANS AFFAIRS

48 CFR Parts 802, 852, and 853

RIN 2900–AR30

VA Acquisition Regulation: Definitions, Solicitation Provisions and Contract Clauses, and Forms

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: This final rule amends the Veterans Affairs Acquisition Regulation (VAAR) to provide needed editorial changes. VA is publishing a technical amendment to make minor administrative corrections in the definitions, clauses, provisions and forms, and to remove duplicate or outdated definitions associated with the previously published rules.

DATES: This rule is effective on November 1, 2021.

FOR FURTHER INFORMATION CONTACT: Mr. Rafael N. Taylor, Senior Procurement Analyst, Procurement Policy and Warrant Management Services, 003A2A, 425 I Street NW, Washington, DC 20001, (202) 382–2787. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION:

Background

The purpose of this rule is to make minor final revisions and edits to three completed parts that are necessary to conform with FAR writing style, standard Government publication formats and drafting standards. VA is updating these parts to ensure standardization in titles with FAR drafting principles, as well as to update any VA organizational changes subsequent to the final rules. In particular, this rulemaking makes technical administrative amendments to part 802, Definitions; part 852, Solicitation Provisions and Contract Clauses; and part 853, Forms.

The three parts addressed in this action have been reviewed and revised as affected parts during the course of the VAAR rewrite project. This is, therefore, a technical, non-substantive change to the texts of these three parts to ensure conformity with those standards.

Discussion and Analysis

Technical corrections include the following:

a. For part 802:

(1) Section 802.101 is amended to revise the definition for the Chief Acquisition Officer; the definition for COTR has been removed; the definition for COR has been added to reflect the current use of COR; the definitions for HCA and SPE have been revised to reflect the current organization structure of VA, and to update the website listed for Vendor Information Pages (VIP) has been updated.

(2) Section 802.101 is also amended to delete the following definitions: Deputy Senior Procurement Executive (DSPE) and Resident Engineer. The DSPE role is currently inactive at the VA and the current definition for ''Resident Engineer'' is inaccurate and unnecessary.

b. For part 852:

(1) Section 852.101 is redesignated as section 852.101–70 to conform with the VAAR numbering convention.

(2) Section 852.102 is amended to correct the word ''chapter'' because it was misspelled and to update website addresses in paragraphs (e) and (f) that have since changed.

(3) Subpart 852.2 is amended to capitalize all the major words in the section titles of the provisions and clauses.

(4) Section 852.216–75 is amended to delete the word ''clause'' in the title and to capitalize the major words in the title of the clause.

c. For part 853:

(1) Subpart 853.2 is amended to remove section 853.201 and section 853.201–1 as they include references to the ''VA Contracting Officer Certification Program'' which no longer exists.

(2) Subpart 853.2 is amended to remove section 853.215 and section 853.215–70 as they are no longer referenced within the VAAR.

(3) Amend Section 853.236 as well as sections 853.236–70, 853.236–71, and 853.236–72 to standardize the format and style convention.

(4) Amend subpart 853.2 to remove sections 853.271–1 and 853.271–2 as this coverage is no longer needed in the VAAR as the authority to perform the functions outlined in these sections are established by other provisions of law.

Notice and Comment

This rule makes administrative changes that do not require notice and comment procedures, consistent with 41 U.S.C. 1707, 48 CFR 1.301, and related authority. The changes will not have a significant effect on any party and will not have a significant cost or administrative impact on contractors or offerors.

Executive Orders 12866 and 13563

Executive Order 12866—Regulatory Planning and Review directs agencies to assess the costs and benefits of available regulatory alternatives and, if regulation

is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563—Improving Regulation and Regulatory Review 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 (OMB) has determined that this rule is not a significant regulatory action under Executive Order 12866. The Regulatory Impact Analysis associated with this rulemaking can be found as a supporting document at *www.regulations.gov.*

Regulatory Flexibility Act

The Secretary hereby certifies that this final rule would not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act (5 U.S.C. 601–612). This rulemaking does not change VA's policy regarding small businesses, does not have an economic impact to individual businesses, and there are no increased or decreased costs to small business entities. Therefore, pursuant to 5 U.S.C. 605(b), the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604 do not apply.

Paperwork Reduction Act

This final rule does not contain any information collection requirements that require approval by the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this rule as not a major rule, as defined by 5 U.S.C. 804(2).

List of Subjects

48 CFR Part 802

Government procurement.

48 CFR Part 852

Government procurement, Reporting and recordkeeping requirements.

48 CFR Part 853

Government procurement.

Signing Authority

Denis McDonough, Secretary of Veterans Affairs, approved this document on September 3, 2021, and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs.

Luvenia Potts,

Regulations Development Coordinator, Office of Regulation Policy & Management, Office of General Counsel, Department of Veterans Affairs.

For the reasons set out in the preamble, VA amends 48 CFR parts 802, 852, and 853 as set forth below.

PART 802—DEFINITIONS OF WORDS AND TERMS

■ 1. The authority citation for part 802 continues to read as follows:

Authority: 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301–1.304.

Subpart 802.1—Definitions

■ 2. Amend section 802.101 by:
■ a. Revising the definition for ''Chief Acquisition Officer;''
■ b. Adding the definition for ''COR'' in alphabetical order;
■ c. Removing the definitions for ''COTR'' and ''DSPE;''
■ d. Revising the definition for ''HCA;''
■ e. Removing the definition for ''Resident Engineer;'' and
■ f. Revising the definitions for ''SPE'' and ''Vendor Information Pages (VIP).''

The addition and revisions read as follows:

§ 802.101 Definitions.

* * * * *

Chief Acquisition Officer (CAO) means the Principal Executive Director, Office of Acquisition, Logistics, and Construction.

COR means Contracting Officer's Representative.

* * * * *

HCA means the Head of the Contracting Activity, an individual appointed in writing by the SPE.

* * * * *

SPE means the Senior Procurement Executive who is also the Executive Director, Office of Acquisition and Logistics. The SPE is responsible for the management direction of the VA acquisition system.

* * * * *

Vendor Information Pages (VIP) means the *VetBiz.va.gov* VIP database at *https://www.vetbiz.va.gov/vip/.*

* * * * *

PART 852—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 3. The authority citation for part 852 continues to read as follows:

Authority: 38 U.S.C. 8127–8128, and 8151–8153; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3), 41 U.S.C. 1303; 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

Subpart 852.1—Instructions for Using Provisions and Clauses

§ 852.101 [Redesignated as 852.101–70]

■ 4. Redesignate section 852.101 as section 852.101–70.

■ 5. Amend section 852.102 by revising the first sentence of paragraph (b) and paragraphs (e) and (f) to read as follows:

§ 852.102 Incorporating provisions and clauses.

* * * * *

(b) For any FAR or 48 CFR chapter 8 (VAAR) provision or clause that requires completion by the contracting officer, the contracting officer shall, as a minimum, insert the title of the provision or clause and the paragraph that requires completion in full text in the quotation, solicitation, or contract. * * *

* * * * *

(e) If one or more FAR provisions or clauses, or portions thereof, are incorporated in a quotation, solicitation, or contract by reference, the contracting officer shall insert in the FAR provision or clause required by paragraph (c) or (d) of this section the following internet address: *https://www.acquisition.gov/browse/index/far.*

(f) If one or more 48 CFR chapter 8 (VAAR) provisions or clauses, or portions thereof, are incorporated in a quotation, solicitation, or contract by reference, the contracting officer shall insert in the FAR provision or clause required by paragraph (c) or (d) of this section the following internet address: *https://www.acquisition.gov/vaar.*

Subpart 852.2—Text of Provisions and Clauses

■ 6. Revise the heading for section 852.203–70 to read as follows:

§ 852.203–70 Commercial Advertising.

■ 7. Revise the heading for section 852.204–70 to read as follows:

§ 852.204–70 Personal Identity Verification of Contractor Personnel.

■ 8. Revise the heading for section 852.207–70 to read as follows:

§ 852.207–70 Report of Employment under Commercial Activities.

■ 9. Revise the heading for section 852.209–70 to read as follows:

§ 852.209–70 Organizational Conflicts of Interest.

■ 10. Revise the heading for section 852.211–70 to read as follows:

§ 852.211–70 Equipment Operation and Maintenance Manuals.

■ 11. Revise the heading for section 852.211–72 to read as follows:

§ 852.211–72 Technical Industry Standards.

■ 12. Revise the heading for section 852.214–71 to read as follows:

§ 852.214–71 Restrictions on Alternate Item(s).

■ 13. Revise the heading for section 852.214–72 to read as follows:

§ 852.214–72 Alternate Item(s).

■ 14. Revise the heading for section 852.214–73 to read as follows:

§ 852.214–73 Alternate Packaging and Packing.

■ 15. Revise the heading for section 852.214–74 to read as follows:

§ 852.214–74 Marking of Bid Samples.

■ 16. Revise the heading for section 852.216–71 to read as follows:

§ 852.216–71 Economic Price Adjustment of Contract Price(s) Based on a Price Index.

■ 17. Revise the heading for section 852.216–72 to read as follows:

§ 852.216–72 Proportional Economic Price Adjustment of Contract Price(s) Based on a Price Index.

■ 18. Revise the heading for section 852.216–73 to read as follows:

§ 852.216–73 Economic Price Adjustment—State Nursing Home Care for Veterans.

■ 19. Revise the heading for section 852.216–74 to read as follows:

§ 852.216–74 Economic Price Adjustment—Medicaid Labor Rates.

■ 20. Amend section 852.216–75 by revising the section heading, introductory text, and clause heading to read as follows:

§ 852.216–75 Economic Price Adjustment—Fuel Surcharge.

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

Economic Price Adjustment—Fuel Surcharge (Nov 2021)

* * * * *

■ 21. Revise the heading for section 852.219–9 to read as follows:

§ 852.219–9 VA Small Business Subcontracting Plan Minimum Requirements.

■ 22. Revise the heading for section 852.219–10 to read as follows:

§ 852.219–10 VA Notice of Total Service-Disabled Veteran-Owned Small Business Set-Aside.

■ 23. Revise the heading for section 852.219–11 to read as follows:

§ 852.219–11 VA Notice of Total Veteran-Owned Small Business Set-Aside.

■ 24. Revise the heading for section 852.222–70 to read as follows:

§ 852.222–70 Contract Work-Hours and Safety Standards—Nursing Home Care for Veterans.

■ 25. Revise the heading for section 852.223–70 to read as follows:

§ 852.223–70 Instructions to Offerors—Sustainable Acquisition Plan.

■ 26. Revise the heading for section 852.223–71 to read as follows:

§ 852.223–71 Safety and Health.

■ 27. Revise the heading for section 852.228–70 to read as follows:

§ 852.228–70 Bond Premium Adjustment.

■ 28. Revise the heading for section 852.228–72 to read as follows:

§ 852.228–72 Assisting Service-Disabled Veteran-Owned and Veteran-Owned Small Businesses in Obtaining Bonds.

■ 29. Revise the heading for section 852.228–73 to read as follows:

§ 852.228–73 Indemnification of Contractor—Hazardous Research Projects.

■ 30. Revise the heading for section 852.232–72 to read as follows:

§ 852.232–72 Electronic Submission of Payment Requests.

■ 31. Revise the heading for section 852.233–70 to read as follows:

§ 852.233–70 Protest Content/Alternative Dispute Resolution.

■ 32. Revise the heading for section 852.233–71 to read as follows:

§ 852.233–71 Alternate Protest Procedure.

■ 33. Revise the heading for section 852.236–71 to read as follows:

§ 852.236–71 Specifications and Drawings for Construction.

■ 34. Revise the heading for section 852.236–79 to read as follows:

§ 852.236–79 Contractor Production Report.

■ 35. Revise the heading for section 852.236–80 to read as follows:

§ 852.236–80 Subcontracts and Work Coordination.

■ 36. Revise the heading for section 852.236–90 to read as follows:

§ 852.236–90 Restriction on Submission and Use of Equal Products.

■ 37. Revise the heading for section 852.236–92 to read as follows:

§ 852.236–92 Notice to Bidders—Additive or Deductive Bid Line Items.

■ 38. Revise the heading for section 852.237–70 to read as follows:

§ 852.237–70 Indemnification and Medical Liability Insurance.

■ 39. Revise the heading for section 852.237–71 to read as follows:

§ 852.237–71 Nonsmoking Policy for Children's Services.

■ 40. Revise the heading for section 852.237–72 to read as follows:

§ 852.237–72 Crime Control Act—Reporting of Child Abuse.

■ 41. Revise the heading for section 852.237–73 to read as follows:

§ 852.237–73 Crime Control Act—Requirement for Background Checks.

■ 42. Revise the heading for section 852.237–74 to read as follows:

§ 852.237–74 Non-discrimination in Service Delivery.

■ 43. Revise the heading for section 852.237–75 to read as follows:

§ 852.237–75 Key Personnel.

■ 44. Revise the heading for section 852.237–76 to read as follows:

§ 852.237–76 Award to Single Offeror.

■ 45. Revise the heading for section 852.241–70 to read as follows:

§ 852.241–70 Disputes—Utility Contracts.

■ 46. Revise the heading for section 852.243–70 to read as follows:

§ 852.243–70 Construction Contract Changes—Supplement.

■ 47. Revise the heading for section 852.246–71 to read as follows:

§ 852.246–71 Rejected Goods.

■ 48. Revise the heading for section 852.246–72 to read as follows:

§ 852.246–72 Frozen Processed Foods.

■ 49. Revise the heading for section 852.246–73 to read as follows:

§ 852.246–73 Noncompliance with Packaging, Packing, and/or Marking Requirements.

■ 50. Revise the heading for section 852.246–75 to read as follows:

§ 852.246–75 Warranty of Construction—Guarantee Period Services.

■ 51. Revise the heading for section 852.246–76 to read as follows:

§ 852.246–76 Purchase of Shellfish.

■ 52. Revise the heading for section 852.247–71 to read as follows:

§ 852.247–71 Delivery Location.

■ 53. Revise the heading for section 852.247–72 to read as follows:

§ 852.247–72 Marking Deliverables.

■ 54. Revise the heading for section 852.247–73 to read as follows:

§ 852.247–73 Packing for Domestic Shipment.

■ 55. Revise the heading for section 852.252–70 to read as follows:

§ 852.252–70 Solicitation Provisions or Clauses Incorporated by Reference.

■ 56. Revise the heading for section 852.270–1 to read as follows:

§ 852.270–1 Representatives of Contracting Officers.

PART 853—FORMS

■ 57. The authority citation for part 853 is revised to read as follows:

Authority: 40 U.S.C. 121(c); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

■ 58. Revise subpart 853.2 to read as follows:

Subpart 853.2—Prescription of Forms

§ 853.236 Construction and architect-engineer contracts.

§ 853.236–70 VA Form 6298, Architect-Engineer Fee Proposal.

§ 853.236–71 VA Form 2138, Order for Supplies or Services (Including Task Orders for Construction or A–E Services).

§ 853.236–72 VA Form 10101, Contractor Production Report.

Subpart 853.2—Prescription of Forms

§ 853.236 Construction and architect-engineer contracts.

§ 853.236–70 VA Form 6298, Architect-Engineer Fee Proposal.

VA Form 6298 is prescribed for use by contractors to submit proposals, as specified in 836.7001(a).

§ 853.236–71 VA Form 2138, Order for Supplies or Services (Including Task Orders for Construction or A–E Services).

VA Form 2138 is prescribed for use to order supplies or services, including task orders for construction or A–E services, as specified in 836.7001(b).

§ 853.236–72 VA Form 10101, Contractor Production Report.

VA Form 10101 is prescribed for use by contractors to submit required information to the resident engineer, as specified in 836.7001(c).

[FR Doc. 2021–20921 Filed 9–30–21; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

48 CFR Parts 852 and 871

RIN 2900–AQ76

VA Acquisition Regulation: Loan Guaranty and Vocational Rehabilitation and Employment Programs

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: The Department of Veterans Affairs (VA) is amending and updating its VA Acquisition Regulation (VAAR) in phased increments to revise or remove any policy superseded by changes in the Federal Acquisition Regulation (FAR), to remove procedural guidance internal to VA into the VA Acquisition Manual (VAAM), and to incorporate any new agency specific regulations or policies. This rulemaking revises VAAR coverage concerning Loan Guaranty and Vocational Rehabilitation and Employment Programs, as well as an affected part concerning Solicitation Provisions and Contract Clauses.

DATES: This rule is effective on November 1, 2021.

FOR FURTHER INFORMATION CONTACT: Mr. Rafael N. Taylor, Senior Procurement Analyst, Procurement Policy and Warrant Management Services, 003A2A, 425 I Street NW, Washington, DC 20001, (202) 382–2787. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION:

Background

On June 30, 2020, VA published a proposed rule in the **Federal Register** (85 FR 39151) which announced VA's intent to amend regulations for VAAR Case RIN 2900–AQ76 (parts 852 and 871). VA provided a 60-day comment period for the public to respond to the proposed rule and submit comments. The comment period for the proposed rule ended on August 31, 2020, and VA received no comments. This rule adopts as a final rule, with two technical non-substantive changes to the proposed rule published in the **Federal Register** on June 30, 2020.

These changes seek to align the VAAR with the FAR and remove outdated and duplicative requirements and reduce burden on contractors. The VAAM incorporates portions of the removed VAAR as well as other internal agency acquisition policy. VA will rewrite certain parts of the VAAR and VAAM, and as VAAR parts are rewritten, will publish them in the **Federal Register**.

Technical Non-Substantive Changes to the Proposed Rule

VA is removing proposed section 871.209, Records and reports. VA has determined this section is unnecessary and no information collection requirements are required under subpart 871.2. Any records and reports requirements related to Veterans training are captured under other existing Veterans Benefits Administration policy and information collection requirements unrelated to this text or are covered by standard record keeping requirements and retention periods as set forth in FAR subpart 4.7. Accordingly, VA has renumbered the remaining proposed sections to 871.209, Prohibition on advertising—training of Veterans (from 871.209), and 871.210, Contract clauses (from 871.211), a result of this removal.

VA has updated the Table of Contents in subpart 817.2 to reflect the above removals and renumbering.

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, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). E.O. 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. The Office of Information and Regulatory Affairs has determined that this rule is not a significant regulatory action under Executive Order 12866. The Regulatory Impact Analysis associated with this rulemaking can be found as a supporting document at *www.regulations.gov.*

Paperwork Reduction Act

This final rule contains no provisions constituting a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521) that require approval by the Office of Management and Budget (OMB).

Regulatory Flexibility Act

The Secretary hereby certifies that this final rule would not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act (5 U.S.C. 601–612). This rulemaking does not change VA's policy regarding small businesses, does not have an economic impact to individual businesses, and there are no increased or decreased costs to small business entities. On this basis, the final rule would not have an economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. Therefore, pursuant to 5 U.S.C. 605(b), the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604 as they do not apply.

Unfunded Mandates

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

Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this rule as not a major rule, as defined by 5 U.S.C. 804(2).

List of Subjects

48 CFR Part 852

Government procurement, Reporting and recordkeeping requirements.

48 CFR Part 871

Government procurement, Vocational rehabilitation and employment.

Signing Authority

Denis McDonough, Secretary of Veterans Affairs, approved this document on August 24, 2021, and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs.

Luvenia Potts,

Regulations Development Coordinator, Office of Regulation Policy & Management, Office of General Counsel, Department of Veterans Affairs.

For the reasons set out in the preamble, VA amends 48 CFR parts 852 and 871 as follows:

PART 852—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 1. The authority citation for part 852 continues to read as follows:

Authority: 38 U.S.C. 8127–8128, and 8151–8153; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3), 41 U.S.C. 1303; 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

■ 2. Revise sections 852.271–72, 852.271–73, and 852.271–74 to read as follows:

852.271–72 Time Spent by Counselee in Counseling Process.

As prescribed in 871.211, insert the following clause:

Time Spent by Counselee in Counseling Process (Nov 2021)

The Contractor agrees that no counselee referred under the provisions of this agreement will be required to participate or engage in additional sessions or expend any extra time in connection with the counseling process, to supply test results or other information, for purposes other than those specified in this contract.

(End of clause)

852.271–73 Use and Publication of Counseling Results.

As prescribed in 871.211, insert the following clause:

Use and Publication of Counseling Results (Nov 2021)

The Contractor agrees that none of the information or data gathered in connection with the services specified in this contract, or studies or materials based thereon or relating thereto, will be publicized without the prior approval of the Under Secretary for Benefits or his/her designee.

(End of clause)

852.271–74 Inspection of Instruction, Counseling or Testing Operations.

As prescribed in 871.211, insert the following clause:

Inspection of Instruction, Counseling or Testing Operations (Nov 2021)

The Contractor shall permit the duly authorized representative of the Department of Veterans Affairs to visit the place of instruction or the counseling and testing operations as may be necessary and to examine the training facilities, the work of the Veterans in training under this contract, and the records of these operations, along with any other rights to examine records and conduct inspections in accordance with the Federal Acquisition Regulation and clauses contained in the contract or order.

(End of clause)

852.271–75 [Removed and Reserved]

■ 3. Remove and reserve section 852.271–75.

■ 4. Part 871 is revised to read as follows:

PART 871—VOCATIONAL REHABILITATION AND EMPLOYMENT PROGRAMS

Subpart 871.1 [Reserved]

Subpart 871.2—Vocational Rehabilitation and Employment Service

871.200 Scope of subpart.

871.201 General.

871.201–1 Requirements for the use of contracts.

871.205 Proration of charges.

871.206 Other fees and charges.

871.207 Payment of tuition or fees.

871.208 Rehabilitation facilities.

871.209 Prohibition on advertising—training of Veterans.

871.210 Contract clauses.

Authority: 38 U.S.C. chapter 31; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

Subpart 871.1—[Reserved]

Subpart 871.2—Vocational Rehabilitation and Employment Service

871.200 Scope of subpart.

This subpart establishes policy and procedures for the vocational rehabilitation and employment services as it pertains to the following:

(a) Contracts for training and rehabilitation services.

(b) Approval of institutions (including rehabilitation facilities), training establishments, and employers under 38 U.S.C. chapter 31.

(c) Contracts for counseling services under 38 U.S.C. chapters 30, 31, 32, 35, and 36.

871.201 General.

871.201–1 Requirements for the use of contracts.

The costs for tuition, fees, books, supplies, and other expenses are

allowable under a contract with an institution, training establishment, or employer for the training and rehabilitation of eligible Veterans under 38 U.S.C. chapter 31, provided the services meet the conditions in the following definitions:

(a) *Courses of instruction by correspondence* means a course of education or training conducted by mail consisting of regular lessons or reading assignments, the preparation of required written work that involves the application of principles studied in each lesson, the correction of assigned work with such suggestions or recommendation as may be necessary to instruct the student, the keeping of student achievement records, and issuance of a diploma, certificate, or other evidence to the student upon satisfactorily completing the requirements of the course.

(b) *Special services or special courses* means those services or courses that VA requests that are supplementary to those the institution customarily provides for similarly circumstanced non-Veteran students and that the contracting officer considers to be necessary for the rehabilitation of the trainee.

871.205 Proration of charges.

A contract must include the exact formula agreed on for the proration of charges in the event that the Veteran's program is interrupted or discontinued before the end of the term, semester, quarter, or other period, or the program is completed in less time than stated in the contract.

871.206 Other fees and charges.

VA may pay fees and other charges that are not prescribed by law but are required by nongovernmental organizations, such as initiation fees required to become a member of a labor union and the dues necessary to maintain membership incidental to training on the job or to obtaining employment during a period in which the Veteran is a participant pursuant to 38 U.S.C. chapter 31, provided there are no facilities feasibly available where the necessary training can be feasibly accomplished or employment obtained without paying such charges. Payment for such fees must be made in accordance with part 813.

871.207 Payment of tuition or fees.

(a) Contracts, agreements, or arrangements requiring the payment of tuition or fees must provide either of the following:

(1) Payment for tuition or fees must be made in arrears and must be prorated in installments over the school year or the length of the course.

(2) An institution may be paid in accordance with paragraph (b) of this section, if the institution operates on a regular term, quarter, or semester basis and normally accepts students only at the beginning of the term, quarter, or semester and if the institution is one of the following:

(i) An institution of higher learning that uses a standard unit of credit recognized by accrediting associations. Such institutions include those that are members of recognized national or regional educational accrediting associations, and those that, although not members of such accrediting associations, grant standard units of credit acceptable at full value without examination by collegiate institutions that are members of national or regional accrediting associations.

(ii) A public tax-supported institution.

(iii) An institution operated and controlled by a State, county, or local board of education.

(b) An institution that meets the exceptions of paragraph (a)(2) of this section and that has a refund policy providing for a graduated scale of charges for purposes of determining refunds may be paid part or all such tuitions or fees for a term, quarter, or other period of enrollment immediately following the date on which the refund expires.

(c) Proration of charges does not apply to a fee for noncontinuing service, such as a registration fee, etc.

(d) The period for which payment of charges may be made is the period of actual enrollment and is subject to the following:

(1) The effective date is the date of the trainee's entrance into training status, except that payment may be made for an entire semester, quarter, or term in institutions operating on that basis if the trainee enters no later than the final date set by the institution for enrolling for full credit.

(2) In those cases where the institution has not set a final date for enrolling for full credit or does not set a date acceptable to VA, payment may be prorated on the basis of attendance, regardless of the refund policy.

(3) If an institution customarily charges for the amount of credit or number of hours of attendance for which a trainee enrolls, payment may be made on that basis when a trainee enrolls after the final date permitted for carrying full credit for the semester or term.

871.208 Rehabilitation facilities.

Charges by rehabilitation facilities for the rehabilitation services provided under 38 U.S.C. chapter 31 are paid in the same manner as charges for educational and vocational services through contract, agreement, or other arrangement.

871.209 Prohibition on advertising—training of Veterans.

The training of persons under a VA contract or the fact that the United States is using the facilities of the institution for training Veterans must not be used in any way to advertise the institution. References in the advertising media or correspondence of the institution shall be limited to a list of courses under 38 U.S.C. chapter 31 and must not be directed or pointed specifically to Veterans.

871.210 Contract clauses.

(a) Contracting officers must use the following clauses, as appropriate, in solicitations and contracts for vocational rehabilitation and employment services as they pertain to training and rehabilitation services and contracts for counseling services:

(1) 852.271–72, Time Spent by Counselee in Counseling Process.

(2) 852.271–73, Use and Publication of Counseling Results.

(3) 852.271–74, Inspection of Instruction, Counseling or Testing Operations.

(b) See 837.110–70(a) for clause 852.237–74, Non-Discrimination in Service Delivery.

[FR Doc. 2021–20891 Filed 9–30–21; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

[Docket No. 210505–0101; RTID 0648–XB377]

Fisheries Off West Coast States; Modification of the West Coast Salmon Fisheries; Inseason Action #26 Through #30

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Inseason modification of 2021 management measures.

SUMMARY: NMFS announces five inseason actions in the 2021 ocean salmon fisheries. These inseason actions

modified the recreational and commercial ocean salmon fishery in the area from the U.S./Canada border to Cape Falcon, OR.

DATES: The effective dates for the inseason actions are set out in this document under the heading Inseason Actions and remains in effect until superseded or modified.

FOR FURTHER INFORMATION CONTACT: Shannon Penna at 562–676–2148, email: *shannon.penna@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The 2021 annual management measures for ocean salmon fisheries (86 FR 26425, May 14, 2021), announced management measures for the commercial and recreational fisheries in the area from the U.S./Canada border to the U.S./Mexico border, effective from 0001 hours Pacific Daylight Time (PDT), May 16, 2021, until the effective date of the 2022 management measures, as published in the **Federal Register**. NMFS is authorized to implement inseason management actions to modify fishing seasons and quotas as necessary to provide fishing opportunity while meeting management objectives for the affected species (50 CFR 660.409). Inseason actions in the salmon fishery may be taken directly by NMFS (50 CFR 660.409(a)—Fixed inseason management provisions) or upon consultation with the Chairman of the Pacific Fishery Management Council (Council) and the appropriate State Directors (50 CFR 660.409(b)—Flexible inseason management provisions).

Management of the salmon fisheries is divided into two geographic areas: North of Cape Falcon (NOF) (U.S./Canada border to Cape Falcon, OR) and south of Cape Falcon (Cape Falcon, OR, to the U.S./Mexico border). The actions described in this document affected the NOF recreational salmon fishery, as set out under the heading Inseason Action.

Consultation on these inseason actions occurred on August 20, 2021, August 26, 2021, and September 2, 2021. Representatives from NMFS, Washington Department of Fish and Wildlife (WDFW), Oregon Department of Fish and Wildlife (ODFW), and Council staff participated in the consultations.

These inseason actions were announced on NMFS' telephone hotline and U.S. Coast Guard radio broadcast on the date of the consultations (50 CFR 660.411(a)(2)).

Inseason Action

Inseason Action #26

Description of the action: Inseason action #26 modified the bag limit in the NOF recreational salmon fishery Queets River to Leadbetter Point (Westport subarea), from a two salmon per day bag limit, no more than one of which may be a Chinook salmon, to a two salmon per day bag limit, beginning at 12:01 a.m. on Friday, August 21, 2021.

Effective date: Inseason action #26 took effect on August 21, 2021, and remains in effect until superseded.

Reason and authorization for the action: The 2021 management measures opened the recreational ocean salmon fishery in the Westport subarea with a bag limit of two salmon per day, no more than one of which may be a Chinook salmon (86 FR 26425, May 14, 2021). Modifying the bag limit to two salmon is consistent with preseason planning and management objectives and provisions of the Pacific Coast Salmon Fishery management Plan (FMP) because the measure would provide greater fishing opportunity for the public to access the available coho quota and Chinook salmon guideline, provide economic benefit to the fishery dependent communities, and was not expected to result in reducing season length or to exceed the recreational quotas.

The NMFS West Coast Region Regional Administrator (RA) considered the landings of Chinook and coho salmon in the NOF recreational salmon fishery, fishery effort that had occurred as well as effort anticipated under the proposal, and the recreational Chinook salmon guideline and coho quotas remaining. The RA determined that inseason action #26 was necessary to meet preseason planning and management objectives to allow access to available salmon quota and support the economy of fishery dependent communities while remaining consistent with the applicable salmon management and conservation objectives. The modification of recreational fishing bag limits is authorized by 50 CFR 660.409(b)(1)(iii).

Consultation date and participants: Consultation on inseason action #26 occurred on August 20, 2021. Representatives from NMFS, WDFW, ODFW, and the Council participated in this consultation.

Inseason Action #27

Description of the action: Inseason action #27 closed the NOF recreational salmon fishery from Leadbetter Point, WA to Cape Falcon, OR (Columbia River subarea) due to anticipated attainment of the quota and guideline.

Effective date: Inseason action #27 took effect at 12:01 a.m., August 30, 2021, and remains in effect until superseded.

Reason and authorization for the action: The purpose of inseason action #27 was to avoid exceeding the subarea quota for coho salmon and the guideline for Chinook salmon in the Columbia River subarea recreational salmon fishery. The NMFS West Coast Region RA considered the landings of coho and Chinook salmon in the NOF recreational salmon fishery to date, fishery catch and effort to date as well as anticipated under the proposal, and the recreational coho salmon quota and Chinook salmon guideline remaining in the Columbia River subarea. The recreational ocean salmon fishery in the Columbia River subarea opened June 19, 2021, with a coho salmon quota of 42,400 and a Chinook salmon guideline of 7,200. Through August 22, 34,800 coho salmon (80 percent of the subarea quota) and 5,547 Chinook salmon (77 percent of the subarea guideline) were caught in the Columbia River subarea. Projected catch in the Columbia River subarea for the week of August 23 to August 29 was 8,027 coho salmon and 973 Chinook salmon, which would result in a cumulative catch of 99 percent of the subarea coho salmon quota and 91 percent of the subarea Chinook salmon guideline. The RA determined that inseason action #27 was necessary to avoid exceeding the subarea quota and guideline set preseason. The modification of recreational fishing season is authorized by 50 CFR 660.409(b)(1)(i).

Consultation date and participants: Consultation on inseason action #27 occurred on August 26, 2021. Representatives from NMFS, WDFW, and ODFW participated in this consultation.

Inseason Action #28

Description of the action: Inseason action #28 closed the NOF recreational salmon fishery from Cape Alava to Queets River (La Push subarea) due to anticipated attainment of the coho salmon quota.

Effective date: Inseason action #28 took effect at 12:01 a.m., September 4, 2021, and remains in effect until superseded.

Reason and authorization for the action: The purpose of inseason action #28 was to avoid exceeding the subarea quota for coho salmon in the La Push subarea recreational salmon fishery. The NMFS West Coast Region RA considered the landings of coho salmon

in the NOF recreational salmon fishery to date, catch and fishery effort to date as well as anticipated under the proposal, and the recreational coho salmon quota remaining in the La Push subarea. The recreational ocean salmon fishery in the La Push subarea opened June 19, 2021, with a coho salmon quota of 1,430. Through August 29, 2021, 1,152 coho salmon were caught in the La Push subarea (81 percent of the subarea quota). Projected catch through September 3, 2021 in the La Push subarea was 1,334 coho salmon, which would result in a cumulative catch of 93 percent of the subarea coho salmon quota. The RA determined that inseason action #28 was necessary to avoid exceeding the subarea quota set preseason. The modification of recreational fishing season is authorized by 50 CFR 660.409(b)(1)(i).

Consultation date and participants: Consultation on inseason action #28 occurred on September 2, 2021. Representatives from NMFS, WDFW, ODFW, and Council staff participated in this consultation.

Inseason Action #29

Description of the action: Inseason action #29 closed the NOF recreational salmon fishery from Queets River to Leadbetter Point (Westport subarea) due to anticipated attainment of the coho salmon quota.

Effective date: Inseason action #29 took effect at 12:01 a.m., September 8, 2021, and remains in effect until superseded.

Reason and authorization for the action: The purpose of inseason action #29 was to avoid exceeding the subarea quota for coho salmon in the Westport subarea recreational salmon fishery. The NMFS West Coast Region RA considered the landings of coho salmon in the NOF recreational salmon fishery to date, catch and fishery effort to date as well as anticipated under the proposal, and the recreational coho salmon quota remaining in the Westport subarea. The recreational ocean salmon fishery in the Westport subarea opened June 19, 2021, with a coho salmon quota of 20,440. Through August 29, 2021, 13,942 coho salmon (68 percent of the subarea quota) were caught in the Westport subarea. Projected catch through September 7, 2021 in the Westport subarea was 20,113 coho salmon, which would result in a cumulative catch of 98 percent of the subarea coho salmon quota. The RA determined that inseason action #29 was necessary to avoid exceeding the subarea quota set preseason. The modification of recreational fishing season is authorized by 50 CFR 660.409(b)(1)(i).

Consultation date and participants: Consultation on inseason action #29 occurred on September 2, 2021. Representatives from NMFS, WDFW, ODFW, and Council staff participated in this consultation.

Inseason Action #30

Description of the action: Inseason action #30 for the commercial salmon troll fishery from the U.S./Canada border to Cape Falcon, OR, modified the landing and possession limit from 20 marked coho salmon per vessel per landing week (Thursday–Wednesday) to 50 marked coho salmon per vessel per landing week (Thursday–Wednesday).

Effective date: Inseason action #30 took effect at 12:01 a.m. on September 3, 2021, and remains in effect until superseded.

Reason and authorization for the action: The purpose of inseason action #30 was to allow greater access to the coho salmon quota in the commercial salmon troll fishery and result in increased fishing interest and the quota being met prior to the scheduled season ending date of September 30, 2021. The RA considered the landed catch of coho and Chinook salmon to date and the amount of quota and guideline remaining, projected catch under the proposal, and the timing of the action relative to the length of the season, and determined that inseason action #30 was necessary to meet management goals set preseason including fully attaining the coho quota. The modification of recreational fishing season is authorized by 50 CFR 660.409(b)(1)(ii).

Consultation date and participants: Consultation on inseason action #30 occurred on September 2, 2021. Representatives from NMFS, WDFW, ODFW, and Council staff participated in this consultation.

All other restrictions and regulations remain in effect as announced for the 2021 ocean salmon fisheries (86 FR 26425, May 14, 2021), as modified by previous inseason action (86 FR 34161, June 29, 2021; 86 FR 37249, July 15, 2021; 86 FR 40182, July 28, 2021; 86 FR 43967, August 11, 2021; 86 FR 48343, August 30, 2021).

The NMFS West Coast Region RA determined that these inseason actions were warranted based on the best available information on Pacific salmon abundance forecasts, landings to date, and anticipated fishery effort and projected catch. The states manage the fisheries in state waters adjacent to the areas of the U.S. exclusive economic zone (3–200 nautical miles (5.6–370.4 kilometers) off the coasts of the states of Washington, Oregon, and California) consistent with these Federal actions. As provided by the inseason notice procedures at 50 CFR 660.411, actual notice of the described regulatory action was given, prior to the time the action was effective, by telephone hotline numbers 206–526–6667 and 800–662–9825, and by U.S. Coast Guard Notice to Mariners broadcasts on Channel 16 VHF–FM and 2182 kHz.

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Fishery Conservation and Management Act. This action is authorized by 50 CFR 660.409, which was issued pursuant to section 304(b), and is exempt from review under Executive Order 12866.

Pursuant to 5 U.S.C. 553(b)(3)(B), there is good cause to waive prior notice and an opportunity for public comment on this action, as notice and comment would be impracticable and contrary to the public interest. Prior notice and opportunity for public comment on this action was impracticable because NMFS had insufficient time to provide for prior notice and the opportunity for public comment between the time Chinook and coho salmon abundance, catch, and effort information was developed and fisheries impacts were calculated, and the time the fishery modifications had to be implemented in order to ensure that fisheries are managed based on the best scientific information available. As previously noted, actual notice of the regulatory action was provided to fishers through telephone hotline and radio notification. This action complies with the requirements of the annual management measures for ocean salmon fisheries (86 FR 26425, May 14, 2021), the FMP, and regulations implementing the FMP under 50 CFR 660.409 and 660.411.

There is good cause under 5 U.S.C. 553(d)(3) to waive the 30-day delay in effective date, as a delay in effectiveness of this action would restrict fishing at levels inconsistent with the goals of the FMP and the current management measures.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: September 28, 2021.

Jennifer M. Wallace,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2021–21390 Filed 9–30–21; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 86, No. 188
Friday, October 1, 2021

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

NUCLEAR REGULATORY COMMISSION

10 CFR Part 72

[NRC–2021–0135]

RIN 3150–AK68

List of Approved Spent Fuel Storage Casks: Holtec International HI–STAR 100 Cask System, Certificate of Compliance No. 1008, Renewal of Initial Certificate and Amendment Nos. 1, 2, and 3

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend its spent fuel storage regulations by revising the Holtec International HI–STAR 100 Cask System listing within the ''List of approved spent fuel storage casks'' to renew, for an additional 40 years, the initial certificate and Amendment Nos. 1, 2, and 3 of Certificate of Compliance No. 1008. The renewal of the initial certificate and Amendment Nos. 1, 2, and 3 revises the certificate of compliance's conditions and technical specifications to address aging management activities related to the structures, systems, and components of the dry storage system to ensure that these will maintain their intended functions during the period of extended storage operations.

DATES: Submit comments by November 1, 2021. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date.

ADDRESSES: Submit your comments, identified by Docket ID NRC–2021–0135, at *https://www.regulations.gov.* If your material cannot be submitted using *https://www.regulations.gov,* call or email the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

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: Kristina Banovac, Office of Nuclear Material Safety and Safeguards; telephone: 301–415–7116, email: *Kristina.Banovac@nrc.gov* and Vanessa Cox, Office of Nuclear Material Safety and Safeguards, telephone: 301–415–8342, email: *Vanessa.Cox@nrc.gov.* Both are staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

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I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2021–0135 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 *https://www.regulations.gov* and search for Docket ID NRC–2021–0135. Address questions about NRC dockets to Dawn Forder, telephone: 301–415–3407, email: *Dawn.Forder@nrc.gov.* For technical questions contact the individuals 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 *https://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.* For the convenience of the reader, instructions about obtaining materials referenced in this document are provided in the ''Availability of Documents'' section.
- *Attention:* The PDR, where you may examine and order copies of public documents, is currently closed. You may submit your request to the PDR via email at *pdr.resource@nrc.gov* or call 1–800–397–4209 between 8:00 a.m. and 4:00 p.m. (EST), Monday through Friday, except Federal holidays.

B. Submitting Comments

Please include Docket ID NRC–2021–0135 in your comment submission. The NRC requests that you submit comments through the Federal rulemaking website at *https://www.regulations.gov.* If your material cannot be submitted using *https://www.regulations.gov,* call or email the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

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 *https://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. Rulemaking Procedure

Because the NRC considers this action to be non-controversial, the NRC is publishing this proposed rule concurrently with a direct final rule in the Rules and Regulations section of this issue of the **Federal Register**. The direct final rule will become effective on December 15, 2021. However, if the NRC receives any significant adverse comment by November 1, 2021, then the NRC will publish a document that withdraws the direct final rule. If the direct final rule is withdrawn, the NRC will address the comments in a subsequent final rule. Absent significant modifications to the proposed revisions requiring republication, the NRC will

not initiate a second comment period on this action in the event the direct final rule is withdrawn.

A significant adverse comment is a comment where the commenter explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. A comment is adverse and significant if:

(1) The comment opposes the rule and provides a reason sufficient to require a substantive response in a notice-and-comment process. For example, a substantive response is required when:

(a) The comment causes the NRC to reevaluate (or reconsider) its position or conduct additional analysis;

(b) The comment raises an issue serious enough to warrant a substantive response to clarify or complete the record; or

(c) The comment raises a relevant issue that was not previously addressed or considered by the NRC.

(2) The comment proposes a change or an addition to the rule, and it is apparent that the rule would be ineffective or unacceptable without incorporation of the change or addition.

(3) The comment causes the NRC to make a change (other than editorial) to the rule.

For a more detailed discussion of the proposed rule changes and associated analyses, see the direct final rule published in the Rules and Regulations section of this issue of the **Federal Register**.

III. Background

Section 218(a) of the Nuclear Waste Policy Act of 1982, as amended, requires that ''[t]he Secretary [of the Department of Energy] shall establish a demonstration program, in cooperation with the private sector, for the dry storage of spent nuclear fuel at civilian nuclear power reactor sites, with the objective of establishing one or more technologies that the [Nuclear Regulatory] Commission may, by rule, approve for use at the sites of civilian nuclear power reactors without, to the maximum extent practicable, the need for additional site-specific approvals by the Commission.'' Section 133 of the Nuclear Waste Policy Act states, in part, that ''[t]he Commission shall, by rule, establish procedures for the licensing of any technology approved by the Commission under Section 219(a) [sic: 218(a)] for use at the site of any civilian nuclear power reactor.''

To implement this mandate, the Commission approved dry storage of spent nuclear fuel in NRC-approved casks under a general license by publishing a final rule that added a new subpart K in part 72 of title 10 of the *Code of Federal Regulations* (10 CFR) entitled ''General License for Storage of Spent Fuel at Power Reactor Sites'' (55 FR 29181; July 18, 1990). This rule also established a new subpart L in 10 CFR part 72 entitled ''Approval of Spent Fuel Storage Casks,'' which contains procedures and criteria for obtaining NRC approval of spent fuel storage cask designs. The NRC subsequently issued a final rule on September 3, 1999 (64 FR 48259) that approved the HI–STAR 100 Cask System design and added it to the list of NRC-approved cask designs in § 72.214 as Certificate of Compliance No. 1008.

IV. Plain Writing

The Plain Writing Act of 2010 (Pub. L. 111–274) requires Federal agencies to write documents in a clear, concise, well-organized manner. The NRC has written this document to be consistent with the Plain Writing Act as well as the Presidential Memorandum, ''Plain Language in Government Writing,'' published June 10, 1998 (63 FR 31885). The NRC requests comment on the proposed rule with respect to clarity and effectiveness of the language used.

V. Availability of Documents

The documents identified in the following table are available to interested persons as indicated.]

Document	ADAMS accession No.
Holtec International HI–STAR 100 Storage System, Certificate of Compliance No. 1008 Renewal Application, dated December 7, 2018.	ML18345A178 (package).
Holtec International Response to the Request for Supplemental Information on the Renewal of the HI–STAR 100 Storage System, Certificate of Compliance No. 1008, dated June 28, 2019.	ML19184A232 (package).
Holtec International Submittal of Supplemental Information Related to Request for Supplemental Information on the Renewal of the HI–STAR 100 Storage System, Certificate of Compliance No. 1008, dated October 10, 2019.	ML19288A089 (package).
Holtec International HI–STAR 100 Storage System, Certificate of Compliance No. 1008 Renewal, Updated Non-Proprietary Documents, dated December 12, 2019.	ML19350A576.
Holtec International Response to the Request for Additional Information on the Renewal of the HI-STAR 100 Storage System, Certificate of Compliance No. 1008, dated June 1, 2020.	ML20153A768 (package).
Holtec International Response to the Request for Additional Information on the Renewal of the HI–STAR 100 Storage System, Certificate of Compliance No. 1008, dated June 11, 2020.	ML20163A713 (package).
Holtec International Response to the Request for Clarification of Additional Information on the Renewal of the HI–STAR 100 Storage System, Certificate of Compliance No. 1008, dated November 13, 2020.	ML20318A321 (package).
Holtec International Response to the Request for Clarification of Additional Information on the Renewal of the HI–STAR 100 Storage System, Certificate of Compliance No. 1008, Updated Attachment, dated November 24, 2020.	ML20329A321 (package).
User Need Memorandum for Rulemaking for Certificate of Compliance No. 1008 Renewal, Initial Issue, Amendment Numbers 1, 2, and 3 to HI–STAR 100 Cask System, dated June 28, 2021.	ML21168A352.
Proposed Certificate of Compliance No. 1008, Renewed Amendment No. 0	ML21168A353.
Proposed Technical Specifications (Appendix A) for Certificate of Compliance No. 1008, Renewed Amendment No. 0.	ML21168A354.
Proposed Technical Specifications (Appendix B) for Certificate of Compliance No. 1008, Renewed Amendment No. 0.	ML21168A355.
Proposed Certificate of Compliance No. 1008, Renewed Amendment No. 1	ML21168A356.
Proposed Technical Specifications (Appendix A) for Certificate of Compliance No. 1008, Renewed Amendment No. 1.	ML21168A357.
Proposed Technical Specifications (Appendix B) for Certificate of Compliance No. 1008, Renewed Amendment No. 1.	ML21168A358.
Proposed Certificate of Compliance No. 1008, Renewed Amendment No. 2	ML21168A359.
Proposed Technical Specifications (Appendix A) for Certificate of Compliance No. 1008, Renewed Amendment No. 2.	ML21168A360.
Proposed Technical Specifications (Appendix B) for Certificate of Compliance No. 1008, Renewed Amendment No. 2.	ML21168A361.

Document	ADAMS accession No.
Proposed Certificate of Compliance No. 1008, Renewed Amendment No. 3	ML21168A362.
Proposed Technical Specifications (Appendix A) for Certificate of Compliance No. 1008, Renewed Amendment No. 3.	ML21168A363.
Proposed Technical Specifications (Appendix B) for Certificate of Compliance No. 1008, Renewed Amendment No. 3.	ML21168A364.
Preliminary Safety Evaluation Report for Renewed Certificate of Compliance No. 1008, Amendment Nos. 0, 1, 2, and 3.	ML21168A365.

The NRC may post materials related to this document, including public comments, on the Federal rulemaking website at *https://www.regulations.gov* under Docket ID NRC–2021–0135.

Dated: September 15, 2021.

For the Nuclear Regulatory Commission.

Margaret M. Doane,

Executive Director for Operations.

[FR Doc. 2021–21428 Filed 9–30–21; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF ENERGY

10 CFR Parts 429 and 431

[EERE–2021–BT–TP–0021]

Energy Conservation Program: Test Procedures for Fans and Blowers

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Request for information.

SUMMARY: The U.S. Department of Energy (''DOE'') is undertaking the preliminary stages of a rulemaking to consider potential test procedures for fans and blowers, including air circulating fan heads. Through this request for information (''RFI''), DOE seeks data and information regarding issues pertinent to whether new test procedures would accurately and fully comply with the requirement that a test procedure measures energy use during a representative average use cycle for the equipment without being unduly burdensome to conduct. DOE welcomes written comments from the public on any subject within the scope of this document (including topics not raised in this RFI), as well as the submission of data and other relevant information.

DATES: Written comments and information are requested and will be accepted on or before November 1, 2021.

ADDRESSES: Interested persons are encouraged to submit comments using the Federal eRulemaking Portal at *www.regulations.gov.* Follow the instructions for submitting comments. Alternatively, interested persons may submit comments, identified by docket number EERE–2021–BT–TP–0021, by any of the following methods:

1. *Federal eRulemaking Portal: www.regulations.gov.* Follow the instructions for submitting comments.

2. *Email:* to *FansBlowers2021TP0021@ee.doe.gov.* Include docket number EERE–2021–BT–TP–0021 in the subject line of the message.

No telefacsimiles (''faxes'') will be accepted. For detailed instructions on submitting comments and additional information on this process, see section III of this document.

Although DOE has routinely accepted public comment submissions through a variety of mechanisms, including the Federal eRulemaking Portal, email, postal mail, or hand delivery/courier, the Department has found it necessary to make temporary modifications to the comment submission process in light of the ongoing Covid–19 pandemic. DOE is currently suspending receipt of public comments via postal mail and hand delivery/courier. If a commenter finds that this change poses an undue hardship, please contact Appliance Standards Program staff at (202) 586–1445 to discuss the need for alternative arrangements. Once the Covid-19 pandemic health emergency is resolved, DOE anticipates resuming all of its regular options for public comment submission, including postal mail and hand delivery/courier.

Docket: The docket for this activity, which includes **Federal Register** notices, comments, and other supporting documents/materials, is available for review at *www.regulations.gov.* All documents in the docket are listed in the *www.regulations.gov* index. However, some documents listed in the index, such as those containing information that is exempt from public disclosure, may not be publicly available.

The docket web page can be found at: *www1.eere.energy.gov/buildings/appliance_standards/product.aspx/productid/65.* The docket web page contains instructions on how to access all documents, including public comments, in the docket. See section III for information on how to submit comments through *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT:

Mr. Jeremy Dommu, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, EE–5B, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 586–9870. Email: *ApplianceStandardsQuestions@ee.doe.gov.*

Ms. Amelia Whiting, U.S. Department of Energy, Office of the General Counsel, GC–33, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 586–2588. Email: *amelia.whiting@hq.doe.gov.*

For further information on how to submit a comment or review other public comments and the docket, contact the Appliance and Equipment Standards Program staff at (202) 287–1445 or by email: *ApplianceStandardsQuestions@ee.doe.gov.*

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3. Sampling
III. Submission of Comments

I. Introduction

On August 19, 2021, DOE published a final determination that fans and blowers are covered equipment for the purpose of the ''Energy Conservation Program for Certain Industrial Equipment'' under the Energy Policy and Conservation Act, as amended (''EPCA''),[1] (42 U.S.C. 6311–6317 as codified). 86 FR 46579. There are currently no DOE test procedures for fans and blowers, including air circulating fan heads. The following

[1] All references to EPCA in this document refer to the statute as amended through the Energy Act of 2020, Public Law 116–260 (Dec. 27, 2020).

sections discuss DOE's authority to establish test procedures for fans and blowers, including air circulating fan heads (''ACFHs''), as well as relevant background information regarding DOE's consideration of potential test procedures for this equipment.

A. Authority and Background

EPCA authorizes DOE to regulate the energy efficiency of a number of consumer products and certain industrial equipment. (42 U.S.C. 6291–6317) Title III, Part C [2] of EPCA, added by Public Law 95–619, Title IV, section 441(a) (42 U.S.C. 6311–6317, as codified), established the Energy Conservation Program for Certain Industrial Equipment, which sets forth a variety of provisions designed to improve energy efficiency of certain commercial and industrial equipment (hereafter referred to as ''covered equipment''). The purpose of Part A–1 is to improve the efficiency of electric motors and pumps and certain other industrial equipment in order to conserve the energy resources of the Nation. (42 U.S.C. 6312(a))

EPCA specifies a list of equipment that constitutes covered equipment.[3] EPCA also provides that ''covered equipment'' includes any other type of industrial equipment for which the Secretary of Energy (''Secretary'') determines inclusion is necessary to carry out the purpose of Part A–1. (42 U.S.C. 6311(1)(L); 42 U.S.C. 6312(b)) EPCA specifies the types of equipment that can be classified as industrial equipment. (42 U.S.C. 6311(2)(B). This equipment includes fans and blowers. (42 U.S.C. 6311(2)(B)(ii) and (iii)). Industrial equipment must be of a type that consumes, or is designed to consume, energy in operation; is distributed in commerce for industrial or commercial use [4]; and is not a covered product as defined in 42 U.S.C. 6291(a)(2) of EPCA other than a component of a covered product with respect to which there is in effect a determination under section 6312(c). (42 U.S.C. 6311(2)(A)).

On August 19, 2021, DOE determined that the inclusion of fans and blowers as covered equipment was necessary to carry out the purpose of Part A–1 and classified fans and blowers as covered equipment. 86 FR 46579.

The energy conservation program under EPCA consists essentially of four parts: (1) Testing, (2) labeling, (3) Federal energy conservation standards, and (4) certification and enforcement procedures. Relevant provisions of EPCA include definitions (42 U.S.C. 6311), test procedures (42 U.S.C. 6314), labeling provisions (42 U.S.C. 6315), energy conservation standards (42 U.S.C. 6313), and the authority to require information and reports from manufacturers (42 U.S.C. 6316).

Federal energy efficiency requirements for covered equipment established under EPCA generally supersede State laws and regulations concerning energy conservation testing, labeling, and standards. (42 U.S.C. 6316(a) and (b); 42 U.S.C. 6297). DOE may, however, grant waivers of Federal preemption for particular State laws or regulations, in accordance with the procedures and other provisions of EPCA. (42 U.S.C. 6316(b)(2)(D)).

The Federal testing requirements consist of test procedures that manufacturers of covered equipment must use as the basis for: (1) Certifying to DOE that their equipment complies with the applicable energy conservation standards adopted pursuant to EPCA (42 U.S.C. 6316(a); 42 U.S.C. 6295(s)), and (2) making representations about the efficiency of that equipment (42 U.S.C. 6314(d)). Similarly, DOE must use these test procedures to determine whether the equipment complies with relevant standards promulgated under EPCA.[5] (42 U.S.C. 6316(a); 42 U.S.C. 6295(s))

Under 42 U.S.C. 6314, EPCA sets forth the criteria and procedures DOE must follow when prescribing or amending test procedures for covered equipment. EPCA requires that any test procedures prescribed or amended under this section must be reasonably designed to produce test results which reflect energy efficiency, energy use or estimated annual operating cost of a given type of covered equipment during a representative average use cycle and requires that test procedures not be unduly burdensome to conduct. (42 U.S.C. 6314(a)(2))

Before prescribing any final test procedures under this section, the Secretary must publish proposed test procedures in the **Federal Register**, and afford interested persons an opportunity (of not less than 45 days' duration) to present oral and written data, views, and arguments on the proposed test procedures. (42 U.S.C. 6314(b))

B. Rulemaking History

As noted, on August 19, 2021, DOE published in the **Federal Register** a final coverage determination classifying fans and blowers as covered equipment (''August 2021 Final Coverage Determination''). 86 FR 46579. DOE established that the term ''blower'' is interchangeable with the term ''fan''. 86 FR 46579, 46583. DOE also defined a fan or blower as ''a rotary bladed machine used to convert electrical or mechanical power to air power, with an energy output limited to 25 kilojoule (kJ)/kilogram (kg) of air. It consists of an impeller, a shaft and bearings and/or driver to support the impeller, as well as a structure or housing. A fan or blower may include a transmission, driver, and/or motor controller.'' 86 FR 46579, 46590; *See* 10 CFR 431.172. Further, DOE determined that fans and blowers are industrial equipment as specified by EPCA and classified fans and blowers as covered equipment.[6] The definition of ''industrial equipment'' explicitly excludes covered products, other than a component of a covered product. (42 U.S.C. 6311(2)(A)(iii)). Therefore, the definition of ''fan and blower'' does not apply to ceiling fans or furnace fans, both covered products defined at 10 CFR 430.2. 86 FR 46579, 46584–46585.

To date DOE has not proposed test procedures or energy conservation standards for fans and blowers. Prior to the August 2021 Final Coverage Determination, on January 10, 2020, DOE received a petition from AMCA, Air Conditioning Contractors of America, and Sheet Metal & Air Conditioning Contractors of America (''the Petitioners'') requesting that DOE establish test procedures for certain categories of commercial and industrial fans based on an upcoming industry test method, AMCA 214.[7] DOE published a

[2] For editorial reasons, upon codification in the U.S. Code, Part C was redesignated Part A–1 and hereafter referred to as Part A–1.

[3] ''Covered equipment'' means one of the following types of industrial equipment: Electric motors and pumps; small commercial package air conditioning and heating equipment; large commercial package air conditioning and heating equipment; very large commercial package air conditioning and heating equipment; commercial refrigerators, freezers, and refrigerator-freezers; automatic commercial ice makers; walk-in coolers and walk-in freezers; commercial clothes washers; packaged terminal air-conditioners and packaged terminal heat pumps; warm air furnaces and packaged boilers; and storage water heaters, instantaneous water heaters, and unfired hot water storage tanks. (42 U.S.C. 6311(1)(A)–(K))

[4] DOE notes that distribution for residential use does not preclude coverage as covered equipment so long as the equipment is of a type that is also distributed in commerce for industrial and commercial use.

[5] There are currently no energy conservation standards for fans and blowers.

[6] ''Industrial equipment'' is any article of specifically listed equipment that is of a type, which (1) in operation consumes, or is designed to consume, energy; (2) to any significant extent, is distributed in commerce for industrial or commercial use; (3) is not a ''covered product,'' and (4) for which the Secretary has determined coverage is necessary to carry out the purpose of Part A–1. (42 U.S.C. 6311(2)(A); 42 U.S.C. 6312(b))

[7] At the time of the petition, AMCA 214–21 was available as a draft version (AMCA 214).

notice of petition and request for public comment (''April 2020 Notice of Petition''). 85 FR 22677, 22677–22678 (April 23, 2020).

To date, DOE has not proposed test procedures or energy conservation standards for fans and blowers, including ACFHs. DOE has identified a number of issues specific to potential test procedures for ACFHs that may benefit from public input.

II. Request for Information

In the following sections, DOE has identified a variety of issues on which it seeks input to determine whether, and if so how, potential test procedures for fans and blowers, including ACFHs, would (1) comply with the requirements in EPCA that test procedures be reasonably designed to produce test results which reflect energy use during a representative average use cycle, and (2) not be unduly burdensome to conduct (42 U.S.C. 6314(a)(2)). Additionally, DOE welcomes comments on any aspect related to the potential test procedures for fans and blowers, including ACFHs that may not specifically be identified in this document.

A. Fans and Blowers

Although EPCA lists fans and blowers as types of industrial equipment, these terms are not defined. (*See* 42 U.S.C. 6311(2)(B)(ii) and (B)(iii)) As noted, DOE has established a definition for ''fans''.[8] As industrial equipment, this equipment excludes ceiling fans and furnace fans, both covered products defined at 10 CFR 430.2. (See 10 CFR 431.171) In the August 2021 Notice of Final Coverage Determination, DOE determined that the definition appropriately covered fans and blowers that are industrial equipment as specified by EPCA. 86 FR 46579, 46585. DOE is publishing this RFI to provide for additional public comment on issues specific to potential test procedures for fans and blowers, including air circulating fan heads, following the final coverage determination *i.e.,* the August 2021 Notice of Final Coverage Determination.

B. Scope and Definitions for ACFHs

1. Definition

ACFHs that are the subject of this RFI are designed to provide concentrated directional airflow and consist of a motor, impeller and guard for mounting on a pedestal, wall mount bracket, ceiling mount bracket, I-beam bracket or other mounting means. ACFHs are different from ceiling fans, which are designed to circulate air rather than provide concentrated directional airflow. As a result, ACFHs have lower diameter-to-maximum operating speed ratio (expressed in inches per revolutions per minute (''in/RPM'')) than ceiling fans.

As previously noted, fans and blowers are defined at 10 CFR 431.172. DOE does not currently define air circulating fans heads. The American National Standards Institute (''ANSI'')/Air Movement and Control Association International, Inc. (''AMCA'') Standard 230–15, ''Laboratory Methods of Testing Air Circulating Fans for Rating and Certification'' (''AMCA 230–15'')[9] is the industry test procedure for air circulating fans, which include ACFHs.[10] Section 5.1 of AMCA 230–15 defines an ''air circulating fan'' as ''a non-ducted fan used for the general circulation of air within a confined space''. It further classifies ACFHs as a category of air circulating fans and is defined in Section 5.1.1 of AMCA 230–15 as follows: ''an assembly consisting of a motor, impeller and guard for mounting on a pedestal having a base and column, wall mount bracket, ceiling mount bracket, I-beam bracket or other commonly accepted mounting means.''

ANSI/AMCA Standard 214–21, ''Test Procedure for Calculating Fan Energy Index for Commercial and Industrial Fans and Blowers'' (''AMCA 214–21'')[11] defines a ''circulating fan'' as ''a fan that is not a ceiling fan that is used to move air within a space that has no provision for connection to ducting or separation of the fan inlet from its outlet. The fan is designed to be used for the general circulation of air''. (*See* Section 3.15 of AMCA 214–21) AMCA 214–21 does not define ACFHs.

DOE reviewed the existing definitions of ACFHs, air circulating fan, and circulating fan, and marketing material for this equipment,[12] and determined that certain ACFHs are designed for use in commercial and industrial applications and meet the definition of fans and blowers as they are rotary bladed machines that convert electrical power to air power, have an energy output limited to 25 kJ/kg and consist of an impeller, a shaft and bearings and, as well as a structure or housing. When establishing the proposed definitions to support any potential test procedure for ACFHs, DOE will consider whether existing definitions in industry standards can be used. DOE is reviewing AMCA 214–21, and AMCA 230–15 and is interested in collecting additional information that would help in establishing definitions.

Issue 1: DOE seeks input and comments on the definition of air circulating fan and ACFH as specified in AMCA 230–15. If these definitions are not appropriate, DOE seeks input on how they should be amended and why. Specifically, DOE seeks feedback on whether the definition of ACFH should also specify a maximum value of diameter-to-maximum operating speed ratio (*e.g.,* 0.06 in/RPM) to distinguish ACFHs from ceiling fans.

Issue 2: DOE requests comments on whether it should consider limiting the definition of ACFHs based on the fan's electrical input power, or any other characteristic that would allow identifying ACFHs that are to any significant extent distributed in commerce for industrial or commercial use. DOE seeks information to support any recommendation to limit the definition of ACFHs based on fan electrical input power or any other characteristics.

Issue 3: DOE requests comments on whether it should consider test procedures for additional categories of air circulating fans other than ACFHs, specifically, personnel coolers, box fans, or table fans that meet the definition of ''fan and blower''.

2. Scope

When establishing the proposed scope of any potential test procedure, DOE

[8] ''A fan (or blower) means a rotary bladed machine used to convert electrical or mechanical power to air power, with an energy output limited to 25 kilojoule (kJ) per kilogram (kg) of air. It consists of an impeller, a shaft and bearings and/or driver to support the impeller, as well as a structure or housing. A fan (or blower) may include a transmission, driver, and/or motor controller.'' (10 CFR 431.172)

[9] AMCA 230–15 was approved by ANSI on October 16, 2015.

[10] In addition to ACFHs, AMCA 230–15 defines four other categories of air circulating fans: (1) Ceiling fans (the subject of a separate DOE rulemaking as discussed in this document); (2) personnel coolers (''a fan used in shops, factories, etc. Generally supplied with wheels or casters on the housing or frame to aid in portability, and with motor and impeller enclosed in a common guard and shroud''); (3) box fans (''a fan used in an office or residential application and having the motor and impeller enclosed in an approximately square box frame having a handle''); and (4) table fans (''a fan intended for use on a desk, table or countertop. The fan may also be provided with the means for mounting to a wall''). *See* Sections 5.1.2 through 5.1.5 of AMCA 230–15.

[11] AMCA 214–21 was approved by ANSI on March 1, 2021.

[12] See for example: *www.industrialfansdirect.com/collections/air-circulator-fans/air-circulator-fan-heads-and-mounts; www.grainger.com/category/hvac-and-refrigeration/cooling-fans/industrial-cooling-fans/industrial-fan-heads.*

may consider whether to specify additional design characteristics (*e.g.,* fan impeller blade tip diameter) to identify ACFHs that would be in the scope of any potential test procedures.

Issue 4: DOE requests comments on whether it should consider limiting the scope of any potential test procedure for ACFHs based on the fan's impeller blade tip diameter, or any other physical design characteristic. DOE seeks information to support any potential exclusions from the scope of potential test procedures.

C. Test Procedure for ACFHs

As noted, there are currently no DOE test procedures for ACFHs.

1. Industry Standards

DOE's established practice is to adopt industry standards as DOE test procedures unless such methodology would be unduly burdensome to conduct or would not produce test results that reflect the energy efficiency, energy use, water use (as specified in EPCA) or estimated operating costs of that product during a representative average use cycle. 10 CFR 431.4; 10 CFR part 430 subpart C appendix A section 8(c). In cases where the industry standard does not meet EPCA statutory criteria for test procedures, DOE will make modifications through the rulemaking process to these standards as the DOE test procedure.

AMCA 214–21 provides methods to establish the fan electrical input power (''FEP'') in kilowatts (''kW'') and fan energy index [13] (''FEI'') for various categories of fans, either by: (1) The measurement of the electrical input power to the fan (*i.e.,* a ''wire-to-air'' test); or by (2) the measurement of the fan shaft power and the application of calculation algorithms to reflect additional motor, transmission, or control energy use. AMCA 214–21 references AMCA 230–15 [14] as the industry test procedure to follow when conducting performance measurements on air circulating fans, including ACFHs.

Issue 5: DOE seeks feedback on whether AMCA 214–21 and AMCA 230–15 would be appropriate for adoption in a potential Federal test procedure for ACFHs. If using AMCA 214–21 and AMCA 230–15 is not appropriate, DOE seeks input on how AMCA 214–21 and AMCA 230–15 should be amended and why, and on any other industry test standard that would be more appropriate.

Issue 6: DOE seeks information and data to assist in evaluating the repeatability and reproducibility of AMCA 214–21 and AMCA 230–15 as applied to ACFHs. DOE seeks input on whether any changes to AMCA 214–21 and AMCA 230–15 are needed to increase its repeatability and reproducibility.

Issue 7: DOE seeks information on whether changes to AMCA 214–21 and AMCA 230–15 are needed to allow for representative energy efficiency ratings for ACFHs, and whether such changes would increase test burden.

2. Metric

AMCA 214–21 provides uniform methods to determine the FEP and FEI of a fan at a given duty point.[15] As explained, FEP describes the electrical input power of a fan in kilowatts. AMCA 214–21 defines FEI as the ratio of the electrical input power of a reference fan to the electrical input power of the actual fan for which the FEI is calculated, both established at the same duty point. FEI is a dimensionless index designed to facilitate the evaluation of a fan's performance against a reference fan. Section 5 of AMCA 214–21 provides the equations necessary to calculate the reference fan electrical input power as a function of airflow and pressure.

AMCA 230–15 provides methods to determine the FEP of air circulating fans (including ACFHs) as well as efficacy (*i.e.,* amount of flow per unit of electrical input power produced in cubic feet per minute per watt (''cfm/W'')) and overall efficiency (*i.e.,* amount of thrust per unit of electrical input power produced in pound-force per watt (''lbf/W'')).

DOE is reviewing the metrics in AMCA 214–21 and AMCA 230–15 and is interested in collecting additional information that would help evaluate use of these metrics in a Federal test procedure.

Issue 8: DOE requests comment on whether the FEP metric (obtained in accordance with AMCA 214–21) is appropriate for adoption in the Federal test procedure for ACFHs, and on whether any changes are necessary to allow for more representative energy efficiency ratings, and whether these changes would increase test burden. If the metrics on AMCA 214–21 are not appropriate, DOE seeks input on how the metrics should be amended and why, and on any other metrics that would be more appropriate. Specifically, DOE requests comment on whether it should consider other performance metrics as measured by AMCA 230–15, such as efficacy and overall efficiency.

3. Sampling

DOE provides sampling provisions for determining represented values of energy use or efficiency of a covered product or equipment. *See generally* 10 CFR part 429 and 10 CFR part 431. These sampling provisions provide uniform statistical methods that require testing a sample of units that is large enough to account for reasonable manufacturing variability among individual units of a basic model, or variability in the test methodology, such that the test results for the overall sample will be reasonably representative of the efficiency of that basic model.

The basic model concept allows manufacturers to group like models for the purpose of DOE's certification requirements, thereby reducing the burden placed on manufacturers by streamlining the amount of testing they must do to rate the energy use or efficiency of their product. DOE's current regulations provide equipment-specific basic model definitions, which typically state that models within the same basic model group have ''essentially identical'' energy or water use characteristics.[16]

The general sampling requirement currently applicable to all covered products and equipment provides that a sample of sufficient size must be randomly selected and tested and that, unless otherwise specified, a minimum of two units must be tested to certify a basic model. 10 CFR 429.11. This minimum is implicit in the requirement to calculate a mean—an average—which requires at least two values. Manufacturers can increase their sample size to narrow the margin of error.

Issue 9: DOE seeks information on whether the statistical sampling plans used for other commercial and industrial equipment at 10 CFR part 429

[13] The FEI of a fan at a given operating point is a dimensionless index defined as the FEP (kW) of a theoretical reference fan described in Section 5 of AMCA 214–21, divided by the actual FEP (kW) of the fan at the same operating point as described in Section 6 of AMCA 241–21. *See* section 4 of AMCA 214–21.

[14] AMCA 230–15 provides methods for conducting laboratory tests to determine the performance characteristics of circulating fans including the FEP in Watts (''W''), speed in RPM, pressure in inch of mercury, airflow in cfm, thrust in pound force (lbf), efficacy in cfm/W, and overall efficiency in lbf/W.

[15] A duty point is characterized by a given airflow and pressure and has a corresponding operating speed. AMCA 214 provides methods to establish the FEP and FEI at any duty point within the operating range of the fan.

[16] *See* 10 CFR 431.12, 431.62, 431.82, 431.102, 431.132, 431.152, 431.202, 431.222, 431.242, 431.262, 431.292, 431.302, 431.322, 431.442, and 431.462.

would be appropriate for ACFHs. If not, DOE requests information and data to explain why not, and what changes would be appropriate.

III. Submission of Comments

DOE invites all interested parties to submit in writing by the date specified under the **DATES** heading, comments and information on matters addressed in this RFI and on other matters relevant to DOE's consideration of amended test procedures for fans and blowers. These comments and information will aid in the development of a test procedure NOPR for fans and blowers if DOE determines that test procedures may be appropriate for this equipment.

Submitting comments via www.regulations.gov. The *www.regulations.gov* web page will require you to provide your name and contact information. Your contact information will be viewable to DOE Building Technologies staff only. Your contact information will not be publicly viewable except for your first and last names, organization name (if any), and submitter representative name (if any). If your comment is not processed properly because of technical difficulties, DOE will use this information to contact you. If DOE cannot read your comment due to technical difficulties and cannot contact you for clarification, DOE may not be able to consider your comment.

However, your contact information will be publicly viewable if you include it in the comment or in any documents attached to your comment. Any information that you do not want to be publicly viewable should not be included in your comment, nor in any document attached to your comment. Following this instruction, persons viewing comments will see only first and last names, organization names, correspondence containing comments, and any documents submitted with the comments.

Do not submit to *www.regulations.gov* information for which disclosure is restricted by statute, such as trade secrets and commercial or financial information (hereinafter referred to as Confidential Business Information (''CBI'')). Comments submitted through *www.regulations.gov* cannot be claimed as CBI. Comments received through the website will waive any CBI claims for the information submitted. For information on submitting CBI, see the Confidential Business Information section.

DOE processes submissions made through *www.regulations.gov* before posting. Normally, comments will be posted within a few days of being submitted. However, if large volumes of comments are being processed simultaneously, your comment may not be viewable for up to several weeks. Please keep the comment tracking number that *www.regulations.gov* provides after you have successfully uploaded your comment.

Submitting comments via email. Comments and documents submitted via email also will be posted to *www.regulations.gov.* If you do not want your personal contact information to be publicly viewable, do not include it in your comment or any accompanying documents. Instead, provide your contact information on a cover letter. Include your first and last names, email address, telephone number, and optional mailing address. The cover letter will not be publicly viewable as long as it does not include any comments.

Include contact information each time you submit comments, data, documents, and other information to DOE. Faxes will not be accepted.

Comments, data, and other information submitted to DOE electronically should be provided in PDF (preferred), Microsoft Word or Excel, WordPerfect, or text (ASCII) file format. Provide documents that are not secured, written in English and free of any defects or viruses. Documents should not contain special characters or any form of encryption and, if possible, they should carry the electronic signature of the author.

Campaign form letters. Please submit campaign form letters by the originating organization in batches of between 50 to 500 form letters per PDF or as one form letter with a list of supporters' names compiled into one or more PDFs. This reduces comment processing and posting time.

Confidential Business Information. According to 10 CFR 1004.11, any person submitting information that he or she believes to be confidential and exempt by law from public disclosure should submit via email two well-marked copies: One copy of the document marked confidential including all the information believed to be confidential, and one copy of the document marked ''non-confidential'' with the information believed to be confidential deleted. DOE will make its own determination about the confidential status of the information and treat it according to its determination.

It is DOE's policy that all comments may be included in the public docket, without change and as received, including any personal information provided in the comments (except information deemed to be exempt from public disclosure).

DOE considers public participation to be a very important part of the process for developing test procedures and energy conservation standards. DOE actively encourages the participation and interaction of the public during the comment period in each stage of this process. Interactions with and between members of the public provide a balanced discussion of the issues and assist DOE in the process. Anyone who wishes to be added to the DOE mailing list to receive future notices and information about this process should contact Appliance and Equipment Standards Program staff at (202) 287–1445 or via email at *ApplianceStandardsQuestions@ee.doe.gov.*

Signing Authority

This document of the Department of Energy was signed on September 27, 2021, by Kelly Speakes-Backman, Principal Deputy Assistant Secretary and Acting Assistant Secretary for Energy Efficiency and Renewable Energy, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on September 28, 2021.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

[FR Doc. 2021–21387 Filed 9–30–21; 8:45 am]

BILLING CODE 6450–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MB Docket No. 21–125; RM–11892; DA 21–1189; FR ID 50300]

Television Broadcasting Services Hazard, Kentucky

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: The Commission has before it a petition for rulemaking filed by Gray Television Licensee, LLC (Petitioner), the licensee of WYMT–TV (CBS), channel 12, Hazard, Kentucky. The Petitioner requests the substitution of channel 20 for channel 12 at in the DTV Table of Allotments.

DATES: Comments must be filed on or before November 1, 2021 and reply comments on or before November 15, 2021.

ADDRESSES: Federal Communications Commission, Office of the Secretary, 45 L Street NE, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve counsel for the Petitioner as follows: Joan Stewart, Esq., Wiley Rein LLP, 1776 K Street NW, Washington, DC 20006.

FOR FURTHER INFORMATION CONTACT: Joyce Bernstein, Media Bureau, at (202) 418–1647; or Joyce Bernstein, Media Bureau, at *Joyce.Bernstein@fcc.gov.*

SUPPLEMENTARY INFORMATION: In support, the Petitioner states the proposed channel substitution serves the public interest because it will resolve significant over-the-air reception problems in WYMT–TV's existing service area. The Petitioner further states that the Commission has recognized the deleterious effects manmade noise has on the reception of digital VHF signals, and that the propagation characteristics of these channels allow undesired signals and noise to be receivable at relatively farther distances compared to UHF channels and nearby electrical devices can cause interference. While the proposed channel 20 facility is predicted to result in loss of service to 15,460 persons, less than 100 persons will continue to receive service from five other television stations, and those persons will continue to receive service from four other television stations.

This is a synopsis of the Commission's *Notice of Proposed Rulemaking,* MB Docket No. 21–125; RM–11892; DA 21–1189, adopted September 21, 2021, and released September 22, 2021. The full text of this document is available for download at *https://www.fcc.gov/edocs.* To request materials in accessible formats (braille, large print, computer diskettes, or audio recordings), please send an email to *FCC504@fcc.gov* or call the Consumer and Governmental Affairs Bureau at (202) 418–0530 (VOICE), (202) 418–0432 (TTY).

This document does not contain information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104–13. In addition, therefore, it does not contain any proposed information collection burden ''for small business concerns with fewer than 25 employees,'' pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4). Provisions of the Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, do not apply to this proceeding.

Members of the public should note that all *ex parte* contacts are prohibited from the time a Notice of Proposed Rulemaking is issued to the time the matter is no longer subject to Commission consideration or court review, *see* 47 CFR 1.1208. There are, however, exceptions to this prohibition, which can be found in § 1.1204(a) of the Commission's rules, 47 CFR 1.1204(a).

See §§ 1.415 and 1.420 of the Commission's rules for information regarding the proper filing procedures for comments, 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Television.

Federal Communications Commission.

Thomas Horan,

Chief of Staff, Media Bureau.

Proposed Rule

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR part 73 as follows:

PART 73—RADIO BROADCAST SERVICE

■ 1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 155, 301, 303, 307, 309, 310, 334, 336, 339.

§ 73.622 [Amended]

■ 2. In § 73.622 in paragraph (i), amend the Post-Transition Table of DTV Allotments under Kentucky by revising the entry for Hazard to read as follows:

§ 73.622 Digital television table of allotments.

* * * * *

(i) * * *

Community	Channel No.
* * * * *	
KENTUCKY	
* * * * *	
Hazard	* 16, 20.
* * * * *	

[FR Doc. 2021–21336 Filed 9–30–21; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MB Docket No. 21–126; RM–11893; DA 21–1190; FR ID 50305]

Television Broadcasting Services Monroe, Louisiana

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: The Commission has before it a petition for rulemaking filed by Gray Television Licensee, LLC (Petitioner), the licensee of KNOE (CBS), channel 8, Monroe, Louisiana. The Petitioner requests the substitution of channel 24 for channel 8 at in the DTV Table of Allotments.

DATES: Comments must be filed on or before November 1, 2021 and reply comments on or before November 15, 2021.

ADDRESSES: Federal Communications Commission, Office of the Secretary, 45 L Street NE, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve counsel for the Petitioner as follows: Joan Stewart, Esq., Wiley Rein LLP, 1776 K Street NW, Washington, DC 20006.

FOR FURTHER INFORMATION CONTACT: Joyce Bernstein, Media Bureau, at (202) 418–1647; or Joyce Bernstein, Media Bureau, at *Joyce.Bernstein@fcc.gov.*

SUPPLEMENTARY INFORMATION: In support, the Petitioner states the proposed channel substitution serves the public interest because it will resolve significant over-the-air reception problems in KNOE's existing service area. The Petitioner further states that the Commission has recognized the deleterious effects manmade noise has on the reception of digital VHF signals, and that the propagation characteristics of these channels allow undesired signals and noise to be receivable at relatively farther distances compared to UHF channels and nearby electrical devices can cause interference. Finally, the Petitioner states that the proposed channel 24 noise limited contour extends beyond the current channel 8 noise limited contour, and thus, no existing viewers will lose service and an additional 12,868 persons would gain service if the channel substitution is granted.

This is a synopsis of the Commission's *Notice of Proposed Rulemaking,* MB Docket No. 21–126; RM–11893; DA 21–1190, adopted September 21, 2021, and released

September 22, 2021. The full text of this document is available for download at *https://www.fcc.gov/edocs.* To request materials in accessible formats (braille, large print, computer diskettes, or audio recordings), please send an email to *FCC504@fcc.gov* or call the Consumer and Governmental Affairs Bureau at (202) 418–0530 (VOICE), (202) 418–0432 (TTY).

This document does not contain information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104–13. In addition, therefore, it does not contain any proposed information collection burden ''for small business concerns with fewer than 25 employees,'' pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4). Provisions of the Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, do not apply to this proceeding.

Members of the public should note that all *ex parte* contacts are prohibited from the time a Notice of Proposed Rulemaking is issued to the time the matter is no longer subject to Commission consideration or court review, *see* 47 CFR 1.1208. There are, however, exceptions to this prohibition, which can be found in § 1.1204(a) of the Commission's rules, 47 CFR 1.1204(a).

See §§ 1.415 and 1.420 of the Commission's rules for information regarding the proper filing procedures for comments, 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Television.

Federal Communications Commission.

Thomas Horan,

Chief of Staff, Media Bureau.

Proposed Rule

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR part 73 as follows:

PART 73—RADIO BROADCAST SERVICE

■ 1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 155, 301, 303, 307, 309, 310, 334, 336, 339.

§ 73.622 [Amended]

■ 2. In § 73.622 in paragraph (i), amend the Post-Transition Table of DTV Allotments under Louisiana by revising the entry for Monroe to read as follows:

§ 73.622 Digital television table of allotments.

* * * * *

(i) * * *

Community	Channel No.
* * * * *	
LOUISIANA	
* * * * *	
Monroe	*13, 24.
* * * * *	

[FR Doc. 2021–21339 Filed 9–30–21; 8:45 am]

BILLING CODE 6712–01–P

Notices

Federal Register
Vol. 86, No. 188
Friday, October 1, 2021

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

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[Document No. AMS–TM–21–0070]

Seafood Processors Pandemic Response and Safety Block Grant Program; Request for Emergency Approval of a New Information Collection

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice of emergency request.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the U.S. Department of Agriculture (USDA), Agricultural Marketing Service's (AMS) intention to receive approval from the Office of Management and Budget (OMB) for a new information collection to administer the Seafood Processors Pandemic Response and Safety (SPRS) Block Grant Program under its Grants Division. Due to the enactment of the Consolidated Appropriations Act, 2021 (CAA), AMS Grants Division is implementing this new grant program under Title VII, subtitle, B, section 751, which directs the Secretary of Agriculture to provide ''grants and loans to small or midsized food processors or distributors, seafood processing facilities and processing vessels, farmers markets, producers, or other organizations to respond to coronavirus, including for measures to protect workers against the Coronavirus Disease 2019 (COVID–19).''

DATES: Submit comments on or before November 30, 2021.

ADDRESSES: Interested persons are invited to submit comments concerning this notice by using the electronic process available at *www.regulations.gov.* Written comments may also be submitted to Grants Division; Transportation and Marketing Program; AMS; USDA; 1400 Independence Avenue SW, Room 2055–South Building, Stop 0201; Washington, DC 20250–0264. All comments should reference the docket number AMS–TM–21–0070, the date of submission, and the page number of this issue of the **Federal Register**. All comments received will be posted without change, including any personal information provided, at *www.regulations.gov;* will be included in the record; and made available to the public.

FOR FURTHER INFORMATION CONTACT: John Miklozek, Director, Grants Division; (202) 720–1403 or email *John.Miklozek@usda.gov.*

SUPPLEMENTARY INFORMATION:

Overview of This Information Collection

Agency: USDA, AMS.

Title: New Grant Program Information Request.

OMB Number: 0581–NEW.

Type of Request: Emergency Approval of a New Information Collection.

Abstract: The Agricultural Marketing Act of 1946 (AMA) (7 U.S.C. 1621 *et seq.*) directs and authorizes USDA to administer Federal grant programs. AMS Grant Programs are administered through the Office of Management and Budget (OMB) Guidance for Grants and Agreements based on its regulations under the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (2 CFR part 200) (85 FR 49506; December 13, 2020). Information collection requirements described in this emergency request are needed for AMS to administer a new competitive grant program, in accordance with 2 CFR part 200, entitled the Seafood Processors Pandemic Response and Safety (SPRS) Block Grant Program under OMB No. 0581–NEW.

SPRS is authorized pursuant to the authority of Title VII, subtitle B, section 751 of the Consolidated Appropriations Act, 2021 (CAA) (Pub. L. 116–260) in response to the ongoing COVID–19 pandemic and the need for worker protections in seafood processing. The AMS Grants Division requests to collect information for this new grant program from states, individuals, small businesses, and nonprofit organizations working in seafood processing.

Because this is a voluntary program, respondents request or apply for this specific competitive grant, and in doing so, they provide information. The information collected is used only by authorized representatives of USDA, AMS, Transportation and Marketing Program's Grants Division to certify that grant participants are complying with applicable program regulations. Data collected is the minimum information necessary to effectively carry out program requirements.

Information collection requirements in this request are essential to carry out the intent of section 751 of the CAA, to provide respondents the type of service they request, and to administer the program.

Upon OMB approval of the SPRS information collection package, AMS will request OMB approval to merge this information collection into the currently approved information collection OMB control number 0581–0240 approved on January 13, 2021.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 27 hours per response.

Respondents: Grant applicants; or grant recipients.

Estimated Number of Respondents: 25.

Estimated Total Annual Responses Including Recordkeeping: 485.

Estimated Number of Responses per Respondent: 19.

Estimated Total Annual Burden on Respondents and Recordkeepers: 1,025 hours.

Comments are invited on: (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 new 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 information collection on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Obtaining OMB's approval of this new information collection enables AMS Grants Division to publish a Request for Applications (RFA) to establish application requirements, the review

and approval process, and grant administration procedures. These procedures will enable eligible entities to develop appropriate grant applications for the program so that AMS can adequately evaluate these new proposals and obligate the funds as required by the CAA.

Erin Morris,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2021–21347 Filed 9–30–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[Document No. AMS–CP–21–0063]

Local Food Purchase Assistance Cooperative Agreement Program

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice of request for emergency approval of a new information collection.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (PRA), this notice announces the U.S. Department of Agriculture (USDA), Agricultural Marketing Service's (AMS) intention to seek approval from the Office of Management and Budget (OMB) for a new information collection to administer the Local Food Purchase Assistance Cooperative Agreement Program (LFPA). AMS is implementing this new cooperative agreement program under the American Rescue Plan Act, which directs the Secretary of Agriculture to enter into cooperative agreements with State, local, and tribal governments to purchase food from local and regional farmers/producers (within the state or within 400 miles) and from socially disadvantaged farmers/producers.

DATES: Submit comments on or November 30, 2021.

ADDRESSES: Interested persons are invited to submit comments concerning this notice by using the electronic process available at *www.regulations.gov.* Written comments may also be submitted to the Commodity Procurement Program; AMS; USDA; 1400 Independence Avenue SW, Room 2517–South Building, Stop 0239; Washington, DC 20250–0239. All comments should reference the docket number AMS–CP–21–0063, the date of publication, and the page number of this issue of the **Federal Register**. All comments received will be posted without change, including any personal information provided, at *www.regulations.gov* and will be included in the record and made available to the public.

FOR FURTHER INFORMATION CONTACT: Elizabeth Lober, Assistant to the Deputy Administrator, Commodity Procurement Program; (202) 313–1411 or email *Elizabeth.Lober@usda.gov.*

SUPPLEMENTARY INFORMATION:

Overview of This Information Collection

Agency: USDA, AMS.

Title: Local Food Purchase Assistance Cooperative Agreement Program (LFPA).

OMB Number: 0581–NEW.

Type of Request: Emergency Approval of a New Information Collection.

Abstract: The Agricultural Marketing Act of 1946 (7 U.S.C. 1621 *et seq.*), as amended, directs and authorizes USDA to administer Federal cooperative agreements programs. AMS cooperative agreement programs are administered according to OMB Guidance for Cooperative Agreements, which is based on OMB's regulations under the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (2 CFR part 200) (85 FR 49506; December 13, 2020). Information collection requirements in this emergency request are needed for AMS to administer a new noncompetitive cooperative agreement program, in accordance with Section 1001(b)(4) of the American Rescue Plan Act (Pub. L. 117–2) (Act). USDA will collect information for this new program to award cooperative agreements and provide other assistance to maintain and improve food and agriculture supply chain resiliency.

Since the LFPA is a voluntary program, respondents request or apply for this specific competitive cooperative agreement, and in doing so, they provide information. The information collected is used only by authorized representatives of USDA, AMS, Commodity Procurement Program to certify that cooperative agreement participants are complying with applicable program regulations, and the data collected is the minimum information necessary to effectively carry out program requirements.

Information collection requirements in this request are essential to carry out the intent of Act, to provide respondents the type of service they request and to administer the program.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 4 hours.

Respondents: Cooperative Agreement applicants; or Cooperative Agreement recipients.

Estimated Number of Respondents: 75.

Estimated Total Annual Responses Including Recordkeeping: 975.

Estimated Number of Responses per Respondent: 5.

Estimated Total Annual Burden on Respondents and Recordkeepers: 4,731.25 hours.

Comments are invited on: (1) Whether the proposed collection of information is necessary for the proper performance of agency functions, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the new collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Obtaining OMB's approval of this new information collection enables AMS to publish a Request for Applications (RFA) to establish application requirements, the review and approval process, and cooperative agreement administration procedures. This will enable eligible entities to develop appropriate cooperative agreement applications for the program so that AMS can adequately evaluate these new proposals and obligate the funds as required by the American Act.

Erin Morris,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2021–21356 Filed 9–30–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

September 28, 2021.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested regarding; whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; the accuracy of the

agency's estimate of burden including the validity of the methodology and assumptions used; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by November 1, 2021 will be considered. Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Animal and Plant Health Inspection Service

Title: Endangered Species Regulations and Forfeiture Procedures.

OMB Control Number: 0579–0076.

Summary of Collection: The Endangered Species Act of 1973 (16 U.S.C. 1513 *et seq.*) directs Federal departments to utilize their authorities under the Act to conserve endangered and threatened species. Section 3 of the Act specifies that the Secretary of Agriculture is authorized to promulgate such regulations as may be appropriate to enforce the Act. The regulations contained in 7 CFR 355 are intended to carry out the provisions of the Endangered Species Act. USDA's Animal and Plant Health Inspection Service (APHIS), Plant Protection and Quarantine (PPQ) program is responsible for implementing these regulations. To enforce the regulations, APHIS will collect information using several forms and activities.

Need and Use of the Information: APHIS will use the following information activities to conserve endangered and threatened species of terrestrial plants: Applications for protected plant permit form PPQ 621, appeals of denial of general permit, marking and notification requirements, notices of arrival form PPQ 368, notices of exportation, validation of documents, waivers of forfeiture procedures by owners of seized property form PPQ 623, claim form PPQ 625, requests for return of property, petitions for remission or mitigation of forfeiture, reports form PPQ 626, and reporting and recordkeeping. Without the collected information, APHIS would not be able to carry out its responsibilities under The Endangered Species Act, and the United States would not be able to fulfill its responsibilities as a signatory to the Convention on International Trade in Endangered Species (CITES) Treaty. The consequences of either would directly impact the protection of endangered plant species around the world.

Description of Respondents: Business or other for-profit.

Number of Respondents: 1,097.

Frequency of Responses: Recordkeeping; Reporting: On occasion.

Total Burden Hours: 15.433.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2021–21440 Filed 9–30–21; 8:45 am]

BILLING CODE 3410–24–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Connecticut Advisory Committee

AGENCY: Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission), and the Federal Advisory Committee Act (FACA), that the Connecticut Advisory Committee to the U.S. Commission on Civil Rights will hold a meeting via web conference or phone call on Monday, October 4, 2021, at 12:30 p.m. The purpose of the meeting is to review an advisory memorandum on voting rights.

DATES: October 4, 2021, Monday, at 12:30 p.m. (ET):

ADDRESSES:

- To join by web conference, use WebEx link: *https://bit.ly/39f0zA3;* password, if needed: USCCR–CT.
- To join by phone only, dial 1–800–360–9505; Access code: 2761 412 5147.

FOR FURTHER INFORMATION CONTACT: Barbara Delaviez at *ero@usccr.gov* or by phone at 202–539–8246.

SUPPLEMENTARY INFORMATION: This meeting is available to the public through the WebEx link above. If joining only via phone, callers can expect to incur charges for calls they initiate over wireless lines, and the Commission will not refund any incurred charges. Individuals who are deaf, deafblind and hard of hearing. may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with the call-in number found through registering at the web link provided for this meeting.

Members of the public are entitled to make comments during the open period at the end of the meeting. Members of the public may also submit written comments; the comments must be received in the Regional Programs Unit within 30 days following the meeting. Written comments may be emailed to Barbara de La Viez at *ero@usccr.gov.* Persons who desire additional information may contact the Regional Programs Unit at (202) 539–8246. Records and documents discussed during the meeting will be available for public viewing as they become available at *www.facadatabase.gov.* Persons interested in the work of this advisory committee are advised to go to the Commission's website, *www.usccr.gov,* or to contact the Regional Programs Unit at the above phone number or email address.

Agenda: Monday, October 4, 2021, at 12:30 p.m. (ET)

I. Welcome and Roll Call
II. Review and Vote on Advisory Memo on Voting Rights
III. Public Comment
IV. Next Steps
V. Adjournment

Dated: September 27, 2021.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2021–21360 Filed 9–30–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–533–866]

Cold-Rolled Steel Flat Products From India: Final Results of the Expedited Five-Year Sunset Review of the Countervailing Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: As a result of this sunset review, the Department of Commerce (Commerce) finds that revoking the countervailing duty (CVD) order on cold-rolled steel flat products (cold-rolled steel) from India would likely

lead to continuation or recurrence of countervailable subsidies at the levels indicated in the ''Final Results of Review'' section of this notice.

DATES: Applicable October 1, 2021.

FOR FURTHER INFORMATION CONTACT: Thomas Hanna, 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) 482–0835.

SUPPLEMENTARY INFORMATION:

Background

On September 20, 2016, Commerce published in the **Federal Register** the *Order.*[1] On June 1, 2021, the Department of Commerce (Commerce) published the notice of initiation of the sunset reviews of the *Order,* pursuant to section 751(c) of the Act.[2] On June 14 and 16, 2021, Commerce received a notice of intent to participate from Cleveland-Cliffs Inc. (Cleveland-Cliffs), United States Steel Corporation (U.S. Steel), California Steel Industries (California Steel), Steel Dynamics Inc. (Steel Dynamics), and Nucor Corporation (Nucor), within the deadline specified in 19 CFR 351.218(d)(1)(i).[3] Cleveland-Cliffs, U.S. Steel, California Steel, Steel Dynamics, and Nucor claimed interested party status under section 771(9)(C) of the Act, as domestic producers of cold-rolled steel flat products in the United States.

Commerce received a substantive response from Cleveland-Cliffs, U.S. Steel, California Steel, Steel Dynamics, and Nucor (collectively, domestic interested parties) within the 30-day deadline specified in 19 CFR 351.218(d)(3)(i).[4] We received no substantive response from any other domestic or respondent interested parties in this proceeding and no hearing was requested. On July 22, 2021, Commerce notified the U.S. International Trade Commission that it did not receive an adequate substantive response from respondent interested parties.[5] As a result, pursuant to section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(C)(2), Commerce conducted an expedited (120-day) sunset review of this CVD Order.

Scope of the Order

The products covered by this order are certain cold-rolled (cold-reduced), flat-rolled steel products, whether or not annealed, painted, varnished, or coated with plastics or other non-metallic substances.

Imports of the subject merchandise are provided for under Harmonized Tariff Schedule of the United States (HTSUS) categories: 7209.15.0000, 7209.16.0030, 7209.16.0060, 7209.16.0070, 7209.16.0091, 7209.17.0030, 7209.17.0060, 7209.17.0070, 7209.17.0091, 7209.18.1530, 7209.18.1560, 7209.18.2510, 7209.18.2520, 7209.18.2580, 7209.18.6020, 7209.18.6090, 7209.25.0000, 7209.26.0000, 7209.27.0000, 7209.28.0000, 7209.90.0000, 7210.70.3000, 7211.23.1500, 7211.23.2000, 7211.23.3000, 7211.23.4500, 7211.23.6030, 7211.23.6060, 7211.23.6090, 7211.29.2030, 7211.29.2090, 7211.29.4500, 7211.29.6030, 7211.29.6080, 7211.90.0000, 7212.40.1000, 7212.40.5000, 7225.50.6000, 7225.50.8080, 7225.99.0090, 7226.92.5000, 7226.92.7050, and 7226.92.8050. The products subject to the order may also enter under the following HTSUS numbers: 7210.90.9000, 7212.50.0000, 7215.10.0010, 7215.10.0080, 7215.50.0016, 7215.50.0018, 7215.50.0020, 7215.50.0061, 7215.50.0063, 7215.50.0065, 7215.50.0090, 7215.90.5000, 7217.10.1000, 7217.10.2000, 7217.10.3000, 7217.10.7000, 7217.90.1000, 7217.90.5030, 7217.90.5060, 7217.90.5090, 7225.19.0000, 7226.19.1000, 7226.19.9000, 7226.99.0180, 7228.50.5015, 7228.50.5040, 7228.50.5070, 7228.60.8000, and 7229.90.1000. While HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of the *Order* is dispositive.[6]

Analysis of Comments Received

All issues raised in this sunset review are addressed in the Issues and Decision Memorandum, which is hereby adopted by this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov.* A list of topics discussed in the Issues and Decision Memorandum is included as an appendix to this notice. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn.*

Final Results of Sunset Review

Pursuant to sections 751(c)(1) and 752(b) of the Act, Commerce determines that revocation of the *Order* would be likely to lead to continuation or recurrence of countervailable subsidies at the following rates:

Producer/exporter	Net countervailable subsidy (percent)
JSW Steel Limited and JSW Steel Coated Products Limited	10.00
All Others	10.00

Administrative Protective Order (APO)

This notice also serves as the only reminder to parties subject to an APO of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305. Timely notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

We are issuing and publishing the final results and this notice in accordance with sections 751(c), 752(b), and 777(i)(1) of the Act, and 19 CFR 351.218.

[1] *See Certain Cold-Rolled Steel Flat Products from Brazil, India, and the Republic of Korea: Amended Final Affirmative Countervailing Duty Determination and Countervailing Duty Order (the Republic of Korea) and Countervailing Duty Orders (Brazil and India),* 81 FR 64436 (September 20, 2016) (*Order*).

[2] *See Initiation of Five-Year (''Sunset'')* Review, 86 FR 29239 (June 1, 2021).

[3] *See* Cleveland-Cliffs' Letter, ''Five-Year (''Sunset'') Review Of Countervailing Duty Order On Cold-Rolled Steel Flat Products from India: Notice Of Intent To Participate In Sunset Review,'' dated June 14, 2021; U.S. Steel's Letter ''Five-Year (''Sunset'') Review of Antidumping and Countervailing Duty Orders on Cold-Rolled Steel Flat Products from India: Notice of Intent to Participate,'' dated June 16, 2021; California Steel's Letter ''Notice of Intent to Participate in the First Five-Year Review of the Countervailing Duty Order on Cold-Rolled Steel Flat Products from India,'' dated June 16, 2021; and Nucor's Letter ''Certain Cold-Rolled Steel Flat Products from India: Notice of Intent to Participate in Sunset Review,'' dated June 16, 2021.

[4] *See* Domestic Interested Parties' Letter, ''First Five-Year (''Sunset'') Review of Countervailing Duty Order on Cold-Rolled Steel Flat Products from India: Domestic Industry's Substantive Response to Notice of Initiation,'' dated July 1, 2021 (Domestic Interested Parties' Substantive Response).

[5] *See* Commerce's Letter, ''Sunset Reviews Initiated on June 1, 2021,'' dated June 1, 2021.

[6] For a full description of the scope of the order, *see* Memorandum, ''Issues and Decision Memorandum for the Expedited First Sunset Review of the Countervailing Duty Order on Cold-Rolled Steel Flat Products from India,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

Dated: September 29, 2021.

Christian Marsh,

Acting Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. History of the Order
IV. Scope of the Order
V. Legal Framework
VI. Discussion of the Issues
VII. Final Results of Sunset Review
VIII. Recommendation

[FR Doc. 2021–21443 Filed 9–30–21; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Initiation of Five-Year (Sunset) Reviews

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: In accordance with the Tariff Act of 1930, as amended (the Act), the Department of Commerce (Commerce) is automatically initiating the five-year reviews (Sunset Reviews) of the antidumping and countervailing duty (AD/CVD) order(s) and suspended investigation(s) listed below. The International Trade Commission (the ITC) is publishing concurrently with this notice its notice of *Institution of Five-Year Reviews* which covers the same order(s) and suspended investigation(s).

DATES: Applicable October 1, 2021.

FOR FURTHER INFORMATION CONTACT: Commerce official identified in the *Initiation of Review* section below at AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230. For information from the ITC, contact Mary Messer, Office of Investigations, U.S. International Trade Commission at (202) 205–3193.

SUPPLEMENTARY INFORMATION:

Background

Commerce's procedures for the conduct of Sunset Reviews are set forth in its *Procedures for Conducting Five-Year (Sunset) Reviews of Antidumping and Countervailing Duty Orders,* 63 FR 13516 (March 20, 1998) and 70 FR 62061 (October 28, 2005). Guidance on methodological or analytical issues relevant to Commerce's conduct of Sunset Reviews is set forth in *Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Duty Proceedings; Final Modification,* 77 FR 8101 (February 14, 2012).

Initiation of Review

In accordance with section 751(c) of the Act and 19 CFR 351.218(c), we are initiating the Sunset Reviews of the following antidumping and countervailing duty order(s) and suspended investigation(s):

DOC case No.	ITC case No.	Country	Product	Commerce contact
A–533–867	731–TA–1298	India	Welded Stainless Pressure Pipe (1st Review)	Mary Kolberg (202) 482–1785.
A–570–898	731–TA–1082	China	Chlorinated Isocyanurates (3rd Review)	Jacky Arrowsmith (202) 482–5255.
A–469–814	731–TA–1083	Spain	Chlorinated Isocyanurates (3rd Review)	Jacky Arrowsmith (202) 482–5255.
C–533–868	701–TA–548	India	Welded Stainless Pressure Pipe (1st Review)	Mary Kolberg (202) 482–1785.

Filing Information

As a courtesy, we are making information related to sunset proceedings, including copies of the pertinent statute and Commerce's regulations, Commerce's schedule for Sunset Reviews, a listing of past revocations and continuations, and current service lists, available to the public on Commerce's website at the following address: *https://enforcement.trade.gov/sunset/.* All submissions in these Sunset Reviews must be filed in accordance with Commerce's regulations regarding format, translation, and service of documents. These rules, including electronic filing requirements via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS), can be found at 19 CFR 351.303.

In accordance with section 782(b) of the Act, any party submitting factual information in an AD/CVD proceeding must certify to the accuracy and completeness of that information. Parties must use the certification formats provided in 19 CFR 351.303(g). Commerce intends to reject factual submissions if the submitting party does not comply with applicable revised certification requirements.

Letters of Appearance and Administrative Protective Orders

Pursuant to 19 CFR 351.103(d), Commerce will maintain and make available a public service list for these proceedings. Parties wishing to participate in any of these five-year reviews must file letters of appearance as discussed at 19 CFR 351.103(d). To facilitate the timely preparation of the public service list, it is requested that those seeking recognition as interested parties to a proceeding submit an entry of appearance within 10 days of the publication of the Notice of Initiation. Because deadlines in Sunset Reviews can be very short, we urge interested parties who want access to proprietary information under administrative protective order (APO) to file an APO application immediately following publication in the **Federal Register** of this notice of initiation. Commerce's regulations on submission of proprietary information and eligibility to receive access to business proprietary information under APO can be found at 19 CFR 351.304–306. Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information, until further notice.[1]

Information Required From Interested Parties

Domestic interested parties, as defined in section 771(9)(C), (D), (E), (F), and (G) of the Act and 19 CFR 351.102(b), wishing to participate in a Sunset Review must respond not later than 15 days after the date of publication in the **Federal Register** of this notice of initiation by filing a notice of intent to participate. The required contents of the notice of intent to participate are set forth at 19 CFR 351.218(d)(1)(ii). In accordance with Commerce's regulations, if we do not receive a notice of intent to participate from at least one domestic interested party by the 15-day deadline, Commerce

[1] *See Temporary Rule Modifying AD/CVD Service Requirements Due to* COVID–19, 85 FR 41363 (July 10, 2020).

will automatically revoke the order without further review.[2]

If we receive an order-specific notice of intent to participate from a domestic interested party, Commerce's regulations provide that *all parties* wishing to participate in a Sunset Review must file complete substantive responses not later than 30 days after the date of publication in the **Federal Register** of this notice of initiation. The required contents of a substantive response, on an order-specific basis, are set forth at 19 CFR 351.218(d)(3). Note that certain information requirements differ for respondent and domestic parties. Also, note that Commerce's information requirements are distinct from the ITC 's information requirements. Consult Commerce's regulations for information regarding Commerce's conduct of Sunset Reviews. Consult Commerce's regulations at 19 CFR part 351 for definitions of terms and for other general information concerning antidumping and countervailing duty proceedings at Commerce.

This notice of initiation is being published in accordance with section 751(c) of the Act and 19 CFR 351.218(c).

Dated: September 16, 2021.

James Maeder,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2021–21539 Filed 9–30–21; 8:45 am]

BILLING CODE 3510–DS–P

[2] *See* 19 CFR 351.218(d)(1)(iii).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–201–820]

Agreement Suspending the Antidumping Duty Investigation on Fresh Tomatoes From Mexico; Preliminary Results of 2019–2020 Administrative Review

AGENCY: Enforcement & Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that the respondents selected for individual examination, Bioparques De Occidente, S.A. de C.V. and its affiliates (Bioparques), Del Campo Y Asociados SA de CV and its affiliates (Del Campo), and Productora Agricola Industrial del Noroeste, SA de CV (Productora Agricola) and its affiliates (collectively Grupo Pinos), are in compliance with the Agreement Suspending the Antidumping Duty Investigation on Fresh Tomatoes from Mexico (2019 Agreement), for the period September 19, 2019, through August 31, 2020, and that the 2019 Agreement is meeting the statutory requirements under the Tariff Act of 1930, as amended (the Act).

DATES: Applicable October 1, 2021.

FOR FURTHER INFORMATION CONTACT: Sally C. Gannon or David Cordell, Enforcement & Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, telephone: (202) 482–0162 or (202) 482–0408, respectively.

SUPPLEMENTARY INFORMATION:

Background

On September 19, 2019, Commerce signed an agreement [1] under section 734(c) of the Tariff Act of 1930, as amended (the Act), with representatives of Mexican fresh tomato producers/exporters [2] accounting for substantially all imports of fresh tomatoes from Mexico, suspending the antidumping duty (AD) investigation on fresh tomatoes from Mexico.[3]

On September 25, 2020, the Florida Tomato Exchange (FTE),[4] a member of the U.S. petitioning industry, filed a request for an administrative review of the 2019 Agreement.[5] On September 30, 2020, Bioparques and Negocio Agricola San Enrique S.A. de C.V. (NASE) also requested reviews.[6]

The review of the 2019 Agreement was initiated on October 30, 2020.[7] Commerce inadvertently identified the period of review (POR) as September 1, 2019, through August 31, 2020, but corrected the POR on January 7, 2021, to reflect the period from September 19, 2019 to August 31, 2020.[8] On January 7, 2021, Commerce selected mandatory respondents and issued its questionnaire to the three largest respondents, listed here in alphabetical order: Bioparques, Del Campo, and Productora Agricola.[9]

Scope of the 2019 Agreement

Merchandise covered by the 2019 Agreement is typically imported under the following heading of the HTSUS: Tomatoes imported from Mexico covered by this Agreement are classified under the following subheading of the Harmonized Tariff Schedules of the United States (HTSUS), according to the season of importation: 0702. The tariff classification is provided for convenience and customs purposes; however, the written description of the scope of this 2019 Agreement is dispositive.[10]

Methodology and Preliminary Results

Commerce has conducted this review in accordance with section 751(a)(1)(C) of the Act, which specifies that Commerce shall ''review the current status of, and compliance with, any agreement by reason of which an

[1] *See Fresh Tomatoes From Mexico: Suspension of Antidumping Duty Investigation,* 84 FR 49987 (September 24, 2019) (*2019 Agreement*).

[2] The Mexican signatories are predominately represented by the following associations: Asociacion Mexicana de Horticultura Protegida, A.C., Asociacion de Productores de Hortalizas del Yaqui y Mayo, Confederacion de Asociaciones Agricolas del Estado de Sinaloa, A.C., Consejo Agricola de Baja California, A.C., and Sistema Producto Tomate.

[3] *Id.*

[4] The members of the FTE are as follows: Ag-Mart Produce, Inc. dba Santa Sweets, Inc., Classie Produce, DiMare Homestead, Inc., DiMare Ruskin, Inc., Gargiulo, Inc., Kern Carpenter Farms, Lipman Family Farms, Mecca Family Farms, Inc., Michael Borek Farms, Pacific Tomato Growers, Ltd., Taylor & Fulton Packing, LLC, Tomatoes of Ruskin, Inc., TomPak, LLC, and West Coast Tomato, LLC.

[5] *See* Letter from FTE, ''Fresh Tomatoes from Mexico: Request for Administrative Review,'' dated September 25, 2020.

[6] *See* Letter from Bioparques and Letter from NASE, both entitled ''Suspension Agreement on Fresh Tomatoes from Mexico—Request for Administrative Review,'' each dated September 30, 2020. Bioparques and NASE explained they had requested reviews primarily to review each of the company's own sales, and ''the amount of any . . . dumping margin involved in the {suspension} agreement.'' Pursuant to section 751(a)(1)(c) of the Act, Commerce reviews ''the current status of, and compliance with, any agreement by reason of which an investigation was suspended, and review the amount of any . . . dumping margin involved in the agreement, in administrative reviews. . . .'' Because there is no dumping margin involved in the 2019 Agreement, in conducting this administrative review, we are not calculating new margins for the companies under review, as we would in an administrative review of an order. Rather, in addition to examining compliance with the terms of the agreement, generally, we are examining whether for the sales during the period of review the respondents complied with the price undertakings specified in section VI of the 2019 Agreement, *i.e.,* not making sales below the Reference Prices established in Appendix A and eliminating the required percentage of dumping from the original investigation, *i.e.,* 85 percent.

[7] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 85 FR 68841 (October 30, 2020).

[8] *See* Memorandum, ''2019–2020 Administrative Review of the 2019 Agreement Suspending the Antidumping Duty Investigation on Fresh Tomatoes from Mexico: Respondent Selection and Corrected Period of Review'' (January 7, 2021*). See also Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 86 FR 8166 (February 4, 2021) at footnote 10. As the 2019 Agreement was signed on September 19, 2019, this date is the beginning of the POR.

[9] *Id. See also* questionnaires issued individually to Bioparques, Del Campo and Productora Agricola, each dated January 7, 2021.

[10] For a complete description of the Scope of the 2019 Agreement, *see* Memorandum, ''Decision Memorandum for the Preliminary Results of the 2019–2020 Administrative Review of the Agreement Suspending the Antidumping Duty Investigation on Fresh Tomatoes from Mexico,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

investigation was suspended.'' In this case, Commerce and representatives of the Mexican tomato producers/exporters accounting for substantially all imports of fresh tomatoes from Mexico signed the 2019 Agreement, which suspended the underlying antidumping duty investigation, on September 19, 2019. Pursuant to the 2019 Agreement, the Mexican signatories agreed that the subject merchandise would be subject to minimum reference prices and that at least 85 percent of the dumping from the original investigation would be eliminated.[11] The Mexican signatories also agreed to other conditions, including quarterly audits,[12] near-the-border inspections by the U.S. Department of Agriculture on all Round and Roma tomatoes and certain other types of tomatoes beginning on April 4, 2020,[13] and limits to adjustments to the sales price due to certain changes in condition and quality after shipment.[14]

After reviewing the information received to date from the respondent companies in their questionnaire and supplemental questionnaire responses, we preliminarily determine that the respondents have adhered to the terms of the 2019 Agreement, except for certain instances of inadvertent and/or inconsequential noncompliance, and that the 2019 Agreement is functioning as intended. Further, we preliminarily determine that the 2019 Agreement continues to meet the statutory requirements under sections 734(c) and (d) of the Act. For a full description of the methodology underlying our conclusions, *see* the Preliminary Decision Memorandum. Commerce is addressing proprietary issues concerning each of the respondents in separate memoranda which we incorporate into the Preliminary Decision Memorandum.[15]

Verification

As provided in section 782(i)(3)(a) of the Act, Commerce intends to verify the information relied upon in making its final results. Normally, Commerce verifies information using standard procedures, including an on-site examination of original accounting, financial, and sales documentation. While we consider the possibility of conducting an on-site verification for some of the information submitted by the respondents, we may also need to verify the information relied upon in making the final results through alternative means in lieu of an on-site verification. Commerce intends to notify parties of its verification procedures.

Public Comment

Interested parties will be notified of the timeline for the submission of case briefs and written comments at a later date. Rebuttal briefs, limited to issues raised in case briefs, may be submitted no later than seven days after the deadline date for case briefs.

Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information, until further notice.[16] Pursuant to 19 CFR 351.309(c)(2) and (d)(2), parties who submit case briefs or rebuttal briefs in this investigation are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.[17]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce within 30 days after the date of publication of this notice. Requests should contain the party's name, address, and telephone number, the number of participants, whether any participant is a foreign national, and a list of the issues to be discussed. If a request for a hearing is made, Commerce intends to hold the hearing at a time and date to be determined. Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

Commerce intends to issue the final results of this administrative review, including the results of its analysis of the issues raised in any written briefs, not later than 120 days after the date of publication of this notice, pursuant to section 751(a)(3)(A) of the Act, unless extended.

We are issuing and publishing these results in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: September 24, 2021.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations.

[FR Doc. 2021–21338 Filed 9–30–21; 8:45 am]

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[11] *See 2019 Agreement,* 84 FR at 49990, at Price Undertaking.

[12] *See 2019 Agreement,* 84 FR at 49991, at Compliance Monitoring.

[13] *Id.* at Inspection of Subject Merchandise. *See also* Memorandum, ''Frequently Asked Questions Regarding Inspections,'' dated March 17, 2020.

[14] *See 2019 Agreement,* 84 FR 49996 at Appendix D.

[15] *See* Preliminary Decision Memorandum at 6 and footnote 47.

[16] *See Temporary Rule,* 85 FR 17006; see also *Temporary Rule Modifying ADICVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020).

[17] *See* 19 CFR 351.309(c)(2) and (d)(2).

DEPARTMENT OF COMMERCE

International Trade Administration

[C–580–879]

Certain Corrosion-Resistant Steel Products From the Republic of Korea: Final Results of the Expedited First Sunset Review of the Countervailing Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) finds that revocation of the countervailing duty (CVD) order on certain corrosion-resistant steel products (CORE) from the Republic of Korea (Korea) would be likely to lead to the continuation or recurrence of a countervailable subsidy at the levels indicated in the ''Final Results of Sunset Review'' section of this notice.

DATES: Applicable October 1, 2021.

FOR FURTHER INFORMATION CONTACT: Josh Simonidis, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0608.

SUPPLEMENTARY INFORMATION:

Background

On July 25, 2016, Commerce published in the **Federal Register** the CVD order on CORE from Korea.[1] On June 1, 2021, Commerce published the notice of initiation of the first sunset review of the CVD order on CORE from Korea, pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act).[2] Commerce received timely notices of intent to participate in this review from Cleveland-Cliffs Inc. (Cleveland-Cliffs) on June 14, 2021, and from United States Steel Corporation (U.S. Steel), California Steel Industries (CSI) and Steel Dynamics Inc. (SDI), and Nucor Corporation (Nucor) (collectively, domestic interested parties) on June 16, 2021, within the deadline specified in

[1] *See Certain Corrosion-Resistant Steel Products from India, Italy Republic of Korea and the People's Republic of China: Countervailing Duty Order,* 81 FR 48387 (July 25, 2016) (*Order*).

[2] *See Initiation of Five-Year (Sunset) Reviews,* 86 FR 29239 (June 1, 2021).

19 CFR 351.218(d)(1)(i).[3] The domestic interested parties claimed interested party status under section 771(9)(C) of the Act, as domestic producers of CORE. On July 1, 2021, Commerce received a complete substantive response for the review from the domestic interested parties within the 30-day deadline specified in 19 CFR 351.218(d)(3)(i).[4]

On July 22, 2021, Commerce notified the U.S. International Trade Commission that it did not receive an adequate substantive response from respondent interested parties.[5] As a result, pursuant to 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(C)(2), Commerce conducted an expedited (120-day) sunset review of the CVD order on CORE from Korea.

Scope of the Order

The products covered by the *Order* are CORE. For a full description of the scope, *see* the Issues and Decision Memorandum.[6]

Analysis of Comments Received

A complete discussion of all issues raised in this sunset review, is provided in the Issues and Decision Memorandum. A list of the topics discussed in the Issues and Decision Memorandum is attached as an appendix to this notice.

The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *https://enforcement.trade.gov/frn/index.html.*

Final Results of Sunset Review

Pursuant to sections 751(c)(1) and 752(b) of the Act, Commerce determines that revocation of the *Order* would be likely to lead to the continuation or recurrence of countervailable subsidies at the rates listed below:

Producer/exporter	Subsidy rate (percent)
Dongbu Steel Co., Ltd./ Dongbu Incheon Steel Co., Ltd	1.19
Union Steel Manufacturing Co. Ltd/Dongkuk Steel Mill Co., Ltd	* 0.72
All Others	1.19

* (*de minimis*)

Notification Regarding Administrative Protective Order (APO)

This notice also serves as the only reminder to parties subject to an APO of their responsibility concerning the destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305. Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

Notification to Interested Parties

We are issuing and publishing these results in accordance with sections 751(c), 752(b), and 777(i)(1) of the Act, and 19 CFR 351.218.

Dated: September 27, 2021.

Christian Marsh,

Acting Assistant Secretary for Enforcement and Compliance.

Appendix

List of Issues Addressed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Scope of the Order
IV. History of the Order
V. Legal Framework
VI. Discussion of the Issues
  1. Likelihood of Continuation or Recurrence of a Countervailable Subsidy
  2. Net Countervailable Subsidy Rates That Are Likely To Prevail
  3. Nature of the Subsidies
VII. Final Results of Review
VIII. Recommendation

[FR Doc. 2021–21444 Filed 9–30–21; 8:45 am]

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[3] *See* Cleveland-Cliffs's Letter, ''Notice of Intent to Participate,'' dated June 14, 2021; *see also* U.S. Steel's Letter, ''Notice of Intent to Participate, dated June 16, 2021; CSI and SDI's Letter, ''Notice of Intent to Participate in the Five Year-Review Review of the Countervailing Duty Order on Certain Corrosion-Resistant Steel Products from the Republic of Korea,'' dated June 16, 2021; and Nucor's Letter, ''Notice of Intent to Participate in Sunset Review,'' dated June 16, 2021.

[4] *See* Domestic Interested Parties' Letter, ''Substantive Response to Notice of Initiation of Sunset Review,'' dated July 1, 2021.

[5] *See* Commerce's Letter, ''Sunset Reviews Initiated on June 1, 2021,'' dated July 22, 2021.

[6] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of the Expedited First Sunset Review of the Countervailing Duty Order on Certain Corrosion-Resistant Steel Products from the Republic of Korea,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–533–843]

Certain Lined Paper Products From India: Preliminary Results of Antidumping Duty Administrative Review; Rescission of Administrative Review, in Part; and Preliminary Determination of No Shipments; 2019–2020

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) is conducting an administrative review of the antidumping duty order on certain lined paper products from India, covering the period of review (POR), September 1, 2019, through August 31, 2020. We preliminarily find that Navneet Education Ltd. (Navneet) made sales of subject merchandise at less than normal value during the POR. We invite interested parties to comment on these preliminary results.

DATES: Applicable October 1, 2021.

FOR FURTHER INFORMATION CONTACT: Samuel Brummitt, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington DC 20230; telephone: (202) 482–7851.

SUPPLEMENTARY INFORMATION:

Background

On September 28, 2006, Commerce published the *Order* in the **Federal Register**.[1] On October 30, 2020, pursuant to section 751(a)(1) of the Tariff Act of 1930, as amended (the Act), Commerce initiated an administrative review of the *Order*.[2] On May 24, 2021, we extended the deadline for the preliminary results to September 30, 2021.[3]

Commerce initiated this administrative review covering the following seventeen companies: Cellpage Ventures Private Limited

[1] *See Notice of Amended Final Determination of Sales at Less Than Fair Value: Certain Lined Paper Products from the People's Republic of China; Notice of Antidumping Duty Orders: Certain Lined Paper Products from India, Indonesia and the People's Republic of China; and Notice of Countervailing Duty Orders: Certain Lined Paper Products from India and Indonesia,* 71 FR 56949 (September 28, 2006) (*Order*).

[2] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 85 FR 68840 (October 30, 2020) (*Initiation Notice*).

[3] *See* Memorandum, ''Extension of Deadline for Preliminary Results of Antidumping Duty Administrative Review; 2019–2020,'' dated May 24, 2021.

(Cellpage); Goldenpalm Manufacturers PVT Limited (Goldenpalm); ITC Limited—Education and Stationery Products Business (ITC Limited); M/s. Bhaskar Paper Products (Bhaskar); Dinakar Process Private Limited (Dinakar); JC Stationery (P) Ltd. (JC Stationery); Kokuyo Riddhi Paper Products Pvt. Ltd. (Kokuyo); Lodha Offset Limited (Lodha); Lotus Global Private Limited (Lotus Global); Magic International Pvt. Ltd. (Magic); Marisa International (Marisa); Navneet; Pioneer Stationery Pvt. Ltd. (Pioneer); PP Bafna Ventures Private Limited (PP Bafna); SAB International (SAB); SGM Paper Products (SGM); and Super Impex.[4] On January 19, 2021, Pioneer, PP Bafna, SAB, SGM, and Super Impex timely withdrew their requests for review.[5] On January 20, 2021, Cellpage, Lotus Global, and Kokuyo timely withdrew their requests for review.[6] On January 28, 2021, ITC Limited, Bhaskar, Dinakar, and JC Stationery timely withdrew their requests for review.[7] As detailed below, we are rescinding the review, in part, with respect to ten of the above companies. This review covers one mandatory respondent, Navneet. The other six companies were not selected for individual examination and remain subject to this administrative review.

Scope of the Order

The merchandise covered by the *Order* is certain lined paper products. The merchandise subject to this order is currently classified under the following Harmonized Tariff Schedule of the United States (HTSUS) subheadings: 4811.90.9035, 4811.90.9080, 4820.30.0040, 4810.22.5044, 4811.90.9050, 4811.90.9090, 4820.10.2010, 4820.10.2020, 4820.10.2030, 4820.10.2040, 4820.10.2050, 4820.10.2060, and 4820.10.4000. Although the HTSUS numbers are provided for convenience and customs purposes, the written product description remains dispositive. A full description of the scope of the *Order* is contained in the Preliminary Decision Memorandum.[8]

Partial Rescission of Review

Pursuant to 19 CFR 351.213(d)(1), Commerce will rescind an administrative review, in whole or in part, if a party who requested the review withdraws the request within 90 days of the date of publication of notice of initiation of the requested review. As noted above, on January 19, 2021, Pioneer, PP Bafna, SAB, SGM, and Super Impex timely withdrew their requests for review.[9] On January 20, 2021, Cellpage, Lotus Global, and Kokuyo timely withdrew their requests for review.[10] On January 28, 2021, ITC Limited, Bhaskar, Dinakar, and JC Stationery timely withdrew their requests for review.[11] Because there is still an active review request for Pioneer and SGM, we are not rescinding the review with respect to these companies.[12] However, because there was a timely withdrawal of requests for review and because there are no other active requests for review, we are rescinding this review with respect to the following companies, pursuant to 19 CFR 351.213(d)(1): Bhaskar, Cellpage, Dinakar, ITC Limited, JC Stationery, Kokuyo, Lotus Global, PP Bafna, SAB, and Super Impex.

Preliminary Determination of No Shipments

On November 23, 2020, Goldenpalm submitted a no-shipment certification.[13] To confirm Goldenpalm's no-shipment claim, on January 28, 2021, Commerce issued a no-shipment inquiry to U.S. Customs and Border Protection (CBP).[14] CBP reported that it had no information to contradict Goldenpalm's no shipments claim during the POR.[15]

Given that Goldenpalm reported that it made no shipments of subject merchandise to the United States during the POR, and there is no information calling Goldenpalm's claim into question, we preliminarily determine that Goldenpalm did not have any reviewable transactions during the POR. Consistent with Commerce's practice, we will not rescind the review with respect to Goldenpalm but, rather, will complete the review and issue instructions to CBP based on the final results.[16]

Methodology

Commerce is conducting this review in accordance with section 751(a)(2) of the Act. Export price is calculated in accordance with section 772 of the Act. Normal value is calculated in accordance with section 773 of the Act. For a full description of the methodology underlying our preliminary results, *see* the Preliminary Decision Memorandum. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and

[4] *Initiation Notice,* 85 FR at 68842.

[5] *See* Pioneer's Letter, ''Withdrawal of Request for Antidumping Duty Administrative Review of Pioneer,'' dated January 19, 2021 (Pioneer's Withdrawal of Request for Review); PP Bafna's Letter, ''Withdrawal of Request for Antidumping Duty Administrative Review of PP Bafna,'' dated January 19, 2021 (PP Bafna's Withdrawal of Request for Review); SAB's Letter, ''Withdrawal of Request for Antidumping Duty Administrative Review of SAB International,'' dated January 19, 2021 (SAB's Withdrawal of Request for Review); SGM's Letter, ''Withdrawal of Request for Antidumping Duty Administrative Review of SGM Paper Products,'' dated January 19, 2021 (SGM's Withdrawal of Request for Review); and Super Impex's Letter, ''Withdrawal of Request for Antidumping Duty Administrative Review of Super Impex,'' dated January 19, 2021 (Super Impex's Withdrawal of Request for Review).

[6] *See* Cellpage's Letter, ''Withdrawal of Request for Antidumping Duty Administrative Review of Cellpage Ventures Private Limited,'' dated January 20, 2021 (Cellpage's Withdrawal of Request for Review); Lotus Global's Letter, ''Withdrawal of Request for Antidumping Duty Administrative Review of Lotus Global Private Limited,'' dated January 20, 2021 (Lotus Global's Withdrawal of Request for Review); and Kokuyo's Letter, ''Withdrawal of Request for Anti-dumping Duty Administrative Review of Kokuyo Riddhi Paper Products Private Limited,'' dated January 20, 2021 (Kokuyo's Withdrawal of Request for Review).

[7] *See* ITC Limited, Bhaskar, Dinakar, and JC Stationery's Letter, ''Withdrawal of Request for Administrative Review,'' dated January 28, 2021 (ITC Limited, Bhaskar, Dinakar, and JC Stationery's Withdrawal of Request for Review).

[8] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of Antidumping Duty Administrative Review: Certain Lined Paper Products from India; 2018–2019,'' dated concurrently and hereby adopted by this notice (Preliminary Decision Memorandum).

[9] *See* Pioneer's Withdrawal of Request for Review; PP Bafna's Withdrawal of Request for Review; SAB's Withdrawal of Request for Review; SGM's Withdrawal of Request for Review; and Super Impex's Withdrawal of Request for Review.

[10] *See* Cellpage's Withdrawal of Request for Review; Lotus Global's Withdrawal of Request for Review; and Kokuyo's Withdrawal of Request for Review.

[11] *See* ITC Limited, Bhaskar, Dinakar, and JC Stationery's Withdrawal of Request for Review.

[12] *See* Petitioners' Letter, ''Request for Administrative Review,'' dated September 30, 2020.

[13] *See* Goldenpalm's Letter, ''Response to Q & V Questionnaire,'' dated November 23, 2020.

[14] *See* Memorandum, ''No Shipment Inquiry,'' dated January 28, 2021.

[15] *See* Memorandum, ''No shipment inquiry with respect to the company below during the period 09/01/2019 through 08/30/2020'' dated March 12, 2021.

[16] Commerce determined to not rescind a review with respect to exporters that demonstrate that they had no knowledge of sales through resellers to the United States because we find it appropriate to instruct CBP to liquidate such entries at the all-others rate applicable to the proceeding. Further, Commerce explained that it is more consistent with the Automatic Assessment Clarification not to rescind a review in part under these circumstances but rather to complete the review and issue appropriate instructions to CBP based on the final results of the review. *See, e.g., Certain Frozen Warmwater Shrimp from Thailand; Preliminary Results of Antidumping Duty Administrative Review, Partial Rescission of Review, Preliminary Determination of No Shipments; 2012–2013,* 79 FR 15951, 15952 (March 24, 2014), unchanged in *Certain Frozen Warmwater Shrimp from Thailand: Final Results of Antidumping Duty Administrative Review, Final Determination of No Shipments, and Partial Rescission of Review; 2012–2013,* 79 FR 51306, 51307 (August 28, 2014) at 6–7 (citing *Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003) (*Automatic Assessment Clarification*)).

Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/.* A list of the topics discussed in the Preliminary Decision Memorandum is attached as an appendix to this notice.

Adverse Facts Available

Sections 776(a)(1) and 776(a)(2) of the Act provide that Commerce shall, subject to section 782(d) of the Act, apply ''facts otherwise available'' if necessary information is not available on the record or if any other person: (A) Withholds information requested by Commerce; (B) fails to provide such information by the deadlines for submission of the information, or in the form and manner requested, subject to subsections (c)(1) and (e) of section 782 of the Act; (C) significantly impedes a proceeding; or (D) provides such information but the information cannot be verified as provided in section 782(i) of the Act. Pursuant to sections 776(a) and (b) of the Act, Commerce has preliminarily relied upon facts otherwise available with adverse inferences to determine the estimated weighted-average dumping margin for Magic International Pvt. Ltd. and Marisa International because they did not submit timely responses to Commerce's quantity and value questionnaire. We are preliminarily assigning to Magic International Pvt. Ltd. and Marisa International, as adverse facts available, the highest rate from the petition, which we have corroborated under section 776(c)(2) of the Act using the highest individual transaction-specific margin calculated for Navneet. For a complete explanation of the analysis underlying the application of AFA, *see* the Preliminary Decision Memorandum.

Rate for Non-Selected Respondents

The statute and Commerce's regulations do not address the establishment of a rate to be applied to companies not selected for individual examination when Commerce limits its examination in an administrative review pursuant to section 777A(c)(2) of the Act. Generally, Commerce looks to section 735(c)(5) of the Act, which provides instructions for calculating the all-others rate in a market economy investigation, for guidance when calculating the rate for companies which were not selected for individual examination in an administrative review. Under section 735(c)(5)(A) of the Act, the all-others rate is normally ''an amount equal to the weighted-average of the estimated weighted-average dumping margins established for exporters and producers individually investigated, excluding any zero or *de minimis* margins, and any margins determined entirely {on the basis of facts available}.''

In this segment of the proceeding, we calculated a margin for Navneet that was not zero, *de minimis,* or based on facts available. Accordingly, we have preliminarily applied the margin calculated for Navneet to the non-individually examined respondents.

Preliminary Results of the Review

As a result of this review, we preliminarily find the following weighted-average dumping margins for the period September 1, 2019 through August 31, 2020.

Producer/exporter	Weighted-average dumping margin (percent)
Navneet Education Ltd	18.35
Lodha Offset Limited	18.35
Pioneer Stationery Pvt. Ltd	18.35
SGM Paper Products	18.35
Magic International Pvt. Ltd	215.93
Marisa International	215.93

Assessment Rates

Upon issuance of the final results, Commerce shall determine, and CBP shall assess, antidumping duties on all appropriate entries covered by this review. If a respondent's weighted-average dumping margin is not zero or *de minimis* (*i.e.,* less than 0.5 percent) in the final results of this review, we will calculate importer-specific *ad valorem* antidumping duty assessment rates based on the ratio of the total amount of dumping calculated for an importer's examined sales and the total entered value of such sales in accordance with 19 CFR 351.212(b)(1). Where either the respondent's weighted-average dumping margin is zero or *de minimis* within the meaning of 19 CFR 351.106(c), or an importer-specific rate is zero or *de minimis,* we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties.

Pursuant to Commerce's *Automatic Assessment Clarification,* for entries of subject merchandise during the POR produced by a respondent for which it did not know its merchandise was destined for the United States, Commerce will instruct CBP to liquidate unreviewed entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction.[17]

We intend to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the notice of final results of administrative review for all shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for respondent noted above will be the rates established in the final results of this administrative review; (2) for merchandise exported by producers or exporters not covered in this administrative review but covered in a prior segment of the proceeding, the cash deposit rate will continue to be the company-specific rate published for the most recently completed segment of this proceeding; (3) if the exporter is not a firm covered in this review, a prior review, or the original investigation, but the producer is, then the cash deposit rate will be the rate established for the most recently completed segment of this proceeding for the producer of the subject merchandise; and (4) the cash deposit rate for all other producers or exporters will continue to be 3.91 percent, the all-others rate established in the investigation.[18] These cash deposit requirements, when imposed, shall remain in effect until further notice.

Disclosure and Public Comment

We will disclose to parties to the proceeding any calculations performed in connection with these preliminary results of review within five days after the date of publication of this notice.[19] Interested parties may submit case briefs not later than 30 days after the date of publication of this notice in the **Federal Register**.[20] Rebuttal briefs, limited to issues raised in the case briefs, may be filed no later than seven days after the

[17] *See Automatic Assessment Clarification.*

[18] *See Order,* 71 FR 56952.

[19] *See* 19 CFR 351.224(b).

[20] *See* 19 CFR 351.309(c)(1)(ii).

date for filing case briefs.[21] Parties who submit case briefs or rebuttal briefs in this proceeding are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.[22] All briefs must be filed electronically using ACCESS. An electronically filed document must be received successfully in its entirety by the established deadline.

Interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, within 30 days after the date of publication of this notice.[23] Requests should contain: (1) The party's name, address, and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. Issues raised in the hearing will be limited to those raised in the respective case and rebuttal briefs. If a request for a hearing is made, Commerce intends to hold the hearing at a time and date to be determined. Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

We intend to issue the final results of this administrative review, including the results of our analysis of the issues raised in any written briefs, not later than 120 days after the date of publication of this notice, pursuant to section 751(a)(3)(A) of the Act.

Notification to Importers

This notice serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties and/or countervailing 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 and/or countervailing duties occurred and the subsequent assessment of double antidumping duties.

Notification to Interested Parties

We are issuing and publishing these results in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.213(h)(1).

Dated: September 27, 2021.

Christian Marsh,

Acting Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope of the Order
IV. Partial Rescission of Administrative Review
V. Preliminary Determination of No Shipments
VI. Companies Not Selected for Individual Examination
VII. Application of Facts Available and Adverse Inference
VIII. Discussion of the Methodology
IX. Currency Conversion
X. Recommendation

[FR Doc. 2021–21404 Filed 9–30–21; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

FOR FURTHER INFORMATION CONTACT: Brenda E. Brown, Office of AD/CVD Operations, Customs Liaison Unit, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, telephone: (202) 482–4735.

Background

Each year during the anniversary month of the publication of an antidumping or countervailing duty order, finding, or suspended investigation, an interested party, as defined in section 771(9) of the Tariff Act of 1930, as amended (the Act), may request, in accordance with 19 CFR 351.213, that the Department of Commerce (Commerce) conduct an administrative review of that antidumping or countervailing duty order, finding, or suspended investigation.

All deadlines for the submission of comments or actions by Commerce discussed below refer to the number of calendar days from the applicable starting date.

Respondent Selection

In the event Commerce limits the number of respondents for individual examination for administrative reviews initiated pursuant to requests made for the orders identified below, Commerce intends to select respondents based on U.S. Customs and Border Protection (CBP) data for U.S. imports during the period of review. We intend to release the CBP data under Administrative Protective Order (APO) to all parties having an APO within five days of publication of the initiation notice and to make our decision regarding respondent selection within 35 days of publication of the initiation **Federal Register** notice. Therefore, we encourage all parties interested in commenting on respondent selection to submit their APO applications on the date of publication of the initiation notice, or as soon thereafter as possible. Commerce invites comments regarding the CBP data and respondent selection within five days of placement of the CBP data on the record of the review.

In the event Commerce decides it is necessary to limit individual examination of respondents and conduct respondent selection under section 777A(c)(2) of the Act:

In general, Commerce finds that determinations concerning whether particular companies should be ''collapsed'' (*i.e.,* treated as a single entity for purposes of calculating antidumping duty rates) require a substantial amount of detailed information and analysis, which often require follow-up questions and analysis. Accordingly, Commerce will not conduct collapsing analyses at the respondent selection phase of a review and will not collapse companies at the respondent selection phase unless there has been a determination to collapse certain companies in a previous segment of this antidumping proceeding (*i.e.,* investigation, administrative review, new shipper review or changed circumstances review). For any company subject to a review, if Commerce determined, or continued to treat, that company as collapsed with others, Commerce will assume that such companies continue to operate in the same manner and will collapse them for respondent selection purposes. Otherwise, Commerce will not collapse companies for purposes of respondent selection. Parties are requested to: (a) Identify which companies subject to review previously were collapsed; and (b) provide a citation to the proceeding in which they were collapsed. Further, if companies are requested to complete a Quantity and Value Questionnaire for purposes of respondent selection, in general each company must report volume and value data separately for itself. Parties should not include data

[21] *See* 19 CFR 351.309(d)(1); *see also Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020) (*Temporary Rule*).

[22] *See* 19 CFR 351.309(c)(2) and (d)(2) and 19 CFR 351.303 (for general filing requirements).

[23] *See* 19 CFR 351.310(c).

for any other party, even if they believe they should be treated as a single entity with that other party. If a company was collapsed with another company or companies in the most recently completed segment of a proceeding where Commerce considered collapsing that entity, complete quantity and value data for that collapsed entity must be submitted.

Deadline for Withdrawal of Request for Administrative Review

Pursuant to 19 CFR 351.213(d)(1), a party that requests a review may withdraw that request within 90 days of the date of publication of the notice of initiation of the requested review. The regulation provides that Commerce may extend this time if it is reasonable to do so. Determinations by Commerce to extend the 90-day deadline will be made on a case-by-case basis.

Deadline for Particular Market Situation Allegation

Section 504 of the Trade Preferences Extension Act of 2015 amended the Act by adding the concept of particular market situation (PMS) for purposes of constructed value under section 773(e) of the Act.[1] Section 773(e) of the Act states that ''if a particular market situation exists such that the cost of materials and fabrication or other processing of any kind does not accurately reflect the cost of production in the ordinary course of trade, the administering authority may use another calculation methodology under this subtitle or any other calculation methodology.'' When an interested party submits a PMS allegation pursuant to section 773(e) of the Act, Commerce will respond to such a submission consistent with 19 CFR 351.301(c)(2)(v). If Commerce finds that a PMS exists under section 773(e) of the Act, then it will modify its dumping calculations appropriately.

Neither section 773(e) of the Act nor 19 CFR 351.301(c)(2)(v) set a deadline for the submission of PMS allegations and supporting factual information. However, in order to administer section 773(e) of the Act, Commerce must receive PMS allegations and supporting factual information with enough time to consider the submission. Thus, should an interested party wish to submit a PMS allegation and supporting new factual information pursuant to section 773(e) of the Act, it must do so no later than 20 days after submission of initial Section D responses.

Opportunity to request a review: Not later than the last day of October 2021,[2] interested parties may request administrative review of the following orders, findings, or suspended investigations, with anniversary dates in October for the following periods:

	Period
Antidumping Duty Proceedings	
Australia: Certain Hot-Rolled Steel Flat Products, A–602–809	10/1/20–9/30/21
Brazil: Carbon and Certain Alloy Steel Wire Rod, A–351–832	10/1/20–9/30/21
Brazil: Certain Hot-Rolled Steel Flat Products, A–351–845	10/1/20–9/30/21
India: Stainless Steel Flanges, A–533–877	10/1/20–9/30/21
Indonesia: Carbon and Certain Alloy Steel Wire Rod, A–560–815	10/1/20–9/30/21
Japan: Certain Hot-Rolled Steel Flat Products, A–588–874	10/1/20–9/30/21
Mexico: Carbon and Certain Alloy Steel Wire Rod, A–201–830	10/1/20–9/30/21
Mexico: Refillable Stainless Flanges, A–201–849	10/1/20–9/30/21
Moldova: Carbon and Certain Alloy Steel Wire Rod, A–841–805	10/1/20–9/30/21
Republic of Korea: Certain Hot-Rolled Steel Flat Products, A–580–883	10/1/20–9/30/21
Taiwan: Steel Concrete Reinforcing Bar, A–583–859	10/1/20–9/30/21
Thailand: Glycine, A–549–837	10/1/20–9/30/21
The Netherlands: Certain Hot-Rolled Steel Flat Products, A–421–813	10/1/20–9/30/21
The People's Republic of China: Barium Carbonate, A–570–880	10/1/20–9/30/21
The People's Republic of China: Barium Chloride, A–570–007	10/1/20–9/30/21
The People's Republic of China: Boltless Steel Shelving Units Prepackaged For Sale, A–570–018	10/1/20–9/30/21
The People's Republic of China: Certain Cut-to-Length Carbon Steel, A–570–849	10/1/20–9/30/21
The People's Republic of China: Electrolytic Manganese Dioxide, A–570–919	10/1/20–9/30/21
The People's Republic of China: Helical Spring Lock Washers, A–570–822	10/1/20–9/30/21
The People's Republic of China: Polyvinyl Alcohol, A–570–879	10/1/20–9/30/21
The People's Republic of China: Steel Wire Garment Hangers, A–570–918	10/1/20–9/30/21
Trinidad and Tobago: Carbon and Certain Alloy Steel Wire Rod, A–274–804	10/1/20–9/30/21
Turkey: Certain Hot-Rolled Steel Flat Products, A–489–826	10/1/20–9/30/21
United Kingdom: Certain Hot-Rolled Steel Flat Products, A–412–825	10/1/20–9/30/21
Countervailing Duty Proceedings	
Brazil: Carbon and Certain Alloy Steel Wire Rod, C–351–833	1/1/20–12/31/20
Brazil: Certain Hot-Rolled Steel Flat Products, C–351–846	1/1/20–12/31/20
India: Stainless Steel Flanges, C–533–878	1/1/20–12/31/20
Iran: Roasted In Shell Pistachios, C–507–601	1/1/20–12/31/20
Republic of Korea: Certain Hot-Rolled Steel Flat Products, C–580–884	1/1/20–12/31/20
The People's Republic of China: Boltless Steel Shelving Units Prepackaged For Sale, C–570–019	1/1/20–12/31/20
Suspension Agreements	
Argentina: Lemon Juice, A–357–818	10/1/20–9/30/21
Russia: Uranium, A–821–802	10/1/20–9/30/21

In accordance with 19 CFR 351.213(b), an interested party as defined by section 771(9) of the Act may request in writing that the Secretary conduct an administrative review. For both antidumping and countervailing duty reviews, the interested party must specify the individual producers or exporters covered by an antidumping finding or an antidumping or countervailing duty order or suspension agreement for which it is requesting a

[1] *See* Trade Preferences Extension Act of 2015, Public Law 114–27, 129 Stat. 362 (2015).

[2] Or the next business day, if the deadline falls on a weekend, federal holiday or any other day when Commerce is closed.

review. In addition, a domestic interested party or an interested party described in section 771(9)(B) of the Act must state why it desires the Secretary to review those particular producers or exporters. If the interested party intends for the Secretary to review sales of merchandise by an exporter (or a producer if that producer also exports merchandise from other suppliers) which was produced in more than one country of origin and each country of origin is subject to a separate order, then the interested party must state specifically, on an order-by-order basis, which exporter(s) the request is intended to cover.

Note that, for any party Commerce was unable to locate in prior segments, Commerce will not accept a request for an administrative review of that party absent new information as to the party's location. Moreover, if the interested party who files a request for review is unable to locate the producer or exporter for which it requested the review, the interested party must provide an explanation of the attempts it made to locate the producer or exporter at the same time it files its request for review, in order for the Secretary to determine if the interested party's attempts were reasonable, pursuant to 19 CFR 351.303(f)(3)(ii).

As explained in *Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003), and *Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694 (October 24, 2011), Commerce clarified its practice with respect to the collection of final antidumping duties on imports of merchandise where intermediate firms are involved. The public should be aware of this clarification in determining whether to request an administrative review of merchandise subject to antidumping findings and orders.[3]

Commerce no longer considers the non-market economy (NME) entity as an exporter conditionally subject to an antidumping duty administrative review.[4] Accordingly, the NME entity will not be under review unless Commerce specifically receives a request for, or self-initiates, a review of the NME entity.[5] In administrative reviews of antidumping duty orders on merchandise from NME countries where a review of the NME entity has not been initiated, but where an individual exporter for which a review was initiated does not qualify for a separate rate, Commerce will issue a final decision indicating that the company in question is part of the NME entity. However, in that situation, because no review of the NME entity was conducted, the NME entity's entries were not subject to the review and the rate for the NME entity is not subject to change as a result of that review (although the rate for the individual exporter may change as a function of the finding that the exporter is part of the NME entity). Following initiation of an antidumping duty administrative review when there is no review requested of the NME entity, Commerce will instruct CBP to liquidate entries for all exporters not named in the initiation notice, including those that were suspended at the NME entity rate.

All requests must be filed electronically in Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS) on Enforcement and Compliance's ACCESS website at *https://access.trade.gov.*[6] Further, in accordance with 19 CFR 351.303(f)(l)(i), a copy of each request must be served on the petitioner and each exporter or producer specified in the request. Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information, until further notice.[7]

Commerce will publish in the **Federal Register** a notice of ''Initiation of Administrative Review of Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation'' for requests received by the last day of October 2021. If Commerce does not receive, by the last day of October 2021, a request for review of entries covered by an order, finding, or suspended investigation listed in this notice and for the period identified above, Commerce will instruct CBP to assess antidumping or countervailing duties on those entries at a rate equal to the cash deposit of estimated antidumping or countervailing duties required on those entries at the time of entry, or withdrawal from warehouse, for consumption and to continue to collect the cash deposit previously ordered.

For the first administrative review of any order, there will be no assessment of antidumping or countervailing duties on entries of subject merchandise entered, or withdrawn from warehouse, for consumption during the relevant provisional measures ''gap'' period of the order, if such a gap period is applicable to the period of review.

This notice is not required by statute but is published as a service to the international trading community.

Dated: September 23, 2021.

James Maeder,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

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[3] *See* the Enforcement and Compliance website at *https://legacy.trade.gov/enforcement/.*

[4] *See Antidumping Proceedings: Announcement of Change in Department Practice for Respondent Selection in Antidumping Duty Proceedings and Conditional Review of the Nonmarket Economy Entity in NME Antidumping Duty Proceedings,* 78 FR 65963 (November 4, 2013).

[5] In accordance with 19 CFR 351.213(b)(1), parties should specify that they are requesting a review of entries from exporters comprising the entity, and to the extent possible, include the names of such exporters in their request.

[6] *See Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures,* 76 FR 39263 (July 6, 2011).

[7] *See Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19,* 85 FR 41363 (July 10, 2020).

DEPARTMENT OF COMMERCE

International Trade Administration

Change in Deadline for Public Comments on U.S. Clean Technologies Export Competitiveness Strategy

AGENCY: International Trade Administration, Department of Commerce.

ACTION: Notice and request for public comments; extension of comment period.

SUMMARY: On August 30, 2021, the International Trade Administration (ITA) published in the **Federal Register** a request for public comment on clean technologies export competitiveness to inform efforts to develop a ''U.S. Clean Technologies Export Competitiveness Strategy.'' ITA has determined that an extension of the comment period until October 15, 2021, is appropriate. Comments previously submitted need not be resubmitted and will be fully considered.

DATES: The comment period for the notice published on August 30, 2021 (86 FR 48399), regarding the request for public comments on clean technologies export competitiveness, is extended from October 1, 2021, to October 15, 2021.

ADDRESSES: You may submit comments, identified by ITA–2021–0005, by either of the following methods:

• *Online Submission (Strongly Preferred):* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *https://*

www.regulations.gov and enter ITA–2021–0005 in the Search box. Click on the ''Comment'' icon, complete the required fields, and enter or attach your comments.

• *Email: cleantech@trade.gov.* Comments submitted by email should be machine-readable and should not be copy-protected.

Due to COVID–19 building closures, we are currently temporarily not accepting comments by mail. However, if you are unable to comment via regulations.gov, you may contact *cleantech@trade.gov* for instructions on submitting your comment.

FOR FURTHER INFORMATION CONTACT: Devin Horne, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Room 28018, Washington, DC 20230; telephone (202) 482–0775; email *cleantech@trade.gov.* Please direct media inquiries to ITA's Office of Public Affairs (202) 482–3809 or *publicaffairs@trade.gov.*

SUPPLEMENTARY INFORMATION: On August 30, 2021, the International Trade Administration (ITA) published in the **Federal Register** a request for public comment on clean technologies export competitiveness to inform efforts to develop a ''U.S. Clean Technologies Export Competitiveness Strategy.'' The request for public comment stated that the comment period would close on October 1, 2021. An extension of the comment period will provide additional opportunity for the public to prepare comments to address the questions posed by ITA. Therefore, ITA is extending the end of the comment period from October 1, 2021, to October 15, 2021. Comments previously submitted need not be resubmitted and will be fully considered.

Dated: September 28, 2021.

Man Cho,

Deputy Director, Office of Energy and Environmental Industries.

[FR Doc. 2021–21447 Filed 9–30–21; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–552–801]

Certain Frozen Fish Fillets From the Socialist Republic of Vietnam: Notice of Court Decision Not in Harmony With the Results of the Antidumping Duty Administrative Review; Notice of Amended Final Results

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On September 20, 2021, the U.S. Court of International Trade (CIT) issued its final judgment in *NTSF Seafoods Joint Stock Company and Vinh Quang Fisheries Corporation* v. *United States,* Court No. 19–00063, sustaining the Department of Commerce (Commerce)'s remand results pertaining to the administrative review of the antidumping duty (AD) order on certain frozen fish fillets from the Socialist Republic of Vietnam covering the period August 1, 2016, through July 31, 2017. Commerce is notifying the public that the CIT's final judgment is not in harmony with Commerce's final results of the administrative review, and that Commerce is amending the final results with respect to the dumping margins assigned to NTSF Seafoods Joint Stock Company (NTSF) and Vinh Quang Fisheries Corporation (Vinh Quang).

DATES: Applicable September 30, 2021.

FOR FURTHER INFORMATION CONTACT: Javier Barrientos, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–2243.

SUPPLEMENTARY INFORMATION:

Background

On April 29, 2019, Commerce published its *Final Results.*[1] In the *Final Results,* Commerce denied NTSF's reported fish meal and fish oil by-product offsets based on NTSF's statements that it ''sold'' the head and bone product (*i.e.,* the inputs to fish meal/oil) to an unaffiliated processor. Given these statements, Commerce concluded that the downstream fish meal/oil products were not produced and sold by NTSF, and, therefore, not eligible for by-product offsets.[2] As a result, Commerce only granted a by-product offset for the fish head and bone product sold by NTSF, and not the downstream fish oil and fish meal produced by the unaffiliated processor.[3]

On December 21, 2020, the CIT issued its *Remand Order.*[4] The *Remand Order* addressed whether three aspects of the *Final Results* were supported by substantial evidence: (1) Commerce's selection of financial statements for its calculation of surrogate financial ratios; (2) Commerce's calculation of surrogate values for NTSF's fingerlings; and (3) Commerce's denial of by-product offsets for fish meal and fish oil. The CIT affirmed Commerce's *Final Results* with respect to issues 1 and 2. With respect to issue 3, the CIT concluded that Commerce's denial of by-product offsets for fish meal and fish oil was unsupported by substantial evidence and, thus, remanded the decision to Commerce to explain its analysis of the record evidence cited by NTSF or otherwise change its determination.[5]

In its Final Remand Redetermination, issued in March 2021, Commerce found that NTSF's fish meal and fish oil by-products were produced pursuant to a tolling arrangement with an unaffiliated processor and determined that NTSF later sold the by-products to unaffiliated purchasers.[6] Commerce, thus, found that by-product offsets for NTSF's sales of fish meal and fish oil were warranted and, accordingly, made changes to the margin calculations for NTSF.[7]

Commerce also made changes to the rate assigned to a reviewed company that it did not individually examine, but which demonstrated its eligibility for separate rate and is a party to the litigation, *i.e.,* Vinh Quang.[8]

On September 20, 2021, the CIT sustained Commerce's Final Remand Redetermination.[9]

[1] *See Certain Frozen Fish Fillets from the Socialist Republic of Vietnam: Final Results, and Final Results of No Shipments of the Antidumping Duty Administrative Review; 2016–2017,* 84 FR 18007 (April 29, 2019) (*Final Results*), and accompanying Issues and Decision Memorandum (IDM).

[2] *See Final Results* IDM at Comment 11.

[3] *Id.*

[4] *See NTSF Seafoods Joint Stock Company and Vinh Quang Fisheries Corporation* v. *United States,* Court No. 19–00063, Slip Op. 20–180 (CIT December 21, 2020) (*Remand Order*).

[5] *Id.*

[6] *See* Final Results of Redetermination Pursuant to Court Remand, *NTSF Seafoods Joint Stock Company and Vinh Quang Fisheries Corporation* v. *United States,* Court No. 19–00063, Slip Op. 20–180 (CIT December 21, 2020), dated March 22, 2021 (Final Remand Redetermination).

[7] *Id.*

[8] *Id.*

[9] *See NTSF Seafoods Joint Stock Company and Vinh Quang Fisheries Corporation* v. *United States,* Court No. 19–00063, Slip Op. 21–121, dated September 20, 2021.

Timken Notice

In its decision in *Timken,*[10] as clarified by *Diamond Sawblades,*[11] the Court of Appeals for the Federal Circuit held that, pursuant to section 516A(c) of the Tariff Act of 1930, as amended (the Act), Commerce must publish a notice of court decision that is not ''in harmony'' with a Commerce determination and must suspend liquidation of entries pending a ''conclusive'' court decision. The CIT's September 20, 2021, judgment constitutes a final decision of the CIT that is not in harmony with Commerce's *Final Results.* Thus, this notice is published in fulfillment of the publication requirements of *Timken.*

Amended Final Results

Because there is now a final court judgment, Commerce is amending the *Final Results* with respect to NTSF and Vinh Quang as follows:[12]

Producer/exporter	Weighted-average dumping margin (dollars/kilogram)
NTSF Seafoods Joint Stock Company	1.28
Vinh Quang Fisheries Corporation	1.28

Cash Deposit Requirements

Because NTSF has a superseding cash deposit rate, *i.e.,* there have been final results published in a subsequent administrative review, we will not issue revised cash deposit instructions to U.S. Customs and Border Protection (CBP). This notice will not affect the current cash deposit rate NTSF. For Vinh Quang, which does not have a superseding cash deposit rate, Commerce will issue revised cash deposit instructions to CBP.

Liquidation of Suspended Entries

At this time, Commerce remains enjoined by the CIT order from liquidating entries that: were exported by NTSF and Vinh Quang and were entered, or withdrawn from warehouse, for consumption during the period August 1, 2016, through July 31, 2017. These entries will remain enjoined pursuant to the terms of the injunction during the pendency of any appeals process.

In the event that the CIT's ruling is not appealed, or, if appealed, upheld by a final and conclusive court decision, Commerce intends to instruct CBP to assess antidumping duties on unliquidated entries of subject merchandise exported by NTSF and Vinh Quang in accordance with 19 CFR 351.212(b). We will instruct CBP to apply the per unit assessment rates listed above to all entries of subject merchandise during the period of review which were exported by NTSF and Vinh Quang.

For NTSF, we will instruct CBP to assess antidumping duties on all appropriate entries covered by this review when the importer-specific *ad valorem* assessment rate is not zero or *de minimis.* Where an importer-specific *ad valorem* assessment rate is zero or *de minimis,*[13] we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties. For entries of subject merchandise during the period of review produced by NTSF for which it did not know its merchandise was destined for the United States, we will instruct CBP to liquidate unreviewed entries at the Vietnam-wide rate if there is no rate for the intermediate company(ies) involved in the transaction.

Notification to Interested Parties

This notice is issued and published in accordance with sections 516A(c) and (e), and 777(i)(1) of the Act.

Dated: September 27, 2021.

Christian Marsh,

Acting Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2021–21405 Filed 9–30–21; 8:45 am]

BILLING CODE 3510–DS–P

[10] *See Timken Co.* v. *United States,* 893 F.2d 337 (Fed. Cir. 1990) (*Timken*).

[11] *See Diamond Sawblades Mfrs. Coalition* v. *United States,* 626 F.3d 1374 (Fed. Cir. 2010) (*Diamond Sawblades*).

[12] *See* Final Remand Redetermination at 16–17.

[13] *See* 19 CFR 351.106(c)(2).

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Sanctuary System Business Advisory Council: Public Meeting

AGENCY: Office of National Marine Sanctuaries (ONMS), National Ocean Service (NOS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Notice of open public meeting.

SUMMARY: Notice is hereby given of a meeting of the Sanctuary System Business Advisory Council (council). The meeting is open to the public, and an opportunity for oral and written comments will be provided.

DATES: The meeting will be held Wednesday, October 20, 2021 from 1 p.m. to 4 p.m. ET, and an opportunity for public comment will be provided around 3:40 p.m. ET. Both times and agenda topics are subject to change.

ADDRESSES: The meeting will be held virtually using Google Meet. To participate, please use the website provided below. If you are unable to participate online, you can also connect to the public meeting using the phone number provided.

Website: meet.google.com/uce-thjd-nrp.

Phone: +1 814–503–0877 PIN: 233 914 133#.

Instructions: To provide an oral public comment during the virtual meeting, please sign up prior to or during the meeting by contacting Katie Denman by phone (240–533–0702) or email (*katie.denman@noaa.gov*). To provide written public comment, please send the comment to Katie Denman (*katie.denman@noaa.gov*) prior to or during the meeting. Please note, no public comments will be recorded. Public comments, including any associated names, will be captured in the minutes of the meeting, will be maintained by the Office of National Marine Sanctuaries (ONMS) as part of its administrative record, and may be subject to release pursuant to the Freedom of Information Act. By signing up to provide a public comment, you agree that these communications, including your name and comment, will be maintained as described here.

FOR FURTHER INFORMATION CONTACT: Katie Denman, Office of National Marine Sanctuaries, 1305 East-West Highway, Silver Spring, Maryland 20910 (Phone: 240–533–0702; Email: *katie.denman@noaa.gov*).

SUPPLEMENTARY INFORMATION: ONMS serves as the trustee for a network of underwater parks encompassing more than 620,000 square miles of marine and Great Lakes waters from Washington State to the Florida Keys, and from Lake Huron to American Samoa. The network includes a system of 15 national marine sanctuaries and Papahānaumokuākea and Rose Atoll marine national monuments. National marine sanctuaries protect our Nation's most vital coastal and marine natural and cultural resources, and through active research, management, and public engagement, sustain healthy environments that are the foundation for thriving communities and stable economies.

One of the many ways ONMS ensures public participation in the designation and management of national marine

sanctuaries is through the formation of advisory councils. The Sanctuary System Business Advisory Council (council) has been formed to provide advice and recommendations to the Director regarding the relationship of ONMS with the business community. Additional information on the council can be found at *https://sanctuaries.noaa.gov/management/bac/.*

Matters to be discussed: The meeting will include updates from ONMS, a presentation from a sanctuary site, and updates from all working groups. For a complete agenda, including times and topics, please visit *http://sanctuaries.noaa.gov/management/bac/meetings.html.*

Authority: 16 U.S.C. 1431, *et seq.*

John Armor,

Director, Office of National Marine Sanctuaries, National Ocean Service, National Oceanic and Atmospheric Administration.

[FR Doc. 2021–21389 Filed 9–30–21; 8:45 am]

BILLING CODE 3510–NK–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Report of Whaling Operations

The Department of Commerce will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. We invite the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. Public comments were previously requested via the **Federal Register** on May 28, 2021 (86 FR 28763) during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: National Oceanic and Atmospheric Administration (NOAA), Commerce.

Title: Report of Whaling Operations.

OMB Control Number: 0648–0311.

Form Number(s): None.

Type of Request: Regular submission, extension of a current information collection.

Number of Respondents: 166 (165 whaling captains, one Native American whaling organization).

Average Hours per Response: 30 minutes for reports on whales struck or on recovery of dead whales, including providing the information to the relevant Native American whaling organization; 5 minutes for the relevant Native American whaling organization to type in each report; and 2.5 hours for the relevant Native American whaling organization to consolidate and submit reports.

Total Annual Burden Hours: 61.

Needs and Uses: This request is for extension of a current information collection.

Native Americans may conduct certain aboriginal subsistence whaling under the Whaling Convention Act in accordance with the provisions of the International Whaling Commission (IWC). In order to respond to obligations under the International Convention for the Regulation of Whaling, the IWC, and the Whaling Convention Act, whaling captains participating in these operations must submit certain information to the relevant Native American whaling organization about strikes on and catch of whales. Anyone retrieving a dead whale is also required to report. Captains must place a distinctive permanent identification mark on any harpoon, lance, or explosive dart used, as well as provide information on the mark and self-identification information. The relevant Native American whaling organization receives the reports, compiles them, and submits the information to NOAA. The information is used to monitor the hunt and to ensure that quotas are not exceeded. The information is also provided to the IWC, which uses it to monitor compliance with its requirements.

Affected Public: Individuals or households; State, Local, or Tribal government.

Frequency: Reporting by whaling captains occurs after each strike or landing and is submitted to the relevant Native American whaling organization. The Native American whaling organization may submit interim reports every month and additionally once at the end of each hunting season (Spring and Fall).

Respondent's Obligation: Mandatory.

Legal Authority: Whaling Convention Act (16 U.S.C. 916–9161).

This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view the Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the collection or the OMB Control Number 0648–0311.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2021–21392 Filed 9–30–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB475]

South Atlantic Fishery Management Council; Public Hearings

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public hearings.

SUMMARY: The South Atlantic Fishery Management Council (Council) will hold four in-person public hearings pertaining to Amendment 32 to the Fishery Management Plan (FMP) for Coastal Migratory Pelagic Resources in the Gulf of Mexico and Atlantic Region. The amendment addresses modifications to the Gulf of Mexico Migratory Group Cobia catch limits, possession limits, size limits, and framework procedure.

DATES: The public hearings will take place October 18–21, 2021. The public hearings will begin at 6 p.m., EST. For specific dates and times, see **SUPPLEMENTARY INFORMATION.**

ADDRESSES:

Council address: South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, N Charleston, SC 29405.

Meeting addresses: The public hearings will be held in Key West, FL; Jupiter, FL; Cocoa Beach, FL; and Jacksonville, FL. For specific locations, see **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: Kim Iverson, Public Information Officer, SAFMC; phone: (843) 571–4366 or toll

free: (866) SAFMC–10; fax: (843) 769–4520; email: *kim.iverson@safmc.net.*

SUPPLEMENTARY INFORMATION: Public hearing documents, an online public comment form, and other materials will be posted to the Council's website at *https://safmc.net/safmc-meetings/public-hearings-scoping-meetings/* as they become available. Written comments should be addressed to John Carmichael, Executive Director, SAFMC, 4055 Faber Place Drive, Suite 201, N Charleston, SC 29405. Written comments must be received by October 21, 2021, by 5 p.m. in order to be included in the public hearing record for the amendment.

Please note, attendees will be expected to follow any current COVID–19 safety protocols as determined by the venue and each city. Such precautions may include wearing masks in the meeting room, room capacity restrictions, and social distancing. Masks may be removed while giving public testimony.

During the hearings, Council staff will brief the public on the purpose and need of the amendment and provide an overview of actions being considered. Staff will answer clarifying questions on the presented information and the proposed actions. Following the presentation and questions, the public will have the opportunity to provide comments on the amendment.

Amendment 32 to the Coastal Migratory Pelagic FMP

The Coastal Migratory Pelagics FMP, which includes Gulf of Mexico Migratory Group Cobia, is jointly managed by the South Atlantic Fishery Management Council and the Gulf of Mexico Fishery Management Council. The Councils are currently considering modifications to the Gulf of Mexico Migratory Group Cobia Catch Limits, Possession Limits, Size Limits, and Framework Procedure. The management area for Gulf Migratory Group Cobia includes the east coast of Florida.

Public Hearing Locations

Monday, October 18, 2021: Harvey Governmental Center, 1200 Truman Ave., Key West, FL 33040; phone: (305) 289–6063;

Tuesday, October 19, 2021: The River Center, Burt Reynolds Park, 805 US Highway 1 Jupiter, FL 33477; phone: (561) 743–7123;

Wednesday, October 20, 2021: Hilton Cocoa Beach Oceanfront, 1550 North Atlantic Avenue, Cocoa Beach, FL 32931; phone: (321) 799–0003; and

Thursday, October 21, 2021: Mudville Grill, 3105 Beach Blvd., Jacksonville, FL 32216; phone: (904) 398–4326.

Special Accommodations

These hearings are physically accessible to people with disabilities. Requests for auxiliary aids should be directed to the Council office (see **ADDRESSES**) 3 days prior to the meeting.

Note: The times and sequence specified in this agenda are subject to change.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: September 28, 2021.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2021–21412 Filed 9–30–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB477]

Western Pacific Fishery Management Council; Public Meetings

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meetings.

SUMMARY: The Western Pacific Fishery Management Council (Council) will hold its 188th Council meeting to take final action on the American Samoa Bottomfish Management Unit Species Rebuilding Plan.

DATES: The meeting will be held on October 19, 2021. For specific times and agendas, see **SUPPLEMENTARY INFORMATION**.

ADDRESSES: The meetings will be held by web conference via WebEx. Instructions for connecting to the web conference and providing oral public comments will be posted on the Council website at *www.wpcouncil.org.* For assistance with the web conference connection, contact the Council office at (808) 522–8220.

The Council has arranged host sites only for the 188th Council meeting at the following venues: Cliff Pointe, 304 W O'Brien Drive, Hagatna, Guam; BRI Building Suite 205, Kopa Di Oru St., Garapan, Saipan, CNMI; and, Tedi of Samoa Building Suite 208B, Fagatogo Village, American Samoa.

FOR FURTHER INFORMATION CONTACT: Kitty M. Simonds, Executive Director, Western Pacific Fishery Management Council; phone: (808) 522–8220.

SUPPLEMENTARY INFORMATION: All times shown are in Hawaii Standard Time. The 188th Council meeting will be held between 2 p.m. and 4 p.m. on October 19, 2021.

Please note that the evolving public health situation regarding COVID–19 may affect the conduct of the October Council and its associated meetings. At the time this notice was submitted for publication, the Council anticipated convening the meeting by web conference with host site locations in Guam, CNMI and American Samoa only for the 188th Council meeting. Council staff will monitor COVID–19 developments and will determine the extent to which in-person public participation at host sites will be allowable consistent with applicable local and federal safety and health guidelines. If public participation will be limited to web conference only or on a first-come-first-serve basis consistent with applicable guidelines, the Council will post notice on its website at *www.wpcouncil.org.*

Agenda items noted as ''Final Action'' refer to actions that may result in Council transmittal of a proposed fishery management plan, proposed plan amendment, or proposed regulations to the U.S. Secretary of Commerce, under Sections 304 or 305 of the MSA. In addition to the agenda items listed here, the Council and its advisory bodies will hear recommendations from Council advisors. An opportunity to submit public comment will be provided throughout the agendas. The order in which agenda items are addressed may change and will be announced in advance at the Council meeting. The meetings will run as late as necessary to complete scheduled business.

Background documents for the 188th Council meeting will be available at *www.wpcouncil.org.* Written public comments on final action items at the 188th Council meeting should be received at the Council office by 5 p.m. HST, October 15, 2021, and should be sent to Kitty M. Simonds, Executive Director; Western Pacific Fishery Management Council, 1164 Bishop Street, Suite 1400, Honolulu, HI 96813, phone: (808) 522–8220 or fax: (808) 522–8226; or email: *info.wpcouncil@noaa.gov.* Written public comments on all other agenda items may be submitted for the record by email throughout the duration of the meeting. Instructions for providing oral public comments during the meeting will be posted on the Council website. This meeting will be recorded (audio only) for the purposes of generating the minutes of the meeting.

Agenda for the 188th Council Meeting

Tuesday, October 19, 2021, 2 p.m. to 4 p.m.

1. Welcome and Introductions
2. Approval of the 188th Agenda
3. American Samoa Territorial Bottomfish Fishery Management Plan
4. American Samoa Bottomfish Rebuilding Plan (Final Action)
5. Public Comment
6. Council Discussion and Action
7. Other Business

Non-emergency issues not contained in this agenda may come before the Council for discussion and formal Council action during its 188th meeting. However, Council action on regulatory issues will be restricted to those issues specifically listed in this document and any regulatory issue arising after publication of this document that requires emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take action to address the emergency.

Special Accommodations

The meeting is accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Kitty M. Simonds, (808) 522–8220 (voice) or (808) 522–8226 (fax), at least 5 days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: September 28, 2021.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2021–21414 Filed 9–30–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB476]

Council Coordination Committee Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of a public meeting; information regarding the agenda.

SUMMARY: The Pacific Fishery Management Council will host a virtual meeting of the Council Coordination Committee (CCC), consisting of the Regional Fishery Management Council (Council) chairs, vice chairs, and executive directors from October 19 to October 21, 2021. The intent of this meeting is to discuss issues of relevance to the Councils and NMFS, including issues related to the implementation of the Magnuson-Stevens Fishery Conservation and Management Reauthorization Act (MSA).

DATES: The online meeting will begin at 1:30 p.m. Eastern Daylight Time (EDT) on Tuesday, October 19, 2021, recess at 5:30 p.m., reconvene at 1:30 p.m. EDT on Wednesday, October 20, 2021, recess at 5:30 p.m., and reconvene on the final day at 1:30 p.m. EDT Thursday, October 21, 2021, adjourning at 5:30 p.m.

ADDRESSES: The meeting will be held online via RingCentral Webinar. Attendees can find information on how to join at *https://www.fisheries.noaa.gov/national/partners/council-coordination-committee* and *http://www.fisherycouncils.org/ccc-meetings.* You may send an email to Mr. Kris Kleinschmidt (*kris.kleinschmidt@noaa.gov*) or contact him at (503) 820–2412 for technical assistance.

Council address: Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220–1384.

FOR FURTHER INFORMATION CONTACT: Mr. Chuck Tracy, Executive Director, Pacific Fishery Management Council; telephone: (503) 820–2415 or (866) 806–7204 toll-free.

SUPPLEMENTARY INFORMATION: The 2007 reauthorization of the Magnuson-Stevens Fishery Conservation and Management Act established the CCC. The CCC consists of the chairs, vice chairs, and executive directors of each of the eight Regional Fishery Management Councils, or their respective proxies. All sessions are open to the public and time will be set aside for public comments at the end of each day and after specific sessions at the discretion of the meeting Chair. The meeting Chair will announce public comment times and instructions to provide comment at the start of each meeting day. Updates to this meeting, briefing materials, and additional information will be posted when available on *https://www.fisheries.noaa.gov/national/partners/council-coordination-committee* and *http://www.fisherycouncils.org/.*

Proposed Agenda

Tuesday, October 19, 2021—1:30 p.m.–5:30 p.m., EDT

1. Welcome and Introduction
2. Approval of Agenda and Minutes
3. NMFS Update and Upcoming Priorities
4. NMFS Science Update
5. Funding and Budget Update
6. CEQ NEPA Regulation Update
7. National Standard 1 Technical Memorandums
8. Public Comment

Adjourn Day 1

Wednesday, October 20, 2021—1:30 p.m.–5:30 p.m., EDT

9. Legislative Outlook
10. Executive Orders
11. Public Comment

Adjourn Day 2

Thursday, October 21, 2021—1:30 p.m.–5:30 p.m., EDT

12. Underserved Communities
13. Report on National Fish Habitat Board
14. PCCC Committees Reports and Guidance
15. Public Comment
16. Wrap-up and Other Business

Adjourn Day 3

The order in which the agenda items are addressed may be adjusted by the meeting Chair to stay on time. The CCC will meet as late as necessary to complete scheduled business.

Although non-emergency issues not contained in the meeting agenda may be discussed, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically listed in this document and any issues arising after publication of this document that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

Requests for sign language interpretation or other auxiliary aids should be directed to Mr. Kris Kleinschmidt (*kris.kleinschmidt@noaa.gov;* (503) 820–2412) at least 10 business days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: September 28, 2021.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2021–21413 Filed 9–30–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Reporting of Sea Turtle Incidental Take in Virginia Chesapeake Bay Pound Net Operations

The Department of Commerce will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. We invite the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. Public comments were previously requested via the **Federal Register** on June 10, 2021 (86 FR 30918) during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: National Oceanic & Atmospheric Administration (NOAA), Commerce.

Title: Reporting of Sea Turtle Incidental Take in Virginia Chesapeake Bay Pound Net Operations.

OMB Control Number: 0648–0470.

Form Number(s): None.

Type of Request: Regular submission (extension of a current information collection).

Number of Respondents: 37.

Average Hours per Response: 10 minutes.

Total Annual Burden Hours: 167 hours.

Needs and Uses: Since 2002, NOAA's National Marine Fisheries Service (NMFS) has promulgated several rules restricting the use of large mesh and stringer pound net leaders in certain Virginia Chesapeake Bay waters during the late spring/early summer each year. On June 17, 2002, an interim final rule was published (67 FR 41196) restricting leader use, which also required year-round reporting of sea turtle takes. In 2004, NMFS issued a final rule further restricting pound net leader use in Virginia (69 FR 24997). The 2004 rule retained the reporting requirement from the 2002 rule. These regulations (modifications to 50 CFR parts 222 and 223) were implemented as a result of high sea turtle strandings each spring in Virginia and the documented take of sea turtles in pound net leaders. On March 31, 2018, a revised Biological Opinion on NMFS gear regulations in the Virginia pound net fishery was completed pursuant to section 7 of the Endangered Species Act of 1973, as amended (ESA). An Incidental Take Statement was included in this Biological Opinion, exempting the incidental take of a certain number of loggerheads, Kemp's ridley, green, and leatherback sea turtles in pound net operations.

A non-discretionary term and condition of the Incidental Take Statement involved the reporting to NMFS of live or dead sea turtles taken in pound net operations (reflected in 50 CFR 223.206). The collection of this information on the incidental take of sea turtles in the Virginia pound net fishery is necessary to ensure sea turtles are being conserved and protected, as mandated by the ESA. Documenting the accurate occurrence of sea turtle incidental take in pound net operations will help to determine if additional regulatory actions or management measures are necessary to protect sea turtles caught in pound net operations. This information will help NMFS better assess the Virginia pound net fishery and its impacts (or lack thereof) on sea turtle populations in the Virginia Chesapeake Bay. The collection of this information is also imperative to ensure that the Incidental Take Statement is not being exceeded, the anticipated take levels are appropriate, and the effects analysis in the Biological Opinion is accurate. Further, reporting the take of live, injured sea turtles caught in pound net gear will ensure these turtles are transferred immediately to a stranding and rehabilitation center for appropriate medical treatment.

Affected Public: Individuals or households.

Frequency: Reporting occurs when sea turtles are encountered in Virginia pound net gear, which could occur occasionally from May through November.

Respondent's Obligation: Mandatory.

Legal Authority: Endangered Species Act.

This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view the Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the collection or the OMB Control Number 0648–0470.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2021–21410 Filed 9–30–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB462]

North Pacific Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of web conference.

SUMMARY: The North Pacific Fishery Management Council (Council) Charter Halibut Management Committee will meet October 26, 2021, through October 27, 2021.

DATES: The meeting will be held on Tuesday, October 26, 2021, from 1 p.m. to 4 p.m. and on Wednesday, October 27, 2021, from 8 a.m. to 4 p.m., Alaska Time.

ADDRESSES: The meeting will be a web conference. Join online through the link at *https://meetings.npfmc.org/Meeting/Details/2495.*

Council address: North Pacific Fishery Management Council, 1007 W 3rd Ave., Anchorage, AK 99501–2252; telephone: (907) 271–2809. Instructions for attending the meeting via video conference are given under **SUPPLEMENTARY INFORMATION**, below.

FOR FURTHER INFORMATION CONTACT: Sarah Marrinan, Council staff; phone: (907) 271–2809; email: *sarah.marrinan@noaa.gov.* For technical support please contact our admin Council staff, email: *npfmc.admin@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Agenda

Tuesday, October 26, 2021, Through Wednesday, October 27, 2021

The Charter Halibut Management Committee agenda will include (a) review of ADF&G preliminary estimates of 2021 charter harvest and recommend management measures to be analyzed for 2022; (b) review Recreational Quota Entity (RQE) funding mechanism

analysis and options and discuss next steps; and (c) other business. The agenda is subject to change, and the latest version will be posted at *https://meetings.npfmc.org/Meeting/Details/2495* prior to the meeting, along with meeting materials.

Connection Information

You can attend the meeting online using a computer, tablet, or smart phone; or by phone only. Connection information will be posted online at: *https://meetings.npfmc.org/Meeting/Details/2495.*

Public Comment

Public comment letters will be accepted and should be submitted electronically to *https://meetings.npfmc.org/Meeting/Details/2495.*

Authority: 16 U.S.C. 1801 *et seq.*

Dated: September 28, 2021.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2021–21411 Filed 9–30–21; 8:45 am]

BILLING CODE 3510–22–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Additions and Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed additions to and deletions from the procurement list.

SUMMARY: The Committee is proposing to add product(s) to the Procurement List that will be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and deletes product(s) previously furnished by such agencies.

DATES: Comments must be received on or before: October 31, 2021.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S Clark Street, Suite 715, Arlington, Virginia, 22202–4149.

FOR FURTHER INFORMATION CONTACT: For further information or to submit comments contact: Michael R. Jurkowski, Telephone: (703) 785–6404, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 8503 (a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Additions

If the Committee approves the proposed additions, the entities of the Federal Government identified in this notice will be required to procure the product(s) listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

The following product(s) are proposed for addition to the Procurement List for production by the nonprofit agencies listed:

Product(s)

NSN(s)—Product Name(s):
6135–01–554–4281—Battery, Non-rechargeable, 9.0V Lithium
6135–01–616–2203—Battery, Non-rechargeable, 7.5V Alkaline

Designated Source of Supply: Eastern Carolina Vocational Center, Inc., Greenville, NC

Contracting Activity: DEFENSE LOGISTICS AGENCY, DLA LAND AND MARITIME

Mandatory for: 100% of the requirement of the Department of Defense

List Designation: C-List

Deletions

The following product(s) are proposed for deletion from the Procurement List:

Product(s)

NSN(s)–Product Name(s):
8105–LL–S05–0146—Bag, Polyethylene, Non-Asbestos Waste, 24″W x 48″L, Opaque Green with Black Printing
8105–LL–S05–0147—Bag, Polyethylene, Non-Asbestos Waste, 36″W x 48″L, Opaque Green with Black Printing
8105–LL–S05–0148—Bag, Polyethylene, Non-Asbestos Waste, 14″W x 48″L, Opaque Green with Black Printing
8105–LL–S04–7842—Bag, Polyethylene, Asbestos Waste, 24″W x 48″L, 6–10 MIL, Opaque Blue with White Printing
8105–LL–S04–7843—Bag, Polyethylene, Asbestos Waste, 36″W x 48″L, 6–10 MIL, Opaque Blue with White Printing
8105–LL–S05–0018—Bag, Polyethylene, Asbestos Waste, 12″W x 24″L, 6–10 MIL, Opaque Blue with White Printing

Designated Source of Supply: Open Door Center, Valley City, ND

Contracting Activity: DLA MARITIME—PUGET SOUND, BREMERTON, WA

Michael R. Jurkowski,

Acting Director, Business Operations.

[FR Doc. 2021–21407 Filed 9–30–21; 8:45 am]

BILLING CODE 6353–01–P

COUNCIL OF THE INSPECTORS GENERAL ON INTEGRITY AND EFFICIENCY

Senior Executive Service Performance Review Board Membership

AGENCY: Council of the Inspectors General on Integrity and Efficiency.

ACTION: Notice.

SUMMARY: This notice sets forth the names and titles of the current membership of the Council of the Inspectors General on Integrity and Efficiency (CIGIE) Performance Review Board as of October 1, 2019.

DATES: *Applicable Date:* October 1, 2021.

FOR FURTHER INFORMATION CONTACT: Individual Offices of Inspectors General at the telephone numbers listed below.

SUPPLEMENTARY INFORMATION:

I. Background

The Inspector General Act of 1978, as amended, created the Offices of Inspectors General as independent and objective units to conduct and supervise audits and investigations relating to Federal programs and operations. The Inspector General Reform Act of 2008, established the Council of the Inspectors General on Integrity and Efficiency (CIGIE) to address integrity, economy, and effectiveness issues that transcend individual Government agencies; and increase the professionalism and effectiveness of personnel by developing policies, standards, and approaches to aid in the establishment of a well-trained and highly skilled workforce in the Offices of Inspectors General. The CIGIE is an interagency council whose executive chair is the Deputy Director for Management, Office of Management and Budget, and is comprised principally of the 73 Inspectors General (IGs).

II. CIGIE Performance Review Board

Under 5 U.S.C. 4314(c)(1)–(5), and in accordance with regulations prescribed by the Office of Personnel Management, each agency is required to establish one or more Senior Executive Service (SES) performance review boards. The purpose of these boards is to review and evaluate the initial appraisal of a senior executive's performance by the supervisor, along with any recommendations to the appointing authority relative to the performance of the senior executive. The current members of the Council of the Inspectors General on Integrity and Efficiency Performance Review Board, as of October 1, 2019, are as follows:

Agency for International Development

Phone Number: (202) 712–1150

CIGIE Liaison—Thomas Ullom (202) 712–1150

Thomas Ullom—Deputy Inspector General.
Justin Brown—Counselor to the Inspector General (SL).
Daniel Altman—Assistant Inspector General for Investigations.
Suzann Gallaher—Deputy Assistant Inspector General for Investigations.
Thomas Yatsco—Assistant Inspector General for Audit.
Alvin A. Brown—Deputy Assistant Inspector General for Audit.
Toayoa Aldridge—Deputy Assistant Inspector General for Audit.
Jason Carroll—Assistant Inspector General for Management.
Parisa Salehi—Deputy Assistant Inspector General for Management.
Nicole Angarella—General Counsel to the Inspector General.

Department of Agriculture

Phone Number: (202) 720–8001

CIGIE Liaison—Angel N. Bethea (202) 720–8001

Ann M. Coffey—Deputy Inspector General.
Christy A. Slamowitz—Counsel to the Inspector General.
Gilroy Harden—Assistant Inspector General for Audit.
Steven H. Rickrode, Jr.—Deputy Assistant Inspector General for Audit.
Yarisis Rivera Rojas—Deputy Assistant Inspector General for Audit.
Peter P. Paradis, Sr.—Deputy Assistant Inspector General for Investigations.
Virginia E. B. Rone—Assistant Inspector General for Data Sciences.
Robert J. Huttenlocker—Assistant Inspector General for Management.

Department of Commerce

Phone Number: (202) 482–4661

CIGIE Liaison—Clark Reid (202) 482–4661

E. Wade Green—Counsel to the Inspector General.
Richard Bachman—Assistant Inspector General for Audits.
Carol Rice—Assistant Inspector General for Audits.
Mark Zabarsky—Principal Assistant Inspector General.

Department of Defense

Phone Number: (703) 604–8324

Acting CIGIE Liaison—Brett Mansfield (703) 604–8300

Daniel R. Blair—Deputy Chief of Staff.
Michael S. Child, Sr.—Deputy Inspector General for Overseas Contingency Operations.
Carol N. Gorman—Assistant Inspector General for Readiness and Cyber Operations.
Paul Hadjiyane—General Counsel.
Carolyn R. Hantz—Assistant Inspector General for Program, Combatant Command and Overseas Contingency Operations.
Glenn A. Fine—Principal Deputy Inspector General.
Janice M. Flores—Assistant Inspector General for Investigations, Internal Operations.
Marguerite C. Garrison—Deputy Inspector General for Administrative Investigations.
Theresa S. Hull—Assistant Inspector General for Acquisition and Sustainment Management.
Kelly P. Mayo—Assistant Inspector General for Investigations.
Troy M. Meyer—Principal Assistant Inspector General for Audit.
Dermot F. O'Reilly—Deputy Inspector General for Investigations.
Michael J. Roark—Deputy Inspector General for Evaluations.
Steven A. Stebbins—Chief of Staff.
Paul K. Sternal—Assistant Inspector General for Investigations, Investigative Operations.
Randolph R. Stone—Assistant Inspector General for Space, Intelligence, Engineering, and Oversight.
Richard B. Vasquez—Assistant Inspector General for Readiness and Global Operations.
Lorin T. Venable—Assistant Inspector General for Financial Management and Reporting.
Jacqueline L. Wicecarver—Deputy Inspector General for Audit.
David G. Yacobucci—Assistant Inspector General for Data Analytics.

Department of Education OIG

Phone Number: (202) 245–6900

CIGIE Liaison—Keith Maddox (202) 748–4339

David Morris—Assistant Inspector General for Management Services.
Robert Mancuso—Assistant Inspector General for Information Technology Audits and Computer Crimes Investigations.
Bryon Gordon—Assistant Inspector General for Audit.
Sean Dawson—Deputy Assistant Inspector General for Audit.
Aaron Jordan—Assistant Inspector General for Investigations.
Mark Smith—Deputy Assistant Inspector General for Investigations.

Department of Energy

Phone Number: (202) 586–4393

CIGIE Liaison—Catherine Ford (202) 586–4393

Jennifer Quinones—Deputy Inspector General.
Nicholas Acker—Counsel to the Inspector General.
Virginia Grebasch—Senior Counsel, FOIA and Privacy Act Officer
Dustin Wright—Assistant Inspector General for Investigations.
Lew Sessions—Deputy Inspector General for Investigations.
Sarah Nelson—Assistant Inspector General for Technology, Financial and Analytics.
Jack Rouch—Deputy Assistant Inspector General for Audits.
John McCoy II—Deputy Assistant Inspector General for Audits.

Environmental Protection Agency

CIGIE Liaison—Jennifer Kaplan (202) 566–0918

Charles Sheehan—Deputy Inspector General.
Edward Shields—Associate Deputy Inspector General.
Kevin Christensen—Assistant Inspector General for Audit and Evaluation.
Helina Wong—Assistant Inspector General for Investigations.

Federal Labor Relations Authority

Phone Number: (202) 218–7744

CIGIE Liaison—Dana Rooney (202) 218–7744

Dana Rooney—Inspector General.

Federal Maritime Commission

Phone Number: (202) 523–5863

CIGIE Liaison—Jon Hatfield (202) 523–5863

Jon Hatfield—Inspector General.

Federal Trade Commission

Phone Number: (202) 326–2355

CIGIE Liaison—Andrew Katsaros (202) 326–2355

Andrew Katsaros—Inspector General.

General Services Administration

Phone Number: (202) 501–0450

CIGIE Liaison—Phyllis Goode (202) 273—7270

Robert C. Erickson—Deputy Inspector General.
Larry L. Gregg—Associate Inspector General.
Edward Martin—Counsel to the Inspector General.
R. Nicholas Goco—Assistant Inspector General for Audits.

Barbara Bouldin—Deputy Assistant Inspector General for Acquisition Program Audits.
Brian Gibson—Deputy Assistant Inspector General for Real Property Audits.
James E. Adams—Assistant Inspector General for Investigations.
Patricia D. Sheehan—Assistant Inspector General for Inspections.
Kristine Preece—Assistant Inspector General for Administration.

Department of Health and Human Services

Phone Number: (202) 619–3148

CIGIE Liaison—Elise Stein (202) 619–2686

Christi Grimm—Chief of Staff.
Robert Owens, Jr.—Deputy Inspector General for Management and Policy.
Caryl Brzymialkiewicz—Assistant Inspector General/Chief Data Officer.
Chris Chilbert—Assistant Inspector General/Chief Information Officer.
Gary Cantrell—Deputy Inspector General for Investigations.
Suzanne Murrin—Deputy Inspector General for Evaluation and Inspections.
Erin Bliss—Assistant Inspector General for Evaluation and Inspections.
Ann Maxwell—Assistant Inspector General for Evaluation and Inspections.
Gregory Demske—Chief Counsel to the Inspector General.
Robert DeConti—Assistant Inspector General for Legal Affairs.
Lisa Re—Assistant Inspector General for Legal Affairs.
Gloria Jarmon—Deputy Inspector General for Audit Services.
Amy Frontz—Assistant Inspector General for Audit Services.
Carrie Hug—Assistant Inspector General for Audit Services.
Brian Ritchie—Assistant Inspector General for Audit Services.

Department of Homeland Security

Phone Number: (202) 981–6000

CIGIE Liaison—Erica Paulson (202) 981–6392

Jennifer Costello—Deputy Inspector General.
Karen Ouzts—Deputy Counsel.
Diana Shaw—Assistant Inspector General for Special Reviews and Evaluations.
Donald Bumgardner—Deputy Assistant Inspector General for Audits.
Maureen Duddy—Deputy Assistant Inspector General for Audits.
Erica Paulson—Assistant Inspector General for External Affairs.
Sondra McCauley—Assistant Inspector General for Audits.
Thomas Salmon—Assistant Inspector General for Integrity and Quality Oversight.
Louise M. McGlathery—Assistant Inspector General for Management.

Department of Housing and Urban Development

Phone Number: (202) 708–0430

CIGIE Liaison—Michael White (202) 402–8410

Charles Jones—Deputy Inspector General.

John Buck—Deputy Assistant Inspector General for Audit.

Kimberly Randall—(Acting) Assistant Inspector General for Audit.

Laura Farrior—Deputy Assistant Inspector General for Management.

Christopher Webber—Deputy Assistant Inspector General for Information Technology.

Jeremy Kirkland—Counsel to the Inspector General.

Brian Pattison—Assistant Inspector General for Evaluation.

Department of the Interior

Phone Number: (202) 208–5635

CIGIE Liaison—Karen Edwards (202) 208–5635

Steve Hardgrove—Chief of Staff.

Kimberly McGovern—Assistant Inspector General for Audits, Inspections and Evaluations.

Matthew Elliott—Assistant Inspector General for Investigations.

Bruce Delaplaine—General Counsel.

Department of Justice

Phone Number: (202) 514–3435

CIGIE Liaison—John Lavinsky (202) 514–3435

William M. Blier—Deputy Inspector General.

Jonathan M. Malis—General Counsel.

Michael Sean O'Neill—Assistant Inspector General for Oversight and Review.

Patricia Sumner—Deputy Assistant Inspector General for Oversight and Review.

Jason R. Malmstrom—Assistant Inspector General for Audit.

Mark L. Hayes—Deputy Assistant Inspector General for Audit.

Sarah E. Lake—Assistant Inspector General for Investigations.

Nina S. Pelletier—Assistant Inspector General for Evaluation and Inspections.

Gregory T. Peters—Assistant Inspector General for Management and Planning.

Cynthia Lowell—Deputy Assistant Inspector for Management and Planning.

Department of Labor

Phone Number: (202) 693–5100

CIGIE Liaison—Luiz A. Santos (202) 693–7062

Larry D. Turner—Deputy Inspector General.
Dee Thompson—Counsel to the Inspector General.
Elliot P. Lewis—Assistant Inspector General for Audit.
Leia Burks—Deputy Assistant Inspector General for Investigations—Labor Racketeering and Fraud.
Thomas D. Williams—Assistant Inspector General for Management and Policy.
Charles Sabatos—Deputy Assistant Inspector General for Management and Policy.
Luiz A. Santos—Assistant Inspector General for Congressional and Public Relations.
Jessica Southwell—Chief Performance and Risk Management Officer.

National Aeronautics and Space Administration

Phone Number: (202) 358–1220

CIGIE Liaison—Renee Juhans (202) 358–1712

George A. Scott—Deputy Inspector General.
Frank LaRocca—Counsel to the Inspector General.
James R. Ives—Assistant Inspector General for Investigations.
Kimberly F. Benoit—Assistant Inspector General for Audits.
Ross W. Weiland—Assistant Inspector General for Management Planning.

National Archives and Records Administration

Phone Number: (301) 837–3000

CIGIE Liaison—John Simms (301) 837–3000

Jewel Butler—Assistant Inspector General for Audit.
Jason Metrick—Assistant Inspector General for Investigations.

National Labor Relations Board

Phone Number: (202) 273–1960

CIGIE Liaison—Robert Brennan (202) 273–1960

David P. Berry—Inspector General.

National Science Foundation

Phone Number: (703) 292–7100

CIGIE Liaison—Lisa Vonder Haar (703) 292–2989

Megan Wallace—Assistant Inspector General for Investigations.
Mark Bell—Assistant Inspector General for Audits.

Alan Boehm—Assistant Inspector General for Management.

Ken Chason—Counsel to the Inspector General.

Nuclear Regulatory Commission

Phone Number: (301) 415–5930

CIGIE Liaison—Judy Gordon (301) 415–5913

David C. Lee—Deputy Inspector General.

Rocco J. Pierri—Assistant Inspector General for Investigations.

Brett M. Baker—Assistant Inspector General for Audits.

Office of Personnel Management

Phone Number: (202) 606–1200

CIGIE Liaison—Faiza Mathon-Mathieu (202) 606–2236

Norbert E. Vint—Deputy Inspector General/Deputy Inspector General Performing the Duties of the Inspector General.

Michael R. Esser—Assistant Inspector General for Audits.

Melissa D. Brown—Deputy Assistant Inspector General for Audits.

Lewis F. Parker, Jr.—Deputy Assistant Inspector General for Audits.

Drew M. Grimm—Assistant Inspector General for Investigations.

Thomas W. South—Deputy Assistant Inspector General for Investigations.

James L. Ropelewski—Assistant Inspector General for Management.

Nicholas E. Hoyle—Deputy Assistant Inspector General for Management.

Gopala Seelamneni—Chief Information Technology Officer.

Peace Corps

Phone Number: (202) 692–2900

CIGIE Liaison—Joaquin Ferrao (202) 692–2921

Kathy Buller—Inspector General (Foreign Service).

Joaquin Ferrao—Deputy Inspector General and Legal Counsel (Foreign Service).

United States Postal Service

Phone Number: (703) 248–2100

CIGIE Liaison—Agapi Doulaveris (703) 248–2286

Elizabeth Martin—General Counsel.

Gladis Griffith—Deputy General Counsel.

Katherine Reilly—Deputy Assistant Inspector General, Mission Support.

Railroad Retirement Board

Phone Number: (312) 751–4690

CIGIE Liaison—Jill Roellig (312) 751–4993

Patricia A. Marshall—Counsel to the Inspector General.

Small Business Administration

Phone Number: (202) 401–0753

CIGIE Liaison—Mary Kazarian (202) 205–6586

Mark P. Hines—Assistant Inspector General for Investigations.

Andrea Deadwyler—Assistant Inspector General for Audits.

Sheldon Shoemaker—Assistant Inspector General for Management and Operations.

Social Security Administration

Phone Number: (410) 966–8385

CIGIE Liaison—Walter E. Bayer, Jr. (202) 358–6319

Steven L. Schaeffer—Chief of Staff.

Rona Lawson—Assistant Inspector General for Audit.

Joseph Gangloff—Chief Counsel to the Inspector General.

Michael Robinson—Senior Advisor to the Inspector General for Law Enforcement.

Jennifer Walker—Assistant Inspector General for Investigations.

Joscelyn Funnié—Counsel for Investigations and Enforcement.

Special Inspector General for the Troubled Asset Relief Program

Phone Number: (202) 622–1419

CIGIE Liaison—Kevin Gerrity (202) 622–8670

Kevin Gerrity—Deputy Special Inspector General.

Vincent Micone III—Assistant Inspector General—Management.

Department of State and the Broadcasting Board of Governors

Phone Number: (571) 348–3804

CIGIE Liaison—Sarah Breen (571) 348–3992

Norman P. Brown—Assistant Inspector General for Audits.

Sandra J. Lewis—Assistant Inspector General for Inspections.

Michael T. Ryan—Assistant Inspector General for Investigations.

Kevin S. Donohue—Deputy General Counsel.

Gayle L. Voshell—Deputy Assistant Inspector General for Audits.

Tinh T. Nguyen—Deputy Assistant Inspector General for Audits, Middle East Region Operations.

Lisa R. Rodely—Deputy Assistant Inspector General for Inspections.

Jeffrey D. Johnson—Deputy Assistant Inspector General for Inspections.

Brian Grossman—Deputy Assistant Inspector General for Investigations.

Donna J. Butler—Assistant Inspector General for Management.

Jeffrey McDermott—Assistant Inspector General for Evaluations and Special Projects.

Department of Transportation

Phone Number: (202) 366–1959

CIGIE Liaison—Nathan P. Richmond: (202) 493–0422

Mitchell L. Behm—Deputy Inspector General.

Joseph W. Comé—Principal Assistant Inspector General for Auditing and Evaluation.

Charles A. Ward—Assistant Inspector General for Audit Operations and Special Reviews.

Matthew E. Hampton—Assistant Inspector General for Aviation Audits.

Barry DeWeese—Assistant Inspector General for Surface Transportation Audits.

Louis C. King—Assistant Inspector General for Financial and Information Technology Audits.

Mary Kay Langan-Feirson—Assistant Inspector General for Acquisition and Procurement Audits.

David Pouliott—Deputy Assistant Inspector General for Surface Transportation Audits.

Anthony Zakel—Deputy Assistant Inspector General for Aviation Audits.

Department of the Treasury

Phone Number: (202) 622–1090

CIGIE Liaison—Rich Delmar (202) 927–3973

Richard K. Delmar—Acting Inspector General.

Jeffrey Lawrence—Assistant Inspector General for Management.

Sally Luttrell—Assistant Inspector General for Investigations.

Deborah L. Harker—Assistant Inspector General for Audit.

Pauletta Battle—Deputy Assistant Inspector General for Financial Management and Transparency Audits.

Lisa A. Carter—Deputy Assistant Inspector General for Financial Sector Audits.

Donna F. Joseph—Deputy Assistant Inspector General for Cyber and Financial Assistance Audits.

Treasury Inspector General for Tax Administration/Department of the Treasury

Phone Number: (202) 622–6500

CIGIE Liaison—David Barnes (Acting) (202) 622–3062

Gladys Hernandez—Chief Counsel.
James Jackson—Deputy Inspector General for Investigations.
Gregory Kutz—Deputy Inspector General for Inspections and Evaluations.
Nancy LaManna—Assistant Inspector General for Audit, Management, Planning, and Workforce Development.
Russell Martin—Assistant Inspector General for Audit, Returns Processing, and Accounting Services.
Michael McKenney—Deputy Inspector General for Audit.
Danny Verneuille—Assistant Inspector General for Audit, Security, and Information Technology Services.
Matthew Weir—Assistant Inspector General for Audit, Compliance, and Enforcement Operations.
Jeffrey Long—Assistant Inspector General for Investigations, Threat, Agent Safety, and Sensitive Investigations Directorate.
Trevor Nelson—Assistant Inspector General for Investigations.
Ruben Florez—Assistant Inspector General for Investigations—Field.

Department of Veterans Affairs

Phone Number: (202) 461–4720

CIGIE Liaison—Jennifer Geldhof (202) 461–4677

Roy Fredrikson—Deputy Counselor to the Inspector General.
Brent Arronte—Deputy Assistant Inspector General for Audits and Evaluations.
John D. Daigh—Assistant Inspector General for Healthcare Inspections.

Dated: September 24, 2021.

Alan F. Boehm,

Executive Director.

[FR Doc. 2021–21383 Filed 9–30–21; 8:45 am]

BILLING CODE 6820–C9–P

DEPARTMENT OF DEFENSE

Department of the Navy

Notice of Availability of Record of Decision for the Northwest Training and Testing Supplemental Environmental Impact Statement/ Overseas Environmental Impact Statement

AGENCY: Department of the Navy, DoD.

ACTION: Notice.

SUMMARY: The United States Department of the Navy (DON), after carefully weighing the operational and environmental consequences of the Proposed Action, is announcing its decision to continue training and testing activities as identified in Alternative 1 in the Northwest Training and Testing (NWTT) Final Supplemental Environmental Impact Statement/ Overseas Environmental Impact Statement (EIS/OEIS), dated September 2020. Under Alternative 1, the U.S. Navy will be able to fully meet current and future training and testing requirements.

SUPPLEMENTARY INFORMATION: Alternative 1 is the DON's preferred alternative and includes changes in the types and tempo of training and testing activities at sea and in associated airspace to meet current and future military readiness requirements. Alternative 1 reflects a representative year of training and testing activities to account for the natural fluctuation of training cycles, testing programs, and deployment schedules that generally limit the maximum level of training and testing from occurring in the reasonably foreseeable future. The complete text of the Record of Decision (ROD) is available on the project website at *www.NWTTEIS.com,* along with the September 2020 NWTT Final Supplemental EIS/OEIS and supporting documents. Single copies of the ROD are available upon request by contacting: Naval Facilities Engineering Command Northwest, Attn: NWTT Supplemental EIS/OEIS Project Manager, 3730 N Charles Porter Avenue, Building 385, Oak Harbor, WA 98278–3500.

Dated: September 24, 2021.

J.M. Pike,

Commander, Judge Advocate General's Corps, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. 2021–21181 Filed 9–30–21; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF EDUCATION

[Docket No. ED–2021–SCC–0112]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Federal Family Educational Loan Program—Servicemembers Civil Relief Act (SCRA)

AGENCY: Federal Student Aid (FSA), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing an extension without change of a currently approved collection.

DATES: Interested persons are invited to submit comments on or before November 1, 2021.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this information collection request by selecting ''Department of Education'' under ''Currently Under Review,'' then check ''Only Show ICR for Public Comment'' checkbox. Comments may also be sent to *ICDocketmgr@ed.gov.*

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Beth Grebeldinger, 202–377–4018.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Federal Family Educational Loan Program—Servicemembers Civil Relief Act (SCRA).

OMB Control Number: 1845–0093.

Type of Review: An extension without change of a currently approved collection.

Respondents/Affected Public: Private Sector; State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 16,731.

Total Estimated Number of Annual Burden Hours: 50,115.

Abstract: The Department of Education (the Department) is requesting extension without change of the currently approved OMB information collection 1845–0093, Federal Family Education Loan (FFEL) Program Servicemembers Civil Relief Act (SCRA). Due to the effects of the COVID–19 pandemic and the suspension of the collection of loans, the Department lacks sufficient data to allow for more accurate updates to the usage of these forms. The regulations require the FFEL loan holder to match its database against the Department of Defense (DOD) Defense Manpower Data Center (DMDC) or other official DOD database and automatically apply the interest rate limitation, as appropriate, to borrowers under the SCRA. There has been no change in the statute or in the regulations at 34 CFR 682.208(j).

Dated: September 28, 2021.

Juliana Pearson,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2021–21442 Filed 9–30–21; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Electricity Advisory Committee

AGENCY: Department of Energy, Office of Electricity.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Electricity Advisory Committee. The Federal Advisory Committee Act requires that public notice of these meetings be announced in the **Federal Register**.

DATES:

Wednesday, October 20, 2021; 11:45 a.m.–6:00 p.m. EST

Thursday, October 21, 2021; 11:45 a.m.–5:00 p.m. EST

ADDRESSES: Due to ongoing precautionary measures surrounding the spread of COVID–19, the October meeting of the EAC will be held via WebEx video and teleconference. In order to track all participants, the Department is requiring that those wishing to attend register for the meeting here: *https://www.energy.gov/oe/october-20-21-2021-meeting-electricity-advisory-committee.* Please note, you must register for each day you would like to attend.

FOR FURTHER INFORMATION CONTACT: Christopher Lawrence, Designated Federal Officer, Office of Electricity, U.S. Department of Energy, Washington, DC 20585; Telephone: (202) 586–5260 or Email: *Christopher.Lawrence@hq.doe.gov.*

SUPPLEMENTARY INFORMATION:

Purpose of the Committee: The Electricity Advisory Committee (EAC) was established in accordance with the provisions of the Federal Advisory Committee Act (FACA), as amended, to provide advice to the U.S. Department of Energy (DOE) in implementing the Energy Policy Act of 2005, executing certain sections of the Energy Independence and Security Act of 2007, and modernizing the nation's electricity delivery infrastructure. The EAC is composed of individuals of diverse backgrounds selected for their technical expertise and experience, established records of distinguished professional service, and their knowledge of issues that pertain to the electric sector.

Tentative Agenda:

October 20, 2021

11:45 a.m.–12:00 p.m. WebEx Attendee Sign-On

12:00 p.m.–12:20 p.m. Welcome, Introductions, Developments since the April 2021 Meeting

12:20 p.m.–12:50 p.m. Update on Office of Electricity Programs and Initiatives

12:50 p.m.–1:20 p.m. Overview of DOE Conducted Carbon-Free Energy Futures Analysis

1:20 p.m.–1:50 p.m. Overview of DOE/OE Energy Storage Activities

1:50 p.m.–2:00 p.m. Break

2:00 p.m.–3:00 p.m. Overview and Discussion of Energy Industrial Base Project

3:00 p.m.–4:30 p.m. Discussion of Supply Chain Congressional Reports Focused on Supply Chain of Large Power Transformers and Battery Storage

4:30 p.m.–4:40 p.m. Break

4:40 p.m.–5:40 p.m. Panel Discussion: *Blackstart in the Variable Generation Era*

5:40 p.m.–6:00 p.m. Wrap-up and Adjourn Day 1

October 21, 2021

11:45 a.m.–12:00 p.m. WebEx Attendee Sign-On

12:00 p.m.–12:10 p.m. Day 2 Opening Remarks

12:10 p.m.–1:10 p.m. Update and Discussion on Section 8008 Voluntary Model Pathways Development

1:10 p.m.–1:45 p.m. Transmission-Distribution Coordination

1:45 p.m.–3:30 p.m. Panel and Discussion: *FERC 2222 and Operational Coordination*

3:30 p.m.–3:40 p.m. Break

3:40 p.m.–3:55 p.m. Subcommittee Update: Energy Storage

3:55 p.m.–4:10 p.m. Subcommittee Update: Smart Grid

4:10 p.m.–4:25 p.m. Subcommittee Update: Grid Resilience for National Security

4:25 p.m.–4:40 p.m. Public Comments

4:40 p.m.–5:00 p.m. Wrap-up and Adjourn October 2021 Meeting of the EAC

The meeting agenda may change to accommodate EAC business. For EAC agenda updates, see the EAC website at: *http://energy.gov/oe/services/electricity-advisory-committee-eac.*

Public Participation: The EAC welcomes the attendance of the public at its meetings. Individuals who wish to offer public comments at the EAC meeting may do so on October 21, but must register in advance. Approximately 15 minutes will be reserved for public comments. Time allotted per speaker will depend on the number who wish to speak but is not expected to exceed three minutes. Anyone who is not able to attend the meeting, or for whom the allotted public comments time is insufficient to address pertinent issues with the EAC, is invited to send a written statement identified by ''Electricity Advisory Committee October 2021 Meeting,'' to Mr. Christopher Lawrence at *Christopher.lawrence@hq.doe.gov.*

Minutes: The minutes of the EAC meeting will be posted on the EAC web page at *http://energy.gov/oe/services/electricity-advisory-committee-eac.* They can also be obtained by contacting Mr. Christopher Lawrence at the address above.

Signed in Washington, DC, on September 28, 2021.

LaTanya R. Butler,

Deputy Committee Management Officer.

[FR Doc. 2021–21415 Filed 9–30–21; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

DOE/NSF Nuclear Science Advisory Committee

AGENCY: Office of Science, Department of Energy

ACTION: Notice of renewal.

SUMMARY: Pursuant the Federal Advisory Committee Act, and the Code of Federal Regulations, and following consultation with the Committee Management Secretariat, General

Services Administration, notice is hereby given that the DOE/NSF Nuclear Science Advisory Committee (NSAC) has been renewed for a two-year period. The Committee will provide advice and recommendations to the Director, Office of Science (DOE), and the Assistant Director, Directorate for Mathematical and Physical Sciences (NSF), on scientific priorities within the field of basic nuclear science research.

Additionally, the Secretary of Energy has determined that renewal of the NSAC is essential to conduct business of the Department of Energy and the National Science Foundation and is in the public interest in connection with the performance of duties imposed by law upon the Department of Energy. The Committee will continue to operate in accordance with the provisions of the Federal Advisory Committee Act, the Department of Energy Organization Act (Pub. L. 95–91), and the rules and regulations in implementation of these acts.

FOR FURTHER INFORMATION CONTACT: Dr. Timothy Hallman at (301) 903–3613, or *timothy.hallman@science.doe.gov.*

Signing Authority

This document of the Department of Energy was signed on September 27, 2021, by Miles Fernandez, Acting Committee Management Officer, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on September 28, 2021.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

[FR Doc. 2021–21376 Filed 9–30–21; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No.13511–007]

Igiugig Village Council; Notice of Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* Non-capacity amendment of license.

b. *Project No.:* 13511–007.

c. *Date Filed:* August 16, 2021.

d. *Applicant:* Igiugig Village Council.

e. *Name of Project:* Igiugig Hydroelectric Project.

f. *Location:* The project is located on the Kvichak River in the Lake and Peninsula Borough, Alaska.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791 (a)–825(r).

h. *Applicant Contact:* Ms. AlexAnna Salmon, President, Igiugig Village Council, #1 Airport Way, Igiugig, AK 99613–4008, (907) 533–3211.

i. *FERC Contact:* Mr. Steven Sachs, (202) 502–8666, *Steven.Sachs@ferc.gov.*

j. Deadline for filing comments, motions to intervene, and protests is 30 days from the issuance of this notice by the Commission. The Commission strongly encourages electronic filing. Please file comments, motions to intervene, and protests using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/doc-sfiling/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. The first page of any filing should include docket number P–13511–007.

The Commission's Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. *Description of Request:* The applicant proposes to place a 10-foot-long, 8-foot-wide, 8.5-foot-tall steel structure at the sportfish access area next to an existing, nearly identical structure. The new structure would serve as a shelter for electrical, control, and monitoring equipment.

l. In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Motions to Intervene, or Protests:* Anyone may submit comments, a motion to intervene, or a protest in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, motions to intervene, or protests must be received on or before the specified comment date for the particular application.

o. *Filing and Service of Responsive Documents:* Any filing must (1) bear in all capital letters the title ''COMMENTS'', ''MOTION TO INTERVENE'', or ''PROTEST'' as applicable; (2) set forth in the heading the name of the applicant and the project number(s) of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person intervening or protesting; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary

basis. A copy of all other filings in reference to this application must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 385.2010.

Dated: September 27, 2021.

Kimberly D. Bose,

Secretary.

[FR Doc. 2021–21422 Filed 9–30–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–2564–011; ER10–2600–011; ER10–2289–011.
Applicants: UniSource Energy Development Company, UNS Electric, Inc., Tucson Electric Power Company.
Description: Amendment to June 21, 2021 Notice of Non-Material Change in Status of Tucson Electric Power Company, et al.
Filed Date: 9/27/21.
Accession Number: 20210927–5086.
Comment Date: 5 p.m. ET 10/18/21.

Docket Numbers: ER21–1576–002.
Applicants: Tri-State Generation and Transmission Association, Inc., Southwest Power Pool, Inc.
Description: Compliance filing: Southwest Power Pool, Inc. submits tariff filing per 35: Compliance Filing in Response to Order issued in ER21–1576 (Tri-State) to be effective 6/1/2021.
Filed Date: 9/27/21.
Accession Number: 20210927–5119.
Comment Date: 5 p.m. ET 10/18/21.

Docket Numbers: ER21–2571–001.
Applicants: Midcontinent Independent System Operator, Inc., Consumers Energy Company, Michigan Electric Transmission Company, LLC.
Description: Tariff Amendment: Midcontinent Independent System Operator, Inc. submits tariff filing per 35.17(b): 2021–09–24_SA 3315 METC–CE 1st Rev TSA to be effective 9/30/2021.
Filed Date: 9/24/21.
Accession Number: 20210924–5070.
Comment Date: 5 p.m. ET 10/15/21.

Docket Numbers: ER21–2766–000.
Applicants: Central Line Solar, LLC.
Description: Supplement to August 25, 2021 Central Line Solar, LLC tariff filing.
Filed Date: 9/23/21.
Accession Number: 20210923–5149.
Comment Date: 5 p.m. ET 10/4/21.

Docket Numbers: ER21–2934–000.
Applicants: East Texas Electric Cooperative, Inc.
Description: Notice of Cancellation of Revenue Requirements for Reactive Service of East Texas Electric Cooperative, Inc.
Filed Date: 9/24/21.
Accession Number: 20210924–5122.
Comment Date: 5 p.m. ET 10/15/21.

Docket Numbers: ER21–2935–000.
Applicants: Southwest Power Pool, Inc.
Description: § 205(d) Rate Filing: 1166R37 Oklahoma Municipal Power Authority NITSA and NOA to be effective 9/1/2021.
Filed Date: 9/27/21.
Accession Number: 20210927–5057.
Comment Date: 5 p.m. ET 10/18/21.

Docket Numbers: ER21–2936–000.
Applicants: Southwest Power Pool, Inc.
Description: § 205(d) Rate Filing: 1534R13 Kansas Municipal Energy Agency NITSA NOA to be effective 9/1/2021.
Filed Date: 9/27/21.
Accession Number: 20210927–5065.
Comment Date: 5 p.m. ET 10/18/21.

Docket Numbers: ER21–2937–000.
Applicants: Southern California Edison Company.
Description: § 205(d) Rate Filing: 2021 SCE Revised TO Tariff Appendix X to be effective 10/1/2021.
Filed Date: 9/27/21.
Accession Number: 20210927–5078.
Comment Date: 5 p.m. ET 10/18/21.

Docket Numbers: ER21–2938–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Amendment to ISA, Service Agreement No. 2118; Queue No. P46 to be effective 2/5/2009.
Filed Date: 9/27/21.
Accession Number: 20210927–5089.
Comment Date: 5 p.m. ET 10/18/21.

Docket Numbers: ER21–2939–000.
Applicants: Southern California Edison Company.
Description: § 205(d) Rate Filing: 2021 SCE Revised WDAT Attachment J to be effective 10/1/2021.
Filed Date: 9/27/21.
Accession Number: 20210927–5096.
Comment Date: 5 p.m. ET 10/18/21.

Docket Numbers: ER21–2940–000.
Applicants: Midcontinent Independent System Operator, Inc., Ameren Illinois Company.
Description: § 205(d) Rate Filing: Midcontinent Independent System Operator, Inc. submits tariff filing per 35.13(a)(2)(iii: 2021–09–27_SA 3705 Ameren Illinois-SIPC Mutual As-Available Agreement to be effective 11/27/2021.
Filed Date: 9/27/21.
Accession Number: 20210927–5098.
Comment Date: 5 p.m. ET 10/18/21.

Docket Numbers: ER21–2941–000.
Applicants: Arizona Public Service Company.
Description: § 205(d) Rate Filing: Service Agreement No. 394 to be effective 9/14/2021.
Filed Date: 9/27/21.
Accession Number: 20210927–5109.
Comment Date: 5 p.m. ET 10/18/21.

Docket Numbers: ER21–2942–000.
Applicants: EnerSmart El Cajon BESS LLC.
Description: Baseline eTariff Filing: Market-Based Rate Application to be effective 11/27/2021.
Filed Date: 9/27/21.
Accession Number: 20210927–5117.
Comment Date: 5 p.m. ET 10/18/21.

Docket Numbers: ER21–2943–000.
Applicants: Florida Power & Light Company.
Description: § 205(d) Rate Filing: FPL & LCEC Revisions to Rate Schedule No. 317 to be effective 9/28/2021.
Filed Date: 9/27/21.
Accession Number: 20210927–5123.
Comment Date: 5 p.m. ET 10/18/21.

Docket Numbers: ER21–2945–000.
Applicants: Florida Power & Light Company.
Description: § 205(d) Rate Filing: FPL & FKEC Revisions to Rate Schedule No. 322 to be effective 9/28/2021.
Filed Date: 9/27/21.
Accession Number: 20210927–5125.
Comment Date: 5 p.m. ET 10/18/21.

Take notice that the Commission received the following electric securities filings:

Docket Numbers: ES21–83–000.
Applicants: NSTAR Electric Company.
Description: Application Under Section 204 of the Federal Power Act for Authorization to Issue Securities of NSTAR Electric Company.
Filed Date: 9/27/21.
Accession Number: 20210927–5130.
Comment Date: 5 p.m. ET 10/18/21.

Docket Numbers: ES21–84–000.
Applicants: The Connecticut Light and Power Company.
Description: Application Under Section 204 of the Federal Power Act for Authorization to Issue Securities of The Connecticut Light and Power Company.
Filed Date: 9/27/21.
Accession Number: 20210927–5132.
Comment Date: 5 p.m. ET 10/18/21.

The filings are accessible in the Commission's eLibrary system (*https://*

elibrary.ferc.gov/idmws/search/fercgensearch.asp) by querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: September 27, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–21409 Filed 9–30–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 14513–003]

Idaho Irrigation District, New Sweden Irrigation District; Notice of Waiver Period for Water Quality Certification Application

On September 2, 2021, Idaho Irrigation District and New Sweden Irrigation District submitted to the Federal Energy Regulatory Commission a copy of their application for a Clean Water Act section 401(a)(1) water quality certification filed with the Idaho Department of Environmental Quality (Idaho DEQ), in conjunction with the above captioned project. Pursuant to 40 CFR 121.6, we hereby notify the Idaho DEQ of the following:

Date of Receipt of the Certification Request: September 2, 2021.

Reasonable Period of Time to Act on the Certification Request: One year.

Date Waiver Occurs for Failure to Act: September 2, 2022.

If the Idaho DEQ fails or refuses to act on the water quality certification request by the above waiver date, then the agency's certifying authority is deemed waived pursuant to section 401(a)(1) of the Clean Water Act, 33 U.S.C. 1341(a)(1).

Dated: September 27, 2021.

Kimberly D. Bose,

Secretary.

[FR Doc. 2021–21423 Filed 9–30–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP21–1139–000.
Applicants: Texas Eastern Transmission, LP.
Description: § 4(d) Rate Filing: Negotiated Rates—Middlesex Ext CPV 911793 to be effective 9/25/2021.
Filed Date: 9/22/21.
Accession Number: 20210922–5039.
Comment Date: 5 p.m. ET 10/4/21.

Docket Numbers: RP21–1140–000.
Applicants: Tallgrass Interstate Gas Transmission, LLC.
Description: § 4(d) Rate Filing: TIGT 2021–09–22 Negotiated Rate Agreement Amendment to be effective 9/1/2021.
Filed Date: 9/22/21.
Accession Number: 20210922–5042.
Comment Date: 5 p.m. ET 10/4/21.

Docket Numbers: RP21–1141–000.
Applicants: Nautilus Pipeline Company, L.L.C.
Description: § 4(d) Rate Filing: Negotiated Rate—Talos 630210 eff 9–22–2021 to be effective 9/22/2021.
Filed Date: 9/22/21.
Accession Number: 20210922–5100.
Comment Date: 5 p.m. ET 10/4/21.

Docket Numbers: RP21–1142–000.
Applicants: Natural Gas Pipeline Company of America LLC.
Description: Compliance filing: Penalty Revenue Crediting Report from January through June 2021 to be effective N/A.
Filed Date: 9/23/21.
Accession Number: 20210923–5000.
Comment Date: 5 p.m. ET 10/5/21.

Docket Numbers: RP21–1144–000.
Applicants: Transcontinental Gas Pipe Line Company, LLC.
Description: § 4(d) Rate Filing: Non-Conforming—Atlantic Sunrise—JPMorgan Chase to be effective 1/1/2022.
Filed Date: 9/23/21.
Accession Number: 20210923–5059.
Comment Date: 5 p.m. ET 10/5/21.

Docket Numbers: RP21–1145–000.
Applicants: Tennessee Gas Pipeline Company, L.L.C.
Description:§ 4(d) Rate Filing: PAL NRA JP Morgan SP370513 & SP370514 to be effective 10/1/2021.
Filed Date: 9/24/21.
Accession Number: 20210924–5040.
Comment Date: 5 p.m. ET 10/6/21.

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.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: September 27, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–21408 Filed 9–30–21; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–ORD–2015–0635; FRL–8988–01–ORD]

Board of Scientific Counselors (BOSC) Chemical Safety for Sustainability and Health and Environmental Risk Assessment Subcommittee Meeting—November 2021

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of public meeting.

SUMMARY: The Environmental Protection Agency (EPA), Office of Research and Development (ORD), gives notice of a series of virtual meetings of the Board of Scientific Counselors (BOSC) Chemical Safety for Sustainability and Health and Environmental Risk Assessment (CSS HERA) Subcommittee to review the recent progress and activities of the Chemical Safety Analytics (CSA) and Emerging Materials and Technologies (EMT) research areas.

DATES:

1. The initial meeting will be held over two days via videoconference:

a. Thursday, November 4, 2021, from 12:00 p.m. to 5:00 p.m. (EDT); and

b. Friday, November 5, 2021, from 12:00 p.m. to 5:00 p.m. (EDT).

Attendees must register by November 3, 2021.

2. A BOSC deliberation videoconference will be held on November 18, 2021, from 11 a.m. to 2 p.m. (EDT).

Attendees must register by November 17, 2021.

3. A final BOSC deliberation videoconference will be held on December 10, 2021, from 11 a.m. to 2 p.m. (EDT).

Attendees must register by December 9, 2021.

Meeting times are subject to change. This series of meetings is open to the public. Comments must be received by November 3, 2021, to be considered by the subcommittee. Requests for the draft agenda or making a presentation at any of the meetings will be accepted until November 3, 2021.

ADDRESSES: Instructions on how to connect to the videoconference will be provided upon registration at: *https://epa-bosc-css-hera-subcommittee-mtg.eventbrite.com.*

Submit your comments to Docket ID No. EPA–HQ–ORD–2015–0635 by one of the following methods:

• *www.regulations.gov:* Follow the online instructions for submitting comments.

▪ *Note:* comments submitted to the *www.regulations.gov* website are anonymous unless identifying information is included in the body of the comment.

• *Email:* Send comments by electronic mail (email) to: *ORD.Docket@epa.gov,* Attention Docket ID No. EPA–HQ–ORD–2015–0635.

▪ *Note:* Comments submitted via email are not anonymous. The sender's email will be included in the body of the comment and placed in the public docket which is made available on the internet.

Instructions: All comments received, including any personal information provided, will be included in the public docket without change and may be made available online at *www.regulations.gov.* Information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute will not be included in the public docket and should not be submitted through *www.regulations.gov* or email. For additional information about the EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/dockets/.*

Public Docket: Publicly available docket materials may be accessed *Online* at *www.regulations.gov.*

Copyrighted materials in the docket are only available via hard copy. The telephone number for the ORD Docket Center is (202) 566–1752.

FOR FURTHER INFORMATION CONTACT: The Designated Federal Officer (DFO), Tom Tracy, via phone/voicemail at: 919–541–4334; or via email at: *tracy.tom@epa.gov.*

Requests for the draft agenda or making a presentation at this series of meetings will be accepted until November 3, 2021.

SUPPLEMENTARY INFORMATION: The Board of Scientific Counselors (BOSC) is a federal advisory committee that provides advice and recommendations to EPA's Office of Research and Development on technical and management issues of its research programs. The meeting agenda and materials will be posted to *https://www.epa.gov/bosc.*

Proposed agenda items for the meetings include, but are not limited to, the following: Review the recent progress and activities of the Chemical Safety Analytics (CSA) and Emerging Materials and Technologies (EMT) research areas.

Information on Services Available: For information on translation services, access, or services for individuals with disabilities, please contact Tom Tracy at 919–541–4334 or *tracy.tom@epa.gov.* To request accommodation of a disability, please contact Tom Tracy at least ten days prior to the meeting to give the EPA adequate time to process your request.

Authority: Public Law 92–463, 1, Oct. 6, 1972, 86 Stat. 770.

Mary Ross,

Director, Office of Science Advisor, Policy and Engagement.

[FR Doc. 2021–21393 Filed 9–30–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9069–01–OAR]

Announcing Upcoming Meeting of Mobile Sources Technical Review Subcommittee

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Pursuant to the Federal Advisory Committee Act, EPA announces an upcoming meeting of the Mobile Sources Technical Review Subcommittee (MSTRS), which is a subcommittee under the Clean Air Act Advisory Committee (CAAAC). This is a virtual meeting and open to the public. The meeting will include discussion of current topics and presentations about activities being conducted by EPA's Office of Transportation and Air Quality. MSTRS listserv subscribers will receive notification when the agenda is available on the Subcommittee website. To subscribe to the MSTRS listserv, send an email to *MSTRS@epa.gov.*

DATES: EPA will hold a virtual public meeting on Thursday, October 14, 2021 from 1:00 p.m. to 5:00 p.m. Eastern Daylight Time (EDT). Please monitor the website *https://www.epa.gov/caaac/mobile-sources-technical-review-subcommittee-mstrs-caaa*c for any changes to meeting logistics. The final meeting agenda will be posted on the website.

ADDRESSES: For information on the public meeting or to register to attend, please contact *MSTRS@epa.gov.*

FOR FURTHER INFORMATION CONTACT: Any member of the public who wishes to attend the meeting or provide comments should express this intent by emailing *MSTRS@epa.gov* no later than Friday, October 8, 2021. Further information concerning this public meeting and general information concerning the MSTRS can be found at: *https://www.epa.gov/caaac/mobile-sources-technical-review-subcommittee-mstrs-caaac.* Other MSTRS inquiries can be directed to Julia Burch, the Designated Federal Officer for MSTRS, Office of Transportation and Air Quality, at 202–564–0961 or *burch.julia@epa.gov.*

SUPPLEMENTARY INFORMATION: During the meeting, the Subcommittee may also hear progress reports from its workgroups as well as updates and announcements on Office of Transportation and Air Quality activities of general interest to attendees.

Participation in virtual public meetings. Please note that EPA is deviating from its typical approach because the President has declared a national emergency. Because of current CDC recommendations, as well as state and local orders for social distancing to limit the spread of COVID–19, EPA cannot hold in-person public meetings at this time.

The virtual public meeting will provide interested parties the opportunity to participate in this Federal Advisory Committee meeting.

EPA is asking all meeting attendees, even those who do not intend to speak, to register for the meeting by sending an email to the address listed in the **FOR FURTHER INFORMATION CONTACT** section above, by Friday, October 8, 2021. This

will help EPA ensure that sufficient participation capacity will be available.

Please note that any updates made to any aspect of the meeting logistics, including potential additional sessions, will be posted online at *https://www.epa.gov/caaac/mobile-sources-technical-review-subcommittee-mstrs-caaac.* While EPA expects the meeting to go forward as set forth above, please monitor the website for any updates.

For individuals with disabilities: For information on access or services for individuals with disabilities, please email *MSTRS@epa.gov.* To request accommodate of a disability, please email *MSTRS@epa.gov,* preferably at least 10 business days prior to the meeting, to give EPA as much time as possible to process your request.

Dated: September 27, 2021.

Julia Burch,

Designated Federal Officer, Mobile Source Technical Review Subcommittee, Office of Transportation and Air Quality.

[FR Doc. 2021–21395 Filed 9–30–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–9058–6]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information 202–564–5632 or *https://www.epa.gov/nepa.*

Weekly receipt of Environmental Impact Statements (EIS)

Filed September 20, 2021 10 a.m. EST Through September 27, 2021 10 a.m. EST

Pursuant to 40 CFR 1506.9.

Notice: Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: *https://cdxnodengn.epa.gov/cdx-enepa-public/action/eis/search.*

EIS No. 20210146, Final, FERC, LA, East Lateral Xpress Project, Review Period Ends: 11/01/2021, Contact: Office of External Affairs 866–208–3372.

EIS No. 20210147, Final, FHWA, VA, Route 220 Martinsville Southern Connector Study, Review Period Ends: 11/01/2021, Contact: Mack Frost 804–775–3352.

EIS No. 20210148, Final, FERC, PA, East 300 Upgrade Project, Review Period Ends: 11/01/2021, Contact: Office of External Affairs 866–208–3372.

EIS No. 20210149, Draft Supplement, FHWA, MD, I–495 & I–270 Managed Lanes Study Supplemental Draft Environmental Impact Statement and Updated Draft Section 4(f) Evaluation, Comment Period Ends: 11/15/2021, Contact: Jeanette Mar 410–779–7152.

Dated: September 27, 2021.

Cindy S. Barger,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 2021–21366 Filed 9–30–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OA–2021–0403; FRL–9005–01–OCFO]

Draft FY 2022–2026 Environmental Protection Agency Strategic Plan

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability; request for public comments.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is announcing the availability of the *Draft FY 2022–2026 EPA Strategic Plan* for public review and comment, which is being revised as required by the Government Performance and Results Act (GPRA) Modernization Act of 2010 (as amended by the Foundations for Evidence-Based Policymaking Act of 2018). The agency anticipates the final *Strategic Plan* will be submitted to Congress in February 2022. For this document, the EPA is seeking comment from individual citizens, states, tribes, local governments, industry, the academic community, non-governmental organizations, and all other interested parties.

DATES: Comments must be received on or before November 12, 2021.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OA–2021–0403 to the Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or withdrawn. 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 for which disclosure is restricted by statute. 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). Out of an abundance of caution for members of the public and our staff, the EPA Docket Center and Reading Room are closed to the public, with limited exceptions, to reduce the risk of transmitting COVID–19. Our Docket Center staff will continue to provide remote customer service via email, phone, and webform. We encourage the public to submit comments via *https://www.regulations.gov/,* as there may be a delay in processing mail and faxes.

FOR FURTHER INFORMATION CONTACT: Holly Green, Director, Planning Division, Office of Planning, Analysis, and Accountability, Office of the Chief Financial Officer, email address: *green.holly@epa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The GPRA Modernization Act of 2010 (Pub. L. 111–352), holds federal agencies accountable for using resources wisely and achieving program results. Specifically, the GPRA Modernization Act requires agencies to develop: *Strategic Plans,* which include a mission statement, long-term goals, objectives, and strategies to achieve them over a four-year time horizon; and two-year Agency Priority Goals to drive significant progress toward Agency leadership priorities. The GPRA Modernization Act also requires agencies to develop *Annual Performance Plans,* which provide annual performance measures and activities toward the *Strategic Plan,* and *Annual Performance Reports,* which evaluate an agency's success in achieving the annual performance measures.

The Foundations for Evidence-Based Policymaking Act of 2018 (Pub. L. 115–435) amended GPRA and requires two additional components in the *Strategic Plan:* An evidence-building plan, known as a *Learning Agenda,* which identifies policy-relevant questions for which agencies intend to develop evidence; and a *Capacity Assessment,* which gauges agencies' capacity to support the development and use of evaluation and other evidence.

The *Strategic Plan* includes seven strategic goals focused on protecting human health and the environment and four cross-agency strategies that describe the essential ways EPA will work to carry out its mission. The *Strategic Plan* also establishes long-term performance goals and FY 2022–2023 Agency Priority Goals by which EPA will hold itself accountable to monitor progress in protecting human health and the environment in collaboration with EPA's partners and stakeholders.

Dated: September 27, 2021.

Faisal Amin,

Chief Financial Officer, Office of the Chief Financial Officer.

[FR Doc. 2021–21349 Filed 9–30–21; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL ELECTION COMMISSION

Sunshine Act Meeting

FEDERAL REGISTER CITATION NOTICE OF PREVIOUS ANNOUNCEMENT: 86 FR 52682.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: Tuesday, September 28, 2021 at 10:00 a.m. and its continuation at the conclusion of the open meeting on September 30, 2021.

CHANGES IN THE MEETING: This meeting also discussed:

Information the premature disclosure of which would be likely to have a considerable adverse effect on the implementation of a proposed Commission action.

* * * * *

CONTACT FOR MORE INFORMATION: Judith Ingram, Press Officer, Telephone: (202) 694–1220.

Vicktoria J. Allen,

Acting Deputy Secretary of the Commission.

[FR Doc. 2021–21502 Filed 9–29–21; 11:15 am]

BILLING CODE 6715–01–P

FEDERAL ELECTION COMMISSION

Sunshine Act Meeting

TIME AND DATE: Wednesday, October 13, 2021 at 10:00 a.m. and its continuation at the conclusion of the open meeting on October 14, 2021.

PLACE: 1050 First Street NE, Washington, DC (This meeting will be a virtual meeting).

STATUS: This meeting will be closed to the public.

MATTERS TO BE CONSIDERED: Compliance matters pursuant to 52 U.S.C. 30109. Matters concerning participation in civil actions or proceedings or arbitration.

ADDITIONAL INFORMATION: This meeting will be cancelled if the Commission is not open due to a funding lapse.

* * * * *

CONTACT PERSON FOR MORE INFORMATION: Judith Ingram, Press Officer, Telephone: (202) 694–1220.

Vicktoria J. Allen,

Acting Deputy Secretary of the Commission.

[FR Doc. 2021–21568 Filed 9–29–21; 4:15 pm]

BILLING CODE 6715–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[CFDA Number: 93.570]

Announcement of Intent To Award Supplement to El Pajaro Community Development Corporation, in Watsonville, CA

AGENCY: Office of Community Services, Administration for Children and Families (ACF), Department of Health and Human Services (HHS).

ACTION: Notice of issuance of a supplement.

SUMMARY: The ACF, OCS, Division of Discretionary Programs announces the intent to award a supplement in the amount of $196,633 to the El Pajaro Community Development Corporation (EPCDC), in Watsonville, CA, to support the renovation of a building, into a shared commercial kitchen and a food packing facility.

DATES: The period of support is from September 30, 2021, to September 29, 2022.

FOR FURTHER INFORMATION CONTACT: Lynda E. Perez, Director, Division of Community Discretionary and Demonstration Programs, 330 C Street SW, Washington, DC 20201, Telephone: 202–401–9365 Email: *Lynda.Perez@acf.hhs.gov.*

SUPPLEMENTARY INFORMATION: The OCS Community Economic Development (CED) program announces the award of $196,633 to El Pajaro Community Development Corporation (EPCDC), in Watsonville, CA. CED is a Federal grant program funding Community Development Corporations (CDCs) that address the economic needs of low-income individuals and families through the creation of sustainable business development and employment opportunities. CED funds are used to development activities, to assist those individuals in successfully maintaining employment, and to ensure that the businesses and jobs created remain viable for at least one year after the end of the grant period.

Award funds will support renovation of food packing facility that is co-connect to a commercial kitchen at the same site. Funds will be used to resolve construction concerns that are needed to finalize building permit and occupancy approval. In addition, funds will be used to help capitalize business start-ups as needed to create the jobs for individuals with low-income.

Statutory Authority: Section 680(a)(2) of the Community Services Block Grant (CSBG) Act of 1981, as amended by the Community Opportunities, Accountability, and Training and Educational Services Act of 1998 (Pub. L. 105–285), as amended.

Elizabeth Leo,

Senior Grant Policy Specialist, Office of Grants Policy, Office of Administration.

[FR Doc. 2021–21420 Filed 9–28–21; 4:15 pm]

BILLING CODE 4184–24–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[CFDA Number: 93.579]

Announcement of the Intent To Award Four Single-Source Grants

AGENCY: Office of Human Services Emergency Preparedness and Response (OHSEPR), Administration for Children and Families (ACF), Department of Health and Human Services (HHS).

ACTION: Notice of issuance of four single-source awards.

SUMMARY: The ACF, OHSEPR announces the intent to award four single-source grants in the amount of up to $300,000 to the following recipients: United Way Worldwide, Alexandria, VA; National Association of Social Workers, Washington, DC; American Public Human Services Association, Arlington, VA; and National Association of County Human Services Administrators, Washington, DC. The purpose of these awards is to facilitate the coordination of human services to U.S. Citizens and their dependents evacuating to the United States from Afghanistan. These organizations are key players in the leadership, coordination, or direct provision of human services after an emergency and have direct access to their constituencies and networks. U.S. citizens and their dependents (repatriates) eligible for temporary assistance under the U.S. Repatriation Program can receive up to 90 days of temporary assistance which includes transportation, food, medical care, cash assistance, temporary lodging, and case management. These awards will ensure appropriate training and technical assistance, coordination, and subject matter expertise as repatriates connect to human services entities.

DATES: The proposed period of performance is September 30, 2021 to September 30, 2022.

FOR FURTHER INFORMATION CONTACT: Natalie Grant, Director, Office of Human Services Emergency Preparedness and Response, 330 C St. SW, Washington, DC 20201. Telephone: 202–205–7843; Email: *Natalie.grant@acf.hhs.gov.*

SUPPLEMENTARY INFORMATION: OHSEPR announces the intent to award the following single-source awards:

Recipient	Award amount of up to
United Way Worldwide, Alexandria, VA	$75,000
National Association of Social Workers, Washington, DC	75,000
American Public Human Services Association, Arlington, VA	75,000
National Association of County Human Services Administrators, Washington, DC	75,000

United Way supports 211, which is the most comprehensive source of information about local resources and services in the United States. United Way's 211 has demonstrated experience providing disaster-related assistance to disaster survivors. United Way's existing network of 211 agencies will provide information and referrals to evacuees from Afghanistan including repatriates eligible for temporary assistance.

NASW is the largest membership organization of professional social workers in the world. NASW has the ability to train a large number of professional social workers across the United States, including many who have provided case management and human services following an emergency. NASW will train its members on how to provide culturally competent case management and human services to evacuees from Afghanistan and ensure appropriate coordination and subject matter expertise.

APHSA is a national membership association representing state and local health and human services agencies and subject matter experts who help execute their mission. APHSA has a direct connection to a network of state and county health and human services executives with first-hand knowledge of and expertise in operating programs and delivering human services following an emergency. APHSA will educate its members on the provision of culturally appropriate human services to evacuees from Afghanistan by providing training and technical assistance.

NACHSA members represent a broad range of human services agencies throughout the United States, including ones that provide public assistance, child care, child protective services, and adult protective services. NACHSA supports the professional development of county human services administrators, whose agencies deliver essential human services. NACHSA will educate its membership on providing culturally appropriate human services to evacuees from Afghanistan and ensure county level coordination of services.

Statutory Authority: Social Security Act, Title XI, Part A, Section 1113, 42 U.S. Code 1313(a)(3).

Elizabeth Leo,

Senior Grants Policy Specialist, Office of Grants Policy, Office of Administration.

[FR Doc. 2021–21418 Filed 9–28–21; 4:15 pm]

BILLING CODE 8414–PC–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0492]

Watson Laboratories, Inc., et al.; Withdrawal of Approval of 36 Abbreviated New Drug Applications; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of June 25, 2021. The document announced the withdrawal of approval of 36 abbreviated new drug applications (ANDAs) from multiple applicants as of July 26, 2021. The document indicated that FDA was withdrawing approval of the following ANDA, after receiving a withdrawal request from Yung Shin Pharmaceutical Ind. Co. Ltd., authorized U.S. agent, Carlsbad Technology, Inc./Simon Law, 5922 Farnsworth Ct., Suite 101, Carlsbad, CA 92008: ANDA 065152, Cephalexin Capsules, Equivalent to (EQ) 250 milligrams (mg) base and EQ 500 mg base. Before FDA withdrew the approval of this ANDA, Yung Shin Pharmaceutical Ind. Co. Ltd. informed FDA that it did not want the approval of the ANDA withdrawn. Because Yung Shin Pharmaceutical Ind. Co. Ltd. timely requested that approval of this ANDA not be withdrawn, the approval of ANDA 065152 is still in effect.

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993–0002, 240–402–6980, *Martha.Nguyen@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of Friday, June 25, 2021 (86 FR 33718), FR Doc. 2021–13593, the following correction is made:

On page 33718, in the table, the entry for ANDA 065152 is removed.

Dated: September 27, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–21371 Filed 9–30–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–3077]

Agency Information Collection Activities; Proposed Collection; Comment Request; Obtaining Information To Understand Challenges and Opportunities Encountered by Compounding Outsourcing Facilities

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) 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 requests comments on the information collection associated with FDA research in obtaining information from pharmacists and other management at outsourcing facilities and related human prescription drug compounding businesses. The research supports a comprehensive analysis of the outsourcing facility sector that informs ongoing FDA work in this area.

DATES: Submit either electronic or written comments on the collection of information by November 30, 2021.

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 November 30, 2021. The *https://www.regulations.gov* electronic filing system will accept

comments until 11:59 p.m. Eastern Time at the end of November 30, 2021. 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–2019–N–3077 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Obtaining Information to Understand Challenges and Opportunities Encountered by Compounding Outsourcing Facilities.'' 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, 240–402–7500.

• 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.govinfo.gov/content/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, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), 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.

Obtaining Information To Understand Challenges and Opportunities Encountered by Compounding Outsourcing Facilities

OMB Control Number 0910–0883—Extension

This information collection supports FDA research in obtaining a range of information pertaining to human prescription drug compounding by outsourcing facilities. Generally, drug compounding is the practice of combining, mixing, or altering ingredients of a drug to create a medication tailored an individual patient's needs. Although compounded drugs can serve an important medical need for certain patients when an approved drug is not medically appropriate, compounded drugs also present a risk to patients. Compounded drugs are not FDA-approved; therefore, they do not undergo FDA premarket review for safety, effectiveness, and quality. Section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353a) describes the conditions that must be satisfied for compounded human prescription drug products to be exempt from certain sections of the FD&C Act: (1) Section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B))

(current good manufacturing practice (CGMP) requirements), (2) section 502(f)(1) (21 U.S.C. 352(f)(1)) (labeling of drugs with adequate directions for use), and (3) section 505 (21 U.S.C. 355) (approval of drugs under new drug applications or abbreviated new drug applications).

The Drug Quality and Security Act of 2013 (Pub. L. 113–54) created outsourcing facilities—a new industry sector of drug compounders held to higher quality standards to protect patient health. Section 503B of the FD&C Act (21 U.S.C. 353b) describes the conditions that outsourcing facilities must satisfy for drug products compounded in an outsourcing facility by or under the direct supervision of a licensed pharmacist to be exempt from the certain sections of the FD&C Act. Outsourcing facilities are intended to offer a more reliable supply of compounded drugs that hospitals, clinics, and other providers need.

FDA continues to find concerning quality and safety problems during inspections of outsourcing facilities. FDA has implemented and will continue to implement programs to support compounding quality and compliance. One initiative is FDA's Compounding Quality Center of Excellence (Center of Excellence), *https://www.fda.gov/drugs/human-drug-compounding/compounding-quality-center-excellence, which was* developed to focus on improving the quality of compounded human prescription drugs to promote patient safety. One of our top priorities is to help ensure that compounded drugs are safe by focusing on quality. FDA, state regulators, pharmacy associations, and compounders, including outsourcing facilities, share the responsibility of patient safety.

The Center of Excellence engages and collaborates with compounders, including outsourcing facilities, and other stakeholders to improve the overall quality of compounded drugs. Furthermore, the Center of Excellence promotes collaboration to help compounders implement robust quality management systems that are better for business and the safety of patients.

To help strengthen the outsourcing facility industry's ability to provide quality compounded drugs to patients who need them, the Center of Excellence offers training sessions and opportunities to develop manufacturing quality and other policies for outsourcing facilities, including CGMPs.

The Center of Excellence offers several training sessions (available at *https://www.fda.gov/drugs/human-drug-compounding/compounding-quality-center-excellence-training-programs*). Self-guided training sessions teach the following topics: (1) Environmental monitoring, (2) sterile drug compounding, (3) cleanroom performance tests, and (4) conducting investigations and formulating corrective and preventive actions. Instructor-led sessions teach the regulatory framework for these topics: (1) Human drug compounding, (2) airflow practices, (3) insanitary conditions and sterility, (4) stability and beyond use dates, (5) requirements for outsourcing facility guides, and (6) conducting investigations and formulating corrective and preventive actions. Management and staff from outsourcing facilities have attended the training sessions. Feedback on the training sessions has been positive, and interest in the sessions continues to grow.

In addition, the Center of Excellence is conducting indepth research to better understand outsourcing facilities' challenges and opportunities in different areas to help guide decisions regarding future training and other engagement. Outsourcing facilities encounter the following challenges and opportunities: (1) Operational barriers and opportunities related to the outsourcing facility market and business viability, (2) knowledge and operational barriers and opportunities related to compliance with Federal policies and good quality drug production, and (3) barriers and opportunities related to outsourcing facility interactions with FDA.

FDA used previous research results under this information collection to develop an understanding of the outsourcing facility sector, the sector's challenges, and opportunities for advancement. The information collected was an essential tool to help FDA identify knowledge and information gaps, operational barriers, and views on interactions with FDA. FDA has presented this information in public settings such as stakeholder meetings. Continuing this collection will enable FDA to deepen our understanding of the outsourcing facility sector and increase our efficacy in developing a Center of Excellence that is responsive to outsourcing facilities' needs. The research results will inform FDA's future activities for the Center of Excellence in the areas of communication, education, training, and other engagement with outsourcing facilities to address challenges and support advancement.

Researchers engage with pharmacists, staff, and management from outsourcing facilities and similar compounding businesses and may use surveys, interviews, and focus groups to obtain information about outsourcing facilities' challenges and opportunities. Within this context, we may pose the following questions or similar, related questions:

1. What financial and operational considerations inform outsourcing facility operational and business model decisions?
2. What factors impact developing a sustainable outsourcing facility business?
3. What financial and operational considerations inform outsourcing facility product decisions?
4. Do outsourcing facilities understand the Federal laws and policies that apply to them? What, if any, knowledge gaps do we need to address?
5. What are outsourcing facilities' challenges when implementing Federal CGMP requirements?
6. How do outsourcing facilities implement quality practices at their facilities?
7. How do outsourcing facilities develop CGMP and quality expertise? How do they obtain this knowledge, and what training do they need?
8. What are the economic consequences of CGMP noncompliance and product failures for outsourcing facilities?
9. What are outsourcing facility management and staff views on current interactions with FDA? How do they want the interactions to change?
10. What are outsourcing facilities' understanding of how to engage with FDA during and following an inspection?

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Surveys, focus groups, and interviews	300	2	600	1	600

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Our original request for the information collection was approved January 21, 2020; however, the subsequent public health emergency inhibited our ability to administer the requested survey. We have therefore made no adjustments to our current burden estimate.

Dated: September 24, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–21382 Filed 9–30–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–1837]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Electronic User Fee Payment Request Forms

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: Submit written comments (including recommendations) on the collection of information by November 1, 2021.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0805. Also include the FDA docket number found in brackets in the heading of this document.

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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Electronic User Fee Payment Request Forms—Form FDA 3913 and Form FDA 3914

OMB Control Number 0910–0805—Extension

Form FDA 3913, User Fee Payment Refund Request, is designed to provide the minimum necessary information for FDA to review and process a user fee payment refund. The information collected includes the organization, contact, and payment information. The information is used to determine the reason for the refund, the refund amount, and who to contact if there are any questions regarding the refund request. A submission of the User Fee Payment Refund Request form does not guarantee that a refund will be issued. FDA estimates an average of 0.40 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed, and complete and review the collection of information. The estimated hours are based on past FDA experience with the user fee payment refund request.

In fiscal year 2020, approximately 474 user fee refunds were processed for cover sheets and invoices, including 0 for Animal Drug User Fees, 0 for Animal Generic Drug User Fees, 1 for Biosimilar Drug User Fees, 0 for Export Certificate Program fees, 0 for Freedom of Information Act requests, 31 for Generic Drug User Fees, 200 for Medical Device User Fees, 240 for Medical Device Federal Unified Registration and Listing fees, 0 for Mammography inspection fees, 1 for Prescription Drug User Fees, and 0 for Tobacco product fees.

Form FDA 3914, User Fee Payment Transfer Request, is designed to provide the minimum necessary information for FDA to review and process a user fee payment transfer request. The information collected includes payment and organization information. The information is used to determine the reason for the transfer, how the transfer should be performed, and who to contact if there are any questions regarding the transfer request. A submission of the User Fee Payment Transfer Request form does not guarantee that a transfer will be performed. FDA estimates an average of 0.25 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed, and complete and review the collection of information. FDA estimated hours are based on past FDA experience with the user fee payment transfer requests.

In fiscal year 2020, approximately 194 user fee payment transfers were processed for cover sheets and invoices, including 0 for Animal Drug User Fees, 0 for Animal Generic Drug User Fees, 1 for Biosimilar Drug User Fees, 34 for Generic Drug User Fees, 78 for Medical Device User Fees, 80 for Medical Device Federal Unified Registration and Listing fees, 0 for Mammography inspection fees, 1 for Prescription Drug User Fees, and 0 for Tobacco product fees.

Respondents for the electronic request forms include domestic and foreign firms (including pharmaceutical, biological, medical device firms, etc.). Specifically, refund request forms target respondents who submitted a duplicate payment or overpayment for a user fee cover sheet or invoice. Respondents may also include firms that withdrew an application or submission. Transfer request forms target respondents who submitted payment for a user fee cover sheet or invoice and need that payment to be re-applied to another cover sheet or invoice (transfer of funds).

The electronic user fee payment request forms streamline the refund and transfer processes, facilitate processing, and improve the tracking of refund or transfer requests. The burden for this collection of information is the same for all customers (small and large organizations). The information being requested or required has been held to the absolute minimum required for the intended use of the data. Respondents

are able to request a user fee payment refund or transfer online at *https://www.fda.gov/forindustry/userfees/default.htm.* This electronic submission is intended to reduce the burden for customers to submit a user fee payment refund and transfer request.

In the **Federal Register** of April 29, 2021 (86 FR 22669), 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 [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
User Fee Payment Refund Request—Form FDA 3913	474	1	474	0.40 (24 minutes)	190
User Fee Payment Transfer Request—Form FDA 3914.	194	1	194	0.25 (15 minutes)	49
Total					239

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The current burden estimate shows a decrease of approximately 642 hours for this information collection over that reported previously. The change reflects increased experience by the respondents to correctly submit fee payments and increased sophistication in use of the forms to request payments made in error. The use of the forms for the user fee programs (*e.g.,* Prescription Drug User Fees, Generic Drug User Fees, Animal Drug User Fees, Animal Generic Drug User Fees, Biosimilar Drug User Fees) are optional.

In addition, new information technology applications have more accurately calculated the number of registrants of drug facilities/food facilities/medical device facilities/medicated feed facilities, and we have therefore revised the number of respondents to the information collection.

Dated: September 27, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–21421 Filed 9–30–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0341]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food Safety; Federal-State Food Regulatory Program Standards

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) 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: Submit written comments (including recommendations) on the collection of information by November 1, 2021.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0760. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–994–7399, *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.

Food Safety; Federal-State Food Regulatory Program Standards

OMB Control Number 0910–0760—Revision

This information collection supports implementation of FDA's Federal-State Regulatory Program Standards, part of our National Integrated Food Safety System (IFSS) Programs and Initiatives. For more information we invite you to visit our website at: *https://www.fda.gov/federal-state-local-tribal-and-territorial-officials/national-integrated-food-safety-system-ifss-programs-and-initiatives.* In the United States, Federal and State governments work cooperatively to ensure the safety of food intended for both human and animal consumption. Part of this effort includes developing and maintaining uniform review criteria by which to assess food safety. FDA has established and maintains a number of program standards aimed at improving the safety evaluation for certain food products including manufactured foods and animal feed. Similarly, we are establishing regulatory program standards for eggs and have developed the ''Eggs Regulatory Program Standards'' (ERPS). The ERPS is intended for use by State and local regulatory officials and identifies 10 elements we believe are essential to the effective regulatory assessment of egg safety. States are encouraged to build systems that are sustainable and implement plans corresponding to the IFSS.

In the course of their normal duties, State, local, Territorial, and Tribal governments collect information pertaining to compliance with the respective State, local, Territorial, and Tribal food safety requirements within their jurisdictions. Although content and format of the information collected may vary, these activities are a usual and customary part of routine regulatory oversight. Respondents to the information collection are State, local, Territorial, and Tribal regulatory agencies.

The ERPS offers forms, worksheets, and templates to help respondents assess and meet the program elements identified and discussed. Respondents are not required to use the sample collection instruments included in the ERPS, however all data elements should be submitted to FDA and supporting documentation retained. The ERPS is

not intended to address any performance appraisal processes that any State, local, Territorial, or Tribal agency may use to evaluate its employees' performance. Funding opportunities are available to respondents who choose to implement the ERPS; however, these opportunities are limited and contingent upon the availability of funds, and are available to those respondents who currently have an egg inspection contract with FDA and thus are subject to auditing. A copy of the ERPS has been posted to FDA–2021–N–0341 and is available at *https://www.regulations.gov.*

In the **Federal Register** of May 14, 2021 (86 FR 26528), 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 RECORDKEEPING BURDEN [1]

Type of respondents; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
State, local, Territorial, and/or Tribal Governments; submission of data elements to FDA consistent with ERPS	10	10	100	50	5,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on our experience with similar information collection, we estimate an initial 10 respondents will participate in the ERPS, and assume an average of 50 burden hours per response is necessary for the attendant recordkeeping and submission of data elements to FDA. We expect participation in the ERPS to increase. Finally, upon submission of the Information Collection Request, we are correcting an inadvertent calculation error in the total burden hours as displayed on page 26530, in Table 1, in our 60-day notice in the **Federal Register** of May 14, 2021 (86 FR 26528).

Dated: September 24, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–21367 Filed 9–30–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0843]

Genus Medical Technologies LLC Versus Food and Drug Administration; Request for Information and Comments; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for information and comments; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is extending the comment period for the notice entitled ''Genus Medical Technologies LLC Versus Food and Drug Administration; Request for Information and Comments'' that appeared in the **Federal Register** of August 9, 2021. The Agency is taking this action to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period for the notice published on August 9, 2021 (86 FR 43553). Submit either electronic or written comments by November 30, 2021.

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 November 30, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 30, 2021. 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–2021–N–0843 for ''Genus Medical Technologies LLC Versus Food and Drug Administration; Request for Information and Comments.'' 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, 240–402–7500.

- 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.govinfo.gov/content/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, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Alexandra Lucas, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–0230, *Drug_Device_Transition_Inquiry@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 9, 2021 (86 FR 43553), FDA published a notice announcing that implementation of a decision from the U.S. Court of Appeals for the District of Columbia Circuit in *Genus Med. Techs., LLC* v. *FDA,* 2021 U.S. app. Lexis 10928 (April 16, 2021) is expected to require some approved products to transition from drug status to device status. That notice provides a 60-day comment period and solicits public comment to inform the Agency's deliberations about products potentially impacted by the *Genus* decision and the way in which impacted products should be transitioned from drug to device status.

FDA is extending the comment period until November 30, 2021, based on requests FDA received from relevant stakeholders. The Agency believes that an additional 60 days will allow adequate time for interested persons to submit comments to inform the Agency's implementation of the *Genus* decision.

Dated: September 28, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–21403 Filed 9–30–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0269]

Sitesh Bansi Patel: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debarring Sitesh Bansi Patel for a period of 5 years from importing articles of food or offering such articles for importation into the United States. FDA bases this order on a finding that Mr. Patel was convicted of a felony count under Federal law for conduct relating to the importation into the United States of an article of food. Mr. Patel was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. As of July 8, 2021 (30 days after receipt of the notice), Mr. Patel has not responded. Mr. Patel's failure to respond and request a hearing constitutes a waiver of his right to a hearing concerning this matter.

DATES: This order is applicable October 1, 2021.

ADDRESSES: Submit applications for termination of debarment to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500, or at *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Enforcement (ELEM–4029), Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 240–402–8743, or at *debarments@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(1)(C) of the FD&C Act (21 U.S.C. 335a(b)(1)(C)) permits FDA to debar an individual from importing an article of food or offering such an article for import into the United States if FDA finds, as required by section 306(b)(3)(A) of the FD&C Act, that the individual has been convicted of a felony for conduct relating to the importation into the United States of any food.

On February 19, 2020, Mr. Patel was convicted as defined in section 306(l)(1)(A) of the FD&C Act, in the U. S. District Court for the Northern District of Texas-Dallas Division, when the court accepted Mr. Patel's plea of guilty and entered judgment against him for the offense of conspiracy to introduce misbranded food into interstate commerce with an intent to defraud and mislead in violation of 18 U.S.C. 371 (21 U.S.C. 331(a) and 333(a)(2)). FDA's finding that the debarment is appropriate is based on the felony conviction referenced herein.

The factual basis for this conviction is as follows: As contained in the Factual Resume, dated February 22, 2019, Mr. Patel was the Vice President of S.K. Laboratories, LLC, and in that role did business with USP Labs. Beginning in or around October 2008 and continuing until at least in or around August 2014, Mr. Patel and others working at USP Labs and S.K. Laboratories engaged in a plan to import a variety of compounds for use and prospective use in dietary supplements with false labeling. To further this plan, Mr. Patel and his co-conspirators ordered a variety of potential dietary compounds from a Chinese company as prospective and actual ingredients for use in dietary supplements, and instructed and agreed to have those powders labeled falsely as other food substances. USP Labs sold dietary supplements called Jack3d and OxyElite Pro, both of which originally contained a substance called 1,3-dimethylamylamine (DMAA), which is also known as methylhexaneamine. The DMAA used in Jack3d and OxyElite Pro was a synthetic stimulant manufactured in China. Mr. Patel and his co-conspirators came to understand that importing and selling purported natural, plant-based substances would be easier than selling synthetic stimulants. USP Labs imported DMAA using false and fraudulent Certificates of Analysis (COAs) and other false and fraudulent documentation and labeling. Some of the false COAs that USP Labs caused to be created for DMAA shipments stated falsely that the substance in the shipments had been extracted from the geranium plant.

In a September 2008 email, Mr. Patel instructed one of his co-conspirators, ''Have your supplier create a COA like this.'' In an email exchange from May

2009, discussing the DMAA in USP Labs' products, Mr. Patel told two of his co-conspirators, ''lol stuff is completely 100% synthethic [sic].'' From at least 2008 until at least 2013, USP Labs frequently imported other potential dietary compounds from China, under false labeling, to determine if they could be used in new dietary supplements. One of those synthetic compounds was called ''aegeline.'' The first aegeline-containing version of OxyElite Pro, which was called OxyElite ''New Formula,'' went on sale in November 2012. USP Labs reformulated the DMAA product in the summer of 2013 to contain aegeline and powder derived from a Chinese herb called cynanchum auriculatum. On or about June 15, 2013, one of Mr. Patel's co-conspirators at USP Labs instructed a Chinese company to have 2 metric tons of ground cynanchum auriculatum root powder shipped internationally to S.K. Laboratories in California for inclusion in USP Labs' products, using the false name ''cynanchum auriculatum root extract.'' USP Labs sent false labels listing ''cynanchum auriculatum (root) extract'' as an ingredient in its OxyElite Pro ''Advanced Formula'' supplement to retailers and wholesalers. On or about October 4, 2013, Mr. Patel and his co-conspirators shipped and caused the shipment of misbranded OxyElite Pro ''Advanced Formula'' into interstate commerce. The food was misbranded because its labeling falsely declared cynanchum auriculatum (root) extract as an ingredient even though it was not contained in the product.

As a result of this conviction FDA sent Mr. Patel, by certified mail on May 27, 2021, a notice proposing to debar him for a period of 5 years from importing articles of food or offering such articles for import into the United States. The proposal was based on a finding under section 306(b)(1)(C) of the FD&C Act that Mr. Patel's felony conviction of conspiracy to introduce misbranded food into interstate commerce with an intent to defraud and mislead in violation of 18 U.S.C. 371 (21 U.S.C. 331(a) and 333(a)(2)) constitutes conduct relating to the importation into the United States of an article of food because Mr. Patel was engaged in a conspiracy with others to import a variety of potential dietary compounds from a Chinese company as prospective and actual ingredients for use in dietary supplements, and instructed and agreed to have those powders labeled falsely as other food substances. The proposal was also based on a determination, after consideration of the relevant factors set forth in section 306(c)(3) of the FD&C Act, that Mr. Patel should be subject to a 5-year period of debarment. The proposal also offered Mr. Patel an opportunity to request a hearing, providing Mr. Patel 30 days from the date of receipt of the letter in which to file the request, and advised Mr. Patel that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Mr. Patel failed to respond within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and waived any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(b)(1)(C) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Mr. Sitesh Bansi Patel has been convicted of a felony count under Federal law for conduct relating to the importation into the United States of an article of food and that he is subject to a 5-year period of debarment.

As a result of the foregoing finding, Mr. Patel is debarred for a period of 5 years from importing articles of food or offering such articles for import into the United States, effective (see **DATES**). Pursuant to section 301(cc) of the FD&C Act (21 U.S.C. 331(cc)), the importing or offering for import into the United States of an article of food by, with the assistance of, or at the direction of Mr. Sitesh Bansi Patel is a prohibited act.

Any application by Mr. Patel for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA–2021–N–0269 and sent to the Dockets Management Staff (see **ADDRESSES**). The public availability of information in these submissions is governed by 21 CFR 10.20(j).

Publicly available submissions will be placed in the docket and will be viewable at *https://www.regulations.gov* or at the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

Dated: September 27, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–21375 Filed 9–30–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2020–N–2231; FDA–2011–N–0362; FDA–2018–N–0073; FDA–2018–N–0074; FDA–2010–N–0155; FDA–2011–N–0781; FDA–2021–N–0525; FDA–2014–N–0987; FDA–2020–N–1657; FDA–2017–N–6931; FDA–2020–N–2217; FDA–2012–N–0369; FDA–2017–N–6730; FDA–2020–N–1207; FDA–2012–N–0115; FDA–2021–N–0363; FDA–2009–N–0025; FDA–2012–N–0547; FDA–2014–N–2347; FDA–2018–N–1129; FDA–2021–N–0387; FDA–2020–N–1261; and FDA–2020–N–1644]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at *https://www.reginfo.gov/public/do/PRAMain.* 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.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Blood Establishment Registration and Product Listing for Manufacturers of Blood and Blood Products and Licensed Devices	0910–0052	7/31/2024
Current Good Manufacturing Practice: Manufacturing, Processing, Packing, and Holding of Drugs; GMP for Finished Pharmaceuticals (Including Gases and Active Pharmaceutical Ingredients)	0910–0139	7/31/2024
Irradiation in the Production, Processing, and Handling of Food	0910–0186	7/31/2024
State Enforcement Notifications	0910–0275	7/31/2024
Veterinary Feed Directive	0910–0363	7/31/2024
Record Retention Requirements for the Soy Protein/Coronary Heart Disease Health Claim	0910–0428	7/31/2024
Prescription Drug Marketing: Administrative Procedures, Policies, and Requirements	0910–0435	7/31/2024
Generic Clearance for the Collection of Qualitative Data on Tobacco Products and Communications	0910–0796	7/31/2024
Survey of Drug Product Manufacturing, Processing, and Packing Facilities	0910–0899	7/31/2024
Current Good Manufacturing Practices for Blood and Related Regulations for Blood Components; and Requirements for Donor Testing, Donor Notification and ''Lookback''	0910–0116	8/31/2024
New Animal Drugs for Investigational Use	0910–0117	8/31/2024
Regulations Under the Federal Import Milk Act	0910–0212	8/31/2024
Medical Device Reporting	0910–0437	8/31/2024
New Plant Varieties Intended for Food Use	0910–0583	8/31/2024
Guidance for Industry and FDA Staff; Class II Special Controls: Automated Blood Cell Separator Device Operating by Centrifugal or Filtration Separation Principle	0910–0594	8/31/2024
Prescription Drug Advertisements	0910–0686	8/31/2024
Animal Food Labeling; Declaration of Certifiable Color Additives	0910–0721	8/31/2024
Survey on the Occurrence of Foodborne Illness Risk Factors in Selected Retail and Food Service Facility Types	0910–0744	8/31/2024
Food and Cosmetic Export Certificates	0910–0793	8/31/2024
National Agriculture and Food Defense Strategy Survey	0910–0855	8/31/2024
Medical Product Communications That are Consistent With the Food and Drug Administration Required Labeling—Questions and Answers	0910–0856	8/31/2024
Drug and Device Manufacturer Communications with Payors, Formulary Committees, and Similar Entities Questions and Answers	0910–0857	8/31/2024
Study of Disclosures to Health Care Providers Regarding Data That Do Not Support Unapproved Use of an Approved Prescription Drug	0910–0900	8/31/2024
Medical Conference Attendees' Observations About Prescription Drug Promotion	0910–0901	8/31/2024

Dated: September 24, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–21386 Filed 9–30–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Final Policy: Updates to Uniform Standard for Waiver of the Ryan White HIV/AIDS Program Core Medical Services Expenditure Requirement

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice of final policy.

SUMMARY: The Ryan White HIV/AIDS Program (RWHAP) statute of the Public Health Services Act requires that RWHAP Part A, B, and C recipients expend not less than 75 percent of Parts A, B, and C grant funds on core medical services for individuals with HIV/AIDS identified and eligible under the statute, after reserving statutory permissible amounts for administrative and clinical quality management (CQM) costs. The statute also grants the Secretary of HHS authority to waive this requirement if certain requirements are met. HRSA has simplified the process for RWHAP Part A, B, and C recipients to request a waiver of the core medical services expenditure amount requirement by replacing HRSA Policy Number 13–07, ''Uniform Standard for Waiver of Core Medical Services Requirement for Grantees Under Parts, A, B, and C'' with Policy Notice 21–01, ''Waiver of the Ryan White HIV/AIDS Program Core Medical Services Expenditure Requirement.''

DATES: The final policy is effective on October 1, 2021.

FOR FURTHER INFORMATION CONTACT: Lieutenant Commander Emeka Egwim, U.S. Public Health Service, Senior Policy Analyst, Division of Policy & Data, HRSA, HIV/AIDS Bureau, 5600 Fishers Lane, Rockville, MD 20857, Phone: (301) 945–9637 or by emailing *RWHAPPolicy@hrsa.gov.* When requesting information, please include this **Federal Register** notice title for reference.

SUPPLEMENTARY INFORMATION: The RWHAP statute also grants the Secretary of HHS authority to waive this requirement for RWHAP Parts A, B, or C recipients if a number of requirements are met and a waiver request is submitted to HRSA for approval. RWHAP Part A, B, and C core medical services waiver requests—if approved—are effective for a 1-year budget period, and apply to funds awarded under the Minority AIDS Initiative.

Currently, for a core medical services waiver request to be approved, (1) core medical services must be available and accessible to all individuals identified and eligible for the RWHAP in the recipient's service area within 30 days, without regard to payer source; (2) there cannot be any AIDS Drug Assistance Program (ADAP) waiting lists in the recipient's service area; and (3) a public process to obtain input on the waiver request from impacted communities, including clients and RWHAP-funded core medical services providers, on the availability of core medical services and the decision to request the waiver must have occurred. The public process may be a part of the same one used to seek input on community needs as part of the annual priority setting and resource allocation, comprehensive planning, statewide coordinated statement of

need, public planning, and/or needs assessment processes.

HRSA has simplified the waiver request process for RWHAP Parts A, B, and C recipients by revising and replacing HRSA Policy Number 13–07: Uniform Standard for Waiver of Core Medical Services Requirement for Grantees Under Part, A, B, and C. The changes reduce the administrative burden for recipients by lessening the documentation they must submit to HRSA when requesting a waiver. Under this final policy, recipients are required to submit a one-page ''HRSA RWHAP Core Medical Services Waiver Request Attestation Form'' to HRSA in lieu of the multiple documents previously required to submit a waiver request.

HRSA also revised the waiver request submission deadlines. This final policy, ''Waiver of the Ryan White HIV/AIDS Program Core Medical Services Expenditure Requirement,'' replaces HRSA Policy Number 13–07 effective October 1, 2021.

In administering the RWHAP, HRSA continually evaluates its policies and processes, and considers making updates where necessary to ensure programmatic efficiency while facilitating recipients' ability to provide care and support services to people with HIV. To inform its policy evaluation and development processes with perspectives representative of the communities served by the RWHAP, HRSA welcomes and considers input from stakeholders of the RWHAP, including recipients, providers, people with HIV, and the general public. To that end, on April 20, 2021, HRSA sought public input when it published the proposed updates to the waiver request process for RWHAP Parts A, B, and C recipients in the **Federal Register** (86 FR 20500), and released a listserv message informing stakeholders where to access and review the **Federal Register** notice. In addition, during the April 27, 2021, ''HAB You Heard'' RWHAP recipient webinar, HRSA conducted a walkthrough of the proposed policy, comparing and contrasting it to the existent policy outlined in HRSA Policy Number 13–07. Subsequently, on August 20, 2021, HRSA published a **Federal Register** notice for 30-day public comment period, and submitted the ICR to OMB for review and approval.

Overview of Public Comments

In response to the proposed policy published in 86 FR 20500, HRSA received 52 responses from stakeholders. The vast majority of respondents were individuals from the general public, followed by RWHAP recipients and HIV patient care advocacy organizations. HRSA considered all feedback in the finalization of the policy, and a discussion of the public comments is included below.

Discussion of Public Comments on the Proposed Policy

Availability of Core Medical Services, ADAP Waiting Lists, and Evidence of a Public Process

Public Comment: Commenters were unanimously supportive of submitting a one-page attestation form in lieu of the multiple pages of supporting documentation required per HRSA Policy Number 13–07 because it would reduce administrative burden. They were equally supportive of the stipulation that, if requested, recipients would need to submit supportive documentation to HRSA if requested.

Response: HRSA appreciates the comments and agrees the new policy will reduce burden for recipients, as well as for HRSA as it reviews the waiver applications. HRSA is finalizing the policy as proposed. As such, when submitting waiver requests, RWHAP recipients will only need to submit the one-page ''HRSA RWHAP Core Medical Services Waiver Request Attestation Form'' to HRSA in lieu of multiple documents currently required to submit a waiver request. HRSA may request additional information or supporting documentation. HRSA approximates this process would require 4 hours per response, representing a reduction of 1.5 hours when compared to the current process, or a total of 88 hours across all recipients expected to submit a waiver application.

Submission Deadlines

Public Comment: Commenters were supportive of the proposed changes regarding waiver request submissions deadlines. One commenter expressed some concern that specific submission deadlines may reduce flexibility for some recipients and may not take into account the urgency of a potential waiver in the case of an emergency or unexpected situation on the part of the recipient. The commenter recommended that HRSA adequately advertise this tenet of the policy and evaluate the deadlines to ensure this change does not adversely impact recipients.

Response: HRSA will finalize the policy as proposed by requiring specific submission deadlines. RWHAP Part A recipients will need to submit the waiver request as an attachment with the grant application or non-competing continuation (NCC) progress report. RWHAP Part B recipients will need to submit the waiver request either in advance of the grant application, with the grant application, with the mandatory NCC progress report, or up to 4 months into the grant award budget period for which the waiver is being requested. RWHAP Part C recipients will need to submit the waiver request as an attachment with the grant application or the mandatory NCC progress report. HRSA thanks the commenters for their input, and will monitor the impact of the new policy on the RWHAP in order to ensure recipients' ability to timely submit waiver requests and their ability to provide care and support services to people with HIV.

Concluding Points

HRSA continues to find opportunities to streamline its policies and processes to facilitate RWHAP recipients' ability to continue to deliver quality care and support services to people with HIV, while increasing HRSA's efficiency in administering the program. Given the participation of RWHAP stakeholders in the public process, HRSA believes HRSA Policy Number 21–01 titled ''Waiver of the Ryan White HIV/AIDS Program Core Medical Services Expenditure Requirement'' meets the overall goal and objective of the RWHAP, and is inclusive of the perspectives of stakeholders, while reducing burden to RWHAP recipients. HRSA expects a period of adjustment to the new process. To that end, HRSA will provide timely technical assistance and other resources to assist recipients with the transition to and implementation of the final policy. Recipients are encouraged to contact HRSA at *RWHAPPolicy@hrsa.gov* for questions or feedback on the new process.

HRSA remains committed to supporting RWHAP recipients in their provision of care and support services to people with HIV. The finalization of HRSA Policy Number 21–01, which reduces burden for recipients requesting a waiver of the Core Medical Services expenditure requirement, is another step indicative of this commitment.

The final policy is set forth below. Upon its Effective Date of October 1, 2021, the policy replaces HRSA Policy Number 13–07.

Waiver of the Ryan White HIV/AIDS Program Core Medical Services Expenditure Requirement

Policy Notice 21–01

Replaces Policy Number 13–07

Scope of Coverage

HRSA HIV/AIDS Bureau RWHAP Parts A, B, and C

Requirements

A HRSA RWHAP Part A, B, or C recipient must meet a number of requirements and submit a waiver request to HRSA to receive a waiver of the core medical services expenditure requirement. First, core medical services must be available and accessible to all individuals identified and eligible for the RWHAP in the recipient's service area within 30 days. Access to core medical services must be without regard to payer source and without the need to spend at least 75 percent of funds remaining from the recipient's RWHAP award after statutory permissible amounts for administrative and CQM are reserved. Second, the HRSA RWHAP recipient must ensure there are no ADAP waiting lists in its service area. Third, a public process to obtain input on the waiver request must have occurred. This process must seek input from impacted communities, including clients and RWHAP-funded core medical services providers on the availability of core medical services and the decision to request the waiver. The public process may be a part of the same one used to seek input on community needs as part of the annual priority setting and resource allocation, comprehensive planning, statewide coordinated statement of need, public planning, and/or needs assessment processes.

Requesting a Waiver

To request a waiver, the Chief Elected Official, Chief Executive Officer, or a designee of either must complete and submit the HRSA RWHAP Core Medical Services Waiver Request Attestation Form (appended below) to HRSA. The form should be submitted according to the applicable deadlines and methods for submission outlined below. By completing and submitting this form, the Chief Elected Official, Chief Executive Officer, or a designee of either attests to meeting the requirements outlined above and agrees to provide supportive evidence to HRSA upon request. No other documentation is required to be submitted with the HRSA RWHAP Core Medical Services Waiver Request Attestation Form.

Deadlines for Submitting Waiver Requests

HRSA RWHAP Part A Waiver Requests

A HRSA RWHAP Part A recipient's request for a waiver should be submitted as an attachment with the grant application or the mandatory NCC progress report, if applicable. In each case, waiver requests do not count towards the submission page limit. Requests for waivers should not be submitted prior to the grant application or mandatory NCC progress report, nor should they be submitted after the start of the grant award budget period for which the waiver is being requested.

HRSA RWHAP Part B Waiver Requests

A HRSA RWHAP Part B recipient's request for a waiver may be submitted either in advance of the grant application, as an attachment to the grant application, with the mandatory NCC progress report, or up to 4 months into the grant award budget period for which the waiver is being requested.

HRSA RWHAP Part C Waiver Requests

A HRSA RWHAP Part C recipient's request for a waiver should be submitted as an attachment to the grant application or the mandatory NCC progress report. Requests for waivers should not be submitted prior to the grant application or mandatory NCC progress report, nor should they be submitted after the start of the grant award budget period for which the waiver is being requested.

Methods for Submitting Waiver Requests

Waiver requests submitted with grant applications must be submitted through *www.grants.gov.* Waiver requests submitted with the mandatory NCC progress report must be submitted through the HRSA Electronic Handbooks (EHB). For waiver requests that are not submitted with grant applications, and not submitted with the mandatory NCC progress report, a recipient must notify its HRSA project officer of its intention to request a waiver. The project officer will initiate a Request for Information in the EHB. The recipient must respond to the EHB task consistent with the deadlines for submitting waiver requests outlined above.

Waiver Review and Notification Process

HRSA will review requests and notify recipients of waiver approval or denial within 4 weeks of receipt of the request.

Approved core medical services waivers will be effective for the 1-year budget period for which it is approved; recipients must submit a new request for each budget period. A recipient approved for a core medical services waiver is not required to implement the approved waiver if it is no longer needed.

This guidance does not have the force and effect of law and is not meant to bind the public in any way, except as authorized by law or as incorporated into a contract. It is intended only to provide clarity to the public regarding existing requirements under the law or agency policies.

BILLING CODE 4165–01–P

HRSA Ryan White HIV/AIDS Program (RWHAP) Core Medical Services Waiver Request Attestation Form

This form is to be completed by the Chief Elected Official, Chief Executive Officer, or a designee of either.

Please initial to attest to meeting each requirement after reading and understanding the explanation.

Name of recipient _____

☐ **RWHAP Part A recipient** ☐ **RWHAP Part B recipient** ☐ **RWHAP Part C recipient**

☐ **Initial request** ☐ **Renewal request**

Year of request _____

REQUIREMENT	EXPLANATION
No ADAP waiting lists	By initialing here and signing this document, you attest there are no AIDS Drug Assistance Program (ADAP) waiting lists in the service area. ☐
Availability of, and accessibility to core medical services to all eligible individuals	By initialing here and signing this document, you attest to the availability of and access to core medical services for all HRSA RWHAP eligible individuals in the service area within 30 days. Such access is without regard to funding source, and without the need to spend on these services, at least 75 percent of funds remaining from your RWHAP award after reserving statutory permissible amounts for administrative and clinical quality management. You also agree to provide HRSA HAB supportive evidence of meeting this requirement upon request. ☐
Evidence of a public process	By initialing here and signing this document, you attest to having had a public process during which input related to the availability of core medical services and the decision to request this waiver was sought from impacted communities, including clients and RWHAP funded core medical services providers. You also agree to provide supportive evidence of such process to HRSA HAB upon request. ☐

_____

SIGNATURE OF CHIEF ELECTED OFFICIAL OR CHIEF EXECUTIVE OFFICER (OR DESIGNEE)

_____

PRINT NAME

_____

TITLE

_____

DATE

Public Burden Statement: An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this project is **0906-0065** and is **valid until 09/30/2024**. Public reporting burden for this collection of information is estimated to average 4 hours per response, including the time for reviewing instructions, searching existing data sources, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to HRSA Reports Clearance Officer, 5600 Fishers Lane, Room 14N39, Rockville, Maryland, 20857.

Diana Espinosa,

Acting Administrator.

[FR Doc. 2021–21241 Filed 9–30–21; 8:45 am]

BILLING CODE 4165–15–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Center for Indigenous Innovation and Health Equity Tribal Advisory Committee; Solicitation of Nominations for Delegates

AGENCY: Office of Minority Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice of solicitation of nominations for delegates for the Center for Indigenous Innovation and Health Equity Tribal Advisory Committee.

SUMMARY: The U.S. Department of Health and Human Services (HHS) Office of Minority Health (OMH) hereby gives notice that OMH is establishing a Center for Indigenous Innovation and Health Equity Tribal Advisory Committee (CIIHE TAC) and accepting nominations of qualified candidates to serve as primary and alternate delegates for the CIIHE TAC, in alignment with the 12 geographic areas served by the Indian Health Service (IHS).

DATES: Nomination letters for the CIIHE TAC must be sent to the address noted below no later than 6:00 p.m. EST on October 29, 2021.

ADDRESSES: All nominations should be emailed to: Violet Woo, Designated Federal Officer for the CIIHE TAC, at *Violet.Woo@hhs.gov.* Please use the subject line ''OMH CIIHE Tribal Advisory Committee''.

FOR FURTHER INFORMATION CONTACT: For information and guidance about the nomination process for CIIHE TAC delegates, please contact Violet Woo, Designated Federal Officer at *Violet.Woo@hhs.gov.* CIIHE TAC nomination guidance and sample nomination letters also are available on the OMH website's Tribal Leader Letters section: *https://www.minorityhealth.hhs.gov/omh/browse.aspx?lvl=3&lvlid=62#tribal-leader-letters.*

SUPPLEMENTARY INFORMATION: Authorized under Section 1707 of the Public Health Service Act, 42 U.S.C. 300u–6, as amended, the mission of OMH is to improve the health of racial and ethnic minority populations through the development of health policies and programs that help eliminate health disparities. OMH awards and other activities are intended to support the identification of effective policies, programs, and practices for improving health outcomes and to promote the sustainability and dissemination of these approaches.

Under the authority of Public Law 116–260 (2021 Consolidated Appropriations Act), Congress directed OMH to create a CIIHE to support research, education, service, and policy development advancing Indigenous solutions that ultimately address health disparities in American Indian/Alaska Native (AI/AN) and Native Hawaiian and Pacific Islander (NHPI) populations. OMH is establishing the CIIHE TAC to ensure that Tribal Leaders have meaningful and timely input in the development of the priorities and activities established to address the focus areas of the CIIHE. The CIIHE TAC shall support, but not supplant, government-to-government consultation activities that OMH undertakes.

TAC Membership: The CIIHE TAC will consist of 16 delegate positions: One from each of the 12 geographic areas served by the Indian Health Service and four National At-Large Member positions.

Alaska Area
Albuquerque Area
Bemidji Area
Billings Area
California Area
Great Plains Area
Nashville Area
Navajo Area
Oklahoma Area
Phoenix Area
Portland Area
Tucson Area
National At-Large Members (4)

OMH recommends a two (2) year term length for each delegate, but delegates' term length will be established by the TAC's charter.

Eligibility: The CIIHE TAC delegates must be: (1) Elected tribal officials from a federally recognized tribe acting in their official capacity as elected officials of their tribe, with authority to act on behalf of the tribe; or (2) individuals designated by an elected tribal official. Designees must have the authority to act on behalf of the tribal official and the tribe and be qualified to represent the views of the AI/AN tribes in the area from which they are nominated. No delegate of the CIIHE TAC may be an employee of the federal government.

Nomination Procedures: CIIHE TAC candidates must be nominated by an elected tribal leader. The nomination letter must be on tribal letterhead and signed by an elected tribal leader, and must include the following information:

- Name of the nominee
- Nominee's official title
- Name of the nominee's tribe
- Date of nominee's election to official tribal position and term length
- Nominee's contact information (mailing address, phone, and email)
- Nominee's expertise that is relevant to the CIIHE TAC
- Name of tribal leader submitting the nomination
- Official title of tribal leader submitting the nomination
- Contact information for tribal leader submitting the nomination and/or administrative office for tribal government

CIIHE TAC nomination guidance and sample nomination letters are available on the OMH website's Tribal Leader Letters section: *https://www.minorityhealth.hhs.gov/omh/browse.aspx?lvl=3&lvlid=62#tribal-leader-letters.*

Selection Process: OMH is responsible for selecting and finalizing CIIHE TAC members.

Eligible nominees will be considered in the following priority order:

1. Tribal President/Chairperson/Governor
2. Tribal Vice-President/Vice-Chairperson/Lt. Governor
3. Elected or Appointed Tribal Official
4. Designated Tribal Official with authority to act on behalf of Tribal leader

In the event that there is more than one nomination for a given IHS area, OMH will make a determination of representation based on submitted nomination materials.

Nominees will be notified of the status of delegate selection in November 2021.

Dated: September 24, 2021.

Violet Woo,

Designated Federal Officer, Center for Indigenous Innovation and Health Equity Tribal Advisory Committee.

[FR Doc. 2021–21253 Filed 9–30–21; 8:45 am]

BILLING CODE 4150–29–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Request for Public Comment: 60 Day Notice for Extension of Fast Track Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery: IHS Customer Service Satisfaction and Similar Surveys

AGENCY: Indian Health Service, HHS.

ACTION: Notice and request for comments. Request for extension of approval.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Indian Health Service (IHS) invites the general public to take this opportunity to comment on the information collection Office of Management and Budget (OMB) Control Number 0917–0036, ''Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.'' This notice announces our intent to submit this previously approved information collection, which expires January 31, 2022, to OMB for approval of an extension and solicit comments on specific aspects for the proposed information collection.

DATES: Consideration will be given to all comments received by November 30, 2021.

For Comments: Submit comments to Evonne Bennett by *Email at Evonne.Bennett@ihs.gov.*

Comments submitted in response to this notice will be made available to the public by publishing them in the 30 day **Federal Register** notice for this information collection. For this reason, please do not include information of a confidential nature, such as sensitive personal information or proprietary information. If comments are submitted via email, the email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. Please note that responses to this public comment request containing any routine notice about the confidentiality of the communication will be treated as public comments that may be made available to the public notwithstanding the inclusion of the routine notice.

A copy of the draft supporting statement is available at *www.regulations.gov* (see Docket ID [IHS_FRDOC_0001].

SUPPLEMENTARY INFORMATION: The IHS is submitting the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995, as amended, and its implementing regulations. This notice is soliciting comments from members of the public and affected agencies as required by 44 U.S.C. 3506(c)(2)(A) and 5 CFR 1320.8(d) concerning the proposed collection of information to: (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; (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 collection techniques of other forms of information technology, *e.g.,* permitting electronic submission of responses.

Title: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery: IHS Customer Service Satisfaction and Similar Surveys.

Type of Information Collection Request: Three year extension approval of this information collection.

OMB Control Number: 0917–0036.

Abstract: The proposed information collection activity provides a means to garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Administration's commitment to improving service delivery. Qualitative feedback is information that provides useful insights on perceptions and opinions, but is not statistical surveys that yield quantitative results that can be generalized to the population of study. This feedback will provide insights into customer or stakeholder perceptions, experiences and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative and actionable communications between the Agency and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management.

The solicitation of feedback will target areas such as: Timeliness, appropriateness, accuracy of information, courtesy, efficiency of service delivery, and resolution of issues with service delivery. Responses will be assessed to plan and inform efforts to improve or maintain the quality of service offered to the public. If this information is not collected, vital feedback from customers and stakeholders on the agency's services will be unavailable.

The agency will only submit a collection for approval under this generic clearance if it meets the following conditions:

- Information gathered will be used only internally for general service improvement and program management purposes and is not intended for release outside of the agency;
- Information gathered will not be used for the purpose of substantially informing influential policy decisions;
- Information gathered will yield qualitative information; the collections will not be designed or expected to yield statistically reliable results or used as though the results are generalizable to the population of study;
- The collections are voluntary;
- The collections are low-burden for respondents (based on considerations of total burden hours, total number of respondents, or burden-hours per respondent) and are low-cost for both the respondents and the Federal Government;
- The collections are non-controversial and do not raise issues of concern to other Federal agencies;
- Any collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the near future; and
- With the exception of information needed to provide remuneration for participants of focus groups and cognitive laboratory studies, personally identifiable information (PII) is collected only to the extent necessary and is not retained.

Feedback collected under this generic clearance provides useful information, but it does not yield data that can be generalized to the overall population. This type of generic clearance for qualitative information will not be used for quantitative information collections that are designed to yield reliably actionable results, such as monitoring trends over time or documenting program performance. Such data uses require more rigorous designs that address: The target population to which generalizations will be made, the sampling frame, the sample design (including stratification and clustering), the precision requirements or power calculations that justify the proposed sample size, the expected response rate, methods for assessing potential non-response bias, the protocols for data collection, and any testing procedures that were or will be undertaken prior to fielding the study. Depending on the degree of influence the results are likely to have, such collections may still be eligible for submission for other generic mechanisms that are designed to yield quantitative results.

As a general matter, information collections will not result in any new system of records containing privacy information and will not ask questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

Current Actions: Extension of approval for a collection of information.

Type of Review: Extension.

Affected Public: Individuals and households, businesses and organizations, and Tribal governments.

Estimated Number of Respondents: 105,000.

Below are projected annual average estimates for the next three years:

Average Expected Annual Number of activities: 100.

Average number of Respondents per Activity: 1,050.

Annual responses: 105,000.

Frequency of Response: Once per request.

Average minutes per response: 10.

Burden hours: 17,500.

There are no direct costs to respondents to report.

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.

Comment Due Date: Your comments regarding this information collection are best assured of having full effect if received within 30 days of the date of this publication.

Elizabeth A. Fowler,

Acting Director, Indian Health Service.

[FR Doc. 2021–21350 Filed 9–30–21; 8:45 am]

BILLING CODE 4165–16–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental & Craniofacial Research; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: NIDCR Special Grants Review Committee.

Date: October 28–29, 2021.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Nisan Bhattacharyya, Ph.D., Scientific Review Officer, Scientific Review Branch, NIDCR, NIH, 6701 Democracy Boulevard, Suite 668, Bethesda, MD 20892, 301–451–2405, *nisan.bhattacharyya@nih.gov.*

(Catalogue of Federal Domestic Assistance Program No. 93.121, Oral Diseases and Disorders Research, National Institutes of Health, HHS)

Dated: September 28, 2021.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–21380 Filed 9–30–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; OD–21–005: Short Courses on Innovative Methodologies and Approaches in the Behavioral and Social Sciences.

Date: October 25, 2021.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Sara Louise Hargrave, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3170, Bethesda, MD 20892, (301) 443–7193, *hargravesl@mail.nih.gov.*

Name of Committee: Genes, Genomes, and Genetics Integrated Review Group; Genetics of Health and Disease Study Section.

Date: November 1–2, 2021.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Christopher Payne, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Rm. 2208, Bethesda, MD 20892, 301–402–3702, *christopher.payne@nih.gov.*

Name of Committee: Population Sciences and Epidemiology Integrated Review Group; Biostatistical Methods and Research Design Study Section.

Date: November 2–3, 2021.

Time: 9:30 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Victoriya Volkova, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3140, Bethesda, MD 20892, (301) 594–7781, *victoriya.volkova@nih.gov.*

Name of Committee: Musculoskeletal, Oral and Skin Sciences Integrated Review Group; Oral, Dental and Craniofacial Sciences Study Section.

Date: November 4–5, 2021.

Time: 9:00 a.m. to 9:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Yi-Hsin Liu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4214, MSC 7814, Bethesda, MD 20892, (301) 435–1781, *liuyh@csr.nih.gov.*

Name of Committee: Applied Immunology and Disease Control Integrated Review Group; Drug Discovery and Mechanisms of Antimicrobial Resistance Study Section.

Date: November 4–5, 2021.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Susan Daum, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3202, Bethesda, MD 20892, 301–827–7233, *susan.boyle-vavra@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowship: Infectious Disease and Immunology B.

Date: November 4–5, 2021.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Uma Basavanna, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301–827–1398, *uma.basavanna@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Renal/Urological Small Business Activities.

Date: November 4, 2021.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Santanu Banerjee, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2106, Bethesda, MD 20892, (301) 435–5947, *banerjees5@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: SBIR/STTR Commercialization Readiness Pilot (CRP) Program.

Date: November 4, 2021.

Time: 9:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Allen Richon, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6184, MSC 7892, Bethesda, MD 20892, 301–379–9351, *allen.richon@nih.hhs.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Oncology.

Date: November 4–5, 2021.

Time: 10:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Reigh-Yi Lin, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Rm. 4152, MSC 7846, Bethesda, MD 20892, (301) 827–6009, *lin.reigh-yi@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: September 27, 2021.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–21381 Filed 9–30–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health and Human Development; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel; Recompetition of the Pediatric Scientist Development.

Date: October 7, 2021.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 6710B Rockledge Drive, Room 2137B, Bethesda, MD 20892 (Video Assisted Meeting).

Contact Person: Joanna Kubler-Kielb, Ph.D., Scientific Review Officer, Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 6710B Rockledge Drive, Room 2137B, Bethesda, MD 20892, 301–435–6916, *kielbj@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel; Developmental Mechanisms of Human Structural Birth Defects.

Date: November 17–18, 2021.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 6710B Rockledge Drive, Room 2125B, Bethesda, MD 20892 (Video Assisted Meeting).

Contact Person: Derek J. McLean, Ph.D., Scientific Review Officer, Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 6710B Rockledge Drive, Room 2125B, Bethesda, MD 20892–7002, 301–443–5082, *derek.mclean@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.865, Research for Mothers and Children, National Institutes of Health, HHS)

Dated: September 28, 2021.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–21397 Filed 9–30–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Initial Review Group; Developmental Biology Study Section.

Date: October 15, 2021.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 6710B Rockledge Drive, Bethesda, MD 20817 (Video Assisted Meeting).

Contact Person: Cathy J. Wedeen, Ph.D., Scientific Review Officer, Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 6710B Rockledge Drive, Room 2121D, Bethesda, MD 20892–7510, (301) 435–6878, *cathy.wedeen@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: September 28, 2021.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–21396 Filed 9–30–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Refugee Resettlement

Public/Private Refugee Cash Assistance Inflationary Increase

AGENCY: Office of Refugee Resettlement (ORR), Administration for Children and Families (ACF), Department of Health and Human Services (HHS).

ACTION: Notice of change in payment ceilings.

SUMMARY: In accordance with ORR regulations, the Director of ORR is announcing an inflationary increase to the public/private Refugee Cash Assistance (RCA) program's monthly payment ceilings, effective October 1, 2021. The current payment ceilings have remained fixed since March 22, 2000, despite inflation. The new payment ceilings accommodate that inflation and will provide arriving ORR-eligible populations greater economic stability as they transition to self-sufficiency.

DATES: The changes described in this **Federal Register** Notice are effective October 1, 2021.

FOR FURTHER INFORMATION CONTACT: Colleen Mahar-Piersma, Refugee Policy Unit, Division of Policy and Procedures, Office of the Director, Office of Refugee Resettlement, Administration for Children and Families, by phone at (202) 260–5493, and email at *refugeepolicy@acf.hhs.gov.*

SUPPLEMENTARY INFORMATION:

ORR-eligible populations are eligible for up to eight months of RCA after their initial ORR eligibility date if they are deemed ineligible for the Temporary Assistance for Needy Families (TANF) program. When TANF was established in 1996, ORR gave states the option to either establish a publicly administered RCA program modeled after their TANF program in terms of eligibility determinations and benefits levels, or the option to establish a public/private partnership (PPP) RCA program. States that chose the PPP RCA model proposed a plan to ORR that created their income eligibility standard and may have included sliding scale payments or incentives for early employment aimed at refugee self-sufficiency, as long as they remained within the established payment ceilings.

ORR established the PPP RCA monthly payment ceilings codified at 45 CFR 400.60(a) using the poverty guidelines developed by the Assistant Secretary for Planning and Evaluation within HHS. These poverty guidelines, which are updated annually, are mainly used for administrative purposes such as determining an individual's eligibility for certain programs. When ORR established the current PPP RCA monthly payment ceilings, it used the 1998 HHS Poverty Guidelines with the following formula: ''50% of the 1998 HHS Poverty Guidelines for each family size, divided by 12 months. . . .'' Where family units were greater than four people, the monthly payment ceiling was increased by $70 for each additional person.

These PPP RCA payment ceilings have remained fixed since March 22, 2000, despite inflation and an increased cost of living nationwide. The payment ceilings are insufficient to meet refugees' initial expenses for housing, utilities, transportation, food, and other essentials, as they acclimate to their new communities and try to secure employment. Refugees generally have no other means of assistance such as savings or family resources to assist in the early days of arrival. Additionally, more than half of current projected ORR-eligible arrivals do not benefit from assistance from the Department of State's Reception and Placement Program, making RCA a critical source of support as they strive for economic self-sufficiency and integration.

As such, in accordance with ORR regulations at 45 CFR 400.60(d), the ORR Director has determined that the PPP RCA payment ceilings need to be adjusted for inflation.

Using ORR's original formula in relation to the 2021 HHS poverty guidelines, the adjusted PPP RCA payment ceilings are:

PUBLIC/PRIVATE RCA PAYMENT CEILINGS

Size of family unit	Monthly payment ceiling
1	$537
2	726
3	915
4	1,104

Where family units are greater than four people, the monthly payment ceiling is increased by $113 for each additional person.

These payment ceilings only apply to RCA recipients within PPP-administered programs. All remaining RCA programs must continue to follow their established TANF rate.

To implement the RCA payment ceilings outlined in this Notice, the State/Replacement Designee (RD) must first revise its State Plan and ORR–1 CMA estimate. ORR will issue further guidance on how a State/RD should address implementation of the new public/private partnership RCA rate in its State Plan and ORR–1 prior to the implementation of the increased rate.

ORR will also conduct minimally, a bi-annual review of the HHS Poverty Guidelines, the established PPP rates, and the availability of funding with the goal of enacting more responsive and equitable cash assistance rates in the public/private RCA program.

(Authority: 45 CFR 400.60)

Dated: September 24, 2021.

Cindy Huang,

Director of the Office of Refugee Resettlement.

[FR Doc. 2021–21369 Filed 9–30–21; 8:45 am]

BILLING CODE 4120–27–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 and Oral Fluid 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 (IITFs) currently certified to meet the standards of the Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine or Oral Fluid (Mandatory Guidelines).

FOR FURTHER INFORMATION CONTACT: Anastasia Donovan, Division of Workplace Programs, SAMHSA/CSAP, 5600 Fishers Lane, Room 16N06B, Rockville, Maryland 20857; 240–276–2600 (voice); *Anastasia.Donovan@samhsa.hhs.gov* (email).

SUPPLEMENTARY INFORMATION: In accordance with Section 9.19 of the 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 *https://www.samhsa.gov/workplace/resources/drug-testing/certified-lab-list.*

The Department of Health and Human Services (HHS) notifies federal agencies of the laboratories and Instrumented Initial Testing Facilities (IITFs) currently certified to meet the standards of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines) using Urine and of the laboratories currently certified to meet the standards of the Mandatory Guidelines using Oral Fluid.

The Mandatory Guidelines using Urine 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 using Oral Fluid were first published in the **Federal Register** on October 25, 2019 (84 FR 57554) with an effective date of January 1, 2020.

The Mandatory Guidelines were initially developed in accordance with Executive Order 12564 and section 503 of Public Law 100–71 and allowed urine drug testing only. The Mandatory Guidelines using Urine have since been revised, and new Mandatory Guidelines allowing for oral fluid drug testing have been published. The Mandatory Guidelines require strict standards that laboratories and IITFs must meet in order to conduct drug and specimen validity tests on specimens for federal agencies. HHS does not allow IITFs to conduct oral fluid testing.

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 using Urine and/or Oral Fluid. An HHS-certified laboratory or IITF must have its letter of certification from HHS/SAMHSA (formerly: HHS/NIDA), which attests that the test facility has met minimum standards. HHS does not allow IITFs to conduct oral fluid testing.

HHS-Certified Laboratories Approved To Conduct Oral Fluid Drug Testing

In accordance with the Mandatory Guidelines using Oral Fluid dated October 25, 2019 (84 FR 57554), the following HHS-certified laboratories meet the minimum standards to conduct drug and specimen validity tests on oral fluid specimens:

At this time, there are no laboratories certified to conduct drug and specimen validity tests on oral fluid specimens.

HHS-Certified Instrumented Initial Testing Facilities Approved To Conduct Urine Drug Testing

In accordance with the Mandatory Guidelines using Urine dated January 23, 2017 (82 FR 7920), the following HHS-certified IITFs meet the minimum standards to conduct drug and specimen validity tests on urine specimens:

Dynacare, 6628 50th Street NW, Edmonton, AB Canada T6B 2N7, 780–784–1190 (Formerly: Gamma-Dynacare Medical Laboratories)

HHS-Certified Laboratories Approved To Conduct Urine Drug Testing

In accordance with the Mandatory Guidelines using Urine dated January 23, 2017 (82 FR 7920), the following HHS-certified laboratories meet the minimum standards to conduct drug and specimen validity tests on urine specimens:

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.)

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)

Desert Tox, LLC, 5425 E Bell Rd, Suite 125, Scottsdale, AZ 85254, 602–457–5411/623–748–5045

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.)

Legacy Laboratory Services Toxicology, 1225 NE 2nd Ave., Portland, OR 97232, 503–413–5295/800–950–5295

MedTox Laboratories, Inc., 402 W County Road D, St. Paul, MN 55112, 651–636–7466/800–832–3244

Minneapolis Veterans Affairs Medical Center, Forensic Toxicology Laboratory, 1 Veterans Drive, Minneapolis, MN 55417, 612–725–2088. Testing for Veterans Affairs (VA) Employees Only

Pacific Toxicology Laboratories, 9348 DeSoto Ave., Chatsworth, CA 91311, 800–328–6942 (Formerly: Centinela Hospital Airport Toxicology Laboratory)

Phamatech, Inc., 15175 Innovation Drive, San Diego, CA 92128, 888–635–5840

Quest Diagnostics Incorporated, 400 Egypt Road, Norristown, PA 19403, 610–631–4600/877–642–2216 (Formerly: SmithKline Beecham

Clinical Laboratories; SmithKline Bio-Science Laboratories)

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 following laboratory voluntarily withdrew from the National Laboratory Certification Program effective September 3, 2021:

Redwood Toxicology Laboratory, 3700 Westwind Blvd., Santa Rosa, CA 95403, 800–255–2159

* 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** on 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.

Anastasia Marie Donovan,

Policy Analyst, Division of Workplace Programs.

[FR Doc. 2021–21402 Filed 9–30–21; 8:45 am]

BILLING CODE 4160–20–P

DEPARTMENT OF THE INTERIOR

Geological Survey

[GX21BD239AV0100; OMB Control Number 1028–NEW]

Agency Information Collection Activities; Information Collection Through Surveys and Interviews To Evaluate and Improve the Cooperative Research Units Program Mission, Functions, and Goals

AGENCY: U.S. Geological Survey, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the U.S. Geological Survey (USGS) are proposing a new information collection.

DATES: Interested persons are invited to submit comments on or before November 30, 2021.

ADDRESSES: Send your comments on this information collection request (ICR) by mail to U.S. Geological Survey, Information Collections Officer, 12201 Sunrise Valley Drive MS 159, Reston, VA 20192; or by email to *gs-info_collections@usgs.gov.* Please reference OMB Control Number 1028–NEW in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Cynthia S. Loftin by email at *cyndy_loftin@usgs.gov,* or by telephone at (207) 581–2843. Individuals who are hearing or speech impaired may call the Federal Relay Service at 1–800–877–8339 for TTY assistance.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995, we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are soliciting comments on the proposed ICR that is described below. We are especially interested in public comment addressing the following issues: (1) Is the collection necessary to the proper functions of the USGS; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the USGS enhance the quality, utility, and clarity of the information to be collected; and (5) how might the USGS minimize the burden of this collection on the respondents, including through the use of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: The USGS Cooperative Fish and Wildlife Research Units Program originated in 1935 to fill a need for qualified wildlife and fisheries professionals and provide evidence based graduate research to inform resource management. Currently the program has 40 individual Units in 38 states and formalizes relationships among a state natural resources management agency, a host university, the USGS, the USFWS, and the Wildlife Management Institute. The program's graduate education and research mission has remained largely unchanged through its tenure, yet the issues challenging fish and wildlife conservation have transformed. This raises questions about the program's support and sustainability into the future and how best to address cooperator needs.

Through focused surveys and interviews, this information collection will ask participants to evaluate their communication and relationships with individuals in the program. The data will be used to examine the structure, communication, and socio-technical connectivity using network analysis and agent based modeling. This information collection aims to improve our understanding of the Cooperative Research Units Program and how it meets its partners' needs.

Title of Collection: Information collection through surveys and interviews to improve the Cooperative Research Units Program mission, functions, and goals.

OMB Control Number: 1028–NEW.

Form Number: None.

Type of Review: New.

Respondents/Affected Public: Universities, state and tribal governments, and businesses which are direct (both formal and informal)

Cooperators of the USGS Cooperative Fish and Wildlife Research Units Program.

Total Estimated Number of Annual Respondents: 1,500.

Total Estimated Number of Annual Responses: 1,500.

Estimated Completion Time per Response: 20 minutes.

Total Estimated Number of Annual Burden Hours: 500 hours.

Respondent's Obligation: Voluntary.

Frequency of Collection: One time.

Total Estimated Annual Nonhour Burden Cost: None.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Cynthia Loftin,

Unit Leader, Maine Cooperative Fish and Wildlife Research Unit.

[FR Doc. 2021–21358 Filed 9–30–21; 8:45 am]

BILLING CODE 4338–11–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[212A2100DD/AAKC001030/A0A501010.999900253G]

Indian Gaming; Approval of Tribal-State Class III Gaming Compact in the State of Minnesota

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: This notice publishes the approval of the Third Amendment to Technical Standards in [the] Tribal-State Compact for Control of Class III Blackjack on the Shakopee Mdewakanton Sioux Community in Minnesota (Amendment) and the State of Minnesota.

DATES: The Amendment takes effect on October 1, 2021.

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, *paula.hart@bia.gov,* (202) 219–4066.

SUPPLEMENTARY INFORMATION: Under section 11 of the Indian Gaming Regulatory Act, Public Law 100–497, 25 U.S.C. 2701 *et seq.,* the Secretary of the Interior shall publish in the **Federal Register** notice of approved Tribal-State compacts for the purpose of engaging in Class III gaming activities on Indian lands. As required by 25 CFR 293.4, all compacts and amendments are subject to review and approval by the Secretary. The Amendment allows for additional propositional wagers and side bets for Blackjack and higher payout percentages for those wagers. The Amendment is approved.

Bryan Newland,

Assistant Secretary—Indian Affairs.

[FR Doc. 2021–21384 Filed 9–30–21; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLWY–957000–XXX–L19100000–BJ0000–LRCSKX00300A; LLCO–956000–XXX–L19100000–BJ0000–LRCSCX913400; LLCO–956000–XXX–L19100000–BJ0000–LRCSCX914400; LLWY–926000–21X–L14400000–BJ0000–LXSSK1810000]

Filing of Plats of Survey, Nebraska and Wyoming

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of official filing.

SUMMARY: The Bureau of Land Management (BLM) is scheduled to file plats of survey 30 calendar days from the date of this publication in the BLM Wyoming State Office, Cheyenne, Wyoming. These surveys, which were executed at the request of the Bureau of Indian Affairs, U.S. Forest Service, and the BLM, are necessary for the management of these lands.

DATES: Protests must be received by the BLM prior to the scheduled date of official filing by November 1, 2021.

ADDRESSES: You may submit written protests to the Wyoming State Director at WY926, Bureau of Land Management, 5353 Yellowstone Road, Cheyenne, Wyoming 82009.

FOR FURTHER INFORMATION CONTACT: Sonja Sparks, BLM Wyoming Chief Cadastral Surveyor, by telephone at (307) 775–6225 or by email at *s75spark@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service at 1–800–877–8339 to contact this office during normal business hours. The Service is available 24 hours a day, 7 days a week, to leave a message or question with this office. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The plats of survey of the following described lands are scheduled to be officially filed in the BLM Wyoming State Office, Cheyenne, Wyoming.

Sixth Principal Meridian, Wyoming

T. 25 N., R. 6 E., Group No. NE189, dependent resurvey and survey, accepted September 7, 2021

T. 50 N., R. 83 W., Group No. 1028, dependent resurvey, accepted September 7, 2021

T. 47 N., R. 85 W., Group No. 1029, dependent resurvey and survey, accepted September 7, 2021

T. 43 N., R. 106 W., Group No. 1030, dependent resurvey, accepted September 7, 2021

T. 33 N., R 81 W., Group No. 1032, dependent resurvey and survey, accepted September 7, 2021

A person or party who wishes to protest one or more plats of survey identified in this notice must file a written notice of protest within 30 calendar days from the date of this publication with the Wyoming State Director at the above address. Any notice of protest received after the scheduled date of official filing will be untimely and will not be considered. A written statement of reasons in support of a protest, if not filed with the notice of protest, must be filed with the State Director within 30 calendar days after the notice of protest is filed. If a notice of protest against a plat of survey is received prior to the scheduled date of official filing, the official filing of the plat of survey identified in the notice of protest will be stayed pending consideration of the protest. A plat of survey will not be officially filed until the next business day following dismissal or resolution of all protests of the plat.

Before including your address, phone number, email address, or other personal identifying information in your protest, you should be aware that your entire protest—including your personal identifying information—may be made publicly available at any time. While you can ask us to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Copies of the preceding described plat and field notes are available to the public at a cost of $4.20 per plat and $0.15 per page of field notes. Requests can be made to *blm_wy_survey_records@blm.gov* or by telephone at 307–775–6222.

(Authority: 43 U.S.C., chapter 3)

Dated: September 7, 2021.

Sonja S. Sparks,

Chief Cadastral Surveyor of Wyoming and Nebraska.

[FR Doc. 2021–21401 Filed 9–30–21; 8:45 am]

BILLING CODE 4310–22–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–548 and 731–TA–1298 (Review)]

Welded Stainless Steel Pressure Pipe From India; Institution of a Five-Year Review

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice that it has instituted a review pursuant to the Tariff Act of 1930 (''the Act''), as amended, to determine whether revocation of the countervailing duty and antidumping duty orders on welded stainless steel pressure pipe from India would be likely to lead to continuation or recurrence of material injury. Pursuant to the Act, interested parties are requested to respond to this notice by submitting the information specified below to the Commission.

DATES: Instituted October 1, 2021. To be assured of consideration, the deadline for responses is November 1, 2021. Comments on the adequacy of responses may be filed with the Commission by December 14, 2021.

FOR FURTHER INFORMATION CONTACT: Lawrence Jones (202–205–3358), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*https://www.usitc.gov*). The public record for this proceeding may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Background.—On November 17, 2016, the Department of Commerce (''Commerce'') issued countervailing duty and antidumping duty orders on imports of welded stainless steel pressure pipe from India (81 FR 81062). The Commission is conducting a review pursuant to section 751(c) of the Act, as amended (19 U.S.C. 1675(c)), to determine whether revocation of the orders would be likely to lead to continuation or recurrence of material injury to the domestic industry within a reasonably foreseeable time. Provisions concerning the conduct of this proceeding may be found in the Commission's Rules of Practice and Procedure at 19 CFR part 201, subparts A and B, and 19 CFR part 207, subparts A and F. The Commission will assess the adequacy of interested party responses to this notice of institution to determine whether to conduct a full review or an expedited review. The Commission's determination in any expedited review will be based on the facts available, which may include information provided in response to this notice.

Definitions.—The following definitions apply to this review:

(1) *Subject Merchandise* is the class or kind of merchandise that is within the scope of the five-year review, as defined by the Department of Commerce.

(2) The *Subject Country* in this review is India.

(3) The *Domestic Like Product* is the domestically produced product or products which are like, or in the absence of like, most similar in characteristics and uses with, the *Subject Merchandise.* In its original determinations, the Commission defined the *Domestic Like Product* as consisting of welded stainless steel pressure pipe, corresponding to the scope.

(4) The *Domestic Industry* is the U.S. producers as a whole of the *Domestic Like Product,* or those producers whose collective output of the *Domestic Like Product* constitutes a major proportion of the total domestic production of the product. In its original determinations, the Commission defined the *Domestic Industry* as consisting of all domestic producers of welded stainless steel pressure pipe.

(5) The *Order Date* is the date that the countervailing duty and antidumping duty orders under review became effective. In this review, the *Order Date* is November 17, 2016.

(6) An *Importer* is any person or firm engaged, either directly or through a parent company or subsidiary, in importing the *Subject Merchandise* into the United States from a foreign manufacturer or through its selling agent.

Participation in the proceeding and public service list.—Persons, including industrial users of the *Subject Merchandise* and, if the merchandise is sold at the retail level, representative consumer organizations, wishing to participate in the proceeding as parties must file an entry of appearance with the Secretary to the Commission, as provided in § 201.11(b)(4) of the Commission's rules, no later than 21 days after publication of this notice in the **Federal Register**. The Secretary will maintain a public service list containing the names and addresses of all persons, or their representatives, who are parties to the proceeding.

Former Commission employees who are seeking to appear in Commission five-year reviews are advised that they may appear in a review even if they participated personally and substantially in the corresponding underlying original investigation or an earlier review of the same underlying investigation. The Commission's designated agency ethics official has advised that a five-year review is not the same particular matter as the underlying original investigation, and a five-year review is not the same particular matter as an earlier review of the same underlying investigation for purposes of 18 U.S.C. 207, the post-employment statute for Federal employees, and Commission rule 201.15(b) (19 CFR 201.15(b)), 79 FR 3246 (Jan. 17, 2014), 73 FR 24609 (May 5, 2008). Consequently, former employees are not required to seek Commission approval to appear in a review under Commission rule 19 CFR 201.15, even if the corresponding underlying original investigation or an earlier review of the same underlying investigation was pending when they were Commission employees. For further ethics advice on this matter, contact Charles Smith, Office of the General Counsel, at 202–205–3408.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and APO service list.—Pursuant to § 207.7(a) of the Commission's rules, the Secretary will make BPI submitted in this proceeding available to authorized applicants under the APO issued in the proceeding, provided that the application is made no later than 21 days after publication of this notice in the **Federal Register**. Authorized applicants must represent interested parties, as defined in 19 U.S.C. 1677(9), who are parties to the proceeding. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Certification.—Pursuant to § 207.3 of the Commission's rules, any person submitting information to the Commission in connection with this proceeding must certify that the information is accurate and complete to the best of the submitter's knowledge. In making the certification, the submitter will acknowledge that information submitted in response to this request for information and throughout this proceeding or other proceeding 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, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements.

Written submissions.—Pursuant to § 207.61 of the Commission's rules, each interested party response to this notice must provide the information specified below. The deadline for filing such responses is November 1, 2021. Pursuant to § 207.62(b) of the Commission's rules, eligible parties (as specified in Commission rule 207.62(b)(1)) may also file comments concerning the adequacy of responses to the notice of institution and whether the Commission should conduct an expedited or full review. The deadline for filing such comments is December 14, 2021. All written submissions must conform with the provisions of § 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of §§ 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's *Handbook on Filing Procedures,* available on the Commission's website at *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf,* elaborates upon the Commission's procedures with respect to filings. Also, in accordance with §§ 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the proceeding must be served on all other parties to the proceeding (as identified by either the public or APO service list as appropriate), and a certificate of service must accompany the document (if you are not a party to the proceeding you do not need to serve your response).

Please note the Secretary's Office will accept only electronic filings at this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov*). No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice.

No response to this request for information is required if a currently valid Office of Management and Budget (''OMB'') number is not displayed; the OMB number is 3117 0016/USITC No. 21–5–500, expiration date June 30, 2023. Public reporting burden for the request is estimated to average 15 hours per response. Please send comments regarding the accuracy of this burden estimate to the Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436.

Inability to provide requested information.—Pursuant to § 207.61(c) of the Commission's rules, any interested party that cannot furnish the information requested by this notice in the requested form and manner shall notify the Commission at the earliest possible time, provide a full explanation of why it cannot provide the requested information, and indicate alternative forms in which it can provide equivalent information. If an interested party does not provide this notification (or the Commission finds the explanation provided in the notification inadequate) and fails to provide a complete response to this notice, the Commission may take an adverse inference against the party pursuant to § 776(b) of the Act (19 U.S.C. 1677e(b)) in making its determination in the review.

Information To Be Provided in Response to This Notice of Institution: As used below, the term ''firm'' includes any related firms.

(1) The name and address of your firm or entity (including World Wide Web address) and name, telephone number, fax number, and Email address of the certifying official.

(2) A statement indicating whether your firm/entity is an interested party under 19 U.S.C. 1677(9) and if so, how, including whether your firm/entity is a U.S. producer of the *Domestic Like Product,* a U.S. union or worker group, a U.S. importer of the *Subject Merchandi*se, a foreign producer or exporter of the *Subject Merchandise,* a U.S. or foreign trade or business association (a majority of whose members are interested parties under the statute), or another interested party (including an explanation). If you are a union/worker group or trade/business association, identify the firms in which your workers are employed or which are members of your association.

(3) A statement indicating whether your firm/entity is willing to participate in this proceeding by providing information requested by the Commission.

(4) A statement of the likely effects of the revocation of the countervailing duty and antidumping duty orders on the *Domestic Industry* in general and/or your firm/entity specifically. In your response, please discuss the various factors specified in § 752(a) of the Act (19 U.S.C. 1675a(a)) including the likely volume of subject imports, likely price effects of subject imports, and likely impact of imports of *Subject Merchandise* on the *Domestic Industry.*

(5) A list of all known and currently operating U.S. producers of the *Domestic Like Product.* Identify any known related parties and the nature of the relationship as defined in § 771(4)(B) of the Act (19 U.S.C. 1677(4)(B)).

(6) A list of all known and currently operating U.S. importers of the *Subject Merchandise* and producers of the *Subject Merchandise* in the *Subject Country* that currently export or have exported *Subject Merchandise* to the United States or other countries since the *Order Date.*

(7) A list of 3–5 leading purchasers in the U.S. market for the *Domestic Like Product* and the *Subject Merchandise* (including street address, World Wide Web address, and the name, telephone number, fax number, and Email address of a responsible official at each firm).

(8) A list of known sources of information on national or regional prices for the *Domestic Like Product* or the *Subject Merchandise* in the U.S. or other markets.

(9) If you are a U.S. producer of the *Domestic Like Product,* provide the following information on your firm's operations on that product during calendar year 2020, except as noted (report quantity data in short tons and value data in U.S. dollars, f.o.b. plant). If you are a union/worker group or trade/business association, provide the information, on an aggregate basis, for the firms in which your workers are employed/which are members of your association.

(a) Production (quantity) and, if known, an estimate of the percentage of total U.S. production of the *Domestic Like Product* accounted for by your firm's(s') production;

(b) Capacity (quantity) of your firm to produce the *Domestic Like Product* (that is, the level of production that your establishment(s) could reasonably have expected to attain during the year, assuming normal operating conditions (using equipment and machinery in place and ready to operate), normal operating levels (hours per week/weeks per year), time for downtime, maintenance, repair, and cleanup, and a typical or representative product mix);

(c) the quantity and value of U.S. commercial shipments of the *Domestic Like Product* produced in your U.S. plant(s);

(d) the quantity and value of U.S. internal consumption/company transfers of the *Domestic Like Product* produced in your U.S. plant(s); and

(e) the value of (i) net sales, (ii) cost of goods sold (COGS), (iii) gross profit, (iv) selling, general and administrative (SG&A) expenses, and (v) operating income of the *Domestic Like Product* produced in your U.S. plant(s) (include both U.S. and export commercial sales, internal consumption, and company transfers) for your most recently completed fiscal year (identify the date on which your fiscal year ends).

(10) If you are a U.S. importer or a trade/business association of U.S. importers of the *Subject Merchandise* from the *Subject Country,* provide the following information on your firm's(s') operations on that product during calendar year 2020 (report quantity data in short tons and value data in U.S. dollars). If you are a trade/business association, provide the information, on an aggregate basis, for the firms which are members of your association.

(a) The quantity and value (landed, duty-paid but not including antidumping or countervailing duties) of U.S. imports and, if known, an estimate of the percentage of total U.S. imports of *Subject Merchandise* from the *Subject Country* accounted for by your firm's(s') imports;

(b) the quantity and value (f.o.b. U.S. port, including antidumping and/or countervailing duties) of U.S. commercial shipments of *Subject Merchandise* imported from the *Subject Country;* and

(c) the quantity and value (f.o.b. U.S. port, including antidumping and/or countervailing duties) of U.S. internal consumption/company transfers of *Subject Merchandise* imported from the *Subject Country.*

(11) If you are a producer, an exporter, or a trade/business association of producers or exporters of the *Subject Merchandise* in the *Subject Country,* provide the following information on your firm's(s') operations on that product during calendar year 2020 (report quantity data in short tons and value data in U.S. dollars, landed and duty-paid at the U.S. port but not including antidumping or countervailing duties). If you are a trade/business association, provide the information, on an aggregate basis, for the firms which are members of your association.

(a) Production (quantity) and, if known, an estimate of the percentage of total production of *Subject Merchandise* in the *Subject Country* accounted for by your firm's(s') production;

(b) Capacity (quantity) of your firm(s) to produce the *Subject Merchandise* in the *Subject Country* (that is, the level of production that your establishment(s) could reasonably have expected to attain during the year, assuming normal operating conditions (using equipment and machinery in place and ready to operate), normal operating levels (hours per week/weeks per year), time for downtime, maintenance, repair, and cleanup, and a typical or representative product mix); and

(c) the quantity and value of your firm's(s') exports to the United States of *Subject Merchandise* and, if known, an estimate of the percentage of total exports to the United States of *Subject Merchandise* from the *Subject Country* accounted for by your firm's(s') exports.

(12) Identify significant changes, if any, in the supply and demand conditions or business cycle for the *Domestic Like Product* that have occurred in the United States or in the market for the *Subject Merchandise* in the *Subject Country* since the *Order Date,* and significant changes, if any, that are likely to occur within a reasonably foreseeable time. Supply conditions to consider include technology; production methods; development efforts; ability to increase production (including the shift of production facilities used for other products and the use, cost, or availability of major inputs into production); and factors related to the ability to shift supply among different national markets (including barriers to importation in foreign markets or changes in market demand abroad). Demand conditions to consider include end uses and applications; the existence and availability of substitute products; and the level of competition among the *Domestic Like Product* produced in the United States, *Subject Merchandise* produced in the *Subject Country,* and such merchandise from other countries.

(13) (OPTIONAL) A statement of whether you agree with the above definitions of the *Domestic Like Product* and *Domestic Industry;* if you disagree with either or both of these definitions, please explain why and provide alternative definitions.

Authority: This proceeding is being conducted under authority of Title VII of the Tariff Act of 1930; this notice is published pursuant to § 207.61 of the Commission's rules.

By order of the Commission.

Issued: September 24, 2021.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2021–21221 Filed 9–30–21; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has received a complaint entitled *Certain Electronic Devices Having Wireless Communication Capabilities and Components Thereof, DN 3568;* the Commission is soliciting comments on any public interest issues raised by the complaint or complainant's filing pursuant to the Commission's Rules of Practice and Procedure.

FOR FURTHER INFORMATION CONTACT: Lisa R. Barton, Secretary to the Commission, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2000. The public version of the complaint can be accessed on the Commission's Electronic Document Information System (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* General information concerning the Commission may also be obtained by accessing its internet server at United States International Trade Commission (USITC) at *https://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's Electronic Document Information System (EDIS) at *https://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission has received a complaint and a submission pursuant to § 210.8(b) of the Commission's Rules of Practice and Procedure filed on behalf of Bell Northern Research, LLC on September 27, 2021. The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain electronic devices having wireless communication capabilities and components thereof. The complainant names as respondents: Lenovo Group Ltd. of China; Lenovo (United States), Inc. of Morrisville, NC; Motorola Mobility LLC of Chicago, IL; TCL Electronics Holdings Limited of Hong Kong; TCT Mobile (US) Inc. of

Irvine, CA; TTE Technology, Inc. of Corona, CA; BLU Products, Inc. of Doral, FL; BBK Electronics Corp. of China; OnePlus Technology Co., Ltd. of China; HMD Global Oy of Finland; HMD America, Inc. of Miami, FL; and Sonim Technologies, Inc. of Austin, TX. The complainant requests that the Commission issue a limited exclusion order, cease and desist orders, and impose a bond upon respondents alleged infringing articles during the 60-day Presidential review period pursuant to 19 U.S.C. 1337(j).

Proposed respondents, other interested parties, and members of the public are invited to file comments on any public interest issues raised by the complaint or § 210.8(b) filing. Comments should address whether issuance of the relief specifically requested by the complainant in this investigation would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) Explain how the articles potentially subject to the requested remedial orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the requested remedial orders;

(iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the requested exclusion order and/or a cease and desist order within a commercially reasonable time; and

(v) explain how the requested remedial orders would impact United States consumers.

Written submissions on the public interest must be filed no later than by close of business, eight calendar days after the date of publication of this notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation. Any written submissions on other issues must also be filed by no later than the close of business, eight calendar days after publication of this notice in the **Federal Register**. Complainant may file replies to any written submissions no later than three calendar days after the date on which any initial submissions were due. No other submissions will be accepted, unless requested by the Commission. Any submissions and replies filed in response to this Notice are limited to five (5) pages in length, inclusive of attachments.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. Submissions should refer to the docket number (''Docket No. 3568'') in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, Electronic Filing Procedures [1]). Please note the Secretary's Office will accept only electronic filings during this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov.*) No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice. Persons with questions regarding filing should contact the Secretary at *EDIS3Help@usitc.gov.*

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,[2] solely for cybersecurity purposes. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.[3]

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of §§ 201.10 and 210.8(c) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.8(c)).

By order of the Commission.

Issued: September 27, 2021.

William Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2021–21345 Filed 9–30–21; 8:45 am]

BILLING CODE 7020–02–P

[1] Handbook for Electronic Filing Procedures: *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf.*

[2] All contract personnel will sign appropriate nondisclosure agreements.

[3] Electronic Document Information System (EDIS): *https://edis.usitc.gov.*

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 731–TA–1082–1083 (Third Review)]

Chlorinated Isocyanurates From China and Spain; Institution of a Five-Year Review

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice that it has instituted reviews pursuant to the Tariff Act of 1930 (''the Act''), as amended, to determine whether revocation of the antidumping duty orders on chlorinated isocyanurates from China and Spain would be likely to lead to continuation or recurrence of material injury. Pursuant to the Act, interested parties are requested to respond to this notice by submitting the information specified below to the Commission.

DATES: Instituted October 1, 2021. To be assured of consideration, the deadline for responses is November 1, 2021. Comments on the adequacy of responses may be filed with the Commission by December 14, 2021.

FOR FURTHER INFORMATION CONTACT: Lawrence Jones (202–205–3358), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*https://*

www.usitc.gov). The public record for this proceeding may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Background.—On June 24, 2005, the Department of Commerce (''Commerce'') issued antidumping duty orders on imports of chlorinated isocyanurates from China (70 FR 36561) and Spain (70 FR 36562). Following the five-year reviews by Commerce and the Commission, effective October 13, 2010, Commerce issued a continuation of the antidumping duty orders on imports of chlorinated isocyanurates from China and Spain (75 FR 62764). Following the second five-year reviews by Commerce and the Commission, effective November 29, 2016, Commerce issued a continuation of the antidumping duty orders on imports of chlorinated isocyanurates from China and Spain (81 FR 85927). The Commission is now conducting a third review pursuant to section 751(c) of the Act, as amended (19 U.S.C. 1675(c)), to determine whether revocation of the orders would be likely to lead to continuation or recurrence of material injury to the domestic industry within a reasonably foreseeable time. Provisions concerning the conduct of this proceeding may be found in the Commission's Rules of Practice and Procedure at 19 CFR part 201, subparts A and B, and 19 CFR part 207, subparts A and F. The Commission will assess the adequacy of interested party responses to this notice of institution to determine whether to conduct a full review or an expedited review. The Commission's determination in any expedited review will be based on the facts available, which may include information provided in response to this notice.

Definitions.—The following definitions apply to this review:

(1) *Subject Merchandise* is the class or kind of merchandise that is within the scope of the five-year review, as defined by the Department of Commerce.

(2) The *Subject Countries* in these reviews are China and Spain.

(3) The *Domestic Like Product* is the domestically produced product or products which are like, or in the absence of like, most similar in characteristics and uses with, the *Subject Merchandise.* In its original determinations, its expedited first five-year review determinations, and its full second five-year review determinations, the Commission defined a single *Domestic Like Product* as all chlorinated isocyanurates, coextensive with Commerce's scope.

(4) The *Domestic Industry* is the U.S. producers as a whole of the *Domestic Like Product,* or those producers whose collective output of the *Domestic Like Product* constitutes a major proportion of the total domestic production of the product. In its original determinations, the Commission defined the *Domestic Industry* as all of the domestic integrated producers of chlorinated isocyanurates as well as all domestic tableters (''tableters'') of chlorinated isocyanurates, which are those companies that only tablet and repackage chlorinated isocyanurates. The Commissioners were evenly divided in the original determinations with respect to whether or not to include tableters in the domestic industry. Three Commissioners found that tableters engaged in sufficient production-related activities to qualify as domestic producers and three Commissioners found that they did not. In its expedited first five-year review determinations, the Commission defined the *Domestic Industry* as all of the domestic integrated producers of chlorinated isocyanurates, and did not include tableters in the domestic industry. Two Commissioners found that the *Domestic Industry* includes tableters. In its full second five-year reviews, the Commission defined the *Domestic Industry* as all of the domestic integrated producers and tableters of chlorinated isocyanurates. One Commissioner found that tableters did not engage in sufficient production-related activities to qualify as domestic producers.

(5) An *Importer* is any person or firm engaged, either directly or through a parent company or subsidiary, in importing the *Subject Merchandise* into the United States from a foreign manufacturer or through its selling agent.

Participation in the proceeding and public service list.—Persons, including industrial users of the *Subject Merchandise* and, if the merchandise is sold at the retail level, representative consumer organizations, wishing to participate in the proceeding as parties must file an entry of appearance with the Secretary to the Commission, as provided in § 201.11(b)(4) of the Commission's rules, no later than 21 days after publication of this notice in the **Federal Register**. The Secretary will maintain a public service list containing the names and addresses of all persons, or their representatives, who are parties to the proceeding.

Former Commission employees who are seeking to appear in Commission five-year reviews are advised that they may appear in a review even if they participated personally and substantially in the corresponding underlying original investigation or an earlier review of the same underlying investigation. The Commission's designated agency ethics official has advised that a five-year review is not the same particular matter as the underlying original investigation, and a five-year review is not the same particular matter as an earlier review of the same underlying investigation for purposes of 18 U.S.C. 207, the post-employment statute for Federal employees, and Commission rule 201.15(b) (19 CFR 201.15(b)), 79 FR 3246 (Jan. 17, 2014), 73 FR 24609 (May 5, 2008). Consequently, former employees are not required to seek Commission approval to appear in a review under Commission rule 19 CFR 201.15, even if the corresponding underlying original investigation or an earlier review of the same underlying investigation was pending when they were Commission employees. For further ethics advice on this matter, contact Charles Smith, Office of the General Counsel, at 202–205–3408.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and APO service list.—Pursuant to § 207.7(a) of the Commission's rules, the Secretary will make BPI submitted in this proceeding available to authorized applicants under the APO issued in the proceeding, provided that the application is made no later than 21 days after publication of this notice in the **Federal Register**. Authorized applicants must represent interested parties, as defined in 19 U.S.C. 1677(9), who are parties to the proceeding. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Certification.—Pursuant to § 207.3 of the Commission's rules, any person submitting information to the Commission in connection with this proceeding must certify that the information is accurate and complete to the best of the submitter's knowledge. In making the certification, the submitter will acknowledge that information submitted in response to this request for information and throughout this proceeding or other proceeding 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, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements.

Written submissions.—Pursuant to § 207.61 of the Commission's rules, each interested party response to this notice must provide the information specified below. The deadline for filing such responses is November 1, 2021. Pursuant to § 207.62(b) of the Commission's rules, eligible parties (as specified in Commission rule 207.62(b)(1)) may also file comments concerning the adequacy of responses to the notice of institution and whether the Commission should conduct an expedited or full review. The deadline for filing such comments is December 14, 2021. All written submissions must conform with the provisions of § 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of §§ 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's *Handbook on Filing Procedures,* available on the Commission's website at *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf,* elaborates upon the Commission's procedures with respect to filings. Also, in accordance with §§ 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the proceeding must be served on all other parties to the proceeding (as identified by either the public or APO service list as appropriate), and a certificate of service must accompany the document (if you are not a party to the proceeding you do not need to serve your response).

Please note the Secretary's Office will accept only electronic filings at this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov*). No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice.

No response to this request for information is required if a currently valid Office of Management and Budget (''OMB'') number is not displayed; the OMB number is 3117 0016/USITC No. 21–5–499, expiration date June 30, 2023. Public reporting burden for the request is estimated to average 15 hours per response. Please send comments regarding the accuracy of this burden estimate to the Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436.

Inability to provide requested information.—Pursuant to § 207.61(c) of the Commission's rules, any interested party that cannot furnish the information requested by this notice in the requested form and manner shall notify the Commission at the earliest possible time, provide a full explanation of why it cannot provide the requested information, and indicate alternative forms in which it can provide equivalent information. If an interested party does not provide this notification (or the Commission finds the explanation provided in the notification inadequate) and fails to provide a complete response to this notice, the Commission may take an adverse inference against the party pursuant to § 776(b) of the Act (19 U.S.C. 1677e(b)) in making its determination in the review.

Information To Be Provided in Response to This Notice of Institution: If you are a domestic producer, union/worker group, or trade/business association; import/export *Subject Merchandise* from more than one *Subject Country;* or produce *Subject Merchandise* in more than one *Subject Country,* you may file a single response. If you do so, please ensure that your response to each question includes the information requested for each pertinent *Subject Country.* As used below, the term ''firm'' includes any related firms.

(1) The name and address of your firm or entity (including World Wide Web address) and name, telephone number, fax number, and Email address of the certifying official.

(2) A statement indicating whether your firm/entity is an interested party under 19 U.S.C. 1677(9) and if so, how, including whether your firm/entity is a U.S. producer of the *Domestic Like Product,* a U.S. union or worker group, a U.S. importer of the *Subject Merchandise*, a foreign producer or exporter of the *Subject Merchandise,* a U.S. or foreign trade or business association (a majority of whose members are interested parties under the statute), or another interested party (including an explanation). If you are a union/worker group or trade/business association, identify the firms in which your workers are employed or which are members of your association.

(3) A statement indicating whether your firm/entity is willing to participate in this proceeding by providing information requested by the Commission.

(4) A statement of the likely effects of the revocation of the antidumping duty orders on the *Domestic Industry* in general and/or your firm/entity specifically. In your response, please discuss the various factors specified in section 752(a) of the Act (19 U.S.C. 1675a(a)) including the likely volume of subject imports, likely price effects of subject imports, and likely impact of imports of *Subject Merchandise* on the *Domestic Industry.*

(5) A list of all known and currently operating U.S. producers of the *Domestic Like Product.* Identify any known related parties and the nature of the relationship as defined in section 771(4)(B) of the Act (19 U.S.C. 1677(4)(B)).

(6) A list of all known and currently operating U.S. importers of the *Subject Merchandise* and producers of the *Subject Merchandise* in each *Subject Country* that currently export or have exported *Subject Merchandise* to the United States or other countries after 2015.

(7) A list of 3–5 leading purchasers in the U.S. market for the *Domestic Like Product* and the *Subject Merchandise* (including street address, World Wide Web address, and the name, telephone number, fax number, and Email address of a responsible official at each firm).

(8) A list of known sources of information on national or regional prices for the *Domestic Like Product* or the *Subject Merchandise* in the U.S. or other markets.

(9) If you are a U.S. producer of the *Domestic Like Product,* provide the following information on your firm's operations on that product during calendar year 2020, except as noted (report quantity data in short tons and value data in U.S. dollars, f.o.b. plant). If you are a union/worker group or trade/business association, provide the information, on an aggregate basis, for the firms in which your workers are employed/which are members of your association.

(a) Production (quantity) and, if known, an estimate of the percentage of total U.S. production of the *Domestic Like Product* accounted for by your firm's(s') production;

(b) Capacity (quantity) of your firm to produce the *Domestic Like Product* (that is, the level of production that your establishment(s) could reasonably have expected to attain during the year, assuming normal operating conditions (using equipment and machinery in place and ready to operate), normal operating levels (hours per week/weeks per year), time for downtime, maintenance, repair, and cleanup, and a typical or representative product mix);

(c) the quantity and value of U.S. commercial shipments of the *Domestic Like Product* produced in your U.S. plant(s);

(d) the quantity and value of U.S. internal consumption/company transfers of the *Domestic Like Product* produced in your U.S. plant(s); and

(e) the value of (i) net sales, (ii) cost of goods sold (COGS), (iii) gross profit, (iv) selling, general and administrative (SG&A) expenses, and (v) operating income of the *Domestic Like Product* produced in your U.S. plant(s) (include both U.S. and export commercial sales, internal consumption, and company transfers) for your most recently completed fiscal year (identify the date on which your fiscal year ends).

(10) If you are a U.S. importer or a trade/business association of U.S. importers of the *Subject Merchandise* from any *Subject Country,* provide the following information on your firm's(s') operations on that product during calendar year 2020 (report quantity data in short tons and value data in U.S. dollars). If you are a trade/business association, provide the information, on an aggregate basis, for the firms which are members of your association.

(a) The quantity and value (landed, duty-paid but not including antidumping or countervailing duties) of U.S. imports and, if known, an estimate of the percentage of total U.S. imports of *Subject Merchandise* from each *Subject Country* accounted for by your firm's(s') imports;

(b) the quantity and value (f.o.b. U.S. port, including antidumping and/or countervailing duties) of U.S. commercial shipments of *Subject Merchandise* imported from each *Subject Country;* and

(c) the quantity and value (f.o.b. U.S. port, including antidumping and/or countervailing duties) of U.S. internal consumption/company transfers of *Subject Merchandise* imported from each *Subject Country.*

(11) If you are a producer, an exporter, or a trade/business association of producers or exporters of the *Subject Merchandise* in any *Subject Country,* provide the following information on your firm's(s') operations on that product during calendar year 2020 (report quantity data in short tons and value data in U.S. dollars, landed and duty-paid at the U.S. port but not including antidumping or countervailing duties). If you are a trade/business association, provide the information, on an aggregate basis, for the firms which are members of your association.

(a) Production (quantity) and, if known, an estimate of the percentage of total production of *Subject Merchandise* in each *Subject Country* accounted for by your firm's(s') production;

(b) Capacity (quantity) of your firm(s) to produce the *Subject Merchandise* in each *Subject Country* (that is, the level of production that your establishment(s) could reasonably have expected to attain during the year, assuming normal operating conditions (using equipment and machinery in place and ready to operate), normal operating levels (hours per week/weeks per year), time for downtime, maintenance, repair, and cleanup, and a typical or representative product mix); and

(c) the quantity and value of your firm's(s') exports to the United States of *Subject Merchandise* and, if known, an estimate of the percentage of total exports to the United States of *Subject Merchandise* from each *Subject Country* accounted for by your firm's(s') exports.

(12) Identify significant changes, if any, in the supply and demand conditions or business cycle for the *Domestic Like Product* that have occurred in the United States or in the market for the *Subject Merchandise* in each *Subject Country* after 2015, and significant changes, if any, that are likely to occur within a reasonably foreseeable time. Supply conditions to consider include technology; production methods; development efforts; ability to increase production (including the shift of production facilities used for other products and the use, cost, or availability of major inputs into production); and factors related to the ability to shift supply among different national markets (including barriers to importation in foreign markets or changes in market demand abroad). Demand conditions to consider include end uses and applications; the existence and availability of substitute products; and the level of competition among the *Domestic Like Product* produced in the United States, *Subject Merchandise* produced in each *Subject Country,* and such merchandise from other countries.

(13) (OPTIONAL) A statement of whether you agree with the above definitions of the *Domestic Like Product* and *Domestic Industry;* if you disagree with either or both of these definitions, please explain why and provide alternative definitions.

Authority: This proceeding is being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to § 207.61 of the Commission's rules.

By order of the Commission.

Issued: September 24, 2021.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2021–21223 Filed 9–30–21; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 21–16]

William C. Gardner, D.D.S.; Decision and Order

On May 11, 2021, the Acting Administrator, Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause and Immediate Suspension of Registration (hereinafter, OSC) to William C. Gardner, D.D.S. (hereinafter, Respondent) of Albuquerque, New Mexico. OSC, at 1. The OSC informed Respondent of the immediate suspension of Respondent's Certificate of Registration No. BG9826427, because Respondent's continued registration constitutes ''an imminent danger to the public health or safety.'' *Id.* (citing 21 U.S.C. 824(d)). The OSC also proposed the revocation of Respondent's DEA registration pursuant to 21 U.S.C. 824(a)(3), because Respondent has ''no state authority to handle controlled substances.'' [1] *Id.*

Specifically, the OSC alleged that the New Mexico Board of Dental Health Care (hereinafter, Board) issued a Decision and Order on November 26, 2019. *Id.* at 2. According to the OSC, this Decision and Order revoked Respondent's New Mexico dental license following the Board's findings, *inter alia,* that Respondent submitted false claim forms to an insurance provider to obtain payment for an unnecessary dental procedure, falsified a radiography (x-ray), and failed to cooperate with the Board's investigation. *Id.* Respondent appealed and obtained a stay of the Board's Decision and Order, but the appeal was dismissed, the stay was lifted, and the

[1] The OSC also proposed the revocation of Respondent's DEA registration pursuant to 21 U.S.C. 824(a)(4) because ''[Respondent's] continued registration is inconsistent with the public interest.'' *Id.* However, in its Submission of Evidence and Motion for Summary Disposition (hereinafter, Motion for Summary Disposition), the Government requested that the motion be granted based on the lack of state authority allegation and stated that if its motion was granted, ''the Government would not intend to continue with [the] proceedings regarding the allegations that Respondent's continued DEA registration would be inconsistent with the public interest.'' Motion for Summary Disposition, at 1 and 7. On July 19, 2021, the Administrative Law Judge assigned to this case issued an Order Granting the Government's Motion for Summary Disposition, and Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge (hereinafter, RD) that granted the Government's Motion for Summary Disposition. RD, at 10. Accordingly, I will not consider the Government's public interest allegations and will only consider the record as is relevant to the lack of state authority allegation.

Board's Decision and Order was enforced as of July 17, 2020. *Id.* Additionally, Respondent's New Mexico controlled substances license expired by its terms on September 30, 2020. *Id.* According to the OSC, on December 12, 2020, the Board issued a Decision and Default Order confirming the revocation of Respondent's dental license.

The OSC notified Respondent of the right to request a hearing on the allegations or to submit a written statement, while waiving the right to a hearing, the procedures for electing each option, and the consequences for failing to elect either option. *Id.* at 6 (citing 21 CFR 1301.43). By letter dated May 27, 2021, Respondent timely requested a hearing.[2] Hearing Request, at 1. The Hearing Request asserted that Respondent's New Mexico dental license was not revoked as of July 17, 2020. *Id.* The Hearing Request also asserted that the grounds recited for the alleged revocation of Respondent's New Mexico dental license were false, that the alleged lifting of the stay was solely the result of egregious errors by Respondent's prior counsel, that the alleged order lifting the stay was not a final order, and that the December 12, 2020 order [3] confirming the revocation of Respondent's dental license had been vacated. *Id.* at 2.

The Office of Administrative Law Judges put the matter on the docket and assigned it to Administrative Law Judge Teresa A. Wallbaum (hereinafter, ALJ), who issued a Briefing Schedule on June 3, 2021, directing the parties to brief the Government's allegation that Respondent currently lacks authority to handle controlled substances in New Mexico. RD, at 2. The Government timely complied with the Briefing Schedule by filing its Motion for Summary Disposition on June 17, 2021. *Id.* The Government requested that the ALJ grant its Motion for Summary Disposition and recommend revocation of Respondent's DEA registration, because Respondent's New Mexico dental license was revoked, Respondent's New Mexico controlled substances license had expired, and thus, Respondent lacks authority to handle controlled substances in New Mexico, the state in which he is registered with the DEA. Motion for Summary Disposition, at 7.

After the ALJ granted Respondent an extension of time, Respondent filed an Objection to Government's Submission of Evidence and Motion for Summary Disposition (hereinafter, Respondent's Objection) on July 12, 2021. RD, at 2. Respondent's Objection argued that ''[a]lthough the Board has attempted to revoke [Respondent's] license twice, in each case that revocation is not yet effective.'' Respondent's Objection, at 5. Specifically, Respondent's Objection asserted that the first Board order revoking Respondent's dental license on November 26, 2019,[4] was not yet final and was still subject to ''two appeals and a motion to stay at the New Mexico Court of Appeals.'' *Id.* Respondent's Objection also asserted that the second Board order confirming Respondent's revocation on December 12, 2020,[5] ''[had] been vacated and [would] not be the subject of an evidentiary hearing until at least September 1, 2021.'' *Id.*

On July 16, 2021, the Government filed a Reply in Support of Motion for Summary Disposition (hereinafter, Government's Reply). The Government's Reply argued that because New Mexico requires both a state professional license and a state controlled substances license for authorization to handle controlled substances, and because Respondent's controlled substances license had expired, which Respondent has not disputed, Respondent lacks authority to handle controlled substances in New Mexico, regardless of the status of his dental license. Government's Reply, at 1. Additionally, the Government's Reply argued that Respondent's argument that his dental license had not yet been revoked was factually erroneous based on the factual findings of an order issued by the New Mexico First Judicial District Court denying Respondent's request for a preliminary injunction against the December 12, 2020 Board order. *Id.* at 2. Moreover, the Government's Reply argued that Respondent's argument that his dental license had not yet been revoked was also legally erroneous because, although he had sought a stay of the Board's first November 26, 2019 order, he had yet to actually obtain the stay. *Id.* Finally, the Government's Reply argued that even if Respondent's dental license had not yet been revoked, Respondent's agreement to not practice dentistry as a condition of release in his criminal cases, and therefore to not prescribe or administer controlled substances without a dental license, on its own sufficiently constitutes a lack of state authority to handle controlled substances. *Id.* at 2–3.

On July 19, 2021, the ALJ granted the Government's Motion for Summary Disposition and recommended that Respondent's DEA registration be revoked, finding that ''[t]here is no genuine issue of material fact in this case'' and that ''[t]he Government has established that Respondent currently lacks both a dental license and the authority to handle controlled substances.'' RD, at 7 and 10. Specifically, the ALJ highlighted that Respondent failed to address or refute that his New Mexico controlled substances licensed had expired and found that ''Respondent's arguments regarding his dental license are nothing more than an impermissible effort to relitigate the state revocation proceedings.'' *Id.* at 8. The ALJ concluded that ''the fact that Respondent may get his registration back, whether through an appeal or otherwise, does not change the answer to the sole inquiry in this case: whether he is *currently* authorized to handle controlled substances in New Mexico.'' *Id.* at 9.

By letter dated August 13, 2021, the ALJ certified and transmitted the record to me for final Agency action. In that letter, the ALJ advised that neither party filed exceptions. I issue this Decision and Order based on the entire record before me. 21 CFR 1301.43(e). I make the following findings of fact.

Findings of Fact

Respondent's DEA Registration

Respondent is the holder of DEA Certificate of Registration No. BG9826427 at the registered address of 8200 Carmel Ave. NE Suite 101, Albuquerque, NM 87122. Government Motion Exhibit (hereinafter, GX) A (DEA Certificate of Registration). Pursuant to this registration, Respondent is authorized to dispense controlled substances in schedules II through V as a practitioner. *Id.* Respondent's registration expires on September 30, 2021. *Id.*

The Status of Respondent's State License

On November 26, 2019, the Board issued a Decision and Order that revoked Respondent's dental license, effective January 1, 2020, after finding that Respondent ''submitted false claim forms to [an insurance provider] for the purpose of obtaining payment for an unnecessary dental procedure . . . falsified a [sic] x-ray/radiograph . . . [and] failed to cooperate with the Board

[2] The Hearing Request was filed on May 28, 2021. Order Directing the Filing of Government Evidence Regarding its Lack of State Authority Allegation and Briefing Schedule (hereinafter, Briefing Schedule), at 1. I find that the Government's service of the OSC was adequate and that the Hearing Request was timely filed on May 28, 2021.

[3] The Hearing Request refers to ''Order in Case No.18–32–COM.''

[4] Respondent's Objection refers to ''[t]he Case 18–61 revocation.''

[5] Respondent's Objection refers to ''[t]he Case 18–32 revocation.''

investigation.'' GX B, at 5–6. On December 19, 2019, the New Mexico County of Santa Fe First Judicial District Court (hereinafter, the Court) stayed the Board's November 26, 2019 Order. GX E. On July 7, 2020, the Court issued an order, following a hearing on June 15, 2020, that dismissed Respondent's appellate case, lifted the December 19th stay, and ordered that the Board could enforce its Decision and Order starting on July 17, 2020. GX F, at 1–3.

On December 12, 2020, the Board issued a Decision and Default Order that again revoked Respondent's dental license, as well as ordered that ''this revocation of Respondent's license does not affect, modify, or change the earlier revocation of Respondent's license on July 17, 2020.'' GX H, at 3. On January 20, 2021, Respondent filed an Application for a Temporary Restraining Order and Preliminary Injunction in which he requested a restraining order against the execution of the December 12, 2020 Board Decision, as well as an injunction regarding the enforcement of the Decision, which the Court denied on February 19, 2021. GX L, at 4–5; GX N, at 2–3 (the Court reasoned in part that Respondent's ''license to practice dentistry is currently revoked based on decisions made in a separate and unrelated case'').

On February 4, 2021, the Second Judicial Court for Bernalillo County in a criminal matter involving Respondent issued a Stipulated Order Amending Conditions of Release ordering that Respondent ''shall not practice dentistry without a license from the [Board].'' GX Q. On April 30, 2021, in a separate criminal matter involving Respondent, the Second Judicial Court for Bernalillo County issued an Order Setting Conditions of Release again ordering that Respondent was not to practice dentistry without a license. GX S, at 1–2.[6]

On April 26, 2021, the Board issued an order that set aside its December 12, 2020 Decision but also ordered that ''Respondent's dental license remains revoked'' as of July 17, 2020. GX I, at 4. On April 26, 2021, the Board also issued a Notice of Contemplated Action against Respondent alleging that Respondent was practicing dentistry without a license and not cooperating with the Board's investigations. GX J, at 4 and 8. On May 21, 2021, the Board issued a Notice of Hearing regarding the allegations in the April 26, 2021 Notice of Contemplated Action. GX J, at 1. On June 1, 2021, Respondent filed an appeal of the denial of his motion to reconsider the Court's July 7, 2020 order and various other appeals. GX G, at 1–2; GX O, at 1–2; GX U, at 1.

It remains uncontested that Respondent's New Mexico controlled substances license is expired. *See* GX W.

According to New Mexico's online records, of which I take official notice, Respondent's New Mexico dental license remains revoked.[7] New Mexico Regulation & Licensing Department Licensee Search and Verification, *https://www.rld.nm.gov/about-us/public-information-hub/online-services* (last visited date of signature of this Order). Further, New Mexico's online records, of which I take official notice, show that Respondent's New Mexico controlled substance license remains expired.[8] *Id.* (last visited date of signature of this Order).

Accordingly, I find that Respondent is not currently licensed to engage in the practice of dentistry or to handle controlled substances in New Mexico, the state in which Respondent is registered with DEA.

Discussion

Pursuant to 21 U.S.C. 824(a)(3), the Attorney General is authorized to suspend or revoke a registration issued under section 823 of the Controlled Substances Act (hereinafter, CSA) ''upon a finding that the registrant . . . has had his State license or registration suspended . . . [or] revoked . . . by competent State authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances.'' With respect to a practitioner, the DEA has also long held that the possession of authority to dispense controlled substances under the laws of the state in which a practitioner engages in professional practice is a fundamental condition for obtaining and maintaining a practitioner's registration. *See, e.g., James L. Hooper, M.D.,* 76 FR 71,371 (2011), *pet. for rev. denied,* 481 F. App'x 826 (4th Cir. 2012); *Frederick Marsh Blanton, M.D.,* 43 FR 27,616, 27,617 (1978).

This rule derives from the text of two provisions of the CSA. First, Congress defined the term ''practitioner'' to mean ''a physician . . . or other person licensed, registered, or otherwise permitted, by . . . the jurisdiction in which he practices . . . , to distribute, dispense, . . . [or] administer . . . a controlled substance in the course of professional practice.'' 21 U.S.C. 802(21). Second, in setting the requirements for obtaining a practitioner's registration, Congress directed that ''[t]he Attorney General shall register practitioners . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.'' 21 U.S.C. 823(f). Because Congress has clearly mandated that a practitioner possess state authority in order to be deemed a practitioner under the CSA, the DEA has held repeatedly that revocation of a practitioner's registration is the appropriate sanction whenever he is no longer authorized to dispense controlled substances under the laws of the state in which he practices. *See, e.g., James L. Hooper,* 76 FR at 71,371–72; *Sheran Arden Yeates, M.D.,* 71 FR 39,130, 39,131 (2006); *Dominick A. Ricci, M.D.,* 58 FR 51,104, 51,105 (1993); *Bobby Watts, M.D.,* 53 FR 11,919, 11,920 (1988); *Frederick Marsh Blanton,* 43 FR at 27,617.

Moreover, because ''the controlling question'' in a proceeding brought under 21 U.S.C. 824(a)(3) is whether the holder of a practitioner's registration ''is currently authorized to handle controlled substances in the [S]tate,'' *Hooper,* 76 FR at 71,371 (quoting *Anne Lazar Thorn,* 62 FR 12,847, 12,848 (1997)), the Agency has also long held that revocation is warranted even where a practitioner is still challenging the underlying action. *Bourne Pharmacy,* 72 FR 18,273, 18,274 (2007); *Wingfield Drugs,* 52 FR 27,070, 27,071 (1987). Thus, it is of no consequence that the action is being appealed. What is consequential is my finding that Respondent is no longer currently authorized to dispense controlled substances in New Mexico, the state in which he is registered.

According to New Mexico statute, ''A person who manufactures, distributes or dispenses a controlled substance or who proposes to engage in the manufacture, distribution or dispensing of a controlled substance shall obtain a registration issued by the board in accordance with its regulations.'' N.M.

[6] I agree with the ALJ that it is unnecessary to rely on the conditions of Respondent's release as a basis for a finding that Respondent lacks state authority to handle controlled substances. *See* RD n.3.

[7] Under the Administrative Procedure Act, an agency ''may take official notice of facts at any stage in a proceeding—even in the final decision.'' United States Department of Justice, Attorney General's Manual on the Administrative Procedure Act 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). Pursuant to 5 U.S.C. 556(e), ''[w]hen an agency decision rests on official notice of a material fact not appearing in the evidence in the record, a party is entitled, on timely request, to an opportunity to show the contrary.'' Accordingly, Respondent may dispute my finding by filing a properly supported motion for reconsideration of findings of fact within fifteen calendar days of the date of this Order. Any such motion and response shall be filed and served by email to the other party and to Office of the Administrator, Drug Enforcement Administration at *dea.addo.attorneys@dea.usdoj.gov.*

[8] *See supra* n.7 regarding official notice.

Stat. Ann. § 30–31–12(A) (West, current through the end of the First Regular Session and First Special Session, 55th Legislature (2021)). In turn, ''dispense'' means ''to deliver a controlled substance to an ultimate user or research subject pursuant to the lawful order of a practitioner, including the administering, prescribing, packaging, labeling or compounding necessary to prepare the controlled substance for that delivery.'' *Id.* at § 30–31–2(H). Further, a ''practitioner'' means ''a physician . . . dentist . . . or other person licensed or certified to prescribe and administer drugs that are subject to the Controlled Substances Act.'' *Id.* at § 30–31–2(P).

Here, the undisputed evidence in the record is that Respondent's New Mexico controlled substance license is expired; therefore, he cannot dispense controlled substances in New Mexico. Further, Respondent's New Mexico dental license has been revoked. As such, he is not a ''practitioner'' licensed or certified to prescribe and administer a controlled substance under New Mexico law. Thus, because Respondent lacks authority to handle controlled substances in New Mexico, Respondent is not eligible to maintain a DEA registration. Accordingly, I will order that Respondent's DEA registration be revoked.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby revoke DEA Certificate of Registration No. BG9826427 issued to William C. Gardner, D.D.S. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(f), I hereby deny any pending application of William C. Gardner to renew or modify this registration, as well as any other pending application of William C. Gardner, D.D.S. for additional registration in New Mexico. This Order is effective November 1, 2021.

Anne Milgram,

Administrator.

[FR Doc. 2021–21424 Filed 9–30–21; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Darryl L. Henry, M.D.; Decision and Order

On June 4, 2021, the Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, Government), issued an Order to Show Cause (hereinafter, OSC) to Darryl L. Henry, M.D. (hereinafter, Registrant) of Elkhart, Indiana. OSC, at 1. The OSC proposed the revocation of Registrant's Certificate of Registration No. FH0303292. *Id.* at 1. It alleged that Registrant is ''without authority to handle controlled substances in the State of Indiana, the state in which [Registrant is] registered with DEA.'' *Id.* at 2 (citing 21 U.S.C. 824(a)(3)).

Specifically, the OSC alleged that Registrant's Indiana medical license was suspended for 90 days by Order of the Medical Licensing Board of Indiana, effective April 22, 2021. *Id.* The OSC also alleged that Registrant's Indiana controlled substances license expired on October 31, 2019. *Id.*

The OSC notified Registrant of the right to request a hearing on the allegations or to submit a written statement, while waiving the right to a hearing, the procedures for electing each option, and the consequences for failing to elect either option. *Id.* (citing 21 CFR 1301.43). The OSC also notified Registrant of the opportunity to submit a corrective action plan. *Id.* at 3 (citing 21 U.S.C. 824(c)(2)(C)).

Adequacy of Service

In a Declaration dated September 2, 2021, a Diversion Investigator (hereinafter, the DI) assigned to the Merrillville, Indiana District Office stated that on or about June 8, 2021, the OSC was mailed to both Registrant's registered address and his mail-to address by the DEA Office of Chief Counsel. Request for Final Agency Action (hereinafter, RFAA) Exhibit (hereinafter, RFAAX) 2 (the DI's Declaration), at 1–2. The DI stated that on June 8, 2021, she and a DEA Task Force Officer attempted to contact Registrant at his mother's residence and spoke with Registrant's mother. *Id.* at 2. According to the DI, Registrant's mother stated that Registrant did not live there and offered to take the OSC and to have Registrant's sister contact Registrant regarding the OSC. *Id.* The DI stated that she then left her contact information with Registrant's mother. *Id.* The DI also stated that on June 8, 2021, she emailed the OSC to Registrant at the email address listed in the DEA's registration database. *Id.* According to the DI, Registrant never responded to the OSC nor did he request a hearing. *Id.*

The Government forwarded its RFAA, along with the evidentiary record, to this office on September 2, 2021. In its RFAA, the Government represents that ''more than thirty days have passed since the [OSC] was served on [Registrant] and no request for hearing has been received by DEA.'' RFAA, at 1. The Government requests that Registrant's DEA registration ''be revoked and any application for renewal, or any other applications, [be] denied, based on [Registrant's] lack of state authority.'' *Id.* at 5.

Based on the DI's Declaration, the Government's written representations, and my review of the record, I find that the Government accomplished service of the OSC on Registrant on or about June 8, 2021. I also find that more than thirty days have now passed since the Government accomplished service of the OSC. Further, based on the DI's Declaration, the Government's written representations, and my review of the record, I find that neither Registrant, nor anyone purporting to represent the Registrant, requested a hearing, submitted a written statement while waiving Registrant's right to a hearing, or submitted a corrective action plan. Accordingly, I find that Registrant has waived the right to a hearing and the right to submit a written statement and corrective action plan. 21 CFR 1301.43(d) and 21 U.S.C. 824(c)(2)(C). I, therefore, issue this Decision and Order based on the record submitted by the Government, which constitutes the entire record before me. 21 CFR 1301.43(e).

Findings of Fact

Registrant's DEA Registration

Registrant is the holder of DEA Certificate of Registration No. FH0303292 at the registered address of 3100 Windsor Ct, Elkhart, IN 46514. RFAAX 3 (DEA's online registration database printout), at 1. Pursuant to this registration, Registrant is authorized to dispense controlled substances in schedules II through V as a practitioner. *Id.* Registrant's registration expires on October 31, 2021 and is in an ''active pending'' status. *Id.*

The Status of Registrant's State License

On September 1, 2021, the Medical Licensing Board of Indiana (hereinafter, the Board) issued a Summary Suspension Order (hereinafter, Order) against Registrant. RFAAX 4, at 1 and 4. According to the Order, on August 21, 2019, Registrant was charged with two counts of sexual battery in Elkhart Superior Court I. *Id.* at 2. The probable cause affidavit alleged that on May 7, 2019, the first of two victims saw Registrant as a patient for a physical examination, during which Registrant made inappropriate sexual comments and unwanted sexual advances on the victim. *Id.* at 2–3. Further, the probable cause affidavit alleged that on May 13,

2019, a second victim saw Registrant as a patient for a physical examination, during which Registrant again made inappropriate sexual comments and unwanted sexual advances on the victim. *Id.* at 3. The Order concluded that Registrant ''represents a clear and immediate danger to the public health and safety if allowed to continue to practice as a medical doctor in Indiana.'' *Id.* at 4.

Accordingly, the Board ordered that Registrant's Indiana medical license, which had been suspended for 90 days effective April 22, 2021,[1] be summarily suspended for an additional 90 days, effective June 24, 2021. *Id.* The Board also ordered that the matter would reset on September 23, 2021 for a hearing to occur at which the Board would consider whether the summary suspension of Registrant's license should be extended for an additional 90 days. *Id.*

According to Indiana's online records, of which I take official notice, Registrant's Indiana medical license remains suspended and Registrant's controlled substances registration remains expired.[2] *http://www.mylicense.in.gov/everification* (last visited date of signature of this Order).

Accordingly, I find that Registrant is not currently licensed to engage in the practice of medicine nor registered to dispense controlled substances in Indiana, the state in which Registrant is registered with the DEA.

Discussion

Pursuant to 21 U.S.C. 824(a)(3), the Attorney General is authorized to suspend or revoke a registration issued under section 823 of the Controlled Substances Act (hereinafter, CSA) ''upon a finding that the registrant . . . has had his State license or registration suspended . . . [or] revoked . . . by competent State authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances.'' With respect to a practitioner, the DEA has also long held that the possession of authority to dispense controlled substances under the laws of the state in which a practitioner engages in professional practice is a fundamental condition for obtaining and maintaining a practitioner's registration. *See, e.g., James L. Hooper, M.D.,* 76 FR 71,371 (2011), *pet. for rev. denied,* 481 F. App'x 826 (4th Cir. 2012); *Frederick Marsh Blanton, M.D.,* 43 FR 27,616, 27,617 (1978).

This rule derives from the text of two provisions of the CSA. First, Congress defined the term ''practitioner'' to mean ''a physician . . . or other person licensed, registered, or otherwise permitted, by . . . the jurisdiction in which he practices . . . , to distribute, dispense, . . . [or] administer . . . a controlled substance in the course of professional practice.'' 21 U.S.C. 802(21). Second, in setting the requirements for obtaining a practitioner's registration, Congress directed that ''[t]he Attorney General shall register practitioners . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.'' 21 U.S.C. 823(f). Because Congress has clearly mandated that a practitioner possess state authority in order to be deemed a practitioner under the CSA, the DEA has held repeatedly that revocation of a practitioner's registration is the appropriate sanction whenever he is no longer authorized to dispense controlled substances under the laws of the state in which he practices. *See, e.g., James L. Hooper,* 76 FR at 71,371–72; *Sheran Arden Yeates, M.D.,* 71 FR 39,130, 39,131 (2006); *Dominick A. Ricci, M.D.,* 58 FR 51,104, 51,105 (1993); *Bobby Watts, M.D.,* 53 FR 11,919, 11,920 (1988); *Frederick Marsh Blanton,* 43 FR at 27,617.

According to Indiana statute, ''[e]very person who dispenses or proposes to dispense any controlled substance within Indiana must have a registration issued by the [Indiana Board of Pharmacy] in accordance with the board's rules.'' Ind. Code § 35–48–3–3(b) (2021). Further, ''dispense'' means ''to deliver a controlled substance to an ultimate user or research subject by or pursuant to the lawful order of a practitioner and includes the prescribing, administering, packaging, labeling, or compounding necessary to prepare the substance for that delivery.'' Ind. Code § 35–48–1–12 (2021).

Here, the undisputed evidence in the record is that Registrant currently lacks authority to dispense controlled substances in Indiana. As already discussed, a physician must hold a controlled substances registration to dispense a controlled substance in Indiana. Thus, because Registrant lacks authority to handle controlled substances in Indiana, Registrant is not eligible to maintain a DEA registration. Accordingly, I will order that Registrant's DEA registration be revoked.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby revoke DEA Certificate of Registration No. FH0303292 issued to Darryl L. Henry, M.D. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(f), I hereby deny any pending application of Darryl L. Henry, M.D. to renew or modify this registration, as well as any other pending application of Darryl L. Henry, M.D. for additional registration in Indiana. This Order is effective November 1, 2021.

Anne Milgram,

Administrator.

[FR Doc. 2021–21425 Filed 9–30–21; 8:45 am]

BILLING CODE 4410–09–P

[1] RFAAX 2, at 2 (the DI's Declaration). The Government did not provide documentation for the original suspension.

[2] Under the Administrative Procedure Act, an agency ''may take official notice of facts at any stage in a proceeding—even in the final decision.'' United States Department of Justice, Attorney General's Manual on the Administrative Procedure Act 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). Pursuant to 5 U.S.C. 556(e), ''[w]hen an agency decision rests on official notice of a material fact not appearing in the evidence in the record, a party is entitled, on timely request, to an opportunity to show the contrary.'' Accordingly, Registrant may dispute my finding by filing a properly supported motion for reconsideration of finding of fact within fifteen calendar days of the date of this Order. Any such motion and response shall be filed and served by email to the other party and to Office of the Administrator, Drug Enforcement Administration at *dea.addo.attorneys@dea.usdoj.gov.*

DEPARTMENT OF JUSTICE

Membership of the Senior Executive Service and Senior Level Standing Performance Review Boards

AGENCY: Department of Justice.

ACTION: Notice of Department of Justice's standing members of the Senior Executive Service and Senior Level Performance Review Boards.

SUMMARY: Pursuant to agency regulations, the Department of Justice announces the membership of its 2021 Senior Executive Service (SES) and Senior Level (SL) Standing Performance Review Boards (PRBs). The purpose of the PRB is to provide fair and impartial review of SES and SL performance appraisals; make recommendations to the appointing authority concerning performance ratings, performance awards, and performance-based pay adjustments; and review and revise, as appropriate, executive development plans.

FOR FURTHER INFORMATION CONTACT: Shawn Flinn, Director, Human Resources, Justice Management

Division, Department of Justice, Washington, DC 20530; (202) 514–4350.

Lee J. Lofthus,

Assistant Attorney General for Administration.

2021 Federal Register

List of Names (Alphabetical Order)

Adan Jr., Angel L.
Adkins Blanch, Charles K.
Ainsworth, Peter J.
Alexander, Samuel C.
Alexandre, Carl
Alvarez, Christopher C.
Amundson, Corey R.
Anderson, Jill W.
Antell, Kira
Antonelli, Bryan M.
Armington, Elizabeth J.
Ary, Vaughn A.
Ashton, Robin C.
Ayers, Nancy L.
Bain, John A.
Ballweg, Mitchell J.
Baltazar Jr., Juan
Barnes, Nanette F.
Barsky, Seth M.
Beard Jr., Harold A.
Beasley, Gene D.
Beasley, John A.
Beasley, Roger L.
Beemsterboer, Joseph S.
Bell, Suzanne L.
Belsan, Timothy M.
Bennett, Megan A.
Benson, Barry F.
Bergami, Thomas E.
Berger Sr., William B.
Bewtra, Aneet K.
Bhattacharyya, Rupa
Birney, William J.
Blue, Matthew
Blumberg, Mark
Board Jr., Daniel L.
Bohling, James C.
Bolden, Scott D.
Boncher, Amy A.
Bond, Rebecca B.
Booth, David S.
Boshek II, Jeffrey C.
Boykin, Lisa T.
Boynton, Brian M.
Braden, Myesha K.
Bradley, Eric W.
Bradley, Patricia V.
Brady, Kelly D.
Bratt, Jay I.
Brink, Patricia A.
Broshow, Brent L.
Brown Cutlar, Shanetta Y.
Brown Jr., Robert M.
Brown, Shannon B.
Brown, Walter W.
Bruffy, Robert L.
Bruner, Jarrod D.
Bryden II, James
Burke, Gregory
Burns, Loneryl C.
Burns, Richard
Byron III, Henry Thomas
Cain, James W.
Campbell, Dianne M.
Carlin, John P.
Carlton, Eugene K.
Carney, Christopher J.
Carpenter, Eleanor A.
Carr, Michael J.
Carroll, Ovie L.
Carvajal, Michael D.
Carwile, P. Kevin
Cekada, Robert
Chambers, Kevin A.
Chandler, Thomas E.
Chavez, Sonya K.
Cheatham, Roy C.
Cheng, Mary M.
Chilakamarri, Varudhini
Chittum III, Thomas L.
Ciolli, Andrew Michael
Clarke, Russell S.
Cobar, Marlon
Cohen, Adam W.
Colangelo, Matthew B.
Coley, Anthony D.
Collier, Andrew T.
Connolly Jr., Robert L.
Connor, Deborah L.
Conrath, Craig W.
Cook, Terence L.
Coppolino, Anthony J.
Cox, Jason W.
Cox, Kevin S.
Cypher, Owen M.
Czarnopys, Gregory P.
D'Alessio Jr., Carmine S.
Daly, Mark F.
Damelin, Scott R.
Dammers, Kim S.
Danks, Ryan J.
Daugherty, Daniel J.
Dauphin, Dennis E.
Davidson, Jeanne E.
Davies, Susan M.
Davis, Nanette L.
Debonis, Dena I.
Deir, James M.
Demarco, Vincent F.
Detineo, Kristen E.
Devito, John B.
Dickinson, Lisa M.
Dintzer, Kenneth M.
Dixon, Robert A.
Dobbs, Bryan K.
Dohman, Ramona L.
Douglas, Nathaniel
Downing, Richard W.
Drennan, Ronald
Driscoll, Kevin O.
Drouet, Suzanne.
Ducot, Gregory E.
Dugger, Ashley
Dunlap, James L.
Dunne, Steven M.
Dworkin, Karen S.
Ehrenstamm, Faye S.
Elliott, Peter J.
Elliott, Ramona D.
Embrey, Diana L.
Emerson, Catherine V.
English, Nicole
Epstein, Eric M.
Eyler, Gustav
Familant, Norman
Feigin, Eric J.
Feldt, Dennis G.
Felte Jr., James F.
Ferguson, Cynthia
Figures, Shomari C.
Finley, Scott T.
Fitzgerald, Paige M.
Fitzpatrick, Jeanette P.
Flentje, August E.
Fleshman, James M.
Fletcher, Brian H.
Flinn, Shawn O.
Foran, Sheila M.
Forcelli, Peter J.
Fountain, Dorothy B.
Frande, Francis H.
Frattarelli, Angelo A.
Fredricks, James J.
Freeman, Mark R.
French, Mickey L.
Friel, Gregory B.
Funston, Robin S.
Gaeta, Joseph R.
Gannon, Curtis E.
Gardner, Joshua E.
Garrison, John M.
Garry, Eileen M.
Gartner, Eric S.
Gary, Arthur E.
Gelber, Bruce S.
Gerido, Steven L.
Geter, Linda
Gette, James D.
Gilbert, Curtis W.
Gilley, John M.
Gilligan, James J.
Ginsburg, Jessica
Glad, Daniel W.
Glynn, John P.
Gold, Victoria R.
Goldberg, Richard N.
Goldberg, Stuart M.
Goldfoot, Josh
Goldfrank, Andrew M.
Goldsmith, Andrew D.
Gomez, Christopher L.
Gonzales, David P.
Goodlander, Margaret V.
Gorman, Patrick T.
Graham, Andrew R.
Granston, Michael D.
Greenfeld, Helaine A.
Griffin Jr., Thomas M.
Griffith, L. Cristina
Griffiths, John R.
Grishaw, Letitia J.
Grocki, Steven J.
Guttentag, Lucas E.
Haar, Daniel E.
Haas, Alexander K.
Hagley, Judith A.
Hanson, Alan R.
Hardee, Norman C.

Harrington, Sarah E.
Harris, Deborah L.
Harris, Kenneth J.
Hart, Rosemary A.
Harvey, Ruth A.
Haungs, Michael J.
Hausken, Gary L.
Heinzelman, Kate E.
Heminger, Justin D.
Henderson, William T.
Hendrix, Dewayne
Henneberg, Maureen A.
Hensley, Henry V.
Herndon Jr., Roland H.
Herren Jr., Thomas C.
Herrup, Paul M.
Hickey, Adam
Hicks, Pamela J.
Himmelhoch, Sarah D.
Hoag, Aaron D.
Hoang, Anthony P.
Hockey Jr, Martin F.
Hodge, Jennifer A. H.
Ho-Gonzalez, William
Howard, Catricia L.
Howe, Susan E.
Hubbert, David A.
Hudgins, Richard A.
Hudson Jr., Donald J.
Hughes, Alphonso J.
Hughes, Johnny L.
Hughes, Michael A.
Hulser, Raymond N.
Huntley, Colin M.
Hyle, Kenneth.
Jaffe, David L.
Jenkins II, Wiley Z.
Johnsen, Dawn E.
Johnson, Cory A.
Johnson, Rachel R.
Jones, Chyrl
Jones, Joseph M.
Jones, Kevin R.
Jones, Timothy W.
Jordan, Jonathan D.
Joyner, Hector E.
Kallis, Steven J.
Kane, Thomas R.
Kanter, Ethan B.
Karp, David J.
Katinsky, David M.
Keener, Donald E.
Keller, Jeffery A.
Keller, John D.
Kelly, Karen
Kelly, Richard T.
Kelton, Zachary J.
Kendall, Paul F.
Kendler, Owen M.
Kennedy, John L.
Kilbourne, James C.
King, Damon A.
Kisor, Colin A.
Klapper, Matthew B.
Kleppinger, Eric D.
Kneedler, Edwin S.
Koffsky, Daniel L.
Krueger, Jeffrey E.
Kumar, Manish
Ladner Jr., Robert D.
Lan, Iris
Langsam, Stefanie G.
Larson, Kari M.
Latour, Michelle E.
Lauder, George H.
Lauria, Jolene A.
Lawrence, David G. B.
Leadingham, Mickey
Lederman, Martin S.
Lepore, Robert A.
Lin, Jean
Lindquist III, John A.
Lipshultz, Jon M.
Liskamm, Amanda N.
Loeb, Emily M.
Lofthus, Leon J.
Lopez, Louis
Lothrop Jr., William W.
Lovett Jr., Stanley A.
Ludwig, Stacy M.
Lynch Jr., John T.
Lyons, Samuel R.
Ma At, Sekou
Mackelburg, William E.
Macklin, James
Mactough, Melissa D.
Madan, Rafael A.
Mahan, Ellen M.
Mahoney, Kristen
Majeed, Sameena S.
Malphrus, Garry D.
Maltby, Jeremy
Manhardt, Kirk T.
Mao, Andy J.
Mariani Jr., Thomas A.
Marshall, Lynda K.
Martin, Dana J.
Martin, Ralph E.
Martinez Jr., Felipe Q.
Masling, Mark S.
Matevousian, Andre V.
Mathias, Karl S.
Matthews-Johnson, Tamarra D.
Mattos Jr., Juan
Maxey, Peter M.
McCarty, Margaret S.
McConkey Jr, Milton G.
McConnell, Christopher L.
McConnell, David M.
McDaniel, Mason B.
McDermond, James E.
McGrath, Brian E.
McHenry III, James R.
McHenry, Teresa L.
McIntosh, Scott R.
McLearen, Alix M.
McNulty, Sheila
McPherson, Jonathan T.
McQuaid, Nicholas L.
Mehta, Aditi M.
Meland, Deborah S.
Melton, Jennifer T.
Mergen, Andrew C.
Merkle, Phillip K.
Messersmith, Cynthia.
Milanowski Jr., Frederick J.
Milusnic, Louis J.
Molina Jr., Ernesto H.
Moossy, Robert J.
Morrow, Robert S.
Mulcahy, Valarie D.
Muoio Jr., Joseph
N Diaye, Lamine
Naccarato, Thomas M.
Netter, Brian D.
Newman, David A.
Nguyen, Vu T.
Nichols, Dana K.
Nunez, Celinez
O'Brien, Holley B.
O'Brien-Rogan, Carole A.
O'Connor, Kevin J.
O'Connor, Patrick T.
O'Hearn, Donald P.
O'Malley, Barbara B.
O'Neill, Kathleen S.
Ocasio, Wilmer
O'Connor, Thomas M.
O'Keefe, Donald M.
Okula, Stanley J.
Olds, Hope S.
Ortiz, David E.
Owens, Angela M.
Padden, Thomas W.
Pallozzi, Vincent C.
Pamerleau, Susan L.
Pane, Martin J.
Patterson, Charlie J.
Paul, Charles D.
Peachey, William C.
Pearlman, Heather L.
Pellegrino, Whitney M.
Pelletier, Jonathan
Perkins, Paul Randolph.
Peterson, Amanda M.
Petrucci, James C.
Phelps, Alan J.
Phelps, Shannon W.
Pincus, David I.
Pinon, Gabriel R.
Pittella, Mark P.
Pleasants, Darek G.
Pliler, William S.
Pollock, Nathaniel
Poole, Jason H.
Poux Jr., Joseph A.
Powers, Richard A.
Prelogar, Elizabeth B.
Price Jr., Marvin N.
Pride Jr., Theron P.
Proffitt, Nick E.
Pullen, Jeffrey D.
Quay III, Herman E.
Quinn, Michael J.
Raab, Michael S.
Ragsdale, Jeffrey R.
Raish, Anne S.
Randall, Allison L.
Rao, Arun G.
Rao, Sangita K.
Rardin, Jared D.
Ratliff, Gerri L.
Reich, Mitchell
Reid, Lauren A.
Reno, Tamara L.
Richardson, Marvin G.
Ricketts, Jennifer D.

Rios, Melissa V.
Rivers, Christopher A.
Robins, Jeffrey S.
Robinson, Roberto I.
Rodriguez, Mary D.
Roessner, Joel J.
Rogers, Melinda
Roper, Matthew J.
Rosenbaum, Eli M.
Rosenbaum, Steven H.
Rossi, Rachel A.
Rothstein, Julius
Rouse, Katrina H.
Ruisanchez, Alberto J.
Rush, Regan L.
Russell, Lisa L.
Sanz Rexach, Gabriel R.
Sawyer, Thomas
Scarantino, Thomas J.
Scheele, Scott A.
Scherer, Jennifer M.
Schofield, Gary G.
Schroeder, Christopher H.
Schwei, Daniel S.G.
Seidman, Ricki L.
Sergi, Joseph A.
Serralta, Gadyaces S.
Seward, Jon M.
Shapiro, Elizabeth J.
Shatz, Eileen M.
Shaw, Cynthia K.
Sheehan, John P.
Sheehey, Kathryn D.
Short, Tracy L.
Simons, Shaheena A.
Singdahlsen, Jeffrey P.
Singer III, Frank J.
Singer, David
Singh, Anita
Smith, Andrew C.
Smith, Corey J.
Smith, David L.
Smith, Johnathan J.
Smith, Linda H.
Smith, Michael D.
Smith, Richard D.
Smith, Rufus J.
Snell, Robert S.
Solomon, Amy L.
Sooknanan, Sparkle L.
Sozio, Ralph
Sproul, Daniel A.
Stafford, Steven C.
Stamos, Theophani K.
Stehlik, Noreene C.
Stemler, Patty M.
Stern, Mark B.
Stewart, Howard P.
Stewart, Malcolm L.
Streeval, Jason C.
Sullivan, John E.
Swartz, Bruce C.
Swingle, Sharon M.
Talebian, Bobak
Tellez, Heriberto H.
Tenenbaum, Alan S.
Tenorio, Christopher
Thielhorn, Kurt H.
Thiemann, Robyn L.
Thompson, Sonya D.
Tobin, Peter C.
Toledo, Randy
Toomey, Kathleen T.
Toscano Jr., Richard A.
Toscas, George Z.
Touhey Jr., James G.
Toulou, Tracy S.
Trate, Bradley M.
True III, William P.
Tsao, Leo
Tulley, Kalina M.
Tyler, Jeffrey R.
Ugolini, Francesca
Underwood Jr., John D.
Vanderplow, Paul D.
Varisco, Matthew P.
Villegas, Monique Y.
Virtue, Timothy R.
Von Blanckensee, B.
Walker, Heather
Ward, Lisa A.
Ward, Nickolous
Ward, Richard R.
Watson, Marcus S.
Watson, Thomas J.
Weaver, David A.
Weaver, James E.
Weinsheimer, G. Bradley
Weiss, Daniel H.
Welsh, Eric D.
Wertz, Rebecca J.
Wetmore, David H.
Wheeler, Nathaniel H.
White III, Clifford J.
Wiegmann, John B.
Wilder, Jeffrey M.
Wilkerson, Kirsten L.
Wilkinson, Robert M.
Williams, Eric
Williams, Jean E.
Wills, James C.
Winn, Peter A.
Winston, Frederic D.
Withers, Shannon D.
Woldemariam, Wintta M.
Wolfson, Paul R. Q.
Wong, Norman Y.
Woodard, Karen D.
Woods, William L.
Wroblewski, Jonathan J.
Wszalek, Larry J.
Wyatt, Arthur G.
Wyderko, Joseph C.
Yancey, Mark A.
Yasuda, Kevin
Yates, John P.
Yavelberg, Jamie A.
Yeager, Michael S.
Young, David L.
Young, William S.
Zubrensky, Michael A.

[FR Doc. 2021–21341 Filed 9–30–21; 8:45 am]

BILLING CODE 4410–CH–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Judgment Under the Clean Air Act

On September 27, 2021, the Department of Justice lodged a proposed consent judgment with the United States District Court for the Eastern District of New York in the lawsuit entitled *United States of America* v. *The City of New York et al.,* Case No. 21–CV–5338.

The United States filed this lawsuit to seek civil penalties and injunctive relief for violations of the Clean Air Act, 42 U.S.C. 7401 *et seq.* (''CAA''). The alleged violations concern the New York City Department of Education's (''NYCDOE'') failure to comply with the Area Source Boiler Rule 40 CFR 63 (the ''Rule'') at approximately 1329 boilers located at 566 public school buildings across New York City. The Complaint alleges that NYCDOE failed to conduct timely tune ups and energy assessments under the Rule, and failed to provide required notifications to the Environmental Protection Agency (''EPA'').

The Consent Judgment requires NYCDOE to implement injunctive relief that includes: Conducting and documenting periodic tune-ups that will identify boilers in need of repair; implementing additional levels of quality review for completed tune-up reports; and providing periodic reports to the United States concerning boilers that are achieving less than 83% combustion efficiency. Further, to mitigate excess emissions caused by NYCDOE's non-compliance, the proposed Consent Judgement requires NYCDOE to convert to natural gas or replace seven large boilers that use number 4 oil prior to March 2023. The Consent Judgment also requires defendants to pay a civil penalty of $1,000,000.

The publication of this notice opens a period for public comment on the proposed Consent Judgment. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *The City of New York, New York City Department of Education,* Civil Action No. 21–CV–5338, D.J. Ref. No. 90–5–2–1–11718. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By email	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

During the public comment period, the Consent Judgment may be examined and downloaded at this Justice Department website: *https://www.justice.gov/enrd/consent-decrees.* We will provide a paper copy of the Consent Judgment upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $13.50 (25 cents per page reproduction cost) payable to the United States Treasury.

Henry Friedman,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2021–21364 Filed 9–30–21; 8:45 am]

BILLING CODE 4410–15–P

NATIONAL SCIENCE FOUNDATION

Agency Information Collection Activities: Comment Request; NSF I-Corps Teams Executive Summary Form

AGENCY: National Science Foundation.

ACTION: Notice.

SUMMARY: The National Science Foundation (NSF) is announcing plans to establish this collection. In accordance with the requirements of the Paperwork Reduction Act of 1995, we are providing opportunity for public comment on this action. After obtaining and considering public comment, NSF will prepare the submission requesting Office of Management and Budget (OMB) clearance of this collection for no longer than 3 years.

DATES: Written comments on this notice must be received by November 30, 2021 to be assured consideration. Comments received after that date will be considered to the extent practicable. Send comments to address below.

FOR FURTHER INFORMATION CONTACT: Suzanne H. Plimpton, Reports Clearance Officer, National Science Foundation, 2415 Eisenhower Avenue, Suite W18200, Alexandria, Virginia 22314; telephone (703) 292–7556; or send email to *splimpto@nsf.gov.* Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339, which is accessible 24 hours a day, 7 days a week, 365 days a year (including Federal holidays).

SUPPLEMENTARY INFORMATION:

Title of Collection: NSF I-Corps Teams Executive Summary Form.

OMB Control No.: 3145–New.

Expiration Date of Approval: Not applicable.

Abstract: The NSF Innovation Corps (I-Corps) Teams Program Executive Summary is an important component of the NSF I-Corps Teams pre-submission process and conveys information needed to direct the proposed team project to the appropriate NSF Program Director (PD) for review and possible proposal submission invitation. This Executive Summary (ES) is to be submitted by the applying team to the cognizant I-Corps Team's PD outlining solicitation-specific aspects of the project (such as proposed team members, technology, commercial application and NSF lineage). In the past, this ES was submitted via email as an attached two-page (maximum) document and was often in varying formats or missing some parts of the required ES elements. The NSF I-Corps Teams Executive Summary Form captures the same requested information, as outlined in NSF I-Corps Teams Program solicitation, but all within one secure, web-based form. In specific, the form collects submitting team member information (composition, roles and a brief description of each member's qualifications), Principal Investigator (PI) information (and a brief description of their connection to the team), NSF lineage (relevant current or previous NSF awards), brief descriptions of: the core technology, the potential commercial application, and the current commercialization plan for the proposed technology. If the proposed I-Corps Team is applying based on participation in a local or regional NSF I-Corps Hub, Node or Site training session, the form will provide fields for the applying team to complete regarding the associated I-Corps Hub, Node or Site senior member's contact information (as a reference), the date of participation, and location of the associated Hub, Node or Site program.

Respondents: Investigators who submit proposals to NSF's I-Corps Teams Program.

Estimated Number of Annual Respondents: 400.

Burden on the Public: 2 hour (per response) for an annual total of 800 hours.

Dated: September 28, 2021.

Suzanne H. Plimpton,

Reports Clearance Officer, National Science Foundation.

[FR Doc. 2021–21439 Filed 9–30–21; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Agency Information Collection Activities: Comment Request; NSF Small Business Innovation Research (SBIR) Program Phase I and Small Business Technology Transfer (STTR) Program Phase I Presubmission Project Pitch Form

AGENCY: National Science Foundation.

ACTION: Notice.

SUMMARY: The National Science Foundation (NSF) is announcing plans to establish this collection. In accordance with the requirements of the Paperwork Reduction Act of 1995, we are providing opportunity for public comment on this action. After obtaining and considering public comment, NSF will prepare the submission requesting Office of Management and Budget (OMB) clearance of this collection for no longer than 3 years.

DATES: Written comments on this notice must be received by November 30, 2021 to be assured consideration. Comments received after that date will be considered to the extent practicable. Send comments to address below.

FOR FURTHER INFORMATION CONTACT: Suzanne H. Plimpton, Reports Clearance Officer, National Science Foundation, 2415 Eisenhower Avenue, Suite W18200, Alexandria, Virginia 22314; telephone (703) 292–7556; or send email to *splimpto@nsf.gov.* Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339, which is accessible 24 hours a day, 7 days a week, 365 days a year (including Federal holidays).

SUPPLEMENTARY INFORMATION:

Title of Collection: NSF Small Business Innovation Research (SBIR) Program Phase I and Small Business Technology Transfer (STTR) Program Phase I Presubmission Project Pitch Form.

OMB Control No.: 3145-New.

Expiration Date of Approval: Not applicable.

Abstract: The NSF Small Business Innovation Research Program (SBIR) Phase I and Small Business Technology Transfer Program (STTR) Phase I Project Pitch is the new NSF SBIR/STTR pre-submission process that conveys information needed to direct the

proposed SBIR/STTR project to the appropriate NSF Program Director (PD) for review and possible proposal submission invitation. This Project Pitch is to be submitted by the applying small business (as ''proposer'') to the relevant NSF SBIR/STTR Phase I technology topic. The Project Pitch outlines solicitation-specific aspects of the project (such as the proposed technology innovation and project objectives with associated level of technical risk). In the past, this Project Pitch (previously referred to as the Executive Summary) was an optional submission via email as an attached two to three-page (maximum) document and was often in varying formats or missing some parts of the required document elements, which in turn caused delays or additional corrections on behalf of the proposer. The NSF SBIR/STTR Phase I Project Pitch form captures the same requested information, as outlined in the NSF SBIR/STTR Phase I Program solicitation, but all within one secure, web-based form. In specific, the form collects submitting proposer company and team information; the proposed technology innovation; the technical objectives and challenges; and the market opportunity. The form also allows the proposer to choose (from a drop-down menu) the most relevant NSF SBIR/STTR Phase I technical topic area, ensuring that the submitted Project Pitch goes to the most appropriate Program Director.

Respondents: Small businesses who submit proposals to NSF's SBIR/STTR Phase I Program.

Estimated Number of Annual Respondents: 2000.

Burden on the Public: 2 hours (per response) for an annual total of 4000 hours.

Dated: September 28, 2021.

Suzanne H. Plimpton,

Reports Clearance Officer, National Science Foundation.

[FR Doc. 2021–21438 Filed 9–30–21; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Advisory Committee for Biological Sciences; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation (NSF) announces the following meeting:

Name and Committee Code: Advisory Committee for Biological Sciences (#1110).

Date and Time: November 3, 2021, 10:00 a.m.–4:30 p.m. EST; November 4, 2021, 10:00 a.m.–12:45 p.m. EST.

Place: National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314.

Due to ongoing social distancing best practices because of COVID–19, the meeting will be held virtually among the Advisory Committee members. Livestreaming will be accessible through this page: *https://nsf.gov/bio/advisory.jsp.*

Type of Meeting: Open.

Contact Person: Karen Cone, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314 Telephone: (703) 292–8400.

Purpose of Meeting: The Advisory Committee (AC) for the Directorate for Biological Sciences (BIO) provides advice, recommendations, and oversight concerning major program emphases, directions, and goals for the research-related activities of the divisions that make up BIO.

Agenda: Agenda items will include a directorate business update, update on BIO's broadening participation portfolio, a joint session with the Mathematical and Physical Sciences Advisory Committee (MPS AC) to discuss the MPS AC subcommittee report on ''MPS and the Living World'', update on Technology, Innovation and Partnerships, updates from the BIO AC liaisons to the Committee on Equal Opportunities in Science and Engineering and to the AC for Environmental Research and Education, discussion with the NSF Director, and discussion of BIO's response to the Division of Biological Infrastructure Committee of Visitors report.

Dated: September 27, 2021.

Crystal Robinson,

Committee Management Officer.

[FR Doc. 2021–21357 Filed 9–30–21; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 70–7019; NRC–2021–0182]

Oregon State University

AGENCY: Nuclear Regulatory Commission.

ACTION: License amendment application; opportunity to request a hearing and to petition for leave to intervene.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) staff has received an application from Oregon State University (OSU or the licensee) to renew special nuclear materials (SNM) license number SNM–2013. The renewed license would authorize the applicant to continue research on used research and test reactor fuel rods that contain greater than critical mass amounts of special nuclear material. The license renewal would allow OSU to continue licensed activities for 10 years beyond its current license.

DATES: A request for a hearing or petition for leave to intervene must be filed by November 30, 2021.

ADDRESSES: Please refer to Docket ID NRC–2021–0182 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 *https://www.regulations.gov* and search for Docket ID NRC–2021–0182. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@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 *https://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 Oregon State University Application for Renewal of SNM–2013 is available in ADAMS under Accession No. ML21235A325.
- *Attention:* The PDR, where you may examine and order copies of public documents, is currently closed. You may submit your request to the PDR via email at *pdr.resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8:00 a.m. and 4:00 p.m. (ET), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Jenny Tobin, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–415–2328, email: *Jennifer.Tobin@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

The NRC has received, by letter dated July 31, 2021 (ADAMS Accession Number ML21235A325), an application from OSU to renew special nuclear materials license number SNM–2013, which authorizes OSU to conduct non-destructive research on used fuel rods from five research and test reactors. The license renewal would allow OSU to continue licensed activities for 10 years. Paragraph 70.38(a) of title 10 of the *Code of Federal Regulations* (10 CFR) states that a specific license expires at the end of the day on the expiration date stated in the license unless the licensee has filed an application for renewal under § 70.33 not less than 30 days

before the expiration date stated in the existing license. The term of the current license expired on August 31, 2021; however, the application for renewal was made at least 30 days prior to the expiration, and thus, the current license is still in effect. The licensee is authorized to use SNM under 10 CFR part 70.

An NRC administrative completeness review, dated September 15, 2021 (ADAMS Accession No. ML21257A435), found the application acceptable for a technical review. During the technical review, the NRC will be reviewing the application in areas that include, but are not limited to, radiation safety, chemical safety, fire safety, security, environmental protection, and material control/accountability. Prior to approving the request to renew special nuclear materials license number SNM–2013, the NRC will need to make the findings required by the Atomic Energy Act of 1954, as amended (the Act), and the NRC's regulations. The NRC's findings will be documented in a safety evaluation report.

II. Opportunity To Request a Hearing and Petition for Leave To Intervene

Within 60 days after the date of publication of this notice, any person (petitioner) whose interest may be affected by this action may file a request for a hearing and petition for leave to intervene (petition) with respect to the renewal of the special nuclear materials license. 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 10 CFR 2.309. If a petition is filed within 60 days, the presiding officer will rule on the petition and, if appropriate, a notice of a hearing will be issued.

Petitions must be filed no later than 60 days from the date of publication of this notice in accordance with the filing instructions in the ''Electronic Submissions (E-Filing'') section of this document. 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).

A State, local governmental body, Federally recognized Indian Tribe, or designated agency thereof, may submit a petition to the Commission to participate as a party under 10 CFR 2.309(h), no later than 60 days from the date of publication of this notice. 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).

For information about filing a petition and about participation by a person not a party under 10 CFR 2.315, see ADAMS Accession No. ML20340A053 (*https://adamswebsearch2.nrc.gov/webSearch2/main.jsp?AccessionNumber=ML20340A053*) and on the NRC website at *https://www.nrc.gov/about-nrc/regulatory/adjudicatory/hearing.html#participate.*

III. Electronic Submissions (E-Filing)

All documents filed in NRC adjudicatory proceedings, including documents filed by an interested State, local governmental body, Federally recognized Indian Tribe, or designated agency thereof that requests to participate under 10 CFR 2.315(c), must be filed in accordance with 10 CFR 2.302. 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, unless an exemption permitting an alternative filing method, as discussed below, is granted. Detailed guidance on electronic submissions is located in the Guidance for Electronic Submissions to the NRC (ADAMS Accession No. ML13031A056) and on the NRC website at *https://www.nrc.gov/site-help/e-submittals.html.*

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 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 *https://www.nrc.gov/site-help/e-submittals/getting-started.html.* After a digital ID certificate is obtained and a docket created, the participant must submit adjudicatory documents in Portable Document Format. Guidance on submissions is available on the NRC's public website at *https://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 timestamps the document and sends the submitter an email confirming receipt of the document. The E-Filing system also distributes an email 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 to 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 *https://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 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 in accordance with 10 CFR 2.302(b)–(d). Participants filing adjudicatory documents in this manner are responsible for serving their documents on all other participants. Participants granted an exemption under 10 CFR 2.302(g)(2) must still meet the electronic formatting requirement in 10 CFR 2.302(g)(1), unless the participant also seeks and is granted an exemption from 10 CFR 2.302(g)(1).

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket, which is publicly available at *https://adams.nrc.gov/ehd,* unless excluded pursuant to an order of 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. 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 should not include copyrighted materials in their submission.

Dated: September 27, 2021.

For the Nuclear Regulatory Commission.

Jacob I. Zimmerman,

Chief, Fuel Facilities Licensing Branch, Division of Fuel Management, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2021–21359 Filed 9–30–21; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. EA–21–014; NRC–2021–0177]

Order Suspending General License Authority To Export Radioactive Material and Deuterium to China General Nuclear (CGN), CGN Subsidiaries, or Related Entities

AGENCY: Nuclear Regulatory Commission.

ACTION: Order; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing an Order suspending the general license authority under NRC regulations to export radioactive material and deuterium to China General Nuclear (CGN), CGN subsidiaries, or related entities.

DATES: This Order takes effect immediately.

ADDRESSES: Please refer to Docket ID NRC–2021–0177 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 *https://www.regulations.gov* and search for Docket ID NRC–2021–0177. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@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 *https://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.*
- *Attention:* The PDR, where you may examine and order copies of public documents, is currently closed. You may submit your request to the PDR via email at *pdr.resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8:00 a.m. and 4:00 p.m. (ET), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Office of International Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–287–9241, email: *IP.Resource@nrc.gov.*

SUPPLEMENTARY INFORMATION: The text of the Order is attached.

Dated: September 27, 2021.

For the Nuclear Regulatory Commission.

Nader L. Mamish,

Director, Office of International Programs.

Attachment—Order

In the Matter of General License Holders—EA–21–014

Order Suspending General License Authority To Export Radioactive Material and Deuterium to China General Nuclear (CGN), CGN Subsidiaries, or Related Entities (Effective Immediately)

The licensees that are subject to this order are authorized by the NRC through the general license granted in sections 110.21 through 110.24 of title 10 of the *Code of Federal Regulations* (CFR), pursuant to Sections 54, 64, 82, and 109b of the Atomic Energy Act of 1954, as amended (AEA), to export radioactive material and deuterium to CGN, CGN subsidiaries, or related entities. The Executive Branch has determined that suspending general license authority under 10 CFR part 110 for exports to CGN, CGN subsidiaries, and related entities is necessary to further the national security interests of the United States and to enhance the United States common defense and security consistent with the Atomic Energy Act of 1954, as amended. This determination is an extension of the licensing framework for civil nuclear exports from the United States to China established by the Executive Branch in 2018. For this reason, the Executive Branch has recommended that the NRC suspend the general license authority in 10 CFR 110.21 through 110.24 for any exports of radioactive material and deuterium to CGN, CGN subsidiaries, and related entities.

Accordingly, pursuant to Sections 161b., 161i., 183, and 186 of the AEA, and 10 CFR 110.20(b) and (f) and 10 CFR 110.50(a)(1) and (2), NRC general license authority to export radioactive material and deuterium to CGN, CGN subsidiaries, or related entities under Sections 54, 64, 82 and 109b of the AEA and 10 CFR 110.21 through 110.24 is suspended, effective immediately. This suspension will remain in effect until further notice.

Dated: September 27, 2021.

For the Nuclear Regulatory Commission.

Nader L. Mamish,

Director, Office of International Programs.

[FR Doc. 2021–21342 Filed 9–30–21; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–454 and 50–455; NRC–2020–0259]

Exelon Generation Company, LLC; Byron Station, Unit Nos. 1 and 2

AGENCY: Nuclear Regulatory Commission.

ACTION: License amendment application; withdrawal by applicant.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has granted the request of Exelon Generation Company, LLC (Exelon, the licensee) to withdraw its application dated September 24, 2020, for proposed amendments to Renewed Facility Operating License Nos. NPF–37 and NPF–66 for Byron Station, Unit Nos. 1 and 2 (Byron), respectively. The proposed amendments would have made changes to technical specifications (TSs) definitions and administrative controls for the permanently defueled condition.

DATES: October 1, 2021.

ADDRESSES: Please refer to Docket ID NRC–2020–0259 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 *https://www.regulations.gov* and search for Docket ID NRC–2021–0259. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@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 *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, 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.

• *Attention:* The PDR, where you may examine and order copies of public documents, is currently closed. You may submit your request to the PDR via email at *pdr.resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8:00 a.m. and 4:00 p.m. (ET), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Joel S. Wiebe, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–6606; email: *Joel.Wiebe@nrc.gov.*

SUPPLEMENTARY INFORMATION: The NRC has granted the request of Exelon to withdraw its application dated September 24, 2020 (ADAMS Accession No. ML20269A401) for proposed amendments to Renewed Facility Operating License Nos. NPF–37 and NPF–66 for Byron, Unit Nos. 1 and 2, respectively, which are located in Ogle County, Illinois. Exelon is the licensee that owns and operates Byron. The proposed amendments would have made changes to TSs definitions and administrative controls for the permanently defueled condition.

The Commission previously issued a proposed finding that the proposed amendments involve no significant hazards consideration published in the **Federal Register** on December 1, 2020 (85 FR 77274). However, by letter dated September 15, 2021 (ADAMS Accession No. ML21258A276), Exelon requested to withdraw the proposed amendments.

Dated: September 28, 2021.

For the Nuclear Regulatory Commission.

Joel S. Wiebe,

Senior Project Manager, Plant Licensing Branch III, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2021–21437 Filed 9–30–21; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–010, 50–237, 50–249, and 72–037; NRC–2021–0030]

Exelon Generation Company, LLC; Dresden Nuclear Power Station, Units 1, 2, and 3 and Independent Spent Fuel Storage Installation

AGENCY: Nuclear Regulatory Commission.

ACTION: License amendment application; withdrawal by applicant.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has granted the request of Exelon Generation Company, LLC (Exelon, the licensee) to withdraw its application dated November 2, 2020, for proposed amendments to Amended Facility Operating License No. DPR–2 and Renewed Facility Operating License Nos. DPR–19 and DPR–25 for Dresden Nuclear Power Station, Units 1, 2, and 3 (Dresden), respectively, and the general license for the Independent Spent Fuel Storage Installation (ISFSI). The proposed amendments would have revised the Dresden emergency plan following the permanent cessation of power operations to reflect the post-shutdown and permanently defueled condition of the units.

DATES: October 1, 2021.

ADDRESSES: Please refer to Docket ID NRC–2021–0030 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 *https://www.regulations.gov* and search for Docket ID NRC–2021–0030. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@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 *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, 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.

• *Attention:* The PDR, where you may examine and order copies of public documents, is currently closed. You may submit your request to the PDR via email at *pdr.resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8:00 a.m. and 4:00 p.m. (ET), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Russell S. Haskell, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–1129; email: *Russell.Haskell@nrc.gov.*

SUPPLEMENTARY INFORMATION: The NRC has granted the request of Exelon to withdraw its application dated November 2, 2020 (ADAMS Accession No. ML20307A434) for proposed amendments to Amended Facility Operating License No. DPR–2 and Renewed Facility Operating License Nos. DPR–19 and DPR–25 for Dresden, Units 1, 2, and 3, respectively, and the general license for the ISFSI, which are located in Grundy County, Illinois. Exelon is the licensee that owns and operates Dresden and its ISFSI. The proposed amendments would have revised the Dresden emergency plan following the permanent cessation of power operations to reflect the post-shutdown and permanently defueled condition of the units. The proposed changes included revision of the emergency response organization staffing and editorial changes.

The Commission previously issued a proposed finding that the proposed amendments involve no significant hazards consideration published in the **Federal Register** on January 26, 2021 (86 FR 7116). However, by letter dated September 15, 2021 (ADAMS Accession No. ML21258A281), Exelon requested to withdraw the proposed amendments.

Dated: September 28, 2021.

For the Nuclear Regulatory Commission.

Russell S. Haskell,

Project Manager, Plant Licensing Branch III, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2021–21398 Filed 9–30–21; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–454 and 50–455; NRC–2020–0275]

Exelon Generation Company, LLC; Byron Station, Unit Nos. 1 and 2

AGENCY: Nuclear Regulatory Commission.

ACTION: License amendment application; withdrawal by applicant.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has granted the request of Exelon Generation Company, LLC (Exelon, the licensee) to withdraw its application dated October 29, 2020, for proposed amendments to Renewed Facility Operating License Nos. NPF–37 and NPF–66 for Byron Station, Unit Nos. 1 and 2 (Byron), respectively. The proposed amendments would have made changes to the Byron licenses and technical specifications (TSs) to reflect the permanent cessation of reactor operations and permanent defueling of the reactors.

DATES: October 1, 2021.

ADDRESSES: Please refer to Docket ID NRC–2020–0275 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 *https://www.regulations.gov* and search for Docket ID NRC–2021–0275. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@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 *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, 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.
- *Attention:* The PDR, where you may examine and order copies of public documents, is currently closed. You may submit your request to the PDR via email at *pdr.resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8:00 a.m. and 4:00 p.m. (ET), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Joel S. Wiebe, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–6606; email: *Joel.Wiebe@nrc.gov.*

SUPPLEMENTARY INFORMATION: The NRC has granted the request of Exelon to withdraw its application dated October 29, 2020 (ADAMS Package Accession No. ML20304A147) for proposed amendments to Renewed Facility Operating License Nos. NPF–37 and NPF–66 for Byron Station, Unit Nos. 1 and 2, respectively, which are located in Ogle County, Illinois. Exelon is the licensee that owns and operates Byron. The proposed amendments would have changed the Byron TSs to permit changes in plant operations when the plants are permanently shut down and defueled. Specifically, the proposed amendments would have revised the Byron renewed facility operating licenses and TSs following the permanent cessation of power operations to reflect the post-shutdown and permanently defueled condition of the units. The proposed amendments would have eliminated TS requirements and license conditions that would not have been applicable once Byron ceased power operations and could no longer place fuel in the reactor vessels. The proposed amendments would have also eliminated obsolete license conditions. Additionally, the proposed amendments would have revised several license conditions and TS requirements, including limiting conditions for operation, usage rules, definitions, surveillance requirements, and administrative controls. The licensing bases for Byron, including the design bases accident analysis, would have also been revised.

The Commission previously issued a proposed finding that the proposed amendments involve no significant hazards consideration published in the **Federal Register** on December 29, 2020 (85 FR 85677). However, by letter dated September 15, 2021 (ADAMS Accession No. ML21258A276), Exelon requested to withdraw the proposed amendments.

Dated: September 28, 2021.

For the Nuclear Regulatory Commission.

Joel S. Wiebe,

Senior Project Manager, Plant Licensing Branch III, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2021–21436 Filed 9–30–21; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–010, 50–237, and 50–249; NRC–2021–0030]

Exelon Generation Company, LLC; Dresden Nuclear Power Station, Units 1, 2, and 3

AGENCY: Nuclear Regulatory Commission.

ACTION: License amendment application; withdrawal by applicant.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has granted the request of Exelon Generation Company, LLC (Exelon, the licensee) to withdraw its application dated September 24, 2020, for proposed amendments to Amended Facility Operating License No. DPR–2 and Renewed Facility Operating License Nos. DPR–19 and DPR–25 for Dresden Nuclear Power Station, Units 1, 2, and 3 (Dresden), respectively. The proposed amendments would have made changes to technical specifications (TSs) definitions and administrative controls for the permanently defueled condition.

DATES: October 1, 2021.

ADDRESSES: Please refer to Docket ID NRC–2021–0030 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 *https://www.regulations.gov* and search for Docket ID NRC–2021–0030. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@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 *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, 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.
- *Attention:* The PDR, where you may examine and order copies of public documents, is currently closed. You

may submit your request to the PDR via email at *pdr.resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8:00 a.m. and 4:00 p.m. (ET), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Russell S. Haskell, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–1129; email: *Russell.Haskell@nrc.gov.*

SUPPLEMENTARY INFORMATION: The NRC has granted the request of Exelon to withdraw its application dated September 24, 2020 (ADAMS Accession No. ML20269A404) for proposed amendments to Amended Facility Operating License No. DPR–2 and Renewed Facility Operating License Nos. DPR–19 and DPR–25 for Dresden, Units 1, 2, and 3, respectively, which are located in Grundy County, Illinois. Exelon is the licensee that owns and operates Dresden. The proposed amendments would have made changes to TSs definitions and administrative controls for the permanently defueled condition.

The Commission previously issued a proposed finding that the proposed amendments involve no significant hazards consideration published in the **Federal Register** on January 26, 2021 (86 FR 7116). However, by letter dated September 15, 2021 (ADAMS Accession No. ML21258A281), Exelon requested to withdraw the proposed amendments.

Dated: September 28, 2021.

For the Nuclear Regulatory Commission.

Russell S. Haskell,

Project Manager, Plant Licensing Branch III, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2021–21399 Filed 9–30–21; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–237 and 50–249; NRC–2021–0030]

Exelon Generation Company, LLC; Dresden Nuclear Power Station, Units 2 and 3

AGENCY: Nuclear Regulatory Commission.

ACTION: License amendment application; withdrawal by applicant.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has granted the request of Exelon Generation Company, LLC (Exelon, the licensee) to withdraw its application dated October 29, 2020, for proposed amendments to Renewed Facility Operating License Nos. DPR–19 and DPR–25 for Dresden Nuclear Power Station, Units 2 and 3 (Dresden), respectively. The proposed amendments would have made changes to the Dresden licenses and technical specifications (TSs) to reflect the permanent cessation of reactor operations and permanent defueling of the reactors.

DATES: October 1, 2021.

ADDRESSES: Please refer to Docket ID NRC–2021–0030 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 *https://www.regulations.gov* and search for Docket ID NRC–2021–0030. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@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 *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, 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.
- *Attention:* The PDR, where you may examine and order copies of public documents, is currently closed. You may submit your request to the PDR via email at *pdr.resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8:00 a.m. and 4:00 p.m. (ET), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Russell S. Haskell, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–1129; email: *Russell.Haskell@nrc.gov.*

SUPPLEMENTARY INFORMATION: The NRC has granted the request of Exelon to withdraw its application dated October 29, 2020 (ADAMS Accession No. ML20303A313) for proposed amendments to Renewed Facility Operating License Nos. DPR–19 and DPR–25 for Dresden, Units 2 and 3, respectively, which are located in Grundy County, Illinois. Exelon is the licensee that owns and operates Dresden. The proposed amendments would have changed the Dresden TSs to permit changes in plant operations when the plants are permanently shut down and defueled. Specifically, the proposed amendments would have revised the Dresden renewed facility operating licenses and TSs following the permanent cessation of power operations to reflect the post-shutdown and permanently defueled condition of the units. The proposed amendments would have eliminated TS requirements and license conditions that would not have been applicable once Dresden ceased power operations and could no longer place fuel in the reactor vessels. The proposed amendments would have also eliminated obsolete license conditions. Additionally, the proposed amendments would have revised several license conditions and TS requirements, including limiting conditions for operation, usage rules, definitions, surveillance requirements, and administrative controls. The licensing bases for Dresden, including the design bases accident analysis, would have also been revised.

The Commission previously issued a proposed finding that the proposed amendments involve no significant hazards consideration published in the **Federal Register** on January 26, 2021 (86 FR 7117). However, by letter dated September 15, 2021 (ADAMS Accession No. ML21258A281), Exelon requested to withdraw the proposed amendments.

Dated: September 28, 2021.

For the Nuclear Regulatory Commission.

Russell S. Haskell,

Project Manager, Plant Licensing Branch III, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2021–21400 Filed 9–30–21; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–454, 50–455, and 72–068; NRC–2020–0275]

Exelon Generation Company, LLC; Byron Station, Unit Nos. 1 and 2 and Independent Spent Fuel Storage Installation

AGENCY: Nuclear Regulatory Commission.

ACTION: License amendment application; withdrawal by applicant.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has granted the

request of Exelon Generation Company, LLC (Exelon, the licensee) to withdraw its application dated November 2, 2020, for proposed amendments to Renewed Facility Operating License Nos. NPF–37 and NPF–66 for Byron Station, Unit Nos. 1 and 2 (Byron), respectively, and the general license for the Independent Spent Fuel Storage Installation (ISFSI). The proposed amendments would have revised the Byron emergency plan following the permanent cessation of power operations to reflect the post-shutdown and permanently defueled condition of the units.

DATES: October 1, 2021.

ADDRESSES: Please refer to Docket ID NRC–2020–0275 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 *https://www.regulations.gov* and search for Docket ID NRC–2020–0275. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@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 *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, 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.
- *Attention:* The PDR, where you may examine and order copies of public documents, is currently closed. You may submit your request to the PDR via email at *pdr.resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8:00 a.m. and 4:00 p.m. (ET), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Joel S. Wiebe, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–6606; email: *Joel.Wiebe@nrc.gov.*

SUPPLEMENTARY INFORMATION: The NRC has granted the request of Exelon to withdraw its application dated November 2, 2020 (ADAMS Accession No. ML20307A333) for proposed amendments to Renewed Facility Operating License Nos. NPF–37 and NPF–66 for Byron Station, Unit Nos. 1 and 2, respectively, and the general license for the ISFSI, which are located in Ogle County, Illinois. Exelon is the licensee that owns and operates Byron and its ISFSI. The proposed amendments would have revised the Byron emergency plan following the permanent cessation of power operations to reflect the post-shutdown and permanently defueled condition of the units. The proposed changes included revision of the emergency response organization staffing and editorial changes.

The Commission previously issued a proposed finding that the proposed amendments involve no significant hazards consideration published in the **Federal Register** on December 29, 2020 (85 FR 85678). However, by letter dated September 15, 2021 (ADAMS Accession No. ML21258A276), Exelon requested to withdraw the proposed amendments.

Dated: September 28, 2021.

For the Nuclear Regulatory Commission.

Joel S. Wiebe,

Senior Project Manager, Plant Licensing Branch III, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2021–21435 Filed 9–30–21; 8:45 am]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket No. CP2021–139]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* October 5, 2021.

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

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

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction
II. Docketed Proceeding(s)

I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the market dominant or the competitive product list, or the modification of an existing product currently appearing on the market dominant or the competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3011.301.[1]

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern market dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3030, and 39 CFR part 3040, subpart B. For request(s) that the Postal Service states concern competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3035, and 39 CFR part 3040, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s):* CP2021–139; *Filing Title:* Notice of United States Postal Service of Filing a Functionally Equivalent Global Reseller Expedited Package 2 Negotiated Service Agreement

[1] *See* Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

and Application for Non-Public Treatment of Materials Filed Under Seal; *Filing Acceptance Date:* September 27, 2021; *Filing Authority:* 39 CFR 3035.105; *Public Representative:* Kenneth R. Moeller; *Comments Due:* October 5, 2021.

This Notice will be published in the **Federal Register**.

Erica A. Barker,

Secretary.

[FR Doc. 2021–21430 Filed 9–30–21; 8:45 am]

BILLING CODE 7710–FW–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93134; File No. SR–CBOE–2021–055]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Rule 4.13 To Allow the Exchange To List up to 12 Standard Monthly Expirations for Certain Index Options

September 27, 2021.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on September 22, 2021, Cboe Exchange, Inc. (the ''Exchange'' or ''Cboe Options'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange filed the proposal as a ''non-controversial'' proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[3] and Rule 19b–4(f)(6) thereunder.[4] 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

Cboe Exchange, Inc. (the ''Exchange'' or ''Cboe Options'') proposes to amend Rule 4.13 to allow it to list up to 12 standard monthly expirations for certain index options. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 4.13 to allow it to list up to 12 standard monthly expirations for Mini-Russell 2000 Index (''Mini-RUT'' or ''MRUT'') and Mini-S&P 500 Index (''Mini-SPX'' or ''XSP'') options. Currently, Rule 4.13(a) provides that the Exchange may list up to 12 standard monthly expirations at any one time for any class that the Exchange (as the Reporting Authority) uses to calculate a volatility index and for CBOE S&P 500 a.m./PM Basis, EAFE, EM, FTSE Emerging, FTSE Developed, FTSE 100, China 50, S&P Select Sector Index (SIXM, SIXE, SIXT, SIXV, SIXU, SIXR, SIXI, SIXY, SIXB, and SIXRE, and SIXC), and S&P 500 ESG Index options. For all other index options, including MRUT and XSP options, the Exchange may list up to six standard monthly expirations at any one time. In addition to this, the Exchange also proposes to amend Rule 4.13(a) to explicitly allow it to list up to 12 standard monthly expirations for S&P 500 Index (''SPX'') and Russell 2000 Index (''RUT'') options. The Exchange uses SPX options to calculate the Cboe Volatility Index (''VIX'') and RUT options to calculate the Cboe Russell 2000 Volatility Index (''RVX''). As stated, Rule 4.13(a) allows the Exchange to list up to 12 standard monthly expirations at any one time for any class that the Exchange (as the Reporting Authority) uses to calculate a volatility index. Therefore, the Exchange may currently list up to 12 standard monthly expirations for SPX and RUT options.[5] The proposed rule change simply amends Rule 4.13(a) to explicitly iterate in the Rule that SPX and RUT are index options for which the Exchange may list up to 12 standard monthly expirations; that is, notwithstanding the Exchange's use of such options to calculate volatility indexes.

The Exchange proposes to amend Rule 4.13(a) to permit the same number of monthly expirations (up to 12) for XSP and MRUT options as currently permitted for the corresponding full-value index options, SPX and RUT options, respectively.[6] More specifically, XSP options are options on the Mini-SPX Index, the value of which is 1/10th the value of the SPX, and MRUT options are options on the Mini-RUT Index, the value of which is 1/10th the value of the RUT Index. The Mini-SPX and Mini-RUT Index contain the same stocks with the same weightings as the corresponding full-value index (SPX and RUT Index, respectively) and are calculated in the same manner as the corresponding full-value index, with the exception of being 1/10th the value of the corresponding full-value index. Accordingly, market participants may use both XSP and SPX options as a hedging vehicle to meet their investment needs in connection with SPX Index-related products and cash positions and, likewise, may use both MRUT and RUT options to meet their investment needs in connection with RUT Index-related products and cash positions. Because of the relation between these reduced-value indexes and the related full-value indexes, the Exchange believes it is appropriate to permit the Exchange to be able to list the same number of monthly expirations for XSP and MRUT options as SPX and RUT options, respectively.

In addition to this, and as described above, pursuant to Rule 4.13(a), the Exchange may already list up to 12 standard monthly expirations for SPX and RUT options as each is currently used to calculate a volatility index for which the Exchange is the Reporting Authority. The proposed rule change merely amends Rule 4.13(a) to explicitly iterate in the Rule that S&P 500 Index and Russell 2000 Index options are index options for which the Exchange may list up to 12 standard monthly expirations; that is, notwithstanding the Exchange's use of such index options in its calculations for volatility indexes.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(iii).

[4] 17 CFR 240.19b–4(f)(6).

[5] The Exchange notes that it currently lists eight standard monthly expirations for RUT options and 12 standard monthly expirations for SPX options.

[6] The Exchange notes that it currently lists P.M.-settled standard third-Friday-of-the-month MRUT and XSP options pursuant to the Exchange's P.M. Pilot Program. *See* Interpretation and Policy .13 to Rule 4.13. The Exchange does not currently list A.M.-settled standard third-Friday-of-the-month MRUT or XSP options.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[7] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[8] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in 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. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[9] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes the proposed rule change to allow the Exchange to list up to 12 standard monthly expirations for XSP and MRUT options[10] will remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, protect investors, because it will allow the Exchange to be able to list the same number of expirations for these reduced-value index options as it currently may for the corresponding full-value index options. The Exchange notes that because the same components comprise the SPX and Mini-SPX indexes and, likewise, the RUT and Mini-RUT indexes, market participants may use each reduced-value index option as a hedging vehicle to meet their investment needs in connection with the corresponding full-value index-related products and cash positions. Therefore, by allowing the Exchange to be able to list a consistent number of expirations between full- and reduced-value options on the SPX Index and on the RUT Index, the proposed rule change will benefit investors by assisting them in more effectively using options that track the same index to meet their investment needs. Further, the proposed rule change to update Rule 4.13(a) to explicitly iterate in the Rule that SPX and RUT options are index options for which the Exchange may list up to 12 standard monthly expirations will remove impediments to and perfect the mechanism of a free and open market and national market system by updating the Rule to be more explicit in connection with the number of monthly expirations that the Exchange is already permitted to list for SPX and RUT options pursuant to Rule 4.13(a) (as the Exchange uses both index options to calculate a volatility index).[11] The Exchange notes that the ability to list up to 12 standard monthly expirations for XSP, MRUT, SPX and RUT options, each of which is an exclusively listed, broad-based option, is consistent with the number of monthly expirations that the Exchange is currently permitted to list for other exclusively-listed, broad-based index options pursuant to Rule 4.13(a), also notwithstanding their use in a volatility index calculation.

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 Exchange does not believe that the proposed rule change will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act as any and all monthly expirations listed for XSP, MRUT, SPX and RUT options will be equally available, or continue to be equally available (as is the case regarding the proposed rule change in connection with SPX and RUT options) to all market participants who trade such options, and the proposed number of expirations will apply, or continue to apply, in the same manner to all XSP, MRUT, SPX and RUT options. The proposed rule change makes it possible for the same expirations to be listed for reduced-value index that are currently available for full-value indexes.

The Exchange does not believe that the proposed rule change regarding the number of standard monthly expirations permissible for XSP, MRUT, SPX and RUT options, will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because options on all such indexes are proprietary Exchange products. To the extent that allowing up to 12 standard monthly expirations for XSP and MRUT options (or SPX and RUT options, as is currently the case) trading on the Exchange may make the Exchange a more attractive marketplace to market participants at other exchanges, such market participants are free to elect to become market participants on the Exchange. As noted above, the Exchange believes being able to list a consistent number of expirations between full- and reduced-value options on the SPX Index and on the RUT Index may permit investors to more effectively use options that track the same index to meet their investment needs.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposal.

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[12] and Rule 19b–4(f)(6) thereunder.[13]

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act[14] normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii)[15] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay. The proposed rule change is composed of two parts. First, the Exchange proposes to include the ticker symbols for SPX and RUT in the rule and states that doing so does not raise any new issues as both index options are already covered by the rule because both are used in a volatility index calculation. Thus, the first change amends Cboe Rule 4.13(a) to explicitly identify by ticker state in the rule that SPX and RUT are index options for which the Exchange may list up to 12 standard monthly expirations. Second,

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(5).

[9] *Id.*

[10] *See supra* note 6.

[11] *See supra* note 5.

[12] 15 U.S.C. 78s(b)(3)(A).

[13] 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.

[14] 17 CFR 240.19b–4(f)(6).

[15] 17 CFR 240.19b–4(f)(6)(iii).

the Exchange proposes to amend Cboe Rule 4.13 to permit it to list up to 12 standard monthly expirations for XSP and MRUT, whereas it can currently list up to 6 standard monthly expirations for those products. Accordingly, the proposal will allow the Exchange to list the same number of monthly expirations (12) for XSP and MRUT as is currently permitted for the corresponding full-value index options, SPX and RUT, respectively. The Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest because the first part of the proposal does not make any substantive change or raise any new issues and the second part of the proposal will allow the Exchange to list, for the reduced-value index options, the same number of standard monthly expirations as are available for the corresponding full-value index options, thus allowing the Exchange to accommodate customer demand for index options based on the same underlying indexes. Therefore, the Commission hereby waives the operative delay and designates the proposal as operative upon filing.[16]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings 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–CBOE–2021–055 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–CBOE–2021–055. 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–CBOE–2021–055 and should be submitted on or before October 22, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–21355 Filed 9–30–21; 8:45 am]

BILLING CODE 8011–01–P

[16] For purposes only of waiving the 30-day operative delay, the Commission also has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[17] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93130; File No. SR–CboeEDGA–2021–020]

Self-Regulatory Organizations; Cboe EDGA Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Exchange's Fee Schedule

September 27, 2021.

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 September 13, 2021, Cboe EDGA Exchange, Inc. (''Exchange'' or ''EDGA'') 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 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

Cboe EDGA Exchange, Inc. (the ''Exchange'' or ''EDGA'' or ''EDGA Equities'') proposes to amend its Fee Schedule. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/equities/regulation/rule_filings/edga/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its Fee Schedule applicable to its equities trading platform (''EDGA Equities'') to modify the fee or rebate associated with certain routing fee codes and eliminate a particular routing fee code.[3]

The Exchange first notes that it operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive or incentives to be insufficient. More specifically, the Exchange is only one of 16 registered equities exchanges, as well as a number of alternative trading systems and other off-exchange venues that do not have similar self-regulatory responsibilities under the Exchange Act, to which market participants may direct their order flow. Based on publicly available information,[4] no single registered equities exchange has more than 14% of the market share. Thus, in such a low-concentrated and highly competitive market, no single equities exchange possesses significant pricing power in the execution of order flow. The Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can shift order flow, discontinue, or reduce use of certain categories of products, in response to fee changes. Accordingly, competitive forces constrain the Exchange's transaction fees, and market participants can readily trade on competing venues if they deem pricing levels at those other venues to be more favorable.

The Exchange assesses fees in connection with orders routed away to various exchanges. Now, the Exchange proposes to modify certain routing fee codes currently under the Fee Codes and Associated Fees section of the Fee Schedule. First, the Exchange proposes to modify fee code C, which is appended to orders routed to Nasdaq BX, Inc. (''Nasdaq BX''), and currently provides a rebate of $0.00110 per share for securities priced at or above $1.00 and 0.10% of the dollar value for securities priced below $1.00. Specifically, the Exchange proposes to modify the description of the fee code to identify Nasdaq BX and to reduce the rebate for securities priced at or above $1.00 to $0.0005 per share.

Second, the Exchange proposes to modify fee code NX, which is appended to orders routed to NYSE National, Inc. (''NYSE National'') using the ROBB, ROCO or ROUC routing strategy, and currently provides a rebate of $0.00200 per share for securities priced at or above $1.00 and is free for securities priced below $1.00. The Exchange proposes to reduce the rebate for securities priced at or above $1.00 to $0.0005 per share.

Third, the Exchange proposes to modify fee code S, which is appended to directed intermarket sweep orders (''ISOs''), and currently assesses a fee of $0.00320 per share for securities priced at or above $1.00 and 0.30% of the dollar value for securities priced below $1.00. The Exchange proposes to increase the fee for securities priced at or above $1.00 to $.00330.

Finally, as a result of minimal use in the last months, the Exchange proposes to eliminate fee code IX in its entirety. Fee code IX is appended to orders routed to the Investors Exchange LLC (''IEX'') using the DIRC routing strategy, and currently assesses a fee of $0.00300 per share for securities priced at or above $1.00 and 0.30% of the dollar value for securities priced below $1.00. The Exchange believes that because so few users elect to route their orders with specifications to which fee code IX is applicable, the current demand does not warrant the infrastructure and ongoing Systems maintenance required to support the separate fee code. Therefore, the Exchange now proposes to delete fee code IX in the Fee Schedule. The Exchange notes that users will continue to be able to choose to route their orders with the same specifications to which fee codes IX currently applies—such orders will simply be assessed the fees currently in place for routed orders generally.[5] That is, if any of the routed orders to which fee code IX currently apply fee code X will be appended to such orders, which also assesses a fee of $0.00300 per share for securities priced at or above $1.00 and 0.30% of the dollar value for securities priced below $1.00.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the objectives of Section 6 of the Act,[6] in general, and furthers the objectives of Section 6(b)(4),[7] in particular, as it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its Members and issuers and other persons using its facilities. The Exchange also believes that the proposed rule change is consistent with the objectives of Section 6(b)(5)[8] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in 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, particularly, is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

As described above, the Exchange operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive or incentives to be insufficient. The Exchange believes that its proposal to reduce the rebates applicable to fee codes C and NX and to increase the fee applicable to fee code S is fair, equitable, and reasonable because the proposed fees and rebate remain consistent with pricing offered by the Exchange's affiliates and competitors and does not represent a significant departure from the Exchange's general pricing structure. Specifically, the proposed fee applicable to fee code S is equal to the fee currently charged for directed ISOs on the Exchange's affiliate, Cboe BZX Exchange, Inc. (''BZX Equities'').[9] Similarly, the proposed rebates applicable to fee codes C and NX are more than that offered by the Nasdaq Stock Market LLC (''Nasdaq''), which does not provide a standard rebate for similar orders.[10] Therefore, the Exchange believes the proposed fees and rebates associated with fee codes C, NX, and S remain consistent with pricing previously

[3] The Exchange initially filed the proposed fee changes September 1, 2021 (SR–CboeEDGA–2021–019). On September 13, 2021, the Exchange withdrew that filing and submitted this proposal.

[4] *See* Cboe Global Markets, U.S. Equities Market Volume Summary, Month-to-Date (August 26, 2021), available at *https://markets.cboe.com/us/equities/market_statistics/*.

[5] The Exchange notes that there are other fee codes that apply to certain other routing specifications, however, those routed orders not otherwise specified in such other routing fee code descriptions yield the general routing fee code X.

[6] 15 U.S.C. 78f.

[7] 15 U.S.C. 78f(b)(4).

[8] 15 U.S.C. 78f.(b)(5).

[9] *See* the standard rate associated with fee code S, appended to Directed ISOs, on the BZX Equities fee schedule at *https://www.cboe.com/us/equities/membership/fee_schedule/bzx/*.

[10] *See* ''Route Rates'' on the Nasdaq fee schedule at *http://nasdaqtrader.com/Trader.aspx?id=PriceListTrading2*.

offered by the Exchange's affiliates and other exchanges and does not represent a significant departure from such pricing.

The Exchange believes the proposed rule change to remove fee code IX is reasonable as the Exchange has observed a minimal amount of volume in orders yielding the fee code and, therefore, the continuation of this fee code does not warrant the infrastructure and ongoing Systems maintenance required to support separate fee codes for specific routed orders. As such, the Exchange also believes that is reasonable and equitable to assess routed orders which meet the specifications to which fee code IX are currently applicable the standard routing fee currently in place for all other routed orders—via fee code X, which also assesses a fee of $0.00300 per share for securities priced at or above $1.00 and 0.30% of the dollar value for securities priced below $1.00. The Exchange believes that the proposed rule change is equitable and not unfairly discriminatory because Members will continue to have the option to elect to route their orders in the same manner (*i.e.,* routed to IEX using the DIRC strategy) and will be automatically and uniformly assessed the applicable standard rates in place for generally all other routed orders. Further, if members do not favor the Exchange's pricing for routed orders, they can send their routable orders directly to away markets instead of using routing functionality provided by the Exchange. Routing through the Exchange is optional, and the Exchange operates in a competitive environment where market participants can readily direct order flow to competing venues or providers of routing services if they deem fee levels to be excessive.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule changes will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe that the proposed modifications represent a significant departure from previous pricing offered by the Exchange or pricing offered by the Exchange's competitors. Further, while the Exchange is proposing to eliminate fee code IX, orders that meet specifications of fee code IX going forward will be assessed the rate for orders routed generally. Members may opt to disfavor the Exchange's pricing if they believe that alternatives offer them better value. Accordingly, the Exchange does not believe that the proposed change will impair the ability of Members or competing venues to maintain their competitive standing in the financial markets.

The Exchange believes the proposed rule change does not impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. Particularly, the proposed fee and rebate modifications will continue to apply to all Members equally, and as noted above, orders currently meeting the specifications of fee code IX will be assessed the rate for orders routed generally under fee code X. The Exchange believes the proposed rule change does not impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. As previously discussed, the Exchange operates in a highly competitive market. Members have numerous alternative venues that they may participate on and direct their order flow, including other equities exchanges, off-exchange venues, and alternative trading systems. Additionally, the Exchange represents a small percentage of the overall market. Based on publicly available information, no single equities exchange has more than 14% of the market share.[11] Therefore, no exchange possesses significant pricing power in the execution of order flow. Indeed, participants can readily choose to send their orders to other exchange and off-exchange venues if they deem fee levels at those other venues to be more favorable. Moreover, the Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues 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.'' [12] The fact that this market is competitive has also long been recognized by the courts. In NetCoalition v. Securities and Exchange Commission, the D.C. Circuit stated as follows: ''[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' . . . ''.[13] Accordingly, the Exchange does not believe its proposed fee change imposes any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective upon filing pursuant to Section 19(b)(3)(A) [14] of the Act and paragraph (f)(2) of Rule 19b–4 [15] 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) [16] 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–*

[11] *Supra* note 3.

[12] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

[13] *NetCoalition* v. *SEC*, 615 F.3d 525, 539 (D.C. Cir. 2010) (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782–83 (December 9, 2008) (SR–NYSEArca–2006–21)).

[14] 15 U.S.C. 78s(b)(3)(A).

[15] 17 CFR 240.19b–4(f)(2).

[16] 15 U.S.C. 78s(b)(2)(B).

CboeEDGA–2021–020 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–CboeEDGA–2021–020. 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 will also be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CboeEDGA–2021–020 and should be submitted on or before October 22, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–21353 Filed 9–30–21; 8:45 am]

BILLING CODE 8011–01–P

[17] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93129; File No. SR–CboeEDGX–2021–040]

Self-Regulatory Organizations; Cboe EDGX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Exchange's Fee Schedule

September 27, 2021.

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 September 13, 2021, Cboe EDGX Exchange, Inc. (''Exchange'' or ''EDGX'') 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 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

Cboe EDGX Exchange, Inc. (the ''Exchange'' or ''EDGX'' or ''EDGX Equities'') proposes to amend its Fee Schedule. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/options/regulation/rule_filings/edgx/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its Fee Schedule applicable to its equities trading platform (''EDGX Equities'') to modify the fee or rebate associated with certain routing fee codes.[3]

The Exchange first notes that it operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive or incentives to be insufficient. More specifically, the Exchange is only one of 16 registered equities exchanges, as well as a number of alternative trading systems and other off-exchange venues that do not have similar self-regulatory responsibilities under the Exchange Act, to which market participants may direct their order flow. Based on publicly available information,[4] no single registered equities exchange has more than 14% of the market share. Thus, in such a low-concentrated and highly competitive market, no single equities exchange possesses significant pricing power in the execution of order flow. The Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can shift order flow, discontinue, or reduce use of certain categories of products, in response to fee changes. Accordingly, competitive forces constrain the Exchange's transaction fees, and market participants can readily trade on competing venues if they deem pricing levels at those other venues to be more favorable.

The Exchange assesses fees and provides rebates in connection with orders routed away to various exchanges. Now, the Exchange proposes to modify certain routing fee codes currently under the Fee Codes and Associated Fees section of the Fee Schedule. First, the Exchange proposes to modify fee code C, which is appended to orders routed to Nasdaq BX, Inc. (''Nasdaq BX''), and currently provides a rebate of $0.00110 per share for securities priced at or above $1.00 and 0.10% of the dollar value for securities priced below $1.00.

[3] The Exchange initially filed the proposed fee changes September 1, 2021 (SR–CboeEDGX–2021–039). On September 13, 2021, the Exchange withdrew that filing and submitted this proposal.

[4] *See* Cboe Global Markets, U.S. Equities Market Volume Summary, Month-to-Date (August 26, 2021), available at *https://markets.cboe.com/us/equities/market_statistics/.*

Specifically, the Exchange proposes to modify the description of the fee code to identify Nasdaq BX and to reduce the rebate for securities priced at or above $1.00 to $0.0005 per share.

Second, the Exchange proposes to modify fee code NX, which is appended to orders routed to NYSE National, Inc. (''NYSE National'') using the ROUC routing strategy, and currently provides a rebate of $0.00200 per share for securities priced at or above $1.00 and is free for securities priced below $1.00. The Exchange proposes to reduce the rebate for securities priced at or above $1.00 to $0.0005 per share.

Third, the Exchange proposes to modify fee code S, which is appended to directed intermarket sweep orders (''ISOs''), and currently assesses a fee of $0.00320 per share for securities priced at or above $1.00 and 0.30% of the dollar value for securities priced below $1.00. The Exchange proposes to increase the fee for securities priced at or above $1.00 to $.00330.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the objectives of Section 6 of the Act,[5] in general, and furthers the objectives of Section 6(b)(4),[6] in particular, as it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its Members and issuers and other persons using its facilities. The Exchange also believes that the proposed rule change is consistent with the objectives of Section 6(b)(5)[7] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in 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, particularly, is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

As described above, the Exchange operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive or incentives to be insufficient. The Exchange believes that its proposal to reduce the rebates applicable to fee codes C and NX and to increase the fee applicable to fee code S is fair, equitable, and reasonable because the proposed fees and rebate remain consistent with pricing offered by the Exchange's affiliates and competitors and does not represent a significant departure from the Exchange's general pricing structure. Specifically, the proposed fee applicable to fee code S is equal to the fee currently charged for directed ISOs on the Exchange's affiliate, Cboe BZX Exchange, Inc. (''BZX Equities'').[8] Similarly, the proposed rebates applicable to fee codes C and NX are more than that offered by the Nasdaq Stock Market LLC (''Nasdaq''), which does not provide a standard rebate for similar orders.[9] Therefore, the Exchange believes the proposed fees and rebates associated with fee codes C, NX, and S remain consistent with pricing previously offered by the Exchange's affiliates and other exchanges and does not represent a significant departure from such pricing.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule changes will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe that the proposed changes represent a significant departure from previous pricing offered by the Exchange or pricing offered by the Exchange's competitors. Members may opt to disfavor the Exchange's pricing if they believe that alternatives offer them better value. Accordingly, the Exchange does not believe that the proposed change will impair the ability of Members or competing venues to maintain their competitive standing in the financial markets.

The Exchange believes the proposed rule change does not impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. Particularly, the proposed fee and rebate modifications will continue to apply to all Members equally. The Exchange believes the proposed rule change does not impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. As previously discussed, the Exchange operates in a highly competitive market. Members have numerous alternative venues that they may participate on and direct their order flow, including other equities exchanges, off-exchange venues, and alternative trading systems. Additionally, the Exchange represents a small percentage of the overall market. Based on publicly available information, no single equities exchange has more than 14% of the market share.[10] Therefore, no exchange possesses significant pricing power in the execution of order flow. Indeed, participants can readily choose to send their orders to other exchange and off-exchange venues if they deem fee levels at those other venues to be more favorable. Moreover, the Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues 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.'' [11] The fact that this market is competitive has also long been recognized by the courts. In *NetCoalition* v. *Securities and Exchange Commission*, the D.C. Circuit stated as follows: ''[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' . . . .''.[12] Accordingly, the Exchange does not believe its proposed fee change imposes any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

[5] 15 U.S.C. 78f.

[6] 15 U.S.C. 78f(b)(4).

[7] 15 U.S.C. 78f.(b)(5).

[8] *See* the standard rate associated with fee code S, appended to Directed ISOs, on the BZX Equities fee schedule at *https://www.cboe.com/us/equities/membership/fee_schedule/bzx/.*

[9] *See* ''Route Rates'' on the Nasdaq fee schedule at *http://nasdaqtrader.com/Trader.aspx?id=PriceListTrading2.*

[10] *Supra* note 3.

[11] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

[12] *NetCoalition* v. *SEC*, 615 F.3d 525, 539 (D.C. Cir. 2010) (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782–83 (December 9, 2008) (SR–NYSEArca–2006–21)).

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective upon filing pursuant to Section 19(b)(3)(A) [13] of the Act and paragraph (f)(2) of Rule 19b–4 [14] 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) [15] 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–CboeEDGX–2021–040 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–CboeEDGX–2021–040. 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 will also be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CboeEDGX–2021–040 and should be submitted on or before October 22, 2021.[16]

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–21352 Filed 9–30–21; 8:45 am]

BILLING CODE 8011–01–P

[13] 15 U.S.C. 78s(b)(3)(A).

[14] 17 CFR 240.19b–4(f)(2).

[15] 15 U.S.C. 78s(b)(2)(B).

[16] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meeting; Cancellation

FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT: 86 FR 53355, September 27, 2021.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: Wednesday, September 29, 2021 at 10:01 a.m.

CHANGES IN THE MEETING: The Closed Meeting scheduled for Wednesday, September 29, 2021 at 10:01 a.m., has been cancelled.

CONTACT PERSON FOR MORE INFORMATION: For further information; please contact Vanessa A. Countryman from the Office of the Secretary at (202) 551–5400.

Dated: September 29, 2021.

Vanessa A. Countryman,

Secretary.

[FR Doc. 2021–21516 Filed 9–29–21; 11:15 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–93132; File No. SR–NYSEArca–2021–82]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Adopt a New Historical Market Data Product To Be Known as the NYSE Options Open-Close Volume Summary

September 27, 2021.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on September 14, 2021, NYSE Arca, Inc. (''NYSE Arca'' or the ''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 adopt a new historical market data product to be known as the NYSE Options Open-Close Volume Summary. Proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

[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 adopt a new historical market data product to be known as the NYSE Options Open-Close Volume Summary, which will be available to all subscribers. The proposed NYSE Options Open-Close Volume Summary is based on market data products currently available on most other options exchanges.[4]

The Exchange proposes to offer the NYSE Options Open-Close Volume Summary, which will be a volume summary of trading activity on the Exchange at the option level by origin (Customer,[5] Professional Customer,[6] Firm,[7] Broker-Dealer, and Market Maker[8]), side of the market (buy or sell), contract volume, and transaction type (opening or closing). The Customer, Professional Customer, Firm, Broker-Dealer, and Market Maker volume will be further broken down into trade size buckets (less than 100 contracts, 100–199 contracts, greater than 199 contracts). The NYSE Options Open-Close Volume Summary is proprietary Exchange trade data and does not include trade data from any other exchange. It is also a historical data product and not a real-time data feed.

Specifically, the NYSE Options Open-Close Volume Summary would include the following data: Aggregate number of buy and sell transactions in the affected series; aggregate volume traded electronically on the Exchange in the affected series; aggregate number of trades effected on the Exchange to open a position;[9] aggregate number of trades effected on the Exchange to close a position;[10] and origin of the orders and quotes involved in trades on the Exchange in the affected series during a particular trading session, specifically aggregated in the following categories of participants: Customer, Professional Customer, Firm, Broker-Dealer, and Market Maker.

The Exchange anticipates a wide variety of market participants to purchase the NYSE Options Open-Close Volume Summary, including, but not limited to, individual customers, buy-side investors, and investment banks. The NYSE Options Open-Close Volume Summary would provide subscribers data that should enhance their ability to analyze options trade and volume data, and to create and test trading models and analytical strategies. The Exchange believes that NYSE Options Open-Close Volume Summary will be a valuable tool that subscribers can use to gain comprehensive insight into the trading activity in a particular options series. The NYSE Options Open-Close Volume Summary is a completely voluntary product, in that the Exchange is not required by any rule or regulation to make this data available and that potential subscribers may purchase it only if they voluntarily choose to do so.

The Exchange proposes to offer two versions of the NYSE Options Open-Close Volume Summary: End of Day Volume Summary and Intra-Day Volume Summary. The End of Day Volume Summary will contain historical data from the previous trading day and would be available after the end of each trading day, generally on a T+1 basis. The Intra-Day Volume Summary would include ''snapshots'' taken every 10 minutes throughout the trading day and would be available within five minutes of the conclusion of each 10-minute period. Each update would represent combined data captured from the current ''snapshot'' and all previous ''snapshots'' and thus would provide open-close data on an aggregate basis.

The Exchange does not currently intend to charge any fees to subscribe to NYSE Options Open-Close Volume Summary. The Exchange will submit a proposed rule change to the Commission when it determines to charge fees associated with the receipt of NYSE Options Open-Close Volume Summary.

The Exchange plans to introduce the NYSE Options Open-Close Volume Summary when the Exchange transitions to the Pillar trading platform, anticipated for the fourth quarter of 2021.[11] The Exchange will announce the exact date that the NYSE Options Open-Close Volume Summary will become available through a NYSE Trader Update.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b)[12] of the Act, in general, and furthers the objectives of Section 6(b)(5)[13] of the Act, in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, 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 it is not designed to permit unfair discrimination among customers, brokers, or dealers.

In adopting Regulation NMS, the Commission granted self-regulatory organizations and broker-dealers increased authority and flexibility to offer new and unique market data to consumers of such data. It was believed that this authority would expand the amount of data available to users and consumers of such data and also spur innovation and competition for the provision of market data. The Exchange believes that the NYSE Options Open-Close Volume Summary options data

[4] *See* Securities Exchange Act Release Nos. 89497 (August 6, 2020), 85 FR 48747 (August 12, 2020) (SR–CboeBZX–2020–059); 89498 (August 6, 2020), 85 FR 48735 (August 12, 2020) (SR–Cboe–EDGX–2020–36); 85817 (May 9, 2019), 84 FR 21863 (May 15, 2019) (SR–CBOE–2019–026); 89496 (August 6, 2020), 85 FR 48743 (August 12, 2020) (SR–C2–2020–010); 89586 (August 17, 2020), 85 FR 51833 (August 21, 2020) (SR–C2–2020–012); 62887 (September 10, 2010), 75 FR 57092 (September 17, 2010) (SR–Phlx–2010–121); 65587 (October 18, 2011), 76 FR 65765 (October 24, 2011) (SR–NASDAQ–2011–144); 61317 (January 8, 2010), 75 FR 2915 (January 19, 2010) (SR–ISE–2009–103); 81632 (September 15, 2017), 82 FR 44235 (September 21, 2017) (SR–GEMX–2017–42); 91963 (May 21, 2021), 86 FR 28662 (May 27, 2021) (SR–EMERALD–2021–18); 91964 (May 21, 2012), 86 FR 28667 (May 27, 2021) (SR–PEARL–2021–24); and 91965 (May 21, 2021), 86 FR 28665 (May 27, 2021) (SR–MIAX–2021–18).

[5] All defined terms are proposed to be defined in Rule 1.1 once the Exchange transitions to the Pillar trading platform. *See infra,* note 11. For options traded on the Exchange, the term ''Customer'' does not include a broker or dealer. *See* Rule 1.1, Definitions.

[6] For options traded on the Exchange, the term ''Professional Customer'' means an individual or organization that (i) is not a broker or dealer, as defined Sections 3(a)(4) and 3(a)(5) of the Exchange Act and rules thereunder, and (ii) places more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s). *See* Rule 1.1, Definitions. *See also* discussion, *supra,* note 5.

[7] For options traded on the Exchange, the term ''Firm'' means a broker-dealer that is not registered as a dealer-specialist or market maker on a registered national securities exchange or association. *See* Rule 1.1, Definitions. *See also* discussion, *supra,* note 5.

[8] With respect to options traded on the Exchange, the term ''Market Maker'' refers to an OTP Holder or OTP Firm that acts as a Market Maker pursuant to Rule 6.32–O. For purposes of the NYSE Arca rules, the term Market Maker includes Lead Market Makers, unless the context otherwise indicates. *See* Rule 1.1, Definitions. *See also* discussion, *supra,* note 5.

[9] An opening buy is a transaction that creates or increases a long position and an opening sell is a transaction that creates or increases a short position.

[10] A closing buy is a transaction made to close out an existing position and a closing sell is a transaction to reduce or eliminate a long position.

[11] *See* Securities Exchange Act Release No. 92304 (June 30, 2021), 86 FR 36440 (July 9, 2021) (SR–NYSE–Arca–2021–47) (Notice of Filing of Proposed Rule Change for New Rules 6.1P–O, 6.37AP–O, 6.40P–O, 6.41P–O, 6.62P–O, 6.64P–O, 6.76P–O, and 6.76AP–O and Amendments to Rules 1.1, 6.1–O, 6.1A–O, 6.37–O, 6.65A–O and 6.96–O).

[12] 15 U.S.C. 78f(b).

[13] 15 U.S.C. 78f(b)(5).

product proposed herein is precisely the sort of market data product evolutions that the Commission envisioned when it adopted Regulation NMS. The proposed rule change would benefit investors by providing access to the NYSE Options Open-Close Volume Summary, which contains information regarding opening and closing activity across different options series during the trading day that would provide investor sentiment and thereby allow market participants to make informed trading decisions throughout the day. Subscribers to the data may also be able to enhance their ability to analyze options trade and volume data and create and test trading models and analytical strategies. The Exchange believes the NYSE Options Open-Close Volume Summary would provide a valuable tool that subscribers can use to gain comprehensive insight into the trading activity in a particular series, but also emphasizes such data is not necessary for trading.

Moreover, other exchanges also offer a substantially identical data product.[14] Specifically, NASDAQ OMX PHLX (''PHLX'') and the NASDAQ Stock Market LLC (''NASDAQ'') offer the PHLX Options Trade Outline (''PHOTO'') and NASDAQ Options Trade Outline (''NOTO''), respectively. The Cboe Exchange, Inc. (''Cboe''), Cboe C2 Exchange, Inc. (''C2''), Cboe BZX Exchange, Inc. (''BZX''), Cboe EDGX Exchange, Inc. (''EDGX'') all offer the market data products called the End of Day and Intraday Open-Close Data. Additionally, Miami International Securities Exchange, LLC (''MIAX''), MIAX Emerald, LLC (''Emerald'') and MIAX PEARL, LLC (''PEARL'') all offer an End of Day Open-Close Report and an Intra-Day Open-Close Report. The Phlx, Nasdaq, Cboe, C2, BZX, EDGX, MIAX, Emerald and PEARL products provide substantially the same information as that included in the proposed NYSE Options Open-Close Volume Summary. Like the proposed product, the data is provided to subscribers in the other exchange's market data products after the end of the trading day and cumulatively every 10 minutes and provided within five minutes of the conclusion of each 10-minute period.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[15] 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. Rather, the Exchange believes that the proposal will promote competition by permitting the Exchange to offer a data product similar to those offered by other competitor options exchanges.[16] The market for proprietary data products is currently competitive and inherently contestable because there is fierce competition for the inputs necessary to the creation of proprietary data. Numerous exchanges compete with each other for listings, trades, and market data itself, providing virtually limitless opportunities for entrepreneurs who wish to produce and distribute their own market data. The proposed introduction of the NYSE Options Open-Close Volume Summary is the Exchange's response to the many competing products available in the marketplace today. The Exchange believes the proposed rule change would contribute to the robust competition among national securities exchanges.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the 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[17] and Rule 19b–4(f)(6) thereunder.[18]

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 change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEArca–2021–82 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–NYSEArca–2021–82. 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–NYSEArca–2021–82 and should be submitted on or before October 22, 2021.

[14] *See supra* note 4.

[15] 15 U.S.C. 78f(b)(8).

[16] *See supra* note 4.

[17] 15 U.S.C. 78s(b)(3)(A).

[18] 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.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–21354 Filed 9–30–21; 8:45 am]

BILLING CODE 8011–01–P

DEPARTMENT OF STATE

[Public Notice: 11546]

Bureau of Political-Military Affairs; Rescission of Statutory Debarment of Dennis Haag Under the International Traffic in Arms Regulations

ACTION: Notice.

SUMMARY: Notice is hereby given that the Department of State has rescinded the statutory debarment of Dennis Haag included in **Federal Register** notice of April 25, 2018.

FOR FURTHER INFORMATION CONTACT: Jae Shin, Director, Office of Defense Trade Controls Compliance, Bureau of Political-Military Affairs, Department of State (202) 632–2107.

SUPPLEMENTARY INFORMATION: Section 38(g)(4) of the Arms Export Control Act (AECA), 22 U.S.C. 2778(g)(4), prohibits the issuance of licenses or other approvals for the export of defense articles or defense services where the applicant, or any party to the export, has been convicted of violating § 38 of the AECA or certain other U.S. criminal statues enumerated in § 38(g)(1) of the AECA. In addition, § 127.7(b) of the International Traffic in Arms Regulations (ITAR) provides for the statutory debarment of any person who has been convicted of violating or conspiring to violate the AECA. As stated in this provision, it is the policy of the Department not to consider applications for licenses or requests for approvals involving any person who has been statutorily debarred. Persons subject to statutory debarment are prohibited from participating directly or indirectly in any activities that are subject to the ITAR.

Mr. Dennis Haag pleaded guilty to violating § 38 of the AECA, and the Department notified the public of the resulting statutory debarment imposed pursuant to ITAR 127.7(c) via notice on April 25, 2018 (83 FR 18112). The notice provided that he and other debarred persons were ''prohibited from participating directly or indirectly in activities that are regulated by the ITAR.''

In accordance with ITAR 127.7(b), reinstatement may only be approved after submission of a request by the debarred party. In response to such a request from the debarred person for reinstatement, the Department has conducted a thorough review of the circumstances surrounding his conviction and has determined that he has taken appropriate steps to address the causes of the violations sufficient to warrant rescission of his statutory debarment. Therefore, pursuant to ITAR 127.7(b), the Department determines it is no longer in the national security and foreign policy interests of the United States to maintain the policy as applied to Mr. Dennis Haag, and the Department hereby rescinds the notice of his statutory debarment.

The Department notes that the **Federal Register** notice of debarment for the debarred party stated that ''Department of State policy permits debarred persons to apply to the Director, Office of Defense Trade Controls Compliance, for reinstatement beginning one year after the date of the debarment. Any decision to grant reinstatement can be made only after the statutory requirements of Section 38(g)(4) of the AECA have been satisfied.'' (See 83 FR 18112). The Department is no longer requiring that export privileges be reinstated pursuant to ITAR 127.11 and § 38(g)(4) of the AECA prior to the rescission of statutory debarment. This change in policy recognizes that the circumstances warranting statutory debarment may be different from those warranting the revocation of export privileges. The Department may find, as it does in this instance, that the national security and foreign policy interests of the United States are not advanced by maintaining the Department-imposed ITAR 127.7(b) prohibition on persons convicted of violating or conspiring to violate the AECA from ''participating directly or indirectly in any activities that are subject to the ITAR'' and where the debarred person may not meet the requirements of ITAR 127.11(b) (implementing the restrictions of § 38(g)(4) of the AECA).

This notice rescinds the statutory debarment of Dennis Haag but does not provide notice of reinstatement of export privileges pursuant to the statutory requirements of § 38(g)(4) of the AECA and ITAR 127.11. As required by the statute, the Department may not issue a license directly to any debarred persons except as may be determined on a case-by-case basis after interagency consultations, a thorough review of the circumstances surrounding the conviction, and a finding that appropriate steps have been taken to mitigate any law enforcement concerns. Any determination by the Department regarding the reinstatement of export privileges with respect to any debarred persons will be made in accordance with the statutory and regulatory requirements and will be the subject of a separate notice. All otherwise eligible persons may engage in exports of defense articles manufactured by him, or that incorporate any of his manufactured items into defense articles for export, or otherwise engage in transactions subject to the ITAR without providing prior written notification of his involvement as otherwise required by ITAR 127.1(d) and the transaction exception requirements of the **Federal Register** notice of statutory debarment.

Timothy Betts,

Acting Assistant Secretary, Bureau of Political-Military Affairs.

[FR Doc. 2021–21372 Filed 9–30–21; 8:45 am]

BILLING CODE 4710–25–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FAA–2020–1157]

Agency Information Collection Activities: Requests for Comments; Clearance of Renewed Approval of Information Collection: Commercial Space Transportation Licensing Regulations

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 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 January 13, 2021. The collection involves information used to make a safety determination on proposed modifications and renewals of expendable launch vehicles. The information to be collected will be used to make licensing determinations.

DATES: Written comments should be submitted by November 1, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting

[19] 17 CFR 200.30–3(a)(12).

''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Charles Huet by email at: *Charles.huet@faa.gov;* phone: 202–267–7427.

SUPPLEMENTARY INFORMATION:

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.

OMB Control Number: 2120–0608.

Title: Commercial Space Transportation Licensing Regulations.

Form Numbers: None.

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 January 13, 2021 (86 FR 2722). The Commercial Space Launch Act of 1984, 49 U.S.C. App. 2601–2623, as recodified at 49 U.S.C. Subtitle IX, Ch. 701—Commercial Space Launch Activities, 49 U.S.C. 70101–70119 (1994), requires certain data be provided in applying for a license to conduct commercial space launch activities. These data are required to demonstrate to the Federal Aviation Administration (FAA), Associate Administrator for Commercial Space Transportation (AST), that a license applicant's proposed activities meet applicable public safety, national security, and foreign policy interests of the United States.

Respondents: Operators holding a license for expendable launch vehicles at the time of part 450 publication. There are 17 licenses eligible for renewal or modification.

Frequency: On occasion as needed.

Estimated Average Burden per Response: 842.5 Hours.

Estimated Total Annual Burden: 10,110 Hours.

Issued in Washington, DC, on September, 28, 2021.

James Hatt,

Manager, ASZ–200.

[FR Doc. 2021–21394 Filed 9–30–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2014–0385; FMCSA–2014–0387; FMCSA–2018–0139; FMCSA–2019–0109]

Qualification of Drivers; Exemption Applications; Hearing

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice of renewal of exemptions; request for comments.

SUMMARY: FMCSA announces its decision to renew exemptions for 12 individuals from the hearing requirement in the Federal Motor Carrier Safety Regulations (FMCSRs) for interstate commercial motor vehicle (CMV) drivers. The exemptions enable these hard of hearing and deaf individuals to continue to operate CMVs in interstate commerce.

DATES: Each group of renewed exemptions were applicable on the dates stated in the discussions below and will expire on the dates provided below. Comments must be received on or before November 1, 2021.

ADDRESSES: You may submit comments identified by the Federal Docket Management System (FDMS) Docket No. FMCSA–2014–0385, Docket No. FMCSA–2014–0387, Docket No. FMCSA–2018–0139, or Docket No. FMCSA–2019–0109 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *www.regulations.gov/,* insert the docket number, FMCSA–2014–0385, FMCSA–2014–0387, FMCSA–2018–0139, or FMCSA–2019–0109 in the keyword box, and click ''Search.'' Next, sort the results by ''Posted (Newer-Older),'' choose the first notice listed, and click on the ''Comment'' button. Follow the online instructions for submitting comments.
- *Mail:* Dockets Operations; U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC, 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'' portion of the **SUPPLEMENTARY INFORMATION** section for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, (202) 366–4001, *fmcsamedical@dot.gov,* FMCSA, DOT, 1200 New Jersey Avenue SE, Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m., ET, Monday through Friday, except Federal holidays. If you have questions regarding viewing or submitting material to the docket, contact Dockets Operations, (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation

A. Submitting Comments

If you submit a comment, please include the docket number for this notice (Docket No. FMCSA–2014–0385, Docket No. FMCSA–2014–0387, Docket No. FMCSA–2018–0139, or Docket No. FMCSA–2019–0109), indicate the specific section of this 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 phone 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 *www.regulations.gov/,* insert the docket number, FMCSA–2014–0385, FMCSA–2014–0387, FMCSA–2018–0139, or FMCSA–2019–0109 in the keyword box, and click ''Search.'' Next, sort the results by ''Posted (Newer-Older),'' choose the first notice listed, click the ''Comment'' 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.

B. Viewing Comments

To view comments go to *www.regulations.gov.* Insert the docket number, FMCSA–2014–0385, FMCSA–2014–0387, FMCSA–2018–0139, or

FMCSA–2019–0109 in the keyword box, and click ''Search.'' Next, sort the results by ''Posted (Newer-Older),'' choose the first notice listed, and click ''Browse Comments.'' If you do not have access to the internet, you may view the docket online by visiting Dockets Operations in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.

C. Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its regulatory 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

Under 49 U.S.C. 31136(e) and 31315(b), FMCSA may grant an exemption from the FMCSRs for no longer than a 5-year period if it finds such exemption would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption. The statute also allows the Agency to renew exemptions at the end of the 5-year period. FMCSA grants medical exemptions from the FMCSRs for a 2-year period to align with the maximum duration of a driver's medical certification.

The physical qualification standard for drivers regarding hearing found in 49 CFR 391.41(b)(11) states that a person is physically qualified to drive a CMV if that person first perceives a forced whispered voice in the better ear at not less than 5 feet with or without the use of a hearing aid or, if tested by use of an audiometric device, does not have an average hearing loss in the better ear greater than 40 decibels at 500 Hz, 1,000 Hz, and 2,000 Hz with or without a hearing aid when the audiometric device is calibrated to American National Standard (formerly ASA Standard) Z24.5—1951.

This standard was adopted in 1970 and was revised in 1971 to allow drivers to be qualified under this standard while wearing a hearing aid, 35 FR 6458, 6463 (Apr. 22, 1970) and 36 FR 12857 (July 3, 1971).

The 12 individuals listed in this notice have requested renewal of their exemptions from the hearing standard in § 391.41(b)(11), in accordance with FMCSA procedures. Accordingly, FMCSA has evaluated these applications for renewal on their merits and decided to extend each exemption for a renewable 2-year period.

III. Request for Comments

Interested parties or organizations possessing information that would otherwise show that any, or all, of these drivers are not currently achieving the statutory level of safety should immediately notify FMCSA. The Agency will evaluate any adverse evidence submitted and, if safety is being compromised or if continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315(b), FMCSA will take immediate steps to revoke the exemption of a driver.

IV. Basis for Renewing Exemptions

In accordance with 49 U.S.C. 31136(e) and 31315(b), each of the 12 applicants has satisfied the renewal conditions for obtaining an exemption from the hearing requirement. The 12 drivers in this notice remain in good standing with the Agency. In addition, for Commercial Driver's License (CDL) holders, the Commercial Driver's License Information System and the Motor Carrier Management Information System are searched for crash and violation data. For non-CDL holders, the Agency reviews the driving records from the State Driver's Licensing Agency. These factors provide an adequate basis for predicting each driver's ability to continue to safely operate a CMV in interstate commerce. Therefore, FMCSA concludes that extending the exemption for each of these drivers for a period of 2 years is likely to achieve a level of safety equal to that existing without the exemption.

In accordance with 49 U.S.C. 31136(e) and 31315(b), the following groups of drivers received renewed exemptions in the month of October and are discussed below.

As of October 1, 2021, and in accordance with 49 U.S.C. 31136(e) and 31315(b), the following seven individuals have satisfied the renewal conditions for obtaining an exemption from the hearing requirement in the FMCSRs for interstate CMV drivers:

Azulita-Jane Camacho (AZ)
Wayne Crowl (IN)
Robert Culp (FL)
Charles Davis (AL)
Christopher Fisher (WA)
John Price (TX)
Jerrell McCrary (NC)

The drivers were included in docket number FMCSA–2014–0385 or FMCSA–2018–0139. Their exemptions are applicable as of October 1, 2021 and will expire on October 1, 2023.

As of October 10, 2021, and in accordance with 49 U.S.C. 31136(e) and 31315(b), the following three individuals have satisfied the renewal conditions for obtaining an exemption from the hearing requirement in the FMCSRs for interstate CMV drivers:

Kurt Bernabei; Steven Gandee (PA); Steven Robelia (WI)

The drivers were included in docket number FMCSA–2019–0109. Their exemptions are applicable as of October 10, 2021 and will expire on October 10, 2023.

As of October 22, 2021, and in accordance with 49 U.S.C. 31136(e) and 31315(b), the following two individuals have satisfied the renewal conditions for obtaining an exemption from the hearing requirement in the FMCSRs for interstate CMV drivers:

Richard Carter (MD) and Clinton Homon (IL)

The drivers were included in docket number FMCSA–2014–0387. Their exemptions are applicable as of October 22, 2021 and will expire on October 22, 2023.

V. Conditions and Requirements

The exemptions are extended subject to the following conditions: (1) Each driver must report any crashes or accidents as defined in § 390.5; and (2) report all citations and convictions for disqualifying offenses under 49 CFR 383 and 49 CFR 391 to FMCSA; and (3) each driver prohibited from operating a motorcoach or bus with passengers in interstate commerce. The driver must also have a copy of the exemption when driving, for presentation to a duly authorized Federal, State, or local enforcement official. In addition, the exemption does not exempt the individual from meeting the applicable CDL testing requirements. Each exemption will be valid for 2 years unless rescinded earlier by FMCSA. The exemption will be rescinded if: (1) the person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315(b).

VI. Preemption

During the period the exemption is in effect, no State shall enforce any law or regulation that conflicts with this

exemption with respect to a person operating under the exemption.

VII. Conclusion

Based upon its evaluation of the 12 exemption applications, FMCSA renews the exemptions of the aforementioned drivers from the hearing requirement in § 391.41 (b)(11). In accordance with 49 U.S.C. 31136(e) and 31315(b), each exemption will be valid for two years unless revoked earlier by FMCSA.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2021–21445 Filed 9–30–21; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2006–26367]

Motor Carrier Safety Advisory Committee; Charter Renewal

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Announcement of charter renewal of the Motor Carrier Safety Advisory Committee (MCSAC).

SUMMARY: FMCSA announces the charter renewal of the MCSAC, a Federal advisory committee that provides FMCSA with advice and recommendations on motor carrier safety programs and motor carrier safety regulations through a consensus process. This charter renewal is effective September 27, 2021, and will expire after 2 years unless it is renewed.

FOR FURTHER INFORMATION CONTACT: Ms. Shannon L. Watson, Senior Advisor to the Associate Administrator for Policy, Federal Motor Carrier Safety Administration, U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590, (202) 360–2925, *mcsac@dot.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to section 14 of the Federal Advisory Committee Act (Pub. L. 92–463), FMCSA is giving notice of the charter renewal for the MCSAC. The MCSAC was established to provide FMCSA with advice and recommendations on motor carrier safety programs and motor carrier safety regulations. The MCSAC comprises up to 25 voting representatives from safety advocacy, safety enforcement officials, labor, and industry stakeholders of motor carrier safety. Applicants from all backgrounds are encouraged to apply; the diversity of the Committee helps ensure the requisite range of views and expertise necessary to discharge its responsibilities. See the MCSAC website for details on pending tasks at *http://www.fmcsa.dot.gov/mcsac.*

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2021–21448 Filed 9–30–21; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2014–0214; FMCSA–2017–0180; FMCSA–2019–0033; FMCSA–2019–0034]

Qualification of Drivers; Exemption Applications; Epilepsy and Seizure Disorders

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice of renewal of exemptions; request for comments.

SUMMARY: FMCSA announces its decision to renew exemptions for five individuals from the requirement in the Federal Motor Carrier Safety Regulations (FMCSRs) that interstate commercial motor vehicle (CMV) drivers have ''no established medical history or clinical diagnosis of epilepsy or any other condition which is likely to cause loss of consciousness or any loss of ability to control a CMV.'' The exemptions enable these individuals who have had one or more seizures and are taking anti-seizure medication to continue to operate CMVs in interstate commerce.

DATES: Each group of renewed exemptions were applicable on the dates stated in the discussions below and will expire on the dates stated in the discussions below. Comments must be received on or before November 1, 2021.

ADDRESSES: You may submit comments identified by the Federal Docket Management System (FDMS) Docket No. FMCSA–2014–0214, Docket No. FMCSA–2017–0180, Docket No. FMCSA–2019–0033, or Docket No. FMCSA–2019–0034 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *www.regulations.gov/,* insert the docket number, FMCSA–2014–0214, FMCSA–2017–0180, FMCSA–2019–0033, or FMCSA–2019–0034 in the keyword box, and click ''Search.'' Next, sort the results by ''Posted (Newer-Older),'' choose the first notice listed, and click on the ''Comment'' button. Follow the online instructions for submitting comments.
- *Mail:* Dockets Operations; U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590–0001 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'' portion of the **SUPPLEMENTARY INFORMATION** section for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, (202) 366–4001, *fmcsamedical@dot.gov,* FMCSA, DOT, 1200 New Jersey Avenue SE, Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m., ET, Monday through Friday, except Federal holidays. If you have questions regarding viewing or submitting material to the docket, contact Dockets Operations, (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation

A. Submitting Comments

If you submit a comment, please include the docket number for this notice (Docket No. FMCSA–2014–0214, Docket No. FMCSA–2017–0180, Docket No. FMCSA–2019–0033, or Docket No. FMCSA–2019–0034), indicate the specific section of this 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 phone 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 *www.regulations.gov/,* insert the docket number, FMCSA–2014–0214, FMCSA–2017–0180, FMCSA–2019–0033, or FMCSA–2019–0034 in the keyword box, and click ''Search.'' Next, sort the results by ''Posted (Newer-Older),'' choose the first notice listed, click the ''Comment'' 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.

B. Viewing Comments

To view comments go to *www.regulations.gov.* Insert the docket number, FMCSA–2014–0214, FMCSA–2017–0180, FMCSA–2019–0033, or FMCSA–2019–0034 in the keyword box, and click ''Search.'' Next, sort the results by ''Posted (Newer-Older),'' choose the first notice listed, and click ''Browse Comments.'' If you do not have access to the internet, you may view the docket online by visiting Dockets Operations in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.

C. Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its regulatory 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

Under 49 U.S.C. 31136(e) and 31315(b), FMCSA may grant an exemption from the FMCSRs for no longer than a 5-year period if it finds such exemption would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption. The statute also allows the Agency to renew exemptions at the end of the 5-year period. FMCSA grants medical exemptions from the FMCSRs for a 2-year period to align with the maximum duration of a driver's medical certification.

The physical qualification standard for drivers regarding epilepsy found in 49 CFR 391.41(b)(8) states that a person is physically qualified to drive a CMV if that person has no established medical history or clinical diagnosis of epilepsy or any other condition which is likely to cause the loss of consciousness or any loss of ability to control a CMV.

In addition to the regulations, FMCSA has published advisory criteria [1] to assist Medical Examiners in determining whether drivers with certain medical conditions are qualified to operate a CMV in interstate commerce.

The five individuals listed in this notice have requested renewal of their exemptions from the epilepsy and seizure disorders prohibition in § 391.41(b)(8), in accordance with FMCSA procedures. Accordingly, FMCSA has evaluated these applications for renewal on their merits and decided to extend each exemption for a renewable 2-year period.

III. Request for Comments

Interested parties or organizations possessing information that would otherwise show that any, or all, of these drivers are not currently achieving the statutory level of safety should immediately notify FMCSA. The Agency will evaluate any adverse evidence submitted and, if safety is being compromised or if continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315(b), FMCSA will take immediate steps to revoke the exemption of a driver.

IV. Basis for Renewing Exemptions

In accordance with 49 U.S.C. 31136(e) and 31315(b), each of the five applicants has satisfied the renewal conditions for obtaining an exemption from the epilepsy and seizure disorders prohibition. The five drivers in this notice remain in good standing with the Agency, have maintained their medical monitoring and have not exhibited any medical issues that would compromise their ability to safely operate a CMV during the previous 2-year exemption period. In addition, for Commercial Driver's License (CDL) holders, the Commercial Driver's License Information System and the Motor Carrier Management Information System are searched for crash and violation data. For non-CDL holders, the Agency reviews the driving records from the State Driver's Licensing Agency. These factors provide an adequate basis for predicting each driver's ability to continue to safely operate a CMV in interstate commerce. Therefore, FMCSA concludes that extending the exemption for each renewal applicant for a period of 2 years is likely to achieve a level of safety equal to that existing without the exemption.

In accordance with 49 U.S.C. 31136(e) and 31315(b), the following groups of drivers received renewed exemptions in the month of October and are discussed below.

As of October 4, 2021, and in accordance with 49 U.S.C. 31136(e) and 31315(b), the following four individuals have satisfied the renewal conditions for obtaining an exemption from the epilepsy and seizure disorders prohibition in the FMCSRs for interstate CMV drivers:

Daniel Maben (MI)
Michael Miller (TX)
William Swann (MD)
Tyler Tilseth (NM)

The drivers were included in docket number FMCSA–2014–0214, FMCSA–2017–0180, or FMCSA–2019–0033. Their exemptions are applicable as of October 4, 2021 and will expire on October 4, 2023.

As of October 15, 2021, and in accordance with 49 U.S.C. 31136(e) and 31315(b), Adam Wilson (MN) has satisfied the renewal conditions for obtaining an exemption from the epilepsy and seizure disorders prohibition in the FMCSRs for interstate CMV drivers.

This driver was included in docket number FMCSA–2019–0034. The exemption is applicable as of October 15, 2021 and will expire on October 15, 2023.

V. Conditions and Requirements

The exemptions are extended subject to the following conditions: (1) Each driver must remain seizure-free and maintain a stable treatment during the 2-year exemption period; (2) each driver must submit annual reports from their treating physicians attesting to the stability of treatment and that the driver has remained seizure-free; (3) each driver must undergo an annual medical examination by a certified ME, as defined by § 390.5; and (4) each driver must provide a copy of the annual medical certification to the employer for retention in the driver's qualification file, or keep a copy of his/her driver's qualification file if he/she is self-employed. The driver must also have a copy of the exemption when driving, for presentation to a duly authorized Federal, State, or local enforcement official. The exemption will be

[1] These criteria may be found in APPENDIX A TO PART 391—MEDICAL ADVISORY CRITERIA, section H. *Epilepsy:* § 391.41(b)(8), paragraphs 3, 4, and 5, which is available on the internet at *https://www.gpo.gov/fdsys/pkg/CFR-2015-title49-vol5/pdf/CFR-2015-title49-vol5-part391-appA.pdf.*

rescinded if: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315(b).

VI. Preemption

During the period the exemption is in effect, no State shall enforce any law or regulation that conflicts with this exemption with respect to a person operating under the exemption.

VII. Conclusion

Based on its evaluation of the five exemption applications, FMCSA renews the exemptions of the aforementioned drivers from the epilepsy and seizure disorders prohibition in § 391.41(b)(8). In accordance with 49 U.S.C. 31136(e) and 31315(b), each exemption will be valid for 2 years unless revoked earlier by FMCSA.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2021–21446 Filed 9–30–21; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2016–0126]

Petition for Extension of Waiver of Compliance

Under part 211 of title 49 Code of Federal Regulations (CFR), this document provides the public notice that on September 14, 2021, the Capital Metropolitan Transportation Authority (CMTY) petitioned the Federal Railroad Administration (FRA) for an extension of a waiver of compliance from certain provisions of the Federal railroad safety regulations contained at 49 CFR 238.309, *Periodic brake equipment maintenance.* The relevant FRA Docket Number is FRA–2016–0126.

By letter dated July 7, 2020, FRA granted CMTY an extension of relief until December 31, 2021, in which to acquire brake components required for CMTY's four GTW G–4 diesel multiple units, due to manufacturing delays of the components. At this time, CMTY requests an additional six-month extension of the previously granted relief, as manufacturing delays are causing additional time to be needed for the final air brake kit to be rebuilt and recertified.

A copy of the petition, as well as any written communications concerning the petition, is available for review online at *www.regulations.gov.*

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 at *http://www.regulations.gov.* Follow the online instructions for submitting comments.

Communications received by November 15, 2021 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), the U.S. Department of Transportation (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/privacy-notice* for the privacy notice of *regulations.gov.*

Issued in Washington, DC.

John Karl Alexy,

Associate Administrator for Railroad Safety, Chief Safety Officer.

[FR Doc. 2021–21451 Filed 9–30–21; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Numbers FRA–2010–0044, FRA–2011–0104, and FRA–2018–0012]

Railroads' Requests To Amend Their Positive Train Control Safety Plans and Positive Train Control Systems

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Notice of availability and request for comments.

SUMMARY: This document provides the public with notice that three host railroads recently submitted requests for amendments (RFA) to their FRA-approved Positive Train Control Safety Plans (PTCSP). As these RFAs may involve requests for FRA's approval of proposed material modifications to FRA-certified positive train control (PTC) systems, FRA is publishing this notice and inviting public comment on railroads' RFAs to their PTCSPs.

DATES: FRA will consider comments received by October 21, 2021. FRA may consider comments received after that date to the extent practicable and without delaying implementation of valuable or necessary modifications to PTC systems.

ADDRESSES:

Comments: Comments may be submitted by going to *https://www.regulations.gov* and following the online instructions for submitting comments.

Instructions: All submissions must include the agency name and the applicable docket number. The relevant PTC docket numbers for the host railroads that filed RFAs to their PTCSPs are cited above and in the **SUPPLEMENTARY INFORMATION** section of this notice. For convenience, all active PTC dockets are hyperlinked on FRA's website at *https://railroads.dot.gov/train-control/ptc/ptc-annual-and-quarterly-reports.* All comments received will be posted without change to *https://www.regulations.gov;* this includes any personal information.

FOR FURTHER INFORMATION CONTACT: Gabe Neal, Staff Director, Signal, Train Control, and Crossings Division, telephone: 816–516–7168, email: *Gabe.Neal@dot.gov.*

SUPPLEMENTARY INFORMATION: In general, Title 49 United States Code (U.S.C.) Section 20157(h) requires FRA to certify that a host railroad's PTC system complies with 49 CFR part 236, subpart I, before the technology may be operated in revenue service. Before making certain changes to an FRA-certified PTC system or the associated FRA-approved PTCSP, a host railroad must submit, and obtain FRA's approval of, an RFA to its PTCSP under Title 49 Code of Federal Regulations (CFR) Section 236.1021.

Under 49 CFR 236.1021(e), FRA's regulations provide that FRA will publish a notice in the **Federal Register** and invite public comment in accordance with 49 CFR part 211, if an RFA includes a request for approval of a material modification of a signal and

train control system. Accordingly, this notice informs the public that host railroads' recent RFAs to their PTCSPs are available in their respective public PTC dockets, and this notice provides an opportunity for public comment on these RFAs.

On September 21, 2021, the following three host railroads jointly submitted an RFA to their respective PTCSPs for their Interoperable Electronic Train Management Systems (I–ETMS): Central Florida Rail Corridor (CFRC), TEXRail (TEX), and Trinity Railway Express (TRE). Their joint RFA is available in Docket Numbers FRA–2010–0044, FRA–2011–0104, and FRA–2018–0012.

Interested parties are invited to comment on any RFAs to railroads' PTCSPs by submitting written comments or data. During FRA's review of railroads' RFAs, FRA will consider any comments or data submitted within the timeline specified in this notice and to the extent practicable, without delaying implementation of valuable or necessary modifications to PTC systems. *See* 49 CFR 236.1021; *see also* 49 CFR 236.1011(e). Under 49 CFR 236.1021, FRA maintains the authority to approve, approve with conditions, or deny railroads' RFAs to their PTCSPs at FRA's sole discretion.

Privacy Act Notice

In accordance with 49 CFR 211.3, FRA solicits comments from the public to better inform its decisions. DOT posts these comments, without edit, including any personal information the commenter provides, to *https://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 https://www.regulations.gov/privacy-notice* for the privacy notice of *regulations.gov.* To facilitate comment tracking, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. If you wish to provide comments containing proprietary or confidential information, please contact FRA for alternate submission instructions.

Issued in Washington, DC.

Carolyn R. Hayward-Williams,

Director, Office of Railroad Systems and Technology.

[FR Doc. 2021–21337 Filed 9–30–21; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Requesting Comments on Tax-Exempt Organization Forms

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning all forms used by tax-exempt organizations. See Appendix A for a list of forms, schedules, and related attachments.

DATES: Written comments should be received on or before November 30, 2021 to be assured of consideration.

ADDRESSES: Direct all written comments to Paul Adams, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224. You must reference the information collection's title, form number, reporting or record-keeping requirement number, and OMB number in your comment.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Jon Callahan, (737) 800–7639, at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet at *jon.r.callahan@irs.gov.*

SUPPLEMENTARY INFORMATION: Today, 73 percent of all tax-exempt organization returns are prepared using software by the taxpayer or with preparer assistance. Section 3101 of the Taxpayer First Act, Public Law 116–25, requires all tax-exempt organizations to electronically file statements or returns in the Form 990 series or Form 8872.

These are forms used by tax-exempt organizations. These include Forms 990, 990–BL, 990–EZ, 990–N, 990–PF, 990–T, 990–W, and related forms and schedules tax-exempt organizations attach to their tax returns (see Appendix-A to this notice). In addition, there are numerous regulations, notices and Treasury Decisions that are covered by the burden estimate provided in this notice. See Appendix B for a list.

Taxpayer Compliance Burden

Tax compliance burden is defined as the time and money taxpayers spend to comply with their tax filing responsibilities. Time-related activities include recordkeeping, tax planning, gathering tax materials, learning about the law and what you need to do, and completing and submitting the return. Out-of-pocket costs include expenses such as purchasing tax software, paying a third-party preparer, and printing and postage. Tax compliance burden does not include a taxpayer's tax liability, economic inefficiencies caused by sub-optimal choices related to tax deductions or credits, or psychological costs.

Proposed PRA Submission to OMB

Title: U.S. Tax-Exempt Income Tax Return.

OMB Number: 1545–0047.

Form Numbers: Forms 990, 990–BL, 990–EZ, 990–N, 990–PF, 990–T, 990–W, 1023, 1023–EZ, 1024, 1024–A, 1028, 1120–POL, 4720, 5578, 5884–C, 5884–D, 6069, 6497, 7203, 8038, 8038–B, 8038–CP, 8038–G, 8038–GC, 8038–R, 8038–T, 8038–TC, 8282, 8328, 8330, 8453–TE., 8453–X, 8718, 8868, 8870, 8871, 8872, 8879–TE, 8886–T, 8899 and all other related forms, schedules, and attachments. (see Appendix-A to this notice).

Abstract: These forms and schedules are used to determine that tax-exempt organizations fulfill the operating conditions within the limitations of their tax exemption. The data is also used for general statistical purposes.

Current Actions: There have been changes in regulatory guidance related to various forms approved under this approval package during the past year. There has been additions and removals of forms included in this approval package. It is anticipated that these changes will have an impact on the overall burden and cost estimates requested for this approval package, however these estimates were not finalized at the time of release of this notice. These estimated figures are expected to be available by the release of the 30-comment notice from Treasury. This approval package is being submitted for renewal purposes only.

Type of Review: Revision of a currently approved collection.

Affected Public: Tax-Exempt Organizations.

Estimated Number of Responses: 1,599,000.

Total Estimated Time: 52.47 million hours.

Estimated Time per Respondent: 32.8 hours.

Total Estimated Out-of-Pocket Costs: $1.47 billion.

Estimated Out-of-Pocket Cost per Respondent: $921.

Total Estimated Monetized Burden (Labor Costs): $4.08 billion.

Estimated Total Monetized Burden (Labor Costs) per Respondent: $2,554.

Note: Amounts below are estimates for FY 2021. Reported time and cost burdens are national averages and do not necessarily reflect a ''typical'' case. Most taxpayers experience lower than average burden, with taxpayer burden varying considerably by taxpayer type. Totals may not add due to rounding.

FISCAL YEAR 2021 ICB ESTIMATES FOR FORM 990 SERIES OF RETURNS AND RELATED FORMS AND SCHEDULES

	FY 20	Program change due to agency discretion	FY 21
Number of Taxpayers	1,606,200	(7,200)	1,599,000
Burden in Hours	52,450,000	20,000	52,470,000
Out-of-Pocket Costs	$1,496,500,000	($23,400,000)	$1,473,100,000
Monetized Total Burden (Labor Costs)	$4,168,800,000	($84,700,000)	$4,084,100,000

Note: FY: 21 is most recent approved burden estimates for OMB number 1545–0047.

FISCAL YEAR 2021 FORM 990 SERIES TAX COMPLIANCE COST ESTIMATES

	Form 990	Form 990–EZ	Form 990–PF	Form 990–T	Form 990–N
Projections of the Number of Returns to be Filed with IRS	321,100	253,200	120,200	165,500	742,000
Estimated Average Time per Response (Hours)	85	45	47	40	2
Estimated Average Out-of-Pocket Costs per Response	$2,600	$500	$2,000	$1,500	$10
Estimated Average Monetized Burden (Labor Costs) per Response	$8,000	$1,200	$3,900	$4,400	$30
Estimated Total Time (Hours) for all Filers	27,220,000	11,450,000	5,600,000	6,570,000	1,630,000
Estimated Total Out-of-Pocket Costs for all Filers	$849,800,000	$139,000,000	$240,200,000	$237,300,000	$6,800,000
Estimated Total Monetized Burden	$2,559,000,000	$312,700,000	$467,800,000	$719,800,000	$24,900,000

Note: *Amounts above are for FY 2021. Reported time and cost burdens are national averages and don't necessarily reflect a ''typical'' case. Most taxpayers experience lower than average burden, with taxpayer burden varying considerably by taxpayer type. Detail may not add due to rounding.*

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: September 28, 2021.

Jon R. Callahan,

Tax Analyst.

Appendix-A

Form No.	Title
1023	Application for Recognition of Exemption Under Section 501(c)(3) of the Internal Revenue Code.
1023–EZ	Streamlined Application for Recognition of Exemption.
1024	Application for Recognition of Exemption Under Section 501(a).
1024–A	Application for Recognition of Exemption Under Section 501(c)(4) of the Internal.
1028	Application for Recognition of Exemption Under Section 521 of the Internal Revenue Code.
1120–POL	U.S. Income Tax Return for Certain Political Organizations.
4720	Return of Certain Excise Taxes on Charities and Other Persons Under Chapter 41 and 42 of the IRC.
5578	Annual Certification of Racial Nondiscrimination for a Private School Exempt From Federal Income Tax.
5884–C	Work Opportunity Credit for Qualified Tax-Exempt Organizations Hiring Qualified Veterans.

Form No.	Title
5884–D	Employee Retention Credit for Certain Tax-Exempt Organizations Affected by Qualified Disasters.
6069	Return of Excise Tax on Excessive Contributions of Black Lung Benefit Trust.
6497	Information Return of Nontaxable Energy Grants or Subsidized Energy Financing.
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[FR Doc. 2021–21379 Filed 9–30–21; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

Prosthetics and Special-Disabilities Programs, Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act, 5 U.S.C. app.2, that a virtual meeting of the Federal Advisory Committee on Prosthetics and Special-Disabilities Programs will be held on Monday, October 18–Tuesday, October 19, 2021. The meeting sessions will begin and end as follow:

Date	Time (Eastern Standard Time)
October 18, 2021	8:30 a.m.–4:30 p.m.
October 19, 2021	8:30 a.m.–3:00 p.m.

The virtual meeting sessions are open to the public.

The purpose of the Committee is to advise the Secretary of Veterans Affairs on VA's prosthetics programs designed to provide state-of-the-art prosthetics and the associated rehabilitation research, development, and evaluation of such technology. The Committee also provides advice to the Secretary on special-disabilities programs, which are defined as any program administered by the Secretary to serve Veterans with spinal cord injuries, blindness or visual impairments, loss of extremities or loss of function, deafness or hearing impairment, and other serious incapacities in terms of daily life functions.

On October 18, 2021 the Committee will convene open virtual sessions on Audiology and Speech Pathology; Blind Rehabilitation Service; Caregiver Support Program; Office of Academic Affiliations; Reasonable Accommodations (Diversity, Equity & Inclusion); and Prosthetic and Sensory Aids Service.

On October 19, 2021 the Committee members will convene open virtual sessions on Recreation and Creative Arts Therapies; National Veterans Sports Program and Special Events; and Subcommittees for Neurology Centers of Excellence.

No time will be allocated at this virtual meeting for receiving oral presentations from the public. The public may submit 1–2-page summaries of their written statements for the Committee's review. Public comments may be received no later than October 09, 2021 for inclusion in the official meeting record. Please send these comments to Judy Schafer, Ph.D., Designated Federal Officer, Rehabilitation and Prosthetic Services, Veterans Health Administration, at *Judy.Schafer@va.gov.*

Members of the public who wish to obtain a copy of the agenda, should contact Judy Schafer, Ph.D. at *Judy.Schafer@va.gov,* and provide your name, professional affiliation, email address, and phone number. For any members of the public that wish to attend virtually, they may use the WebEx link: *https://veteransaffairs.webex.com/veteransaffairs/j.php?MTID=m195d4026a5a13978ba8fcfd08ee9729b* meeting number (access code) 27617060216; meeting password: YKcMw7qV@67 audio only: 404.397.1596/27617060216##. Real time closed captioning will be available.

Dated: September 28, 2021.

LaTonya L. Small,

Federal Advisory Committee Management Office.

[FR Doc. 2021–21431 Filed 9–30–21; 8:45 am]

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Part II

Department of Transportation

Federal Aviation Administration

14 CFR Part 13

Update to Investigative and Enforcement Procedure; Final Rule

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 13

[Docket No.: FAA–2018–1051; Amdt. No.: 13–40]

RIN 2120–AL00

Update to Investigative and Enforcement Procedures

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

ACTION: Final rule.

SUMMARY: This final rule amends the procedural rules governing FAA investigations and enforcement actions. The revisions include updates to statutory and regulatory references, updates to agency organizational structure, elimination of inconsistencies, clarification of ambiguity, increases in efficiency, and improved readability.

DATES: Effective November 30, 2021.

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

FOR FURTHER INFORMATION CONTACT: For technical questions concerning this action regarding 14 CFR part 13, subparts A through C, E, and F, contact Cole R. Milliard, Office of the Chief Counsel, AGC–300, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone (202) 267–3452; email *Cole.Milliard@faa.gov,* or Jessica E. Kabaz-Gomez, Office of the Chief Counsel, AGC–300, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone (202) 267–7395; email *Jessica.Kabaz-Gomez@faa.gov.* For questions concerning this action regarding 14 CFR part 13, subparts D and G, contact John A. Dietrich, Office of the Chief Counsel, FAA Office of Adjudication, AGC–70, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone (202) 267–3433; email *John.A.Dietrich@faa.gov.*

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Authority for This Rulemaking

FAA's authority to issue rules on aviation safety is in title 49 of the United States Code. Subtitle I, section 106 describes the authority of the Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. The Administrator has authority to issue regulations and procedures necessary for safety in air commerce and national security under 49 U.S.C. 44701(a)(5). The Administrator also has authority to prescribe regulations he considers necessary to carry out Subtitle VII, Part A of title 49 under 49 U.S.C. 40113(a).

This rulemaking is promulgated under the authority of numerous additional statutes relevant to procedures and other rules covering a wide variety of enforcement actions. Generally, this rulemaking relies on the duties and powers delegated to the Administrator of FAA under 49 CFR 1.83. It also relies on the power of the Administrator to conduct investigations; prescribe regulations, standards, and procedures; and issue orders per 49 U.S.C. 40113–40114. Sections 46101–46110 of title 49 U.S.C. contain procedures and other requirements governing investigations, enforcement, complaints of violations, service, evidence, regulations and orders, and judicial review. Section 6002 of title 18 U.S.C. is the authority for witness immunity in FAA formal investigations (see 14 CFR 13.119).

The Administrator's duties and powers related to aviation safety in 49 U.S.C. 44701, and the authority of the Administrator to issue, amend, modify, suspend, and revoke certificates per 49 U.S.C. 44702–44703, 44709–44710, 44724, 44726, and 46111 also provide authority for this rulemaking. The rulemaking further relies on the Administrator's power to impose and collect civil penalties under 49 U.S.C. 46301. The Administrator's powers with respect to aircraft maintenance (49 U.S.C. 44713, 44725), aircraft registration (49 U.S.C. 44103–44106), aircraft noise levels (49 U.S.C. 47531–47532), airports (49 U.S.C. 47106, 47107, 47111, 47122, and 47306), and hazardous materials (49 U.S.C. 5121–5124) are also part of the authority for this rulemaking. These various authorities prescribe the standards enforced via the procedures provided in part 13.

I. Overview of Final Rule

This rulemaking revises subparts A through G of part 13, which provide procedural rules governing investigations and enforcement actions taken by FAA. It updates statutory and regulatory references, eliminates inconsistencies, clarifies ambiguity, increases efficiency, and improves readability. There are no substantive amendments to subpart B, which addresses administrative actions, or to subpart F, which governs formal fact-finding investigations under orders of investigation. This final rule does, however, include substantive amendments to subparts A, C, D, E, and G.

Subpart A addresses FAA's investigative procedures. Amendments include a new re-delegation provision in § 13.1, applicable to the whole of part 13; removal of current § 13.5(e), which addresses complaints filed against

members of the armed services, to align with the removal of current § 13.21; and the addition of a definition for the date of service of a written answer to a formal complaint in § 13.5(e) in this final rule as no definition is provided in current § 13.5(f), which § 13.5(e) replaces.

Subpart C addresses legal enforcement actions. This final rule provides a new emergency procedure allowing for an expedited administrative appeal process when issuing a notice under 14 CFR 13.20(d) simultaneously with a temporary emergency order under 49 U.S.C. 40113 and 46105(c). FAA is amending § 13.13 to update the list of required elements for a proposed consent order to include a withdrawal of all requests for hearing or appeals in any forum as well as an express waiver of attorney's fees and costs. This final rule also amends § 13.17(a) to replace the term ''operator'' with ''the individual commanding the aircraft'' to align with the underlying statute. Finally, this final rule removes § 13.29 pertaining to FAA enforcement procedures against individuals who present dangerous or deadly weapons for screening at airports or in checked baggage, as these proceedings are now under the Transportation Security Administration's authority.

Current subpart D provides the rules of practice applicable to FAA hearings involving legal enforcement actions pertaining to certain FAA-issued certificates, hazardous materials violations by any person, and other types of enforcement actions. This final rule amends the applicability section of subpart D to no longer apply to hearings for emergency orders of compliance issued under the Hazardous Materials Transportation Act,[1] because 49 CFR part 109, DOT Hazardous Material Procedural Regulations, now provides the procedures for this process.

Additional amendments to subpart D recognize the role and function of FAA's Office of Adjudication and provide for the use of alternative dispute resolution (ADR) procedures. This final rule consolidates sections relating to filing and service; updates addresses; allows for filing and service by fax and email; clarifies the discovery process, including a modification to the subpoena rule; and consolidates and incorporates the appeal procedures stated in other subparts of part 13 into subpart D. Finally, a new provision in subpart D at § 13.67 provides an expedited review process for the subjects of emergency orders to which § 13.20 applies.

[1] 49 U.S.C. 5101–5127.

Subpart E provides for orders of compliance under the Hazardous Materials Transportation Act. This final rule harmonizes procedures associated with notices of proposed orders of compliance and consent orders issued under subpart E with procedures for non-hazardous material notices and orders in subpart C. This final rule also moves subpart D-related provisions regarding rules of practice in hearings from subpart E to subpart D, and updates procedures that have been superseded by subsequent amendments to the hazardous material (hazmat) statutes. Finally, this final rule adds a new cross-reference to the procedures in 49 CFR part 109, subpart C, applicable to hazmat emergency orders issued by all DOT modes.

Subpart G provides the rules of practice in FAA civil penalty actions. Just as with subpart D, this final rule amends subpart G to include recognition of FAA's Office of Adjudication, the use of mediation as an ADR procedure, and the addition of fax and email as options for filing and service. This final rule also codifies the current practice of treating timely petitions for reconsideration of administrative law judge (ALJ) initial decisions as appeals to the FAA decisionmaker. Additionally, this final rule requires a party applying for a subpoena to make a showing of the general relevance and reasonable scope of the evidence sought by the subpoena. Other changes codify existing practices and create consistency within subpart G.

II. Background

A. Statement of the Problem

The majority of the rules in part 13 were last amended a decade or more ago. Since then, there have been statutory, organizational, and technological changes that necessitate updates. This rulemaking updates outdated statutory references and reflects the organizational changes made in FAA's Office of the Chief Counsel prior to the publication of the notice of proposed rulemaking (NPRM) (84 FR 3614, February 12, 2019), including the revised position titles and new offices within the Office of the Chief Counsel described in the NPRM.

Additionally, this final rule updates many antiquated provisions in the current part 13. Adoption of fax and email as additional options in the filing and service provisions make these administrative proceedings more efficient, expeditious, and cost-effective. The final rule also provides for use of ADR in subpart D and subpart G proceedings. ADR is now commonplace in Federal courts and other agencies, but has not been an option in the current part 13 provisions.

In some instances, the current rules do not reflect procedures and practices in part 13 that have evolved or been refined since the last amendment of these rules. This final rule captures these procedures and practices. For example, it incorporates the informal practice of serving the ALJ in subpart G civil penalty provisions in addition to the filing of documents with FAA's Hearing Docket. The final rule also codifies the current practice of treating certain motions and orders as notices of appeal to the FAA decisionmaker.

This final rule adds a new administrative appeal process for emergency orders to which § 13.20 applies. In the current regulation, the only recourse for litigating such an order is a direct appeal under 49 U.S.C. 46110 to a U.S. court of appeals, without an opportunity to develop a record through the administrative process before appellate review. The new process balances the Administrator's interest in responding to conditions posing an immediate threat to public safety with the interest of providing subjects of these emergency orders a meaningful post-deprivation administrative process.

Finally, many of the changes in this final rule address discrepancies between similar provisions across part 13 and harmonize the rules of practice in agency enforcement proceedings. Other amendments reword and reorganize provisions for clarity and ease of use.

B. Summary of the NPRM

The NPRM was published in the **Federal Register** on February 12, 2019 (84 FR 3614). The comment period for the NPRM closed on May 13, 2019. The NPRM proposed substantive amendments to subparts A, C, D, E, and G. Proposed amendments in the NPRM include:

- Streamlining and updating statutory and regulatory references, eliminating inconsistencies, clarifying existing ambiguities, increasing efficiency, and improving readability;
- Amending the required elements of proposed consent orders to include a withdrawal of any pending request for hearing or appeal and an express waiver of attorney's fees and costs;
- Adding service and filing by fax and email in subpart D and subpart G proceedings;
- Amending subparts D and G that recognize the role and function of FAA's Office of Adjudication;

• Clarifying, updating, and aligning the provisions in subparts D and G for requesting, quashing, modifying, and enforcing subpoenas;

• Adding ADR as an option for parties who have requested a subpart D or subpart G hearing (which may help lower the number of subpart D and subpart G hearings);

• Adding a request for an informal conference as an option for replying to a hazardous materials notice of proposed order of compliance issued under subpart E to reflect current practice and harmonize the options for responding to a notice throughout part 13;

• Adding an expedited administrative appeal process for emergency orders issued under 14 CFR 13.20, including orders of compliance and cease and desist orders, but not including hazardous materials orders that are separately addressed in subpart E; and

• Removing the ''mailing rule,'' in subpart G, that automatically extends parties' deadlines by five days when served by mail. Instead, a party requiring additional time would need to seek an extension of time.

C. General Overview of Comments

FAA received comments from nine commenters. Commenters included the Administrative Conference of the United States (ACUS), the Air Line Pilots Association (ALPA), the Aircraft Owners and Pilots Association (AOPA), the Experimental Aircraft Association (EAA), and the National Business Aviation Association (NBAA). These commenters generally supported the proposed changes. Some of these commenters, however, suggested changes, which FAA discusses in more detail later in this preamble. Additionally, four individuals commented. Some of the individuals' comments fell outside the scope of this rulemaking, and others are discussed in more detail later in this preamble.

FAA received comments on the following general areas of the proposal:

• FAA's Authority;
• Service of Formal Complaints;
• Date of Service of a Formal Complaint;
• FAA Actions Resulting from Formal Complaints;
• Administrative Actions;
• Consent Orders;
• Deposition Authority;
• Witness Fees;
• Record on Appeal;
• Appeals and Judicial Review;
• Expedited Proceedings;
• Dispute Resolution;
• Federal Docket Management System and Use of Email for Filing and Service;
• Time for Responding after Service by Mail;
• Valid Service of Documents;
• Disqualification/Recusal;
• Motion for a More Definite Statement; and
• Technological Advances in all Adjudications and Proceedings.

III. Discussion of Public Comments and Final Rule

A. FAA's Authority

Current § 13.3(a) notes the Administrator's statutory authority to conduct investigations and perform related functions, including the issuance of investigative subpoenas. Current § 13.3(b) contains the delegation of the Administrator's investigative powers for routine investigations to FAA's various services and offices for matters within their respective areas of oversight responsibility. It also delegates the Administrator's powers for compulsory processes to certain officials in the Office of the Chief Counsel. Current § 13.3(c) provides that those delegated officials in the Office of the Chief Counsel may issue orders of investigation per the formal investigation process in subpart F. Current § 13.3(d) addresses complaints about violations of certain airport-related laws.

In the NPRM, FAA proposed to revise § 13.3 to update and simplify the language by removing the statutory citations. FAA also proposed reorganizing § 13.3(b) and (c) so that § 13.3(b) would solely address the Administrator's delegation of investigative powers for routine investigations, and § 13.3(c) would pertain only to the Administrator's delegation of powers for certain compulsory processes. Further, FAA proposed revising § 13.3(c) by listing the actions authorized by the statutes cited in the second sentence of current § 13.3(b).

NBAA requested FAA combine proposed §§ 13.3(a) and (c) into a single paragraph. NBAA stated that proposed § 13.3(a) and (c) are duplicative and likely to cause misunderstandings about FAA's authority under proposed § 13.1. NBAA further asserted that confusion stemming from current § 13.3 has led to FAA issuing subpoenas that are not appropriately limited. It therefore requested that the rule be revised to limit the Administrator's authority to issue subpoenas to that provided in proposed §§ 13.57, 13.111, and 13.228. In support, NBAA stated that full procedural protections for challenging subpoenas are available in subparts D, F, and G. NBAA urged that if FAA needs to issue subpoenas, FAA should issue an Order of Investigation under subpart F. According to NBAA, FAA has ''unlimited discretion as to the scope of inquiry and limits due process while obtaining the very evidence FAA will then use against the company or individual to prosecute the FAA's case.'' Lastly, NBAA stated its concerns that subpoenas issued to individuals are contrary to the Pilot's Bill of Rights (PBR),[2] while subpoenas issued to businesses coerce production of evidence contrary to the Compliance Philosophy.[3]

FAA does not agree that § 13.3(a) and (c) are duplicative, or that they should be combined. Proposed § 13.1 applies to all of part 13 and provides broadly that the Chief Counsel, each Deputy Chief Counsel, and the Assistant Chief Counsel for Enforcement may redelegate any authority they have under part 13. Proposed § 13.3 mentions the powers of the Administrator generally with regard to investigations. Although proposed § 13.3(a) and (c) both include powers of the Administrator, these paragraphs are not duplicative. Proposed paragraph (a) contains the same list of the Administrator's statutory powers as in current § 13.3(a). Proposed paragraph (c) captures the delegation in the second sentence of current § 13.3(b), pertaining to the Administrator's statutory authority with regard to ''compulsory processes,'' to certain officials in the Office of the Chief Counsel.[4] Rather than use the vague description ''compulsory processes,'' proposed § 13.3(c) identifies what those processes are. Thus, some of the Administrator's powers mentioned in proposed paragraph (a) are delegated to certain officials in the Office of the Chief Counsel by proposed paragraph (c). These paragraphs also perform different functions; one describes, the other delegates.

Next, FAA does not agree that the subpoena authority provided by this rule should be limited in the manner requested by NBAA. Subpoenas issued under proposed § 13.3(c) (and proposed § 13.111 in the context of a formal investigation) are an exercise of the power of an administrative agency to investigate possible violations of and

[2] The Pilot's Bill of Rights, Public Law 112–153, 126 Stat. 1159 (2012) (codified at 49 U.S.C. 44703 note).

[3] Compliance Philosophy was renamed Compliance Program in October 2018. *https://www.faa.gov/about/initiatives/cp/* (last visited November 1, 2019).

[4] The sections of the Federal Aviation Act and Hazardous Materials Transportation Act cited there are now codified at 49 U.S.C. 40108, 40113, 40114, 45302, 46104 and 47122.

confirm compliance with law.[5] When FAA seeks to enforce one of these investigative subpoenas, it must show that ''the inquiry is within the authority of the agency, the demand is not too indefinite, and the information sought is reasonably relevant.''[6] So, contrary to NBAA's concerns, FAA's investigative subpoena power is not unlimited, and the subject of an investigative subpoena has a means to contest it. Finally, neither the PBR nor FAA's Compliance Program address investigative subpoenas. The PBR provisions NBAA refers to in its comment only concern Letters of Investigation.[7] FAA issues investigative subpoenas to obtain evidence during an investigation, while the decision to take compliance action occurs after conducting a thorough investigation.[8] FAA made no changes as a result of this comment.

Based on the foregoing discussion, FAA is not making any changes to its proposal for § 13.3 based on NBAA's comments. However, as explained in more detail in section III.S. of this preamble, the final rule amends proposed paragraph (c) of § 13.3 to align with the statutory language containing the delegated authority.

B. Service of Formal Complaints

The current § 13.5 provides that FAA will mail a copy of the formal complaint to ''each person named in the complaint.'' In the NPRM, FAA proposed to change this language so that FAA would mail a copy to ''the subject(s) of the complaint.''

EAA requested that FAA withdraw the proposed change in the language describing who would receive copies of a formal complaint. EAA stated the proposed change would mean that witnesses and ''interested parties'' mentioned in a complaint would not be entitled to receive a copy. In support of its comment, EAA cited the public nature of the concerns often raised by complaints.

FAA has consistently mailed copies of formal complaints only to those persons accused of a violation (''subjects''). The proposed language therefore matches FAA's longstanding practice. FAA finds it would be inappropriate to serve copies of a formal complaint on anyone other than those accused in the complaint. FAA uses the formal complaint, and answer if filed, to determine if there are reasonable grounds for an investigation. Even if there are reasonable grounds, the investigation may not substantiate a violation. Serving a copy of a complaint on persons whose names appear in the complaint, but who are not the individual alleged to have committed a violation (*e.g.,* a witness), is unnecessary, particularly when FAA has not yet determined if an investigation into the complaint is even appropriate. FAA can contact witnesses and other relevant parties as part of any investigation justified by the complaint. Further, release of the formal complaint to persons other than the alleged violator(s) could violate the Privacy Act, as a formal complaint may contain personally identifiable information (PII). Therefore, FAA has adopted this rule as proposed in the NPRM.

C. Date of Service of a Formal Complaint

Current § 13.5(f) requires that an answer to a complaint be filed within 20 days after service. In the NPRM, FAA proposed moving the provisions of current § 13.5(f) to § 13.5(e) and adding language to clarify that the date of service of the complaint is the date of mailing.

EAA requested that FAA not implement these proposed changes. EAA stated that using the date of mailing is contrary to ''due process notions of service and notice'' and fails to take into account lost mailings. According to EAA, this would conflict with the proposed language in § 13.18(e), which uses the date of receipt, as well as the PBR and Rule 4 of the Federal Rules of Civil Procedure. Lastly, EAA stated that the proposed change would create a presumption of service even when there is no constructive or actual service.

Using the date of mailing as the date of service is a common provision in both an FAA statute and in other procedural regulations.[9] Under 49 U.S.C. 46103(b)(1)(C) and (b)(2), the Administrator may generally serve a person by certified or registered mail, with the date of mailing deemed the date of service.[10] This is consistent with due process requirements.[11] Current and proposed §§ 13.43 and 13.211 provide that the date of mailing is the date of service on a party when a document is mailed in subpart D hearings. The NTSB's Rules of Practice in Air Safety Proceedings also designate the date of mailing to be the date of service.[12]

Concerns regarding PBR are misplaced, as the PBR does not apply to formal complaints. Section 2, paragraph (a) of the PBR states that a ''proceeding conducted under subpart C, D, or F of part 821 of title 49, Code of Federal Regulations, relating to denial, amendment, modification, suspension, or revocation of an airman certificate, shall be conducted, to the extent practicable, in accordance with the Federal Rules of Civil Procedure and the Federal Rules of Evidence.''[13] Formal complaints are not conducted under 49 CFR part 821, subpart C, D, or F. No other part of the PBR applies to formal complaints. FAA is therefore adopting the proposed rule without change.

Finally, EAA's reliance on proposed § 13.18(e) is misplaced. The proposed language in § 13.18(e) permits the Administrator to issue an order of assessment if an individual does not respond to a notice of proposed assessment within 15 days of receipt. Thus, it neither defines the date of service nor conflicts with proposed § 13.5(e).

D. FAA Actions Resulting From Formal Complaints

Current § 13.5(j) is restated in proposed § 13.5(g). In general, it provides that if an investigation resulting from a formal complaint substantiates any allegation of wrongdoing, FAA may take enforcement action.

EAA requested FAA revise proposed § 13.5(g) to allow the Administrator to issue administrative or compliance action when an investigation substantiates the allegations in a complaint, in accordance with FAA's compliance and enforcement order, FAA Order 2150.3C. EAA expressed

[5] *U.S.* v. *Morton Salt Co.,* 338 U.S. 632, 642–43 (1950).

[6] *Id.* at 652.

[7] PBR, section 2(b)(2)(C) and (D).

[8] FAA Order 2150.3C, Chapter 4, ¶ 2.b.

[9] *See NLRB* v. *Local 264, Laborers' Int'l Union of N. Am.,* 529 F.2d 778, 784 (8th Cir. 1976) (noting, in finding that NLRB had power to create rule establishing date of mailing as date of service, that this kind of rule was ''not novel or unique'' and that ''it had been explicitly sanctioned'' in Fed. R. Civ. P. 5(b) and several administrative agencies' procedures).

[10] *See Skydive Myrtle Beach Inc.* v. *Horry Cty. Dept. of Airports,* 735 F. App'x 810, 814 (4th Cir. 2018) (stating that § 46103(b) articulates the proper methods of service for proceedings resulting from the enforcement of Part A of Subtitle VII of Title 49); *cf. Avia Dynamics, Inc.* v. *FAA,* 641 F.3d 515, 520 (D.C. Cir. 2011) (holding that informal orders of an advisory nature are not subject to the procedural requirements in section 46103); *Adm'r* v. *Dangberg,* NTSB Order No. EA–5694, 2013 WL 7206204, at *3 (Dec. 18, 2013) (stating that in proceedings before National Transportation Safety Board, section 46103(b)(2), not Fed. R. Civ. P. 4, governs date of service for FAA orders served on certificate holders).

[11] *See Jones* v. *Flowers,* 547 U.S. 220, 226 (2006) (in which the Supreme Court stated that certified mail service is constitutionally sufficient where it is ''reasonably calculated to reach the intended recipient when sent'').

[12] 49 CFR 821.7(a)(4) and 821.8(e).

[13] Public Law 112–153, 126 Stat. 1159, section 2(a) (2012) (codified at 49 U.S.C. 44703 note).

concern that proposed § 13.5(g), because it solely references the issuance of a notice of proposed order or other enforcement action, could be construed to prohibit FAA from taking administrative action or compliance action.

FAA did not intend to limit its ability to choose an appropriate response to a violation of law, including taking administrative or compliance action. Therefore, in this final rule FAA has amended § 13.5(g) to make clear that the Administrator may take action in accordance with applicable law and FAA policy if an investigation substantiates allegations set forth in a complaint.

E. Administrative Actions

Section 13.11 currently states that FAA may take administrative action rather than legal enforcement action for a violation or apparent violation and defines such administrative action. In the NPRM, FAA proposed updating the statutory references and simplifying the language for readability, without changing the requirements of this section.

EAA and NBAA requested that FAA further amend § 13.11 to include compliance actions, consistent with FAA Order 8000.373A, ''Federal Aviation Administrative Compliance Program'' (which created compliance actions), as an option for addressing a violation.

The requested changes are unnecessary. FAA established the Compliance Program, including compliance actions, in 2015.[14] It is an agency policy relying in part on the agency's prosecutorial discretion. Accordingly, FAA did not need to codify it in its regulations. Instead, FAA implemented the policy in FAA Order 8000.373A and further addressed it in FAA Order 2150.3C, ''FAA Compliance and Enforcement Program,'' and FAA Order 8900.1, ''Flight Standards Information Management System.'' The absence of an express reference to compliance actions in part 13 does not prevent FAA from taking compliance actions where appropriate.

In addition, despite retaining the reference to administrative action, this rulemaking, and part 13 generally, focuses primarily on two areas: (1) How the Office of the Chief Counsel conducts legal enforcement actions; and (2) due process for those subject to legal enforcement action. Compliance actions are not legal enforcement actions, and the Office of the Chief Counsel does not administer compliance actions. Therefore, FAA did not change the final rule in response to these comments and adopts § 13.11 as proposed.

F. Consent Orders

Current § 13.13 addresses disposition of a legal enforcement action through a consent order. Paragraph (b) specifies the required contents for a consent order. In the NPRM, FAA proposed retaining most of the existing requirements and adding requirements for an express waiver of attorney's fees and costs, and a withdrawal of the request for hearing or notice of appeal.

NBAA requested that FAA amend the rule to allow for consent orders that do not include all the required terms listed in proposed § 13.13(b). In support of this request, NBAA expressed concern that the proposed changes to § 13.13(b) would take away the ability of the parties to negotiate consent order terms such as fees and costs, or waive these requirements in certain circumstances.

As a matter of practice, FAA's experience is that certain terms of a consent agreement are non-negotiable. This rule codifies FAA's expectations, for transparency. If the subject of an enforcement action wants the benefits of a consent order, it must be willing to include the terms in § 13.13(b). FAA did not change the final rule in response to this comment, and adopts this section as proposed.

G. Deposition Authority

Section 13.37 currently sets forth the powers of a hearing officer in subpart D hearings, while § 13.205 sets forth the powers of an ALJ in subpart G hearings. In the NPRM, FAA proposed clarifying revisions to these sections, including removing language regarding depositions from §§ 13.37(e) and 13.205(a)(3), adding language regarding discovery to § 13.37(h), and adding language allowing a hearing officer or ALJ to take any other authorized action as new paragraph (m) in § 13.37 and new paragraph (a)(11) in § 13.205.

EAA requested that FAA preserve the language regarding depositions in current §§ 13.37(e) and 13.205(a)(3). Specifically, EAA stated that despite the additional language proposed by FAA, these sections would no longer expressly empower hearing officers and ALJs to take or require depositions.

FAA does not agree to preserve this language. The proposed amendments to §§ 13.37(e) and 13.205(a)(3) do not eliminate the ability for hearing officers or ALJs to require the taking of depositions. Hearing officers retain the authority under § 13.37 to regulate discovery proceedings in subpart D hearings. Depositions are included as a form of discovery in proposed § 13.53(d). Parties may apply for a subpoena to require attendance at a deposition under § 13.57. In subpart G hearings, parties may serve notices of depositions, as described in proposed § 13.220(j)(3), and file motions to compel discovery under § 13.220(m). Inasmuch as both subparts D and G provide for depositions and motions to compel, FAA's proposed changes maintain the authority of hearing officers and ALJs with regard to depositions. Additionally, as EAA recognized, the proposed rule includes a catch-all power for hearing officers and ALJs to regulate depositions. FAA did not change the final rule in response to this comment and adopts the deposition authority as proposed.

H. Witness Fees

Current §§ 13.57 and 13.229 address witness fees in subpart D and subpart G hearings, respectively. Section 13.57(d) allows a hearing officer to shift the burden of paying a witness from the party requesting the witness's appearance to FAA under certain conditions. Section 13.229(a) requires the party requesting the witness's appearance to pay witness fees unless otherwise authorized by the ALJ. In the NPRM, FAA proposed, among other changes, removing these fee-shifting provisions.

EAA requested that FAA retain the fee-shifting authority in § 13.57(d) and incorporate it into § 13.229. In support of this request, EAA stated that FAA enjoys a financial advantage over respondents.

As explained in the NPRM, the current fee-shifting authority has not been used, is not supported by any identified statutory authority, and runs contrary to the American Rule [15] that parties pay their own costs. Parties seeking to recover fees and expenses in subpart G hearings may still pursue an award under the Equal Access to Justice Act of 1980 (''EAJA'') [16] and FAA's Rules Implementing the EAJA (14 CFR part 14). FAA did not change the final rule in response to this comment, and adopts §§ 13.57(d) and 13.229 as proposed.

I. Record on Appeal

Current § 13.63 describes the contents of the record in a subpart D hearing. The NPRM proposed redesignating the

[14] FAA Order 8000.373 (June 26, 2015) (canceled by Order 8000.373A in 2018); *see generally https://www.faa.gov/about/initiatives/cp/* (last visited July 7, 2020).

[15] *Alyeska Pipeline Service Co.* v. *Wilderness Society,* 421 U.S. 240 (1975).

[16] 28 U.S.C. 2412.

existing provisions as § 13.63(a) and adding new provisions at § 13.63(b) and (c).

EAA noted that the proposed amendment to § 13.63(a) may unintentionally exclude from the appeal record exhibits that are offered at the subpart D hearing but not admitted into evidence. The commenter added that the proposed language was inconsistent with proposed § 13.225 in subpart G.

FAA agrees that evidence offered as exhibits at a hearing but not admitted into evidence should still be a part of the record on appeal, as provided in the proposed subpart G provisions. FAA has amended § 13.63(a) in this final rule to clarify that the record on appeal will include evidence proffered but not admitted at the hearing, consistent with proposed §§ 13.225 and 13.230(a).

J. Appeals and Judicial Review

In the NPRM, FAA proposed adding a new § 13.65 to consolidate all provisions for appeals, motions for reconsideration, and petitions for judicial review for subpart D hearings into one section. Proposed § 13.65(e) delineates the authority of the Director of the Office of Adjudication as advisor to the Administrator for appeals.

EAA requested that FAA add a provision requiring notice and an opportunity for review. In support, EAA expressed concern that the proposed § 13.65(e) substantively expands the power of the Office of Adjudication.

The proposed revisions do not expand the power of the Office of Adjudication. Rather, § 13.65(e) merely codifies powers previously delegated to the Director of the Office of Adjudication by the FAA Administrator. Additional information on this delegation is contained in the Notice of Delegation of Authority published in the **Federal Register** on April 26, 2016 (81 FR 24686). FAA did not change the final rule in response to this comment, and adopts § 13.65(e) as proposed.

K. Expedited Proceedings

In the NPRM, FAA proposed adding a new § 13.67 to provide an expedited hearing and appeal process for emergency proceedings requested in accordance with § 13.20(d). New § 13.67(a) gives accelerated deadlines for developing the record, commencing the hearing, and issuing the hearing officer's decision.

EAA requested that FAA change the time for respondents to file an answer from 3 days to 10 days. In support of this request, EAA noted that three days is not enough time for a party to evaluate the complaint, secure counsel, and file an answer. EAA further distinguished the 3 days in the proposed rule from the 10 days allowed in proceedings before the National Transportation Safety Board (NTSB) under 49 CFR 821.53.

FAA finds that three days to provide an answer is reasonable considering an expedited hearing must commence within 40 days under proposed § 13.67(a)(6). The 40-day deadline is driven by the 80-day period during which FAA's time-limited (or temporary) emergency order is effective. The process in § 13.67 allows a respondent to have both a hearing and an appeal to the Administrator completed prior to the expiration of the 80-day time-limited immediately effective order. The subject of the action will already be familiar with the complaint, as proposed § 13.67(a)(2) provides that the Administrator files a copy of the notice of proposed action as the complaint. Under proposed §§ 13.20(d)(3) and 13.67(a)(2) and (3), the subject has 10 days from service of the notice of proposed action to appeal from the notice by requesting a hearing, FAA has 3 days after the receipt of the request for a hearing to file the notice as its complaint, and the subject has 3 days after receipt of the complaint to file an answer to the complaint. Therefore, a subject may have as many as 16 days (or more, considering holidays or weekend days that may extend deadlines per proposed § 13.45(a)) from first seeing the allegations in which to decide whether to secure counsel and to file an answer. FAA finds this provides adequate notice and time for subjects to secure counsel.

Additionally, the commenter's comparison to the NTSB's 10-day period for filing an answer is not germane, as that longer filing period only applies to answers filed in non-emergency NTSB appeals. For emergency appeals, the NTSB provides five days to answer, which is comparable to the period in subpart D.[17] The proposed § 13.67(a)(3) deadline is necessarily shorter than for actions that are not immediately effective, as the expedited process is designed to finish within 80 days. Additionally, the commenter's comparison to 49 CFR 821.53 is not germane as that provision does not address the time for filing an answer, but rather the time for an appeal of FAA's emergency order to the NTSB. FAA did not change the final rule in response to this comment, and adopts the provisions on expedited proceedings as proposed.

[17] 49 CFR 821.55(b).

L. Dispute Resolution

In the NPRM, FAA proposed adding new §§ 13.69 and 13.236 to provide parties pursuing an appeal under subpart D or G, respectively, an opportunity to resolve the matter through mediation. Both sections proposed that any mediator used be mutually acceptable to the parties and be prohibited from participating in a subsequent adjudication of the same matter.

Comment on Separation of Functions

NBAA requested that FAA revise the proposed rules to clarify that the Office of Adjudication will not be involved in mediation for any matter for which that Office could serve as an advisor to the Administrator. In support of this request, NBAA expressed concern about insufficient separation of functions if mediators in the Office of Adjudication provide ADR and then subsequently serve as an advisor to the Administrator in the same matter. NBAA further noted that since the Chief Counsel's office reorganized, field attorneys who handle civil penalty cases now report directly to the Assistant Chief Counsel for Enforcement, who is co-located in Washington, DC with the Director of the Office of Adjudication. FAA infers from this comment that NBAA is concerned that their proximity will erode the functional, organizational, and ethical boundaries between litigants, adjudicators, and mediators. NBAA requested that FAA make a similar clarification to the commercial space transportation regulations in 14 CFR part 406.

FAA declines to make the requested clarifications. Both §§ 13.69 and 13.236 already prohibit a mediator from participating in the adjudication of the same case. In addition, these rules do not prevent the parties from using a mediator from a source outside the Office of Adjudication. Regarding NBAA's request to amend the commercial space regulations in 14 CFR parts 400 through 460, this request is outside the scope of this rulemaking, which is limited to 14 CFR part 13. FAA did not make any changes to the final rule in response to this comment.

ACUS Guidance Comment

ACUS noted that the proposed rules provide for the use of mediation and make settlement procedures more flexible for both FAA and opposing parties. While ACUS did not request a specific change to the language in §§ 13.69 and 13.236, it suggested that FAA consider ACUS guidance materials

and model rules on ADR and settlement procedures.

FAA reviewed ACUS's comment and finds that the proposed ADR provisions are consistent with the Administrative Dispute Resolution Act of 1996 and the guidance materials and model rules cited by ACUS. FAA did not change the final rule in response to this comment.

Comment on Superfluity and Choice of Mediator

An individual commenter stated that the dispute resolution provisions in proposed §§ 13.69 and 13.236 are superfluous because DOT already encourages parties to use mediation.[18] The commenter requested that FAA's rule require only neutral, third-party mediators instead of in-house mediators, asserting that in-house mediators may be unfairly biased in favor of the DOT and FAA.

Regarding the individual commenter's statement that the new ADR provisions are superfluous given DOT's ADR policy statement, FAA explained in the NPRM that the proposed ADR provisions complement the DOT policy statement by codifying the use of voluntary mediation in FAA's regulations. FAA believes that this will ensure that parties are aware of their option to use mediation as they consider the overarching enforcement process described in subpart D. Contrary to the commenter's interpretation, these rules, which are adopted as proposed, do not require the use of FAA, DOT, or other government-employee mediators. Rather, the rules provide that the parties may engage the services of any mutually acceptable mediator.

M. Federal Docket Management System and Use of Email for Filing and Service

Current § 13.210 describes where and how to file documents for subpart G matters, as well as how to access documents filed with the Hearing Docket via the internet. It also defines the date of filing. In the NPRM, FAA proposed changes to § 13.210 to update addresses, provide for fax and email filing, and describe the date of filing for each method of filing. FAA also proposed to remove the provision in current paragraph (e) allowing accessibility to all documents in the Hearing Docket through the Federal Docket Management System (FDMS). In the preamble of the NPRM, FAA explained its intention to continue to provide the Administrator's final decisions on appeal, with an index, on its website.

EAA, NBAA, and an individual commenter requested that FAA continue using either FDMS or another electronic system for posting decisions and other filings. EAA and the individual commenter stated that the public should have access to all the materials currently available on FDMS, and its access should not be limited to final decisions available through FAA's website as proposed in the NPRM. The individual commenter also stated, that under the proposed rule, the public would have to subscribe to paid online reporting services for the materials currently available on FDMS, and suggested that this raises due process concerns.

NBAA noted the only reason given for the proposed change is administrative efficiency. NBAA stated the public would be better served by having the final decisions available in the same location as all U.S. Government documents instead of on FAA's website. Both NBAA and EAA stated that FAA's reason for the proposed change—administrative efficiency—does not outweigh the inefficiency and loss of benefit to the public that will result from the proposed change. Lastly, ACUS requested that FAA consider its guidance materials on electronic case management and providing access to adjudicative documents.

FAA's decision to discontinue use of FDMS balances costs and benefits to both FAA and the public associated with the change. Contrary to NBAA's assertion, FDMS is not where all U.S. Government documents are currently stored. Rather, FDMS is a centralized tool created and used mainly for rulemaking and public comments on rulemaking rather than for judicial dockets.

Further, while FDMS is suitable for receiving comments on rulemaking documents, it is different from systems like the Federal judiciary's Public Access to Court Electronic Records (PACER) and Case Management/Electronic Case Filing System (CM/ECF), or the Government Accountability Office's Electronic Protest Docketing System (EPDS). Systems such as CM/ECF and EPDS require parties to ensure private information is not included in documents filed into the case docket. Current § 13.210 requires parties to file documents by sending them to the Hearing Docket Clerk. The Hearing Docket clerk, in turn, must upload the documents to FDMS so that they are publicly accessible pursuant to current § 13.210(e). This places the responsibility on FAA to ensure that it does not release private, proprietary, or otherwise sensitive information in documents made publicly available. As a result, the FAA Hearing Docket clerk must review each filed paper document for sensitive information, create a version of each document that is publicly releasable, and submit the releasable version to FDMS staff for uploading into the system. Thus, using FDMS does not expedite filing; rather, it adds delay due to the time required for processing and creates an administrative burden on FAA.

Moreover, as ACUS recognizes, FAA may not post documents that are prohibited from public release under the Privacy Act, or exempted from release under the Freedom of Information Act (FOIA), meaning that what FAA posts on FDMS is only an incomplete representation of the official, paper docket. FAA can thoroughly review a document for Privacy Act and FOIA issues before releasing it in paper to each specific requester, whereas FDMS makes filings available to anyone who can access the internet.

As explained in the NPRM, the agency is mindful of the public's interest in cost-effective electronic filing and access to materials. Electronic docket systems such as PACER, CM/ECF, and EPDS impose user fees for electronic filing and access to documents. While FAA proposed to eliminate public internet access to the entire docket, the proposed changes do allow for electronic filing through email and fax without charging fees. Additionally, the Office of Adjudication will continue to publish and index Decisions and Orders of the FAA Administrator on its website, also without requiring a fee. Thus, FAA determined that the benefits provided to parties and to FAA outweigh any inefficiencies created by the proposed rule. FAA did not change the final rule in response to this comment.

Comment Urging Mandatory Email Filing

An individual commenter urged FAA to require email filing and email service for all documents in subpart G cases, rather than permitting the parties to choose their method of filing and service with the option of using email.

FAA declines to impose this requirement. By giving parties the choice to file and serve documents by email, rather than requiring it, FAA is permitting more efficient, expeditious, and cost-effective filing and service, without creating an undue hardship on parties lacking access to the internet. FAA did not change the final rule in response to this comment.

[18] DOT Statement of Policy on Alternative Dispute Resolution (67 FR 40367, June 12, 2002).

N. Time for Responding After Service by Mail

Section 13.211(e) currently allows parties in civil penalty proceedings to add five additional days to the prescribed period they have to respond to documents that are served by mail. In the NPRM, FAA proposed eliminating these five additional days to respond after service by mail.

AOPA, EAA, and an individual commenter requested FAA retain the ''five-day mailing rule'' by preserving the additional time provided in current § 13.211(e) to respond to documents served by mail. AOPA stated the five additional days adequately compensates for possible delays involved with service by mail. AOPA suggested that requiring a party to seek an extension of time if needed, as FAA explained in the NPRM, is less efficient and creates additional workload.

FAA agrees with the comments on the five-day mailing rule. This final rule restores the additional time provision to subpart G in § 13.211(g) and adds it to subpart D in § 13.45(b) to maintain consistency between both subparts. The final rule also updates the paragraph designation in § 13.45 to reflect the addition of the five-day mailing rule.

O. Valid Service of Documents

Section 13.211(g) currently defines ''valid service'' of documents in civil penalty proceedings. Current § 13.211(h) provides what constitutes a ''presumption of service.'' FAA proposed revising the provision on valid service and moving it from § 13.211(g) to § 13.211(f), as well as removing the presumption of service provisions in paragraph (h) as duplicative of the instructions for valid service.

EAA requested that FAA retain the presumption of service provision in current § 13.211(h). EAA asserted that the language deeming service valid in proposed paragraph (f) is significantly different from the current presumption of service language, which requires an acknowledgement of receipt. In addition, EAA asserted that FAA's proposed changes conflict with notions of due process and fairness, the PBR, and the intent of Fed. R. Civ. P. 4.

FAA agrees with the comments that the language deeming service valid in proposed paragraph (f) is significantly different from the current presumption of service language, which requires an acknowledgement of receipt. This final rule restores the provision defining ''presumption of service'' to § 13.211(h).

P. Disqualification/Recusal

Sections 13.39, 13.205(c), and 13.218(f)(6) address the disqualification and recusal of administrative adjudicators under their respective subparts. In the NPRM, FAA did not propose any changes to these regulations.

ACUS requested that FAA consider ACUS's guidance and its model rule on ALJ/hearing officer recusal. In support, ACUS stated that recusal is important for maintaining the integrity of an adjudication, protects the parties, and promotes public confidence in agency adjudication.

In light of the recommendations on Recusal Rules for Administrative Adjudicators (84 FR 2139, Feb. 6, 2019) cited in ACUS's comment, the agency notes that subpart D does not have procedural recusal provisions akin to those in § 13.205. As a result, FAA has amended this final rule by adding language to § 13.39 and proposed § 13.218(f)(6) to address motions for disqualification consistent with ACUS's guidance and model rule. This amendment, however, does not include a provision for interlocutory appeal of a disqualification decision, because subpart D (unlike subpart G) does not currently provide for interlocutory appeals. Rather, a party may appeal a disqualification decision under the general appeal provisions in proposed §§ 13.65 and 13.67(b). FAA has not amended the subpart G disqualification provisions in proposed § 13.205(c), as the proposed language provides more detail than the guidance and model rule cited by the commenter.

Q. Motion for a More Definite Statement

Current § 13.218(f)(3) describes how to file a motion for a more definite statement, whether by the complainant or respondent. In the NPRM, FAA proposed only grammatical and stylistic changes to § 13.218(f)(3).

AOPA and an individual commenter requested that FAA amend § 13.218(f)(3)(i) and (ii) to make them consistent with regard to the consequences of a party's failure to supply a more definite statement. Both AOPA and the individual commenter noted a discrepancy between proposed § 13.218(f)(3)(i) and proposed § 13.218(f)(3)(ii) in how an ALJ would handle a motion for a more definite statement depending on whether it is made by the complainant (FAA) or respondent. Proposed rule § 13.218(f)(3)(i) provides that if the complainant fails to provide a more definite statement, the ALJ ''may'' strike the offending statement. Proposed § 13.218(f)(3)(ii), however, states that if the respondent fails to provide a more definite statement, the ALJ ''must'' strike the offending statement. AOPA noted that the current regulations provide that the ALJ ''shall'' strike the offending statement regardless of which party failed to comply. AOPA requested that both provisions provide that the ALJ ''may'' strike the offending statement.

FAA has changed the final rule in response to this comment. FAA intended for both provisions to be changed from ''shall'' to ''may'' and has revised § 13.218(f)(3)(ii) to correct the typographical error in the NPRM.

R. Technological Advances in All Adjudications and Proceedings

ACUS requested that FAA consider ACUS's guidance and model rules for incorporating technology advances into discovery, case management, and hearings.

FAA has considered ACUS's guidance and model rules. However, the requested changes, including recommendations to add video hearings and use complex case management systems, go beyond the scope of this rulemaking. The rules do not prevent the use of advanced technology in managing a case. Video systems for hearings, for example, might be appropriate on a case-by-case basis or for a class of cases. If necessary, these matters can be addressed by standing orders issued under subpart D or specific orders of an ALJ or hearing officer. FAA did not change the final rule in response to this comment.

S. Other Differences Between the NPRM and the Final Rule

The final rule contains the following additional changes to correct style, format, inconsistencies, and typographical errors, including:

- Changing the verb tense in § 13.3(b) to provide that the Administrator ''has delegated'' certain authority, rather than ''may delegate'' authority, to more closely reflect the verb tense in the current rule.
- Reformatting § 13.3(c) to enumerate the list of delegated authority from the Administrator in separate paragraphs as § 13.3(c)(1) through (4), and adding a delegation for petitioning a court of the United States to enforce a subpoena or order as § 13.3(c)(5). FAA intended the proposed list of delegated authority in the NPRM to mirror the authority provided by the statutes cited in current § 13.3(b), which include the authority to petition a court of the United States to enforce a subpoena or order.
- Inserting ''formal'' to modify ''investigations'' in § 13.3(c)(2) as the Agency did not intend for this final rule to change the nature or scope of the existing delegations in § 13.3.

• Replacing the term ''subparagraph'' in § 13.15(c)(3) with ''paragraph'' for consistency with the organizational structure used in the Code of Federal Regulations.[19]

• Removing ''under 49 U.S.C. 46103'' from § 13.16(g) as the reference is unnecessary, and to make the service provisions in § 13.16(f) and (g) align.

• Changing § 13.17(a) from passive voice to active voice for readability.

• Adding the Chief Counsel to the delegation of authority in § 13.18(c) as provided in current § 13.18(c), as the omission was unintentional.

• Removing citation to 49 U.S.C. 46301(g) in § 13.18(h), as it does not apply to cases covered by § 13.18 and is not cited in current § 13.18(h).

• Adding a ''will'' to § 13.19(b)(1) to make clear that the notice issuance is mandatory.

• Replacing ''determination of an emergency'' with ''determination that safety in air transportation or air commerce requires the immediate effectiveness of an order'' in § 13.19(d) to conform to the language in the applicable statutory provisions.

• Adding headings to §§ 13.16(a) and (b), 13.20(a) and (b), 13.43(c)(3), 13.53(a), and 13.57(a) through (c) per **Federal Register** styling requirements.

• Correcting the cross-reference to subpart D in § 13.35(a).

• Replacing the reference to ''an order'' in § 13.63(a) with ''the hearing officer's decision'' and reformatting § 13.63(a) into § 13.63(a)(1), (2), and (3).

• Removing the cross-reference to ''§ 13.25'' in § 13.67(c) because 14 CFR 13.25 was removed.

• Removing the extraneous qualifier ''of this part'' from cross-references in §§ 13.101, 13.201, and 13.202.

• Removing the ''(a)'' paragraph level in § 13.201, as there is only one paragraph in that section.

• Streamlining the heading in § 13.205(b) by changing it from ''Limitations on the power of the administrative law judge'' to ''Limitations.''

• Removed ''on or after August 2, 1990, and'' from § 13.208(d) as it is no longer necessary.

• Replacing ''Portable Document Format'' with ''PDF'' in § 13.210(h).

• Adding the implied ''Not later than'' to § 13.228(a)(1) and (2), for grammatical completeness.

• Removing ''unless otherwise agreed by the parties'' in § 13.233(c) and (e), as duplicative of the exceptions stated in § 13.233(c)(1) and (2) and (e)(1) and (2). Removing the duplicative ''may'' from § 13.233(j).

[19] See 1 CFR 21.11.

• Updating §§ 13.16(g)(2), 13.17(e)(2), 13.18(a)(2), 13.19(b) introductory text and (b)(1), 13.45(a), 13.47, 13.49(a)(1) and (e), 13.57(b), 13.61, 13.65(d)(1) and (e)(1)(vii), 13.69(a), 13.75(b), 13.101(b), 13.123(b), 13.127, 13.207, 13.208(d)(3), 13.213(a), 13.217(f)(1), 13.218(f), 13.219(d), 13.220(i)(2), (k), (l)(1), and (n), 13.221, 13.222(a) and (b), 13.223, 13.232(a), 13.233(d)(1), (h), (j) introductory text, and (j)(1), 13.234(a), 13.235(d), and 13.236 to correct typographical errors, improve readability, and for stylistic consistency.

T. Redesignation Table

Current section	New section
Subpart A:	
N/A	§ 13.1.
§ 13.1	§ 13.2.
§ 13.3	§ 13.3.
§ 13.5(a)	§ 13.5(a).
§ 13.5(b)	§ 13.5(b).
§ 13.5(c)	§ 13.5(c).
§ 13.5(d)	§ 13.5(d).
§ 13.5(e)	Removed.
§ 13.5(f)	§ 13.5(e).
§ 13.5(g)	§ 13.5(f).
§ 13.5(h)	§ 13.5(f)(1).
§ 13.5(i)	§ 13.5(f)(2).
§ 13.5(j)	§ 13.5(g).
§ 13.5(k)	§ 13.5(h).
§ 13.7	§ 13.7.
Subpart B:	
§ 13.11	§ 13.11.
Subpart C:	
§ 13.13(a)	§ 13.13(a).
§ 13.13(b)	§ 13.13(b).
§ 13.13(c)	§ 13.13(b)(5).
§ 13.14	Removed.
§ 13.15(a)	§ 13.15(a).
§ 13.15(b)	§ 13.15(b).
§ 13.15(c)(1)	§ 13.15(c)(1).
§ 13.15(c)(2)	§ 13.15(c)(2)(ii), (c)(3), (c)(4).
§ 13.15(c)(3)	§ 13.15(c)(2)(i).
§ 13.15(c)(4)	§ 13.15(c)(2)(i).
§ 13.15(c)(5)	§ 13.15(c)(5).
§ 13.16(a)–(c)	§ 13.16(a)–(c).
§ 13.16(d)	§ 13.16(e).
§ 13.16(e)	§ 13.16(d).
§ 13.16(f)–(j)	§ 13.16(f)–(j).
§ 13.16(k)	§ 13.15(l).
§ 13.16(l)	§ 13.15(m).
§ 13.16(m)	§ 13.15(k).
§ 13.16(n)	§ 13.16(n).
§ 13.17	§ 13.17.
§ 13.18	§ 13.18.
§ 13.19(a)–(b)	§ 13.19(a).
§ 13.19(c)	§ 13.19(b).
§ 13.19(d)	Removed.
N/A	§ 13.19(c).
N/A	§ 13.19(d).
§ 13.20(a)	§ 13.20(a).
§ 13.20(b)	§ 13.20(b).
§ 13.20(c)	§ 13.20(c)(1).
§ 13.20(d)	§ 13.20(c)(2).
§ 13.20(e)	§ 13.20(c)(4).
§ 13.20(f)	§§ 13.20(c)(3), 13.63(b).
§ 13.20(g)	§ 13.65(a).
§ 13.20(h)	§ 13.65(b).
§ 13.20(i)	§ 13.65(c).
§ 13.20(j)	§ 13.65(d).
§ 13.20(k)	§ 13.45(c).
§ 13.20(l)	§ 13.20(f).
§ 13.20(m)	Removed.
N/A	§ 13.20(e).
§ 13.21	Removed.
§ 13.23	Removed.
§ 13.25	Removed.
§ 13.27	Removed.
§ 13.29	Removed.
Subpart D:	
§ 13.31	§ 13.31.
§ 13.33	§ 13.33(b).
N/A	§ 13.33(a), (c).
§ 13.35(a)	§ 13.35(a), § 13.43(c).
§ 13.35(b)	§ 13.35(a).
§ 13.35(c)	§ 13.35(c).
§ 13.35(d)	§ 13.35(b).
§ 13.37(a)–(j)	§ 13.37(a)–(j).
N/A	§ 13.37(k).
§ 13.37(k)	§ 13.37(l).
N/A	§ 13.37(m).
§ 13.39	§ 13.39.
N/A	§ 13.41.
§ 13.43(a)	§ 13.43(a).
N/A	§ 13.43(b)–(d), (e).
§ 13.43(b)	§ 13.43(f).
§ 13.43(c)	§ 13.43(g).
§ 13.43(d)	§ 13.43(h).
§ 13.43(e)	§ 13.43(h).
§ 13.44	§ 13.45(a).
N/A	§ 13.45(b).
§ 13.44(b)	§ 13.45(c), (d).
§ 13.45	§ 13.47(b).
§ 13.47	§ 13.47(a).
§ 13.49(a)	§ 13.49(a)(1).
N/A	§ 13.49(b).
§ 13.49(c)	§ 13.49(a)(2).
§ 13.49(d)	§ 13.49(c).
§ 13.49(e)	§ 13.49(d).
§ 13.49(f)	§ 13.49(e).
§ 13.49(g)	Removed.
N/A	§ 13.49(g).
§ 13.49(h)	§ 13.49(h).
§ 13.51	§ 13.51.
§ 13.53	§ 13.53(d).
N/A	§ 13.53(a)–(c), (e).
§ 13.55	§ 13.55.
§ 13.57(a)	§ 13.57(a).
§ 13.57(b)	§ 13.57(b).
§ 13.57(c)	§ 13.57(c).
§ 13.57(d)	Removed.
N/A	§ 13.57(d).
N/A	§ 13.57(e).
N/A	§ 13.57(f).
§ 13.59(a)	§ 13.59(a).
§ 13.59(b)	§ 13.59(b).
§ 13.59(c)	§ 13.49(f).
§ 13.61	§ 13.61.
§ 13.63	§ 13.63(a).
N/A	§ 13.63(b)–(c).
N/A	§ 13.65.
N/A	§ 13.67.
N/A	§ 13.69.
Subpart E:	
§ 13.71	§ 13.71.
§ 13.73	§ 13.73.
§ 13.75	§ 13.75.
§ 13.77	§ 13.77.
§ 13.79	§ 13.63(b).
§ 13.81(a)	§ 13.81(a).
§ 13.81(b)	Removed.
§ 13.81(c)	§ 13.81(b).
§ 13.81(d)	§ 13.81(c).
§ 13.81(e)–(g)	Removed.
§ 13.83(a)	§ 13.65(a).
§ 13.83(b)	Removed.
§ 13.83(c)	Removed.
§ 13.83(d)	§ 13.65(b).
§ 13.83(e)	§ 13.65(c).
§ 13.83(f)	Removed.
§ 13.83(g)	§ 13.65(d).
§ 13.83(h)	Removed.
§ 13.85	Removed.
§ 13.87	§ 13.45(b)–(c).
Subpart F:	
§ 13.101	§ 13.101.
§ 13.103	§ 13.103.
§ 13.105	§ 13.105.
§ 13.107	§ 13.107.
§ 13.109	§ 13.109.
§ 13.111	§ 13.111.

Current section	New section
§ 13.113	§ 13.113.
§ 13.115	§ 13.115.
§ 13.117	§ 13.117.
§ 13.119	§ 13.119.
§ 13.121	§ 13.121.
§ 13.123	§ 13.123.
§ 13.125	§ 13.125.
§ 13.127	§ 13.127.
§ 13.129	§ 13.129.
§ 13.131	§ 13.131.
Subpart G:	
§ 13.201	§ 13.201.
§ 13.202	§ 13.202.
§ 13.203	§ 13.203.
§ 13.204	§ 13.204.
§ 13.205(a)(1)–(9)	§ 13.205(a)(1)–(9).
§ 13.205(b)	§ 13.205(a)(10), (b).
N/A	§ 13.205(a)(11).
§ 13.205(c)	§ 13.205(c).
§ 13.206	§ 13.206.
§ 13.207	§ 13.207.
§ 13.208	§ 13.208.
§ 13.209(a)	§ 13.209(a).
§ 13.209(b)	§ 13.209(a)–(b), (d), § 13.210.
§ 13.209(c)	§ 13.209(c).
§ 13.209(d)	§ 13.209(d).
§ 13.209(e)	§ 13.209(e).
§ 13.209(f)	§ 13.209(f).
§ 13.210(a)	§ 13.210(a), (b), (c), (g).
§ 13.210(b)	§ 13.210(d).
§ 13.210(c)	§ 13.210(e).
§ 13.210(d)	§ 13.210(f).
§ 13.210(e)	Removed.
N/A	§ 13.210(h).
§ 13.211(a)	§ 13.211(a).
§ 13.211(b)	§ 13.211(c).
§ 13.211(c)	§ 13.211(d).
§ 13.211(d)	§ 13.211(e).
§ 13.211(e)	§ 13.211(g).
§ 13.211(f)	§ 13.211(b).
§ 13.211(g)	§ 13.211(f).
§ 13.211(h)	§ 13.211(h).
§ 13.212	§ 13.212.
§ 13.213	§ 13.213.
§ 13.214	§ 13.214.
§ 13.215	§ 13.215.
§ 13.216	§ 13.216.
§ 13.217	§ 13.217.
§ 13.218	§ 13.218.
N/A	§ 13.218(f)(7).
§ 13.219	§ 13.219.
§ 13.220	§ 13.220.
§ 13.221	§ 13.221.
§ 13.222	§ 13.222.
§ 13.223	§ 13.223.
§ 13.224	§ 13.224.
§ 13.225	§ 13.225.
§ 13.226	§ 13.226.
§ 13.227	§ 13.227.
§ 13.228	§ 13.228.
§ 13.229	§ 13.229.
§ 13.230	§ 13.230.
§ 13.231	§ 13.231.
§ 13.232(a)	§ 13.232(a).
§ 13.232(b)	§ 13.232(b).
§ 13.232(c)	§ 13.232(c).
§ 13.232(d)	§ 13.232(e).
N/A	§ 13.232(d).
§ 13.233	§ 13.233.
§ 13.234	§ 13.234.
§ 13.235	§ 13.235.
N/A	§ 13.236.

IV. Regulatory Notices and Analyses

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

FAA has determined that this final rule is not a ''significant regulatory action'' as defined in section 3(f) of Executive Order 12866, and is not ''significant'' as defined in DOT's Regulatory Policies and Procedures. This final rule will not result in an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal government or communities. It will not cause a serious inconsistency or otherwise interfere with an action taken or planned by another agency, as this project only concerns FAA. It would not materially alter the budgetary impact of entitlements, grants, user fees, or loan programs, or the rights and obligations of recipients thereof, as it does not impact on any of these things. It would not raise novel legal issues, as the amendments it makes are based on established law and precedent. Finally, this final rule complies with DOT's Regulatory Policies and Procedures.

A. Regulatory Evaluation

This portion of the preamble summarizes the FAA's analysis of the economic impacts of this rule. This rule amends FAA's investigative and enforcement procedures to update position title references and reflect organizational changes in the Office of the Chief Counsel, updates outdated statutory and regulatory references, updates outdated addresses, and provides uniformity across part 13. The rule also reorganizes and rewords existing provisions to eliminate inconsistencies, clarify ambiguity, increase efficiency, and improve readability. These changes will ensure that the public has current information and rule language that is easier to understand. The cost of these changes is minimal.

This final rule also provides the option for an expedited administrative process to subjects of emergency orders to which § 13.20 applies. Currently, part 13 does not provide for an expedited administrative process for the subjects of such orders. The only recourse for litigating such an order is a direct appeal under 49 U.S.C. 46110 to a U.S. court of appeals, which can be costly and slow. This final rule adds the option of an expedited administrative hearing before a hearing officer followed by an expedited administrative appeal to the Administrator. The expedited process is consistent with existing processes for issuing other types of emergency orders and notices of proposed actions. Also, expedited subpart D proceedings are not new, as current subpart E uses subpart D procedures for appeals of hazardous materials emergency orders of compliance issued under current § 13.81(a). Because the new expedited procedures process is similar to existing processes, the costs stemming from the new process will be minimal. Finally, parties could appeal an order issued after exhaustion of the expedited administrative process to a U.S. court of appeals under 49 U.S.C. 46110.

The expedited administrative process may also lead to an efficient resolution of the matter without an appeal to a U.S. court of appeals. This could result in avoided initial filing fees. An appeal to a U.S. court of appeals requires an initial $500 filing fee [20] versus no initial filing fee in the expedited administrative process. Expedited administrative proceedings could reduce time and costs for affected parties compared to an appeal to a U.S. court of appeals. Potential cost savings might result because of net savings in attorneys' fees, *i.e.,* the difference in cost of hiring an attorney for a potentially lengthy U.S. court of appeals case versus the expedited administrative process. In addition, the expedited administrative process could resolve the matter in a far shorter time than a U.S. court of appeals, as the Administrator must issue the final order in the expedited administrative process within 80 days. U.S. court of appeals cases, on the other hand, could result in protracted litigation costs. Additionally,

[20] *https://www.uscourts.gov/services-forms/fees/court-appeals-miscellaneous-fee-schedule.*

a direct appeal to a U.S. court of appeals could require a remand to the agency for it to consider matters that otherwise could have been resolved under the expedited administrative process. After exhaustion of the expedited administrative process, a respondent could still appeal to a U.S. court of appeals. Even if a respondent resorts to judicial review first, the court of appeals has discretion to require further administrative proceedings, if, for example, the court believes doing so would help develop the record in the case. Therefore, even if the case is not resolved by the expedited administrative process, the U.S. court of appeals could use records developed during that process, reducing the potential costs of a judicial appeal.

As FAA does not know how many persons subject to emergency orders would opt for expedited hearings, and of these how many would end up before a U.S. court of appeals, FAA cannot conclude how many persons would potentially receive cost savings. However, FAA expects small cost savings because emergency orders issued under § 13.20 are infrequent.

The rule also provides the additional option of using mediation as an ADR procedure in actions under subparts D and G to reduce the potential burden associated with litigating these matters. Litigation could be avoided if mediation results in a mutually agreeable outcome. If mediation is successful and parties can avoid litigation, there is the potential for cost savings as the cost of mediation is likely to be less than that of litigation.

As with the option for an expedited hearing, mediation may not fully resolve a matter and the respondent may still choose to litigate. However, mediation may reduce the cost of litigation because it can narrow issues and provide for greater cooperation during discovery. FAA does not know how many parties would participate in a mediation process. The annual average number of subpart D and G cases received by the FAA Hearing Docket from 2015 through 2019 was 41. FAA estimates that the average annual number of parties opting for mediation would likely not exceed this number. As FAA expects the cost savings of opting for mediation will be minimal, FAA concludes that the total cost savings of providing this option will be minimal.

This final rule also adds the less burdensome options of serving and filing a single copy of a document in subpart D and G proceedings by email or fax. This has the potential of minimal cost savings. Currently, the parties must file by mail or personally deliver an original and a copy of each document, and serve a copy on each party. Service by these methods imposes costs not applicable to emailing or faxing, like postage, copying, and delivery fees.

This final rule also removes the FAA Hearing Docket Clerk's authority in civil penalty cases under subpart G to issue blank subpoenas upon request by a party, and instead requires a party applying for a subpoena to show the general relevance and reasonable scope of the evidence sought by the subpoena. Under this final rule, only the ALJ will have the authority to issue a subpoena upon a showing of the general relevance and reasonable scope of the evidence sought by the subpoena. The burden is on the party requesting the subpoena to prove it is appropriate. Because this change could avoid subpoenas that impose irrelevant and burdensome requests for testimony, documents, and tangible things, it is potentially cost saving.

Finally, current § 13.210(e)(1) explains that materials filed in FAA's Hearing Docket in civil penalty adjudications are made publicly available on the FDMS website, *www.regulations.gov.* FAA is discontinuing use of the FDMS website for such materials, but will continue to make Administrator final decisions available on FAA's website. Based on current billing, this rule will save FAA approximately $50,000 per year from discontinuing the use of the FDMS website for part 13 adjudication docket materials.[21] Over a 10-year period of analysis this cost savings would total about $500,000 or about $351,179 present value at a 7% discount rate.

FAA concludes that this rule will result in small cost savings as explained herein.

B. Regulatory Flexibility Determination

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

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

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

This final rule is likely to affect a substantial number of small entities, but as it will provide small cost savings it is not expected to have a significant economic impact on a substantial number of small entities.

This final rule codifies current practice, and rewrites and reorganizes a part of the CFR to make it more understandable. It updates outdated references and addresses. It adds less burdensome and faster-moving administrative appeal options. It also adds less burdensome options for serving and filing papers. It may eliminate some requests for subpoenas that otherwise would cost parties or subpoenaed persons time and money to defend against. FAA has determined this final rule will result in small cost savings.

If an agency determines that a rulemaking will not result in a significant economic impact on a substantial number of small entities, the head of the agency may so certify under section 605(b) of the RFA. Therefore, as provided in section 605(b) and based on the foregoing, the head of FAA certifies that this final rule does not result in a significant economic impact on a substantial number of small entities.

C. International Trade Impact Assessment

The Trade Agreements Act of 1979 (Pub. L. 96–39), as amended by the Uruguay Round Agreements Act (Pub. L. 103–465), prohibits Federal agencies from establishing standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. Pursuant to these Acts, the establishment of standards is not considered an unnecessary obstacle to the foreign commerce of the United States, so long as the standard has a

[21] Savings based on the portion of FAA's total annual billing costs for dockets and FDMS services attributable to adjudication materials.

legitimate domestic objective, such as the protection of safety, and does not operate in a manner that excludes imports that meet this objective. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards.

FAA has assessed the potential effect of this final rule and determined that it would impose the same small cost savings on domestic and international entities and thus has a neutral trade impact.

D. Unfunded Mandates Assessment

Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed or final agency rule that may result in an expenditure of $100 million or more (in 1995 dollars) in any one year by State, local, and tribal governments, in the aggregate, or by the private sector; such a mandate is deemed to be a ''significant regulatory action.'' FAA currently uses an inflation-adjusted value of $155 million in lieu of $100 million. This final rule does not contain such a mandate; therefore, the requirements of Title II of the Act do not apply.

E. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) requires that FAA consider the impact of paperwork and other information collection burdens imposed on the public. According to the 1995 amendments to the Paperwork Reduction Act (5 CFR 1320.8(b)(3)(vi)), an agency may not collect or sponsor the collection of information, nor may it impose an information collection requirement unless it displays a currently valid Office of Management and Budget (OMB) control number.

In the proposed rule, FAA identified one provision with Paperwork Reduction Act (PRA) implications that will require a new OMB control number: § 13.5. FAA did not receive any comments regarding its proposed revision to the information collection in § 13.5. However, as FAA was developing this final rule, it realized that it had not provided the notice required by 5 CFR part 1320. Accordingly, on August 4, 2020, the FAA published its 60-day PRA notice, 85 FR 47288. FAA received no comments in response to the notice. The FAA received OMB Control No. 2120–0795 for the information collection in § 13.5. The FAA will be publishing the final 30-day PRA notice requesting public comment. FAA notes that the provision of this final rule that requires information collection request approval will be effective upon OMB approval.

F. International Compatibility and Cooperation

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

G. Environmental Analysis

FAA Order 1050.1F identifies FAA actions that are categorically excluded from preparation of an environmental assessment or environmental impact statement under the National Environmental Policy Act in the absence of extraordinary circumstances. FAA has determined this rulemaking action qualifies for the categorical exclusion identified in paragraph 5–6.6 and involves no extraordinary circumstances.

V. Executive Order Determinations

A. Executive Order 13132, Federalism

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

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

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

C. Executive Order 13609, Promoting International Regulatory Cooperation

Executive Order 13609, Promoting International Regulatory Cooperation, promotes international regulatory cooperation to meet shared challenges involving health, safety, labor, security, environmental, and other issues and to reduce, eliminate, or prevent unnecessary differences in regulatory requirements. FAA has analyzed this action under the policies and agency responsibilities of Executive Order 13609, and has determined that this action will have no effect on international regulatory cooperation.

D. Executive Order 13892, Promoting the Rule of Law Through Transparency and Fairness

Executive Order 13892, Promoting the Rule of Law Through Transparency and Fairness in Civil Administrative Enforcement and Adjudication, promotes transparency to the regulated community when agencies conduct enforcement actions and adjudications. FAA has analyzed this action and determined it incorporates the policy and principles articulated in the Executive order.

VI. How To Obtain Additional Information

A. Rulemaking Documents

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

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

Copies may also be obtained by sending a request (identified by notice, amendment, or docket number of this rulemaking) to the Federal Aviation Administration, Office of Rulemaking, ARM–1, 800 Independence Avenue SW, Washington, DC 20591, or by calling (202) 267–9677.

B. Comments Submitted to the Docket

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

C. Small Business Regulatory Enforcement Fairness Act

The Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996 requires FAA to comply with small entity requests for information or advice about compliance with statutes and regulations within its jurisdiction. A small entity with questions regarding this document, may contact its local FAA official, or the person listed under the **FOR FURTHER INFORMATION CONTACT**

heading at the beginning of the preamble. To find out more about SBREFA on the internet, visit *www.faa.gov/regulations_policies/rulemaking/sbre_act/.*

List of Subjects in 14 CFR Part 13

Administrative practice and procedure, Air transportation, Aviation safety, Hazardous materials transportation, Investigations, Law enforcement, Penalties.

The Amendment

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

PART 13—INVESTIGATIVE AND ENFORCEMENT PROCEDURES

■ 1. The authority citation for part 13 is revised to read as follows:

Authority: 18 U.S.C. 6002; 28 U.S.C. 2461 (note); 49 U.S.C. 106(g), 5121–5124, 5127, 40113–40114, 44103–44106, 44701–44703, 44709–44710, 44713, 46101–46111, 46301, 46302 (for a violation of 49 U.S.C. 46504), 46304–46316, 46318, 46501–46502, 46504–46507, 47106, 47107, 47111, 47122, 47306, 47531–47532; 49 CFR 1.83.

■ 2. Revise subpart A to read as follows:

Subpart A—General Authority to Re-Delegate and Investigative Procedures

Sec.
13.1 Re-delegation.
13.2 Reports of violations.
13.3 Investigations (general).
13.5 Formal complaints.
13.7 Records, documents, and reports.

§ 13.1 Re-delegation.

Unless otherwise specified, the Chief Counsel, each Deputy Chief Counsel, and the Assistant Chief Counsel for Enforcement may re-delegate the authority delegated to them under this part.

§ 13.2 Reports of violations.

(a) Any person who knows of any violation of 49 U.S.C. subtitle VII, 49 U.S.C. chapter 51, or any rule, regulation, or order issued under those statutes, should report the violation to FAA personnel.

(b) FAA personnel will review each report made under this section to determine whether any additional investigation or action is warranted.

§ 13.3 Investigations (general).

(a) The Administrator may conduct investigations; hold hearings; issue subpoenas; require the production of relevant documents, records, and property; and take evidence and depositions.

(b) The Administrator has delegated the authority to conduct investigations to the various services and offices for matters within their respective areas.

(c) The Administrator delegates to the Chief Counsel, each Deputy Chief Counsel, and the Assistant Chief Counsel for Enforcement the authority to:

(1) Issue orders;

(2) Conduct formal investigations;

(3) Subpoena witnesses and records in conducting a hearing or investigation;

(4) Order depositions and production of records in a proceeding or investigation; and

(5) Petition a court of the United States to enforce a subpoena or order described in paragraphs (c)(3) and (4) of this section.

(d) A complaint against the sponsor, proprietor, or operator of a federally assisted airport involving violations of the legal authorities listed in § 16.1 of this chapter must be filed in accordance with the provisions of part 16 of this chapter.

§ 13.5 Formal complaints.

(a) Any person may file a complaint with the Administrator with respect to a violation by a person of any requirement under 49 U.S.C. subtitle VII, 49 U.S.C. chapter 51, or any rule, regulation, or order issued under those statutes, as to matters within the jurisdiction of the Administrator. This section does not apply to complaints against the Administrator or employees of the FAA acting within the scope of their employment.

(b) Complaints filed under this section must—

(1) Be submitted in writing and identified as a complaint seeking an appropriate order or other enforcement action;

(2) Be submitted to the Federal Aviation Administration, Office of the Chief Counsel, Attention: Formal Complaint Clerk (AGC–300), 800 Independence Avenue SW, Washington, DC 20591;

(3) Set forth the name and address, if known, of each person who is the subject of the complaint and, with respect to each person, the specific provisions of the statute, rule, regulation, or order that the complainant believes were violated;

(4) Contain a concise but complete statement of the facts relied upon to substantiate each allegation;

(5) State the name, address, telephone number, and email of the person filing the complaint; and

(6) Be signed by the person filing the complaint or an authorized representative.

(c) A complaint that does not meet the requirements of paragraph (b) of this section will be considered a report under § 13.2.

(d) The FAA will send a copy of a complaint that meets the requirements of paragraph (b) of this section to the subject(s) of the complaint by certified mail.

(e) A subject of the complaint may serve a written answer to the complaint to the Formal Complaint Clerk at the address specified in paragraph (b)(2) of this section no later than 20 days after service of a copy of the complaint. For purposes of this paragraph (e), the date of service is the date on which the FAA mailed a copy of the complaint to the subject of the complaint.

(f) After the subject(s) of the complaint have served a written answer or after the allotted time to serve an answer has expired, the Administrator will determine if there are reasonable grounds for investigating the complaint, and—

(1) If the Administrator determines that a complaint does not state facts that warrant an investigation or action, the complaint may be dismissed without a hearing and the reason for the dismissal will be given, in writing, to the person who filed the complaint and the subject(s) of the complaint; or

(2) If the Administrator determines that reasonable grounds exist, an informal investigation may be initiated or an order of investigation may be issued in accordance with subpart F of this part, or both. The subject(s) of a complaint will be advised which official has been delegated the responsibility under § 13.3(b) or (c), as applicable, for conducting the investigation.

(g) If the investigation substantiates the allegations set forth in the complaint, the Administrator may take action in accordance with applicable law and FAA policy.

(h) The complaint and other records relating to the disposition of the complaint are maintained in the Formal Complaint Docket (AGC–300), Office of the Chief Counsel, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591. Any interested person may examine any docketed material at that office at any time after the docket is established, except material that is required to be withheld from the public under applicable law, and may obtain a copy upon paying the cost of the copy.

§ 13.7 Records, documents, and reports.

Each record, document, and report that FAA regulations require to be maintained, exhibited, or submitted to the Administrator may be used in any

investigation conducted by the Administrator; and, except to the extent the use may be specifically limited or prohibited by the section which imposes the requirement, the records, documents, and reports may be used in any civil penalty action, certificate action, or other legal proceeding.

■ 3. Revise subpart B to read as follows:

Subpart B—Administrative Actions

§ 13.11 Administrative disposition of certain violations.

(a) If, after an investigation, FAA personnel determine that an apparent violation of 49 U.S.C. subtitle VII, 49 U.S.C. chapter 51, or any rule, regulation, or order issued under those statutes, does not require legal enforcement action, an appropriate FAA official may take administrative action to address the apparent violation.

(b) An administrative action under this section does not constitute a formal adjudication of the matter, and may take the form of—

(1) A Warning Notice that recites available facts and information about the incident or condition and indicates that it may have been a violation; or

(2) A Letter of Correction that states the corrective action the apparent violator has taken or agrees to take. If the apparent violator does not complete the agreed corrective action, the FAA may take legal enforcement action.

■ 4. Revise subpart C to read as follows:

Subpart C—Legal Enforcement Actions

Sec.
13.13 Consent orders.
13.14 [Reserved]
13.15 Civil penalties: Other than by administrative assessment.
13.16 Civil penalties: Administrative assessment against a person other than an individual acting as a pilot, flight engineer, mechanic, or repairman; administrative assessment against all persons for hazardous materials violations.
13.17 Seizure of aircraft.
13.18 Civil penalties: Administrative assessment against an individual acting as a pilot, flight engineer, mechanic, or repairman.
13.19 Certificate actions appealable to the National Transportation Safety Board.
13.20 Orders of compliance, cease and desist orders, orders of denial, and other orders.
13.21 through 13.29 [Reserved]

§ 13.13 Consent orders.

(a) The Chief Counsel, each Deputy Chief Counsel, and the Assistant Chief Counsel for Enforcement may issue a consent order to resolve any matter with a person that may be subject to legal enforcement action.

(b) A person that may be subject to legal enforcement action may propose a consent order. The proposed consent order must include—

(1) An admission of all jurisdictional facts;

(2) An express waiver of the right to further procedural steps and of all rights to legal review in any forum;

(3) An express waiver of attorney's fees and costs;

(4) If a notice or order has been issued prior to the proposed consent order, an incorporation by reference of the notice or order and an acknowledgment that the notice or order may be used to construe the terms of the consent order; and

(5) If a request for hearing or appeal is pending in any forum, a provision that the person will withdraw the request for hearing or notice of appeal.

§ 13.14 [Reserved]

§ 13.15 Civil penalties: Other than by administrative assessment.

(a) The FAA uses the procedures in this section when it seeks a civil penalty other than by the administrative assessment procedures in § 13.16 or § 13.18.

(b) The authority of the Administrator to seek a civil penalty, and the ability to refer cases to the United States Attorney General, or the delegate of the Attorney General, for prosecution of civil penalty actions sought by the Administrator is delegated to the Chief Counsel, each Deputy Chief Counsel, and the Assistant Chief Counsel for Enforcement. This delegation applies to cases involving one or more of the following:

(1) An amount in controversy in excess of:

(i) $400,000, if the violation was committed by a person other than an individual or small business concern; or

(ii) $50,000, if the violation was committed by an individual or small business concern.

(2) An in rem action, seizure of aircraft subject to lien, suit for injunctive relief, or for collection of an assessed civil penalty.

(c) The Administrator may compromise any civil penalty proposed under this section, before referral to the United States Attorney General, or the delegate of the Attorney General, for prosecution.

(1) The Administrator, through the Chief Counsel, a Deputy Chief Counsel, or the Assistant Chief Counsel for Enforcement sends a civil penalty letter to the person charged with a violation. The civil penalty letter contains a statement of the charges; the applicable law, rule, regulation, or order; and the amount of civil penalty that the Administrator will accept in full settlement of the action or an offer to compromise the civil penalty.

(2) Not later than 30 days after receipt of the civil penalty letter, the person cited with an alleged violation may respond to the civil penalty letter by—

(i) Submitting electronic payment, a certified check, or money order in the amount offered by the Administrator in the civil penalty letter. The agency attorney will send a letter to the person charged with the violation stating that payment is accepted in full settlement of the civil penalty action; or

(ii) Submitting one of the following to the agency attorney:

(A) Written material or information that may explain, mitigate, or deny the violation or that may show extenuating circumstances; or

(B) A written request for an informal conference to discuss the matter with the agency attorney and to submit any relevant information or documents that may explain, mitigate, or deny the violation; or that may show extenuating circumstances.

(3) The documents, material, or information submitted under paragraph (c)(2)(ii) of this section may include support for any claim of inability to pay the civil penalty in whole or in part, or for any claim of small business status as defined in 49 U.S.C. 46301(i).

(4) The Administrator will consider any material or information submitted under paragraph (c)(2)(ii) of this section to determine whether the person is subject to a civil penalty or to determine the amount for which the Administrator will compromise the action.

(5) If the parties cannot agree to compromise the civil penalty, the Administrator may refer the civil penalty action to the United States Attorney General, or the delegate of the Attorney General, to begin proceedings in a U.S. district court to prosecute and collect a civil penalty.

§ 13.16 Civil penalties: Administrative assessment against a person other than an individual acting as a pilot, flight engineer, mechanic, or repairman; administrative assessment against all persons for hazardous materials violations.

(a) *General.* The FAA uses the procedures in this section when it assesses a civil penalty against a person other than an individual acting as a pilot, flight engineer, mechanic, or repairman for a violation cited in the first sentence of 49 U.S.C. 46301(d)(2), or in 49 U.S.C. 47531, or any

implementing rule, regulation, or order, except when the U.S. district courts have exclusive jurisdiction.

(b) *District court jurisdiction.* The U.S. district courts have exclusive jurisdiction of any civil penalty action initiated by the FAA for violations described in paragraph (a) of this section if—

(1) The amount in controversy is more than $400,000 for a violation committed by a person other than an individual or small business concern;

(2) The amount in controversy is more than $50,000 for a violation committed by an individual or a small business concern;

(3) The action is in rem or another action in rem based on the same violation has been brought;

(4) The action involves an aircraft subject to a lien that has been seized by the Government; or

(5) Another action has been brought for an injunction based on the same violation.

(c) *Hazardous materials violations.* An order assessing a civil penalty for a violation under 49 U.S.C. chapter 51, or a rule, regulation, or order issued under 49 U.S.C. chapter 51, is issued only after the following factors have been considered:

(1) The nature, circumstances, extent, and gravity of the violation;

(2) With respect to the violator, the degree of culpability, any history of prior violations, the ability to pay, and any effect on the ability to continue to do business; and

(3) Other matters that justice requires.

(d) *Delegation of authority.* The authority of the Administrator is delegated to each Deputy Chief Counsel and the Assistant Chief Counsel for Enforcement, as follows:

(1) Under 49 U.S.C. 46301(d), 47531, and 5123, and 49 CFR 1.83, to initiate and assess civil penalties for a violation of those statutes or a rule, regulation, or order issued under those provisions;

(2) Under 49 U.S.C. 5123, 49 CFR 1.83, 49 U.S.C. 46301(d), and 49 U.S.C. 46305, to refer cases to the Attorney General of the United States or a delegate of the Attorney General for collection of civil penalties;

(3) Under 49 U.S.C. 46301(f), to compromise the amount of a civil penalty imposed; and

(4) Under 49 U.S.C. 5123(e) and (f) and 49 CFR 1.83, to compromise the amount of a civil penalty imposed.

(e) *Order assessing civil penalty.* (1) An order assessing civil penalty may be issued for a violation described in paragraph (a) or (c) of this section, or as otherwise provided by statute, after notice and opportunity for a hearing, when:

(i) A person charged with a violation agrees to pay a civil penalty for a violation; or

(ii) A person charged with a violation does not request a hearing under paragraph (g)(2)(ii) of this section within 15 days after receipt of a final notice of proposed civil penalty.

(2) The following also serve as an order assessing civil penalty:

(i) An initial decision or order issued by an administrative law judge as described in § 13.232(e).

(ii) A decision or order issued by the FAA decisionmaker as described in § 13.233(j).

(f) *Notice of proposed civil penalty.* A civil penalty action is initiated by sending a notice of proposed civil penalty to the person charged with a violation, the designated agent for the person, or if there is no such designated agent, the president of the company charged with a violation. In response to a notice of proposed civil penalty, a company may designate in writing another person to receive documents in that civil penalty action. The notice of proposed civil penalty contains a statement of the charges and the amount of the proposed civil penalty. Not later than 30 days after receipt of the notice of proposed civil penalty, the person charged with a violation may—

(1) Submit the amount of the proposed civil penalty or an agreed-upon amount, in which case either an order assessing civil penalty or compromise order under paragraph (n) of this section may be issued in that amount;

(2) Submit to the agency attorney one of the following:

(i) Written information, including documents and witness statements, demonstrating that a violation of the regulations did not occur or that a penalty or the amount of the penalty is not warranted by the circumstances.

(ii) A written request to reduce the proposed civil penalty, stating the amount of reduction and the reasons and providing any documents supporting a reduction of the proposed civil penalty, including records indicating a financial inability to pay or records showing that payment of the proposed civil penalty would prevent the person from continuing in business.

(iii) A written request for an informal conference to discuss the matter with the agency attorney and to submit relevant information or documents; or

(3) Request a hearing conducted in accordance with subpart G of this part.

(g) *Final notice of proposed civil penalty.* A final notice of proposed civil penalty will be sent to the person charged with a violation, the designated agent for the person, the designated agent named in accordance with paragraph (f) of this section, or the president of the company charged with a violation. The final notice of proposed civil penalty contains a statement of the charges and the amount of the proposed civil penalty and, as a result of information submitted to the agency attorney during informal procedures, may modify an allegation or a proposed civil penalty contained in a notice of proposed civil penalty.

(1) A final notice of proposed civil penalty may be issued—

(i) If the person charged with a violation fails to respond to the notice of proposed civil penalty within 30 days after receipt of that notice; or

(ii) If the parties participated in any procedures under paragraph (f)(2) of this section and the parties have not agreed to compromise the action or the agency attorney has not agreed to withdraw the notice of proposed civil penalty.

(2) Not later than 15 days after receipt of the final notice of proposed civil penalty, the person charged with a violation may do one of the following:

(i) Submit the amount of the proposed civil penalty or an agreed-upon amount, in which case either an order assessing civil penalty or a compromise order under paragraph (n) of this section may be issued in that amount; or

(ii) Request a hearing conducted in accordance with subpart G of this part.

(h) *Request for a hearing.* Any person requesting a hearing, under paragraph (f)(3) or (g)(2)(ii) of this section must file the request with the FAA Hearing Docket Clerk and serve the request on the agency attorney in accordance with the requirements in subpart G of this part.

(i) *Hearing.* The procedural rules in subpart G of this part apply to the hearing.

(j) *Appeal.* Either party may appeal the administrative law judge's initial decision to the FAA decisionmaker under the procedures in subpart G of this part. The procedural rules in subpart G of this part apply to the appeal.

(k) *Judicial review.* A person may seek judicial review only of a final decision and order of the FAA decisionmaker in accordance with § 13.235.

(l) *Payment.* (1) A person must pay a civil penalty by:

(i) Sending a certified check or money order, payable to the Federal Aviation Administration, to the FAA office identified in the notice of proposed civil penalty, the final notice of proposed civil penalty, or the order assessing civil penalty; or

(ii) Making an electronic payment according to the directions specified in the notice of proposed civil penalty, the final notice of proposed civil penalty, or the order assessing civil penalty.

(2) The civil penalty must be paid within 30 days after service of the order assessing civil penalty, unless otherwise agreed to by the parties. In cases where a hearing is requested, an appeal to the FAA decisionmaker is filed, or a petition for review of the FAA decisionmaker's decision is filed in a U.S. court of appeals, the civil penalty must be paid within 30 days after all litigation in the matter is completed and the civil penalty is affirmed in whole or in part.

(m) *Collection of civil penalties.* If an individual does not pay a civil penalty imposed by an order assessing civil penalty or other final order, the Administrator may take action to collect the penalty.

(n) *Compromise.* The FAA may compromise the amount of any civil penalty imposed under this section under 49 U.S.C. 5123(e), 46301(f), or 46318 at any time before referring the action to the United States Attorney General, or the delegate of the Attorney General, for collection.

(1) When a civil penalty is compromised with a finding of violation, an agency attorney issues an order assessing civil penalty.

(2) When a civil penalty is compromised without a finding of violation, the agency attorney issues a compromise order that states the following:

(i) The person has paid a civil penalty or has signed a promissory note providing for installment payments.

(ii) The FAA makes no finding of a violation.

(iii) The compromise order will not be used as evidence of a prior violation in any subsequent civil penalty proceeding or certificate action proceeding.

§ 13.17 Seizure of aircraft.

(a) The Chief Counsel, or a Regional Administrator for an aircraft within the region, may issue an order authorizing a State or Federal law enforcement officer or a Federal Aviation Administration safety inspector to seize an aircraft that is involved in a violation for which a civil penalty may be imposed on its owner or the individual commanding the aircraft.

(b) Each person seizing an aircraft under this section places it in the nearest available and adequate public storage facility in the judicial district in which it was seized.

(c) The Regional Administrator or Chief Counsel, without delay, sends a written notice and a copy of this section to the registered owner of the seized aircraft and to each other person shown by FAA records to have an interest in it, stating the—

(1) Time, date, and place of seizure;

(2) Name and address of the custodian of the aircraft;

(3) Reasons for the seizure, including the violations alleged or proven to have been committed; and

(4) Amount that may be tendered as—

(i) A compromise of a civil penalty for the alleged violation; or

(ii) Payment for a civil penalty imposed for a proven violation.

(d) The Chief Counsel or Assistant Chief Counsel for Enforcement immediately sends a report to the United States Attorney for the judicial district in which it was seized, requesting the United States Attorney to institute proceedings to enforce a lien against the aircraft.

(e) The Regional Administrator or Chief Counsel directs the release of a seized aircraft when—

(1) The alleged violator pays a civil penalty or an amount agreed upon in compromise, and the costs of seizing, storing, and maintaining the aircraft;

(2) The aircraft is seized under an order of a court of the United States in proceedings in rem initiated under 49 U.S.C. 46305 to enforce a lien against the aircraft;

(3) The United States Attorney General, or the delegate of the Attorney General, notifies the FAA that the United States Attorney General, or the delegate of the Attorney General, refuses to institute proceedings in rem under 49 U.S.C. 46305 to enforce a lien against the aircraft; or

(4) A bond in the amount and with the sureties prescribed by the Chief Counsel or the Assistant Chief Counsel for Enforcement is deposited, conditioned on payment of the penalty or the compromise amount, and the costs of seizing, storing, and maintaining the aircraft.

§ 13.18 Civil penalties: Administrative assessment against an individual acting as a pilot, flight engineer, mechanic, or repairman.

(a) *General.* (1) This section applies to each action in which the FAA seeks to assess a civil penalty by administrative procedures against an individual acting as a pilot, flight engineer, mechanic, or repairman under 49 U.S.C. 46301(d)(5) for a violation listed in 49 U.S.C. 46301(d)(2). This section does not apply to a civil penalty assessed for a violation of 49 U.S.C. chapter 51, or a rule, regulation, or order issued thereunder.

(2) Notwithstanding the provisions of paragraph (a)(1) of this section, the U.S. district courts have exclusive jurisdiction of any civil penalty action involving an individual acting as a pilot, flight engineer, mechanic, or repairman for violations described in paragraph (a)(1), or under 49 U.S.C. 46301(d)(4), if:

(i) The amount in controversy is more than $50,000;

(ii) The action involves an aircraft subject to a lien that has been seized by the government; or

(iii) Another action has been brought for an injunction based on the same violation.

(b) *Definitions.* As used in this part, the following definitions apply:

(1) *Flight engineer* means an individual who holds a flight engineer certificate issued under part 63 of this chapter.

(2) *Individual acting as a pilot, flight engineer, mechanic, or repairman* means an individual acting in such capacity, whether or not that individual holds the respective airman certificate issued by the FAA.

(3) *Mechanic* means an individual who holds a mechanic certificate issued under part 65 of this chapter.

(4) *Pilot* means an individual who holds a pilot certificate issued under part 61 of this chapter.

(5) *Repairman* means an individual who holds a repairman certificate issued under part 65 of this chapter.

(c) *Delegation of authority.* The authority of the Administrator is delegated to the Chief Counsel and each Deputy Chief Counsel, and the Assistant Chief Counsel for Enforcement, as follows:

(1) To initiate and assess civil penalties under 49 U.S.C. 46301(d)(5);

(2) To refer cases to the Attorney General of the United States, or the delegate of the Attorney General, for collection of civil penalties; and

(3) To compromise the amount of a civil penalty under 49 U.S.C. 46301(f).

(d) *Notice of proposed assessment.* A civil penalty action is initiated by sending a notice of proposed assessment to the individual charged with a violation specified in paragraph (a) of this section. The notice of proposed assessment contains a statement of the charges and the amount of the proposed civil penalty. The individual charged with a violation may do the following:

(1) Submit the amount of the proposed civil penalty or an agreed-upon amount, in which case either an order of assessment or a compromise order will be issued in that amount.

(2) Answer the charges in writing by submitting information, including documents and witness statements, demonstrating that a violation of the regulations did not occur or that a

penalty, or the amount of the penalty, is not warranted by the circumstances.

(3) Submit a written request to reduce the proposed civil penalty, stating the amount of reduction and the reasons, and providing any documents supporting a reduction of the proposed civil penalty, including records indicating a financial inability to pay.

(4) Submit a written request for an informal conference to discuss the matter with an agency attorney and submit relevant information or documents.

(5) Request that an order of assessment be issued so that the individual charged may appeal to the National Transportation Safety Board.

(e) *Failure to respond to notice of proposed assessment.* An order of assessment may be issued if the individual charged with a violation fails to respond to the notice of proposed assessment within 15 days after receipt of that notice.

(f) *Order of assessment.* An order of assessment, which imposes a civil penalty, may be issued for a violation described in paragraph (a) of this section after notice and an opportunity to answer any charges and be heard as to why such order should not be issued.

(g) *Appeal.* Any individual who receives an order of assessment issued under this section may appeal the order to the National Transportation Safety Board. The appeal stays the effectiveness of the Administrator's order.

(h) *Judicial review.* A party may seek judicial review only of a final decision and order of the National Transportation Safety Board under 49 U.S.C. 46301(d)(6) and 46110. Neither an initial decision, nor an order issued by an administrative law judge that has not been appealed to the National Transportation Safety Board, nor an order compromising a civil penalty action, may be appealed under any of those sections.

(i) *Compromise.* The FAA may compromise any civil penalty imposed under this section at any time before referring the action to the United States Attorney General, or the delegate of the Attorney General, for collection.

(1) When a civil penalty is compromised with a finding of violation, an agency attorney issues an order of assessment.

(2) When a civil penalty is compromised without a finding of violation, the agency attorney issues a compromise order of assessment that states the following:

(i) The individual has paid a civil penalty or has signed a promissory note providing for installment payments;

(ii) The FAA makes no finding of violation; and

(iii) The compromise order will not be used as evidence of a prior violation in any subsequent civil penalty proceeding or certificate action proceeding.

(j) *Payment.* (1) An individual must pay a civil penalty by:

(i) Sending a certified check or money order, payable to the Federal Aviation Administration, to the FAA office identified in the order of assessment; or

(ii) Making an electronic payment according to the directions specified in the order of assessment.

(2) The civil penalty must be paid within 30 days after service of the order of assessment, unless an appeal is filed with the National Transportation Safety Board. In cases where an appeal is filed with the National Transportation Safety Board, or a petition for review is filed with a U.S. court of appeals, the civil penalty must be paid within 30 days after all litigation in the matter is completed and the civil penalty is affirmed in whole or in part.

(k) *Collection of civil penalties.* If an individual does not pay a civil penalty imposed by an order of assessment or other final order, the Administrator may take action provided under the law to collect the penalty.

§ 13.19 Certificate actions appealable to the National Transportation Safety Board.

(a) The Administrator may issue an order amending, modifying, suspending, or revoking all or part of any type certificate, production certificate, airworthiness certificate, airman certificate, air carrier operating certificate, air navigation facility certificate, or air agency certificate if as a result of a reinspection, reexamination, or other investigation, the Administrator determines that the public interest and safety in air commerce requires it, if a certificate holder has violated an aircraft noise or sonic boom standard or regulation prescribed under 49 U.S.C. 44715(a), or if the holder of the certificate is convicted of violating 16 U.S.C. 742j-1(a).

(b) The agency attorney will issue a notice before issuing a non-immediately effective order to amend, modify, suspend, or revoke a type certificate, production certificate, airworthiness certificate, airman certificate, air carrier operating certificate, air navigation facility certificate, air agency certificate, or to revoke an aircraft certificate of registration because the aircraft was used to carry out or facilitate an activity punishable under a law of the United States or a State related to a controlled substance (except a law related to simple possession of a controlled substance), by death or imprisonment for more than one year, and the owner of the aircraft permitted the use of the aircraft knowing that the aircraft was to be used for the activity.

(1) A notice of proposed certificate action will advise the certificate holder or aircraft owner of the charges or other reasons upon which the Administrator bases the proposed action, and allows the holder to answer any charges and to be heard as to why the certificate should not be amended, suspended, modified, or revoked.

(2) In response to a notice of proposed certificate action described in paragraph (b)(1) of this section, the certificate holder or aircraft owner, within 15 days of the date of receipt of the notice, may—

(i) Surrender the certificate and waive any right to contest or appeal the charged violations and sanction, in which case the Administrator will issue an order;

(ii) Answer the charges in writing by submitting information, including documents and witness statements, demonstrating that a violation of the regulations did not occur or that the proposed sanction is not warranted by the circumstances;

(iii) Submit a written request for an informal conference to discuss the matter with an agency attorney and submit relevant information or documents; or

(iv) Request that an order be issued in accordance with the notice of proposed certificate action so that the certificate holder or aircraft owner may appeal to the National Transportation Safety Board.

(c) In the case of an emergency order amending, modifying, suspending, or revoking a type certificate, production certificate, airworthiness certificate, airman certificate, air carrier operating certificate, air navigation facility certificate, or air agency certificate, a person affected by the immediate effectiveness of the Administrator's order may petition the National Transportation Safety Board for a review of the Administrator's determination that an emergency exists.

(d) A person may not petition the National Transportation Safety Board for a review of the Administrator's determination that safety in air transportation or air commerce requires the immediate effectiveness of an order where the action is based on the circumstances described in paragraph (d)(1), (2), or (3) of this section.

(1) The revocation of an individual's airman certificates for the reasons stated

in paragraph (d)(1)(i) or (ii) of this section:

(i) A conviction under a law of the United States or a State related to a controlled substance (except a law related to simple possession of a controlled substance), of an offense punishable by death or imprisonment for more than one year if the Administrator finds that—

(A) An aircraft was used to commit, or facilitate the commission of the offense; and

(B) The individual served as an airman, or was on the aircraft, in connection with committing, or facilitating the commission of, the offense.

(ii) Knowingly carrying out an activity punishable, under a law of the United States or a State related to a controlled substance (except a law related to simple possession of a controlled substance), by death or imprisonment for more than one year; and—

(A) An aircraft was used to carry out or facilitate the activity; and

(B) The individual served as an airman, or was on the aircraft, in connection with carrying out, or facilitating the carrying out of, the activity.

(2) The revocation of a certificate of registration for an aircraft, and any other aircraft the owner of that aircraft holds, if the Administrator finds that—

(i) The aircraft was used to carry out or facilitate an activity punishable, under a law of the United States or a State related to a controlled substance (except a law related to simple possession of a controlled substance), by death or imprisonment for more than one year; and

(ii) The owner of the aircraft permitted the use of the aircraft knowing that the aircraft was to be used for the activity described in paragraph (d)(2)(i) of this section.

(3) The revocation of an airman certificate, design organization certificate, type certificate, production certificate, airworthiness certificate, air carrier operating certificate, airport operating certificate, air agency certificate, or air navigation facility certificate if the Administrator finds that the holder of the certificate or an individual who has a controlling or ownership interest in the holder—

(i) Was convicted in a court of law of a violation of a law of the United States relating to the installation, production, repair, or sale of a counterfeit or fraudulently-represented aviation part or material; or

(ii) Knowingly, and with the intent to defraud, carried out or facilitated an activity described in paragraph (d)(3)(i) of this section.

§ 13.20 Orders of compliance, cease and desist orders, orders of denial, and other orders.

(a) *General.* This section applies to all of the following:

(1) Orders of compliance;

(2) Cease and desist orders;

(3) Orders of denial;

(4) Orders suspending or revoking a certificate of registration (but not revocation of a certificate of registration because the aircraft was used to carry out or facilitate an activity punishable, under a law of the United States or a State related to a controlled substance (except a law related to simple possession of a controlled substance), by death or imprisonment for more than one year and the owner of the aircraft permitted the use of the aircraft knowing that the aircraft was to be used for the activity); and

(5) Other orders issued by the Administrator to carry out the provisions of the Federal aviation statute codified at 49 U.S.C. subtitle VII that apply this section by statute, rule, regulation, or order, or for which there is no specific administrative process provided by statute, rule, regulation, or order.

(b) *Applicability of procedures.* (1) Prior to the issuance of a non-immediately effective order covered by this section, the Administrator will provide the person who would be subject to the order with notice, advising the person of the charges or other reasons upon which the proposed action is based, and the provisions in paragraph (c) of this section apply.

(2) If the Administrator is of the opinion that an emergency exists related to safety in air commerce and requires immediate action and issues an order covered by this section that is immediately effective, the provisions of paragraph (d) of this section apply.

(c) *Non-emergency procedures.* (1) Within 30 days after service of the notice, the person subject to the notice may:

(i) Submit a written reply;

(ii) Agree to the issuance of the order as proposed in the notice of proposed action, waiving any right to contest or appeal the agreed-upon order issued under this option in any administrative or judicial forum;

(iii) Submit a written request for an informal conference to discuss the matter with an agency attorney; or

(iv) Request a hearing in accordance with the non-emergency procedures of subpart D of this part.

(2) After an informal conference is held or a reply is filed, if the agency attorney notifies the person that some or all of the proposed agency action will not be withdrawn, the person may, within 10 days after receiving the agency attorney's notification, request a hearing on the parts of the proposed agency action not withdrawn, in accordance with the non-emergency procedures of subpart D of this part.

(3) If a hearing is requested in accordance with paragraph (c)(1)(iv) or (c)(2) of this section, the non-emergency procedures of subpart D of this part apply.

(4) Failure to request a hearing within the periods provided in paragraph (c)(1)(iv) or (c)(2) of this section:

(i) Constitutes a waiver of the right to a hearing and appeal; and

(ii) Authorizes the agency to make appropriate findings of fact and to issue an appropriate order without further notice or proceedings.

(d) *Emergency procedures.* (1) If the Administrator is of the opinion that an emergency exists related to safety in air commerce and requires immediate action, the Administrator issues simultaneously:

(i) An immediately effective order that expires 80 days after the date of issuance and sets forth the charges or other reasons upon which the order is based; and

(ii) A notice of proposed action that:

(A) Sets forth the charges or other reasons upon which the notice of proposed action is based; and

(B) Advises that within 10 days after service of the notice, the person may appeal the notice by requesting an expedited hearing in accordance with the emergency procedures of subpart D of this part.

(2) The Administrator will serve the immediately effective order and the notice of proposed action together by personal or overnight delivery and by certified or registered mail to the person subject to the order and notice of proposed action.

(3) Failure to request a hearing challenging the notice of proposed action under the expedited procedures in subpart D of this part within 10 days after service of the notice:

(i) Constitutes a waiver of the right to a hearing and appeal under subpart D of this part; and

(ii) Authorizes the Administrator, without further notice or proceedings, to make appropriate findings of fact, issue an immediately effective order without expiration, and withdraw the 80-day immediately effective order.

(4) The filing of a request for hearing under subpart D of this part does not stay the effectiveness of the 80-day

immediately effective order issued under this section.

(e) *Delegation of authority.* The authority of the Administrator under this section is delegated to the Chief Counsel, each Deputy Chief Counsel, and the Assistant Chief Counsel for Enforcement.

§§ 13.21 through 13.29 [Reserved]

■ 5. Revise subpart D to read as follows:

Subpart D—Rules of Practice for FAA Hearings

Sec.
13.31 Applicability.
13.33 Parties, representatives, and notice of appearance.
13.35 Request for hearing, complaint, and answer.
13.37 Hearing officer: Assignment and powers.
13.39 Disqualification of hearing officer.
13.41 Separation of functions and prohibition on ex parte communications.
13.43 Service and filing of pleadings, motions, and documents.
13.44 [Reserved]
13.45 Computation of time and extension of time.
13.47 Withdrawal or amendment of the complaint, answer, or other filings.
13.49 Motions.
13.51 Intervention.
13.53 Discovery.
13.55 Notice of hearing.
13.57 Subpoenas and witness fees.
13.59 Evidence.
13.61 Argument and submittals.
13.63 Record, decision, and aircraft registration proceedings.
13.65 Appeal to the Administrator, reconsideration, and judicial review.
13.67 Procedures for expedited proceedings.
13.69 Other matters: Alternative dispute resolution, standing orders, and forms.

§ 13.31 Applicability.

This subpart applies to proceedings in which a hearing has been requested in accordance with § 13.20 or § 13.75. Hearings under this subpart are considered informal and are provided through the Office of Adjudication.

§ 13.33 Parties, representatives, and notice of appearance.

(a) *Parties.* Parties to proceedings under this subpart include the following: Complainant, respondent, and where applicable, intervenor.

(1) Complainant is the FAA Office that issued the notice of proposed action under the authorities listed in § 13.31.

(2) Respondent is the party filing a request for hearing.

(3) Intervenor is a person permitted to participate as a party under § 13.51.

(b) *Representatives.* Any party to a proceeding under this subpart may appear and be heard in person or by a representative. A representative is an attorney, or another representative designated by the party.

(c) *Notice of appearance*—(1) *Content.* The representative of a party must file a notice of appearance that includes the representative's name, address, telephone number, and, if available, fax number, and email address.

(2) *Filing.* A notice of appearance may be incorporated into an initial filing in a proceeding. A notice of appearance by additional representatives or substitutes after an initial filing in a proceeding must be filed independently.

§ 13.35 Request for hearing, complaint, and answer.

(a) *Initial filing and service.* A request for hearing must be filed with the FAA Hearing Docket, and a copy must be served on the official who issued the notice of proposed action, in accordance with the requirements in § 13.43 for filing and service of documents. The request for hearing must be in writing and describe the action proposed by the FAA, and must contain a statement that a hearing is requested under this subpart.

(b) *Complaint.* Within 20 days after service of the copy of the request for hearing, the official who issued the notice of proposed action must forward a copy of that notice, which serves as the complaint, to the FAA Hearing Docket.

(c) *Answer.* Within 30 days after service of the copy of the complaint, the Respondent must file an answer to the complaint. All allegations in the complaint not specifically denied in the answer are deemed admitted.

§ 13.37 Hearing officer: Assignment and powers.

As soon as practicable after the filing of the complaint, the Director of the Office of Adjudication will assign a hearing officer to preside over the matter. The hearing officer may—

(a) Give notice concerning, and hold, prehearing conferences and hearings;

(b) Administer oaths and affirmations;

(c) Examine witnesses;

(d) Adopt procedures for the submission of evidence in written form;

(e) Issue subpoenas;

(f) Rule on offers of proof;

(g) Receive evidence;

(h) Regulate the course of proceedings, including but not limited to discovery, motions practice, imposition of sanctions, and the hearing;

(i) Hold conferences, before and during the hearing, to settle and simplify issues by consent of the parties;

(j) Dispose of procedural requests and similar matters;

(k) Issue protective orders governing the exchange and safekeeping of information otherwise protected by law, except that national security information may not be disclosed under such an order;

(l) Issue orders and decisions, and make findings of fact, as appropriate; and

(m) Take any other action authorized by this subpart.

§ 13.39 Disqualification of hearing officer.

(a) *Motion and supporting affidavit.* Any party may file a motion for disqualification under § 13.49(g). A party must state the grounds for disqualification, including, but not limited to, a financial or other personal interest that would be affected by the outcome of the enforcement action, personal animus against a party to the action or against a group to which a party belongs, prejudgment of the adjudicative facts at issue in the proceeding, or any other prohibited conflict of interest. A party must submit an affidavit with the motion for disqualification that sets forth, in detail, the matters alleged to constitute grounds for disqualification.

(b) *Timing.* A motion for disqualification must be filed prior to the issuance of the hearing officer's decision under § 13.63(b). Any party may file a response to a motion for disqualification, but must do so no later than 5 days after service of the motion for disqualification.

(c) *Decision on motion for disqualification.* The hearing officer must render a decision on the motion for disqualification no later than 15 days after the motion has been filed. If the hearing officer finds that the motion for disqualification and supporting affidavit show a basis for disqualification, the hearing officer must withdraw from the proceedings immediately. If the hearing officer finds that disqualification is not warranted, the hearing officer must deny the motion and state the grounds for the denial on the record. If the hearing officer fails to rule on a party's motion for disqualification within 15 days after the motion has been filed, the motion is deemed granted.

(d) *Self-disqualification.* A hearing officer may disqualify himself or herself at any time.

§ 13.41 Separation of functions and prohibition on ex parte communications.

(a) *Separation of powers.* The hearing officer independently exercises the powers under this subpart in a manner conducive to justice and the proper dispatch of business. The hearing officer

must not participate in any appeal to the Administrator.

(b) *Ex parte communications.* (1) No substantive ex parte communications between the hearing officer and any party are permitted.

(2) A hearing, conference, or other event scheduled with prior notice will not constitute ex parte communication prohibited by this section. A hearing, conference, or other event scheduled with prior notice, may proceed in the hearing officer's sole discretion if a party fails to appear, respond, or otherwise participate, and will not constitute an ex parte communication prohibited by this section.

(3) For an appeal to the Administrator under this subpart, FAA attorneys representing the complainant must not advise the Administrator or engage in any ex parte communications with the Administrator or his advisors.

§ 13.43 Service and filing of pleadings, motions, and documents.

(a) *General rule.* A party must file all requests for hearing, pleadings, motions, and documents with the FAA Hearing Docket, and must serve a copy upon all parties to the proceedings.

(b) *Methods of filing.* Filing must be by email, personal delivery, expedited or overnight courier express service, mail, or fax.

(c) *Address for filing.* A person filing a document with the FAA Hearing Docket must use the address identified for the method of filing as follows:

(1) *If delivery is in person, or by expedited or overnight express courier service.* Federal Aviation Administration, 600 Independence Avenue SW, Wilbur Wright Building—Suite 2W100, Washington, DC 20597; Attention: FAA Hearing Docket, AGC–70.

(2) *If delivery is via U.S. mail, or U.S. certified or registered mail.* Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; Attention: FAA Hearing Docket, AGC–70, Wilbur Wright Building—Suite 2W100.

(3) *Contact information.* The FAA Office of Adjudication will make available on its website an email address and fax number for the FAA Hearing Docket, as well as other contact information.

(d) *Requirement to file an original document and number of copies.* A party must file an original document and one copy when filing by personal delivery or by mail. Only one copy must be filed if filing is accomplished by email or fax.

(e) *Filing by email.* A document that is filed by email must be attached as a Portable Document Format (PDF) file to an email. The document must be signed in accordance with § 13.207. The email message does not constitute a submission, but serves only to deliver the attached PDF file to the FAA Hearing Docket.

(f) *Methods of service*—(1) *General.* A person may serve any document by email, personal delivery, expedited or overnight courier express service, mail, or fax.

(2) *Service by email.* Service of documents by email is voluntary and requires the prior consent of the person to be served by email. A person may retract consent to be served by email by filing and serving a written retraction. A document that is served by email must be attached as a PDF file to an email message.

(g) *Certificate of service.* A certificate of service must accompany all documents filed with the FAA Hearing Docket. The certificate of service must be signed, describe the method of service, and state the date of service.

(h) *Date of filing and service.* If a document is sent by fax or email, the date of filing and service is the date the email or fax is sent. If a document is sent by personal delivery or by expedited or overnight express courier service, the date of filing and service is the date that delivery is accomplished. If a document is mailed, the date of filing and service is the date shown on the certificate of service, the date shown on the postmark if there is no certificate of service, or the mailing date shown by other evidence if there is no certificate of service or postmark.

§ 13.44 [Reserved]

§ 13.45 Computation of time and extension of time.

(a) In computing any period of time prescribed or allowed by this subpart, the date of the act, event, default, notice, or order is not to be included in the computation. The last day of the period so computed is to be included unless it is a Saturday, Sunday, or Federal holiday, in which event the period runs until the end of the next day that is not a Saturday, Sunday, or a Federal holiday.

(b) Whenever a party must respond within a prescribed period after service by mail, 5 days are added to the prescribed period.

(c) The parties may agree to extend the time for filing any document required by this subpart with the consent of—

(1) The Director of the Office of Adjudication prior to the designation of a hearing officer;

(2) The hearing officer prior to the filing of a notice of appeal; or

(3) The Director of the Office of Adjudication after the filing of a notice of appeal.

(d) If the parties do not agree, a party may make a written request to extend the time for filing to the appropriate official identified in paragraph (c) of this section. The appropriate official may grant the request for good cause shown.

§ 13.47 Withdrawal or amendment of the complaint, answer, or other filings.

(a) *Withdrawal.* At any time before the hearing, the complainant may withdraw the complaint, and the respondent may withdraw the request for hearing.

(b) *Amendments.* At any time more than 10 days before the date of hearing, any party may amend its complaint, answer, or other pleading, by filing the amendment with the FAA Hearing Docket and serving a copy of it on every other party. After that time, amendment requires approval of the hearing officer. If an initial pleading is amended, the hearing officer must allow the other parties a reasonable opportunity to respond.

§ 13.49 Motions.

(a) *Motions in lieu of an answer.* A respondent may file a motion to dismiss or a motion for a more definite statement in place of an answer. If the hearing officer denies the motion, the respondent must file an answer within 10 days.

(1) *Motion to dismiss.* The respondent may file a motion asserting that the allegations in the complaint fail to state a violation of Federal aviation statutes, a violation of regulations in this chapter, lack of qualification of the respondent, or other appropriate grounds.

(2) *Motion for more definite statement.* The respondent may file a motion that the allegations in the notice be made more definite and certain.

(b) *Motion to dismiss request for hearing.* The FAA may file a motion to dismiss a request for hearing based on jurisdiction, timeliness, or other appropriate grounds.

(c) *Motion for decision on the pleadings or for summary decision.* After the complaint and answer are filed, either party may move for a decision on the pleadings or for a summary decision, in the manner provided by Rules 12 and 56, respectively, of the Federal Rules of Civil Procedure.

(d) *Motion to strike.* Upon motion of either party, the hearing officer may order stricken, from any pleadings, any insufficient allegation or defense, or any

redundant, immaterial, impertinent, or scandalous matter.

(e) *Motion to compel.* Any party may file a motion asking the hearing officer to order any other party to produce discovery requested in accordance with § 13.53 if—

(1) The other party has failed to timely produce the requested discovery; and

(2) The moving party certifies it has in good faith conferred with the other party in an attempt to obtain the requested discovery prior to filing the motion to compel.

(f) *Motion for protective order.* The hearing officer may order information contained in anything filed, or in any testimony given pursuant to this subpart withheld from public disclosure when, in the judgment of the hearing officer, disclosure would be detrimental to aviation safety; disclosure would not be in the public interest; or the information is not otherwise required to be made available to the public. Any person may make written objection to the public disclosure of any information, stating the ground for such objection.

(g) *Other motions.* Any application for an order or ruling not otherwise provided for in this subpart must be made by motion.

(h) *Responses to motions.* Any party may file a response to any motion under this subpart within 10 days after service of the motion.

§ 13.51 Intervention.

Any person may move for leave to intervene in a proceeding and may become a party thereto, if the hearing officer, after the case is sent to the hearing officer for hearing, finds that the person may be bound by the order to be issued in the proceedings or has a property or financial interest that may not be adequately represented by existing parties, and that the intervention will not unduly broaden the issues or delay the proceedings. Except for good cause shown, a motion for leave to intervene may not be considered if it is filed less than 10 days before the hearing.

§ 13.53 Discovery.

(a) *Filing.* Discovery requests and responses are not filed with the FAA Hearing Docket unless in support of a motion, offered for impeachment, or other permissible circumstances as approved by the hearing officer.

(b) *Scope of discovery.* Any party may discover any matter that is not privileged and is relevant to any party's claim or defense.

(c) *Time for response to written discovery requests.* (1) Written discovery includes interrogatories, requests for admission or stipulations, and requests for production of documents.

(2) Unless otherwise directed by the hearing officer, a party must serve its response to a discovery request no later than 30 days after service of the discovery request.

(d) *Depositions.* After the respondent has filed a request for hearing and an answer, either party may take testimony by deposition.

(e) *Limits on discovery.* The hearing officer may limit the frequency and extent of discovery upon a showing by a party that—

(1) The discovery requested is cumulative or repetitious;

(2) The discovery requested can be obtained from another less burdensome and more convenient source;

(3) The party requesting the information has had ample opportunity to obtain the information through other discovery methods permitted under this section; or

(4) The method or scope of discovery requested by the party is unduly burdensome or expensive.

§ 13.55 Notice of hearing.

The hearing officer must set a reasonable date, time, and location for the hearing, and must give the parties adequate notice thereof, and of the nature of the hearing. Due regard must be given to the convenience of the parties with respect to the location of the hearing.

§ 13.57 Subpoenas and witness fees.

(a) *Application.* The hearing officer, upon application by any party to the proceeding, may issue subpoenas requiring the attendance of witnesses or the production of documents or tangible things at a hearing or for the purpose of taking depositions, as permitted by law. The application for producing evidence must show its general relevance and reasonable scope. Absent good cause shown, a party must file a request for a subpoena at least:

(1) 15 days before a scheduled deposition under the subpoena; or

(2) 30 days before a scheduled hearing where attendance at the hearing is sought.

(b) *Procedure.* A party seeking the production of a document in the custody of an FAA employee must use the discovery procedure found in § 13.53, and if necessary, a motion to compel under § 13.49. A party that applies for the attendance of an FAA employee at a hearing must send the application, in writing, to the hearing officer. The application must set forth the need for that employee's attendance.

(c) *Fees.* Except for an employee of the agency who appears at the direction of the agency, a witness who appears at a deposition or hearing is entitled to the same fees and allowances as provided for under 28 U.S.C. 1821. The party who applies for a subpoena to compel the attendance of a witness at a deposition or hearing, or the party at whose request a witness appears at a deposition or hearing, must pay the witness fees and allowances described in this section.

(d) *Service of subpoenas.* Any person who is at least 18 years old and not a party may serve a subpoena. Serving a subpoena requires delivering a copy to the named person. Except for the complainant, the party that requested the subpoena must tender at the time of service the fees for 1 day's attendance and the allowances allowed by law if the subpoena requires that person's attendance. Proving service, if necessary, requires the filing with the FAA Hearing Docket of a statement showing the date and manner of service and the names of the persons served. The server must certify the statement.

(e) *Motion to quash or modify the subpoena.* A party, or any person served with a subpoena, may file a motion to quash or modify the subpoena with the hearing officer at or before the time specified in the subpoena for compliance. The movant must describe, in detail, the basis for the application to quash or modify the subpoena including, but not limited to, a statement that the testimony, document, or tangible thing is not relevant to the proceeding, that the subpoena is not reasonably tailored to the scope of the proceeding, or that the subpoena is unreasonable and oppressive. A motion to quash or modify the subpoena will stay the effect of the subpoena pending a decision by the hearing officer on the motion.

(f) *Enforcement of subpoena.* If a person disobeys a subpoena, a party may apply to a U.S. district court to seek judicial enforcement of the subpoena.

§ 13.59 Evidence.

(a) Each party to a hearing may present the party's case or defense by oral or documentary evidence, submit evidence in rebuttal, and conduct such cross-examination as may be needed for a full disclosure of the facts.

(b) Except with respect to affirmative defenses and notices of proposed denial, the burden of proof is upon the complainant.

§ 13.61 Argument and submittals.

The hearing officer must give the parties adequate opportunity to present arguments in support of motions,

objections, and the final order. The hearing officer may determine whether arguments are to be oral or written. At the end of the hearing, the hearing officer may allow each party to submit written proposed findings and conclusions and supporting reasons for them.

§ 13.63 Record, decision, and aircraft registration proceedings.

(a) *The record.* (1) The testimony and exhibits admitted at a hearing, together with all papers, requests, and rulings filed in the proceedings, are the exclusive basis for the issuance of the hearing officer's decision.

(2) On appeal to the Administrator, the record shall include all of the information identified in paragraph (a)(1) of this section and evidence proffered but not admitted at the hearing.

(3) Any party may obtain a transcript of the hearing from the official reporter upon payment of the required fees.

(b) *Hearing officer's decision.* The decision by the hearing officer must include findings of fact based on the record, conclusions of law, and an appropriate order.

(c) *Certain aircraft registration proceedings.* If the hearing officer determines that an aircraft is ineligible for a certificate of aircraft registration in proceedings relating to aircraft registration orders suspending or revoking a certificate of registration under § 13.20, the hearing officer may suspend or revoke the aircraft registration certificate.

§ 13.65 Appeal to the Administrator, reconsideration, and judicial review.

(a) Any party to a hearing may appeal from the order of the hearing officer by filing with the FAA Hearing Docket a notice of appeal to the Administrator within 20 days after the date of issuance of the order. Filing and service of the notice of appeal, and any other papers, are accomplished according to the procedures in § 13.43.

(b) If a notice of appeal is not filed from the order issued by a hearing officer, such order is final with respect to the parties. Such order is not binding precedent and is not subject to judicial review.

(c) Any person filing an appeal authorized by paragraph (a) of this section must file an appeal brief with the Administrator within 40 days after the date of issuance of the order, and serve a copy on the other party. A reply brief must be filed within 40 days after service of the appeal brief and a copy served on the appellant.

(d) On appeal, the Administrator reviews the record of the proceeding and issues an order dismissing, reversing, modifying or affirming the order. The Administrator's order includes the reasons for the Administrator's action. The Administrator considers only whether:

(1) Each finding of fact is supported by a preponderance of the reliable, probative, and substantial evidence;

(2) Each conclusion is made in accordance with law, precedent, and policy; and

(3) The hearing officer committed any prejudicial error.

(e) The Director and legal personnel of the Office of Adjudication serve as the advisors to the Administrator for appeals under this section.

(1) The Director has the authority to:

(i) Manage all or portions of individual appeals; and to prepare written decisions and proposed final orders in such appeals;

(ii) Issue procedural and other interlocutory orders aimed at proper and efficient appeal management, including, without limitation, scheduling and sanctions orders;

(iii) Grant or deny motions to dismiss appeals;

(iv) Dismiss appeals upon request of the appellant or by agreement of the parties;

(v) Stay decisions and orders of the Administrator, pending judicial review or reconsideration by the Administrator;

(vi) Summarily dismiss repetitious or frivolous petitions to reconsider or modify orders;

(vii) Correct typographical, grammatical, and similar errors in the Administrator's decisions and orders, and to make non-substantive editorial changes; and

(viii) Take all other reasonable steps deemed necessary and proper for the management of the appeals process, in accordance with this part and applicable law.

(2) The Director's authority in paragraph (e)(1) of this section may be re-delegated, as necessary, except to hearing officers and others materially involved in the hearing that is the subject of the appeal.

(f) Motions to reconsider the final order of the Administrator must be filed with the FAA Hearing Docket within thirty days of service of the Administrator's order.

(g) Judicial review of the Administrator's final order under this section is provided in accordance with 49 U.S.C. 5127 or 46110, as applicable.

§ 13.67 Procedures for expedited proceedings.

(a) When an expedited administrative hearing is requested in accordance with § 13.20(d), the procedures in this subpart will apply except as provided in paragraphs (a)(1) through (7) of this section.

(1) Service and filing of pleadings, motions, and documents must be by overnight delivery, and fax or email. Responses to motions must be filed within 7 days after service of the motion.

(2) Within 3 days after receipt of the request for hearing, the agency must file a copy of the notice of proposed action, which serves as the complaint, to the FAA Hearing Docket.

(3) Within 3 days after receipt of the complaint, the person that requested the hearing must file an answer to the complaint. All allegations in the complaint not specifically denied in the answer are deemed admitted. Failure to file a timely answer, absent a showing of good cause, constitutes withdrawal of the request for hearing.

(4) Within 3 days of the filing of the complaint, the Director of the Office of Adjudication will assign a hearing officer to preside over the matter.

(5) The parties must serve discovery as soon as possible and set time limits for compliance with discovery requests that accommodate the accelerated adjudication schedule set forth in this subpart. The hearing officer will resolve any failure of the parties to agree to a discovery schedule.

(6) The expedited hearing must commence within 40 days after the notice of proposed action was issued.

(7) The hearing officer must issue an oral decision and order dismissing, reversing, modifying, or affirming the notice of proposed action at the close of the hearing. If a notice of appeal is not filed, such order is final with respect to the parties and is not subject to judicial review.

(b) Any party to the expedited hearing may appeal from the initial decision of the hearing officer to the Administrator by filing a notice of appeal within 3 days after the date on which the decision was issued. The time limitations for the filing of documents for appeals under this section will not be extended by reason of the unavailability of the hearing transcript.

(1) Any appeal to the Administrator under this section must be perfected within 7 days after the date the notice of appeal was filed by filing a brief in support of the appeal. Any reply to the appeal brief must be filed within 7 days after the date the appeal brief was served on that party. The Administrator must issue an order deciding the appeal no later than 80 days after the date the notice of proposed action was issued.

(2) The Administrator's order is immediately effective and constitutes the final agency decision. The Administrator's order may be appealed pursuant to 49 U.S.C. 46110. The filing of an appeal under 49 U.S.C. 46110 does not stay the effectiveness of the Administrator's order.

(c) At any time after an immediately effective order is issued, the FAA may request the United States Attorney General, or the delegate of the Attorney General, to bring an action for appropriate relief.

§ 13.69 Other matters: Alternative dispute resolution, standing orders, and forms.

(a) Parties may use mediation to achieve resolution of issues in controversy addressed by this subpart. Parties seeking alternative dispute resolution services may engage the services of a mutually acceptable mediator. The mediator must not participate in the adjudication under this subpart of any matter in which the mediator has provided mediation services. Mediation discussions and submissions will remain confidential consistent with the provisions of the Administrative Dispute Resolution Act, the principles of Federal Rule of Evidence 408, and other applicable Federal laws.

(b) The Director of the Office of Adjudication may issue standing orders and forms needed for the proper dispatch of business under this subpart.

■ 6. Revise subpart E to read as follows:

Subpart E—Orders of Compliance Under the Hazardous Materials Transportation Act

Sec.
13.71 Applicability.
13.73 Notice of proposed order of compliance.
13.75 Reply or request for hearing.
13.77 Consent order of compliance.
13.79 [Reserved]
13.81 Emergency orders.
13.83 through 13.87 [Reserved]

§ 13.71 Applicability.

(a) An order of compliance may be issued after notice and an opportunity for a hearing in accordance with §§ 13.73 through 13.77 whenever the Chief Counsel, a Deputy Chief Counsel, or the Assistant Chief Counsel for Enforcement has reason to believe that a person is engaging in the transportation or shipment by air of hazardous materials in violation of the Hazardous Materials Transportation Act, as amended and codified at 49 U.S.C. chapter 51, or any rule, regulation, or order issued under 49 U.S.C. chapter 51, for which the FAA exercises enforcement responsibility, and the circumstances do not require the issuance of an emergency order under 49 U.S.C. 5121(d).

(b) If circumstances require the issuance of an emergency order under 49 U.S.C. 5121(d), the Chief Counsel, a Deputy Chief Counsel, or the Assistant Chief Counsel for Enforcement will issue an emergency order of compliance as described in § 13.81.

§ 13.73 Notice of proposed order of compliance.

The Chief Counsel, a Deputy Chief Counsel, or the Assistant Chief Counsel for Enforcement may issue to an alleged violator a notice of proposed order of compliance advising the alleged violator of the charges and setting forth the remedial action sought in the form of a proposed order of compliance.

§ 13.75 Reply or request for hearing.

(a) Within 30 days after service upon the alleged violator of a notice of proposed order of compliance, the alleged violator may—

(1) Submit a written reply;

(2) Submit a written request for an informal conference to discuss the matter with an agency attorney; or

(3) Request a hearing in accordance with subpart D of this part.

(b) If, after an informal conference is held or a reply is filed, the agency attorney notifies the person named in the notice that some or all of the proposed agency action will not be withdrawn or will not be subject to a consent order of compliance, the alleged violator may, within 10 days after receiving the agency attorney's notification, request a hearing in accordance with subpart D of this part.

(c) Failure of the alleged violator to file a reply or request a hearing within the period provided in paragraph (a) or (b) of this section, as applicable—

(1) Constitutes a waiver of the right to a hearing under subpart D of this part and the right to petition for judicial review; and

(2) Authorizes the Administrator to make any appropriate findings of fact and to issue an appropriate order of compliance, without further notice or proceedings.

§ 13.77 Consent order of compliance.

(a) At any time before the issuance of an order of compliance, an agency attorney and the alleged violator may agree to dispose of the case by the issuance of a consent order of compliance.

(b) The alleged violator may submit a proposed consent order to an agency attorney. The proposed consent order must include—

(1) An admission of all jurisdictional facts;

(2) An express waiver of the right to further procedural steps and of all rights to legal review in any forum;

(3) An express waiver of attorney's fees and costs;

(4) If a notice has been issued prior to the proposed consent order of compliance, an incorporation by reference of the notice and an acknowledgement that the notice may be used to construe the terms of the consent order of compliance; and

(5) If a request for hearing is pending in any forum, a provision that the alleged violator will withdraw the request for a hearing and request that the case be dismissed.

§ 13.79 [Reserved]

§ 13.81 Emergency orders.

(a) Notwithstanding §§ 13.73 through 13.77, the Chief Counsel, each Deputy Chief Counsel, or the Assistant Chief Counsel for Enforcement may issue an emergency order of compliance, which is effective upon issuance, in accordance with the procedures in subpart C of 49 CFR part 109, if the person who issues the order finds that there is an ''imminent hazard'' as defined in 49 CFR 109.1.

(b) The FAA official who issued the emergency order of compliance may rescind or suspend the order if the criteria set forth in paragraph (a) of this section are no longer satisfied, and, when appropriate, may issue a notice of proposed order of compliance under § 13.73.

(c) If at any time in the course of a proceeding commenced in accordance with § 13.73 the criteria set forth in paragraph (a) of this section are satisfied, the official who issued the notice may issue an emergency order of compliance, even if the period for filing a reply or requesting a hearing specified in § 13.75 has not expired.

§§ 13.83 through 13.87 [Reserved]

■ 7. Revise subpart F to read as follows:

Subpart F—Formal Fact-Finding Investigation Under an Order of Investigation

Sec.
13.101 Applicability.
13.103 Order of investigation.
13.105 Notification.
13.107 Designation of additional parties.
13.109 Convening the investigation.
13.111 Subpoenas.
13.113 Noncompliance with the investigative process.
13.115 Public proceedings.
13.117 Conduct of investigative proceeding or deposition.

13.119 Immunity and orders requiring testimony or other information.
13.121 Witness fees.
13.123 Submission by party to the investigation.
13.125 Depositions.
13.127 Reports, decisions, and orders.
13.129 Post-investigation action.
13.131 Other procedures.

§ 13.101 Applicability.

(a) This subpart applies to fact-finding investigations in which an investigation has been ordered under § 13.3(c) or § 13.5(f)(2).

(b) This subpart does not limit the authority of any person to issue subpoenas, administer oaths, examine witnesses, and receive evidence in any informal investigation as otherwise provided by law.

§ 13.103 Order of investigation.

The order of investigation—

(a) Defines the scope of the investigation by describing the information sought in terms of its subject matter or its relevancy to specified FAA functions;

(b) Sets forth the form of the investigation which may be either by individual deposition or investigative proceeding or both; and

(c) Names the official who is authorized to conduct the investigation and serve as the presiding officer.

§ 13.105 Notification.

Any person under investigation and any person required to testify and produce documentary or physical evidence during the investigation will be advised of the purpose of the investigation, and of the place where the investigative proceeding or deposition will be convened. This may be accomplished by a notice of investigation or by a subpoena. A copy of the order of investigation may be sent to such persons when appropriate.

§ 13.107 Designation of additional parties.

(a) The presiding officer may designate additional persons as parties to the investigation, if in the discretion of the presiding officer, it will aid in the conduct of the investigation.

(b) The presiding officer may designate any person as a party to the investigation if—

(1) The person petitions the presiding officer to participate as a party;

(2) The disposition of the investigation may as a practical matter impair the ability to protect the person's interest unless allowed to participate as a party; and

(3) The person's interest is not adequately represented by existing parties.

§ 13.109 Convening the investigation.

The presiding officer will conduct the investigation at a location convenient to the parties involved and as expeditious and efficient as handling of the investigation permits.

§ 13.111 Subpoenas.

(a) At the discretion of the presiding officer, or at the request of a party to the investigation, the presiding officer may issue a subpoena directing any person to appear at a designated time and place to testify or to produce documentary or physical evidence relating to any matter under investigation.

(b) Subpoenas must be served by personal service on the person or an agent designated in writing for the purpose, or by registered or certified mail addressed to the person or agent. Whenever service is made by registered or certified mail, the date of mailing will be considered the time when service is made.

(c) Subpoenas extend in jurisdiction throughout the United States and any territory or possession thereof.

§ 13.113 Noncompliance with the investigative process.

(a) If a person disobeys a subpoena, the Administrator or a party to the investigation may petition a court of the United States to enforce the subpoena in accordance with applicable statutes.

(b) If a party to the investigation fails to comply with the provisions of this subpart or an order issued by the presiding officer, the Administrator may bring a civil action to enforce the requirements of this subpart or any order issued under this subpart in a court of the United States in accordance with applicable statutes.

§ 13.115 Public proceedings.

(a) All investigative proceedings and depositions must be public unless the presiding officer determines that the public interest requires otherwise.

(b) The presiding officer may order information contained in any report or document filed or in any testimony given pursuant to this subpart withheld from public disclosure when, in the judgment of the presiding officer, disclosure would adversely affect the interests of any person and is not required in the public interest or is not otherwise required by statute to be made available to the public. Any person may make written objection to the public disclosure of information, stating the grounds for such objection.

§ 13.117 Conduct of investigative proceeding or deposition.

(a) The presiding officer may question witnesses.

(b) Any witness may be accompanied by counsel.

(c) Any party may be accompanied by counsel and either the party or counsel may—

(1) Question witnesses, provided the questions are relevant and material to the matters under investigation and would not unduly impede the progress of the investigation; and

(2) Make objections on the record and argue the basis for such objections.

(d) Copies of all notices or written communications sent to a party or witness must, upon request, be sent to that person's attorney of record.

§ 13.119 Immunity and orders requiring testimony or other information.

(a) Whenever a person refuses, on the basis of a privilege against self-incrimination, to testify or provide other information during the course of any investigation conducted under this subpart, the presiding officer may, with the approval of the United States Attorney General, or the delegate of the Attorney General, issue an order requiring the person to give testimony or provide other information. However, no testimony or other information so compelled (or any information directly or indirectly derived from such testimony or other information) may be used against the person in any criminal case, except in a prosecution for perjury, giving a false statement, or otherwise failing to comply with the order.

(b) The presiding officer may issue an order under this section if—

(1) The testimony or other information from the witness may be necessary to the public interest; and

(2) The witness has refused or is likely to refuse to testify or provide other information on the basis of a privilege against self-incrimination.

(c) Immunity provided by this section will not become effective until the person has refused to testify or provide other information on the basis of a privilege against self-incrimination, and an order under this section has been issued. An order, however, may be issued prospectively to become effective in the event of a claim of the privilege.

§ 13.121 Witness fees.

All witnesses appearing, other than employees of the Federal Aviation Administration, are entitled to the same fees and allowances as provided for under 28 U.S.C. 1821.

§ 13.123 Submission by party to the investigation.

(a) During an investigation conducted under this subpart, a party may submit to the presiding officer—

(1) A list of witnesses to be called, specifying the subject matter of the expected testimony of each witness; and

(2) A list of exhibits to be considered for inclusion in the record.

(b) If the presiding officer determines that the testimony of a witness or the receipt of an exhibit in accordance with paragraph (a) of this section will be relevant, competent, and material to the investigation, the presiding officer may subpoena the witness or use the exhibit during the investigation.

§ 13.125 Depositions.

Depositions for investigative purposes may be taken at the discretion of the presiding officer with reasonable notice to the party under investigation. Depositions must be taken before the presiding officer or other person authorized to administer oaths and designated by the presiding officer. The testimony must be reduced to writing by the person taking the deposition, or under the direction of that person, and where possible must then be subscribed by the deponent. Any person may be compelled to appear and testify and to produce physical and documentary evidence.

§ 13.127 Reports, decisions, and orders.

The presiding officer must issue a written report based on the record developed during the formal investigation, including a summary of principal conclusions. A summary of principal conclusions must be prepared by the official who issued the order of investigation in every case that results in no action, or no action as to a particular party to the investigation. All such reports must be furnished to the parties to the investigation and made available to the public on request.

§ 13.129 Post-investigation action.

A decision on whether to initiate subsequent action must be made on the basis of the record developed during the formal investigation and any other information in the possession of the Administrator.

§ 13.131 Other procedures.

Any question concerning the scope or conduct of a formal investigation not covered in this subpart may be ruled on by the presiding officer on his or her own initiative, or on the motion of a party or a person testifying or producing evidence.

■ 8. Revise subpart G to read as follows:

Subpart G—Rules of Practice In FAA Civil Penalty Actions

Sec.

13.201 Applicability.
13.202 Definitions.
13.203 Separation of functions.
13.204 Appearances and rights of parties.
13.205 Administrative law judges.
13.206 Intervention.
13.207 Certification of documents.
13.208 Complaint.
13.209 Answer.
13.210 Filing of documents.
13.211 Service of documents.
13.212 Computation of time.
13.213 Extension of time.
13.214 Amendment of pleadings.
13.215 Withdrawal of complaint or request for hearing.
13.216 Waivers.
13.217 Joint procedural or discovery schedule.
13.218 Motions.
13.219 Interlocutory appeals.
13.220 Discovery.
13.221 Notice of hearing.
13.222 Evidence.
13.223 Standard of proof.
13.224 Burden of proof.
13.225 Offer of proof.
13.226 Public disclosure of information.
13.227 Expert or opinion witnesses.
13.228 Subpoenas.
13.229 Witness fees.
13.230 Record.
13.231 Argument before the administrative law judge.
13.232 Initial decision.
13.233 Appeal from initial decision.
13.234 Petition to reconsider or modify a final decision and order of the FAA decisionmaker on appeal.
13.235 Judicial review of a final decision and order.
13.236 Alternative dispute resolution.

§ 13.201 Applicability.

This subpart applies to all civil penalty actions initiated under § 13.16 in which a hearing has been requested.

§ 13.202 Definitions.

For this subpart only, the following definitions apply:

Administrative law judge means an administrative law judge appointed pursuant to the provisions of 5 U.S.C. 3105.

Agency attorney means the Deputy Chief Counsel or the Assistant Chief Counsel responsible for the prosecution of enforcement-related matters under this subpart, or attorneys who are supervised by those officials or are assigned to prosecute a particular enforcement-related matter under this subpart. Agency attorney does not include the Chief Counsel or anyone from the Office of Adjudication.

Complaint means a document issued by an agency attorney alleging a violation of a provision of the Federal aviation statute listed in the first sentence of 49 U.S.C. 46301(d)(2) or in 49 U.S.C. 47531, or of the Federal hazardous materials transportation statute, 49 U.S.C. 5121–5128, or a rule, regulation, or order issued under those statutes, that has been filed with the FAA Hearing Docket after a hearing has been requested under § 13.16(f)(3) or (g)(2)(ii).

Complainant means the FAA office that issued the notice of proposed civil penalty under § 13.16.

FAA decisionmaker means the Administrator of the Federal Aviation Administration, acting in the capacity of the decisionmaker on appeal, or any person to whom the Administrator has delegated the Administrator's decisionmaking authority in a civil penalty action. As used in this subpart, the FAA decisionmaker is the official authorized to issue a final decision and order of the Administrator in a civil penalty action.

Mail includes U.S. mail, U.S. certified mail, U.S. registered mail, or use of an expedited or overnight express courier service, but does not include email.

Office of Adjudication means the Federal Aviation Administration Office of Adjudication, including the FAA Hearing Docket, the Director of the Office of Adjudication and legal personnel, or any subsequently designated office (including its head and any legal personnel) that advises the FAA decisionmaker regarding appeals of initial decisions and orders to the FAA decisionmaker.

Order assessing civil penalty means a document that contains a finding of a violation of a provision of the Federal aviation statute listed in the first sentence of 49 U.S.C. 46301(d)(2) or in 49 U.S.C. 47531, or of the Federal hazardous materials transportation statute, 49 U.S.C. 5121–5128, or a rule, regulation, or order issued under those statutes, and may direct payment of a civil penalty. Unless an appeal is filed with the FAA decisionmaker in a timely manner, an initial decision or order of an administrative law judge is considered an order assessing civil penalty if an administrative law judge finds that an alleged violation occurred and determines that a civil penalty, in an amount found appropriate by the administrative law judge, is warranted. Unless a petition for review is filed with a U.S. Court of Appeals in a timely manner, a final decision and order of the Administrator is considered an order assessing civil penalty if the FAA decisionmaker finds that an alleged violation occurred and a civil penalty is warranted.

Party means the Respondent, the complainant and any intervenor.

Personal delivery includes hand-delivery or use of a contract or express messenger service. ''Personal delivery''

does not include the use of Federal Government interoffice mail service.

Pleading means a complaint, an answer, and any amendment of these documents permitted under this subpart.

Properly addressed means a document that shows an address contained in agency records; a residential, business, or other address submitted by a person on any document provided under this subpart; or any other address shown by other reasonable and available means.

Respondent means a person named in a complaint.

Writing or written includes paper or electronic documents that are filed or served by email, mail, personal delivery, or fax.

§ 13.203 Separation of functions.

(a) Civil penalty proceedings, including hearings, are prosecuted by an agency attorney.

(b) An agency employee who has engaged in the performance of investigative or prosecutorial functions in a civil penalty action must not participate in deciding or advising the administrative law judge or the FAA decisionmaker in that case, or a factually-related case, but may participate as counsel for the complainant or as a witness in the public proceedings.

(c) The Chief Counsel and the Director and legal personnel of the Office of Adjudication will advise the FAA decisionmaker regarding any appeal of an initial decision or order in a civil penalty action to the FAA decisionmaker.

§ 13.204 Appearances and rights of parties.

(a) Any party may appear and be heard in person.

(b) Any party may be accompanied, represented, or advised by an attorney or representative designated by the party, and may be examined by that attorney or representative in any proceeding governed by this subpart. An attorney or representative who represents a party must file a notice of appearance in the action, in the manner provided in § 13.210, and must serve a copy of the notice of appearance on each party, and on the administrative law judge, if assigned, in the manner provided in § 13.211, before participating in any proceeding governed by this subpart. The attorney or representative must include the name, address, and telephone number, and, if available, fax number and email address, of the attorney or representative in the notice of appearance.

(c) Any person may request a copy of a document in the record upon payment of reasonable costs. A person may keep an original document, data, or evidence, with the consent of the administrative law judge, by substituting a legible copy of the document for the record.

§ 13.205 Administrative law judges.

(a) *Powers of an administrative law judge.* In accordance with the rules of this subpart, an administrative law judge may:

(1) Give notice of, and hold, prehearing conferences and hearings;

(2) Administer oaths and affirmations;

(3) Issue subpoenas as authorized by law;

(4) Rule on offers of proof;

(5) Receive relevant and material evidence;

(6) Regulate the course of the hearing in accordance with the rules of this subpart;

(7) Hold conferences to settle or to simplify the issues by consent of the parties;

(8) Dispose of procedural motions and requests;

(9) Make findings of fact and conclusions of law, and issue an initial decision;

(10) Bar a person from a specific proceeding based on a finding of obstreperous or disruptive behavior in that specific proceeding; and

(11) Take any other action authorized by this subpart.

(b) *Limitations.* The administrative law judge must not issue an order of contempt, award costs to any party, or impose any sanction not specified in this subpart. If the administrative law judge imposes any sanction not specified in this subpart, a party may file an interlocutory appeal of right under § 13.219(c).

(c) *Disqualification.* The administrative law judge may disqualify himself or herself at any time. A party may file a motion for disqualification under § 13.218.

§ 13.206 Intervention.

(a) A person may submit a motion for leave to intervene as a party in a civil penalty action. Except for good cause shown, a motion for leave to intervene must be submitted not later than 10 days before the hearing.

(b) The administrative law judge may grant a motion for leave to intervene if the administrative law judge finds that intervention will not unduly broaden the issues or delay the proceedings and—

(1) The person seeking to intervene will be bound by any order or decision entered in the action; or

(2) The person seeking to intervene has a property, financial, or other legitimate interest that may not be addressed adequately by the parties.

(c) The administrative law judge may determine the extent to which an intervenor may participate in the proceedings.

§ 13.207 Certification of documents.

(a) *Signature required.* The attorney of record, the party, or the party's representative must sign, by hand, electronically, or by other method acceptable to the administrative law judge, or, if the matter is on appeal, to the FAA decisionmaker, each document tendered for filing with the FAA Hearing Docket or served on the administrative law judge and on each other party.

(b) *Effect of signing a document.* By signing a document, the attorney of record, the party, or the party's representative certifies that the attorney, the party, or the party's representative has read the document and, based on reasonable inquiry and to the best of that person's knowledge, information, and belief, the document is—

(1) Consistent with the rules in this subpart;

(2) Warranted by existing law or a good faith argument for extension, modification, or reversal of existing law; and

(3) Not unreasonable or unduly burdensome or expensive, not made to harass any person, not made to cause unnecessary delay, and not made to cause needless increase in the cost of the proceedings or for any other improper purpose.

(c) *Sanctions.* If the attorney of record, the party, or the party's representative signs a document in violation of this section, the administrative law judge or the FAA decisionmaker must:

(1) Strike the pleading signed in violation of this section;

(2) Strike the request for discovery or the discovery response signed in violation of this section and preclude further discovery by the party;

(3) Deny the motion or request signed in violation of this section;

(4) Exclude the document signed in violation of this section from the record;

(5) Dismiss the interlocutory appeal and preclude further appeal on that issue by the party who filed the appeal until an initial decision has been entered on the record; or

(6) Dismiss the appeal of the administrative law judge's initial decision to the FAA decisionmaker.

§ 13.208 Complaint.

(a) *Filing.* The agency attorney must file the complaint with the FAA Hearing

Docket, or may file a written motion to dismiss a request for hearing under § 13.218 instead of filing a complaint, not later than 20 days after receipt by the agency attorney of a request for hearing. When filing the complaint, the agency attorney must follow the filing instructions in § 13.210. The agency attorney may suggest a location for the hearing when filing the complaint.

(b) *Service.* An agency attorney must serve a copy of the complaint on the respondent, the president of the corporation or company named as a respondent, or a person designated by the respondent to accept service of documents in the civil penalty action. When serving the complaint, the agency attorney must follow the service instructions in § 13.211.

(c) *Contents.* A complaint must set forth the facts alleged, any regulation allegedly violated by the respondent, and the proposed civil penalty in sufficient detail to provide notice of any factual or legal allegation and proposed civil penalty.

(d) *Motion to dismiss stale allegations or complaint.* Instead of filing an answer to the complaint, a respondent may move to dismiss the complaint, or that part of the complaint, alleging a violation that occurred more than 2 years before an agency attorney issued a notice of proposed civil penalty to the respondent.

(1) An administrative law judge may not grant the motion and dismiss the complaint or part of the complaint if the administrative law judge finds that the agency has shown good cause for any delay in issuing the notice of proposed civil penalty.

(2) If the agency fails to show good cause for any delay, an administrative law judge may dismiss the complaint, or that part of the complaint, alleging a violation that occurred more than 2 years before an agency attorney issued the notice of proposed civil penalty to the respondent.

(3) A party may appeal the administrative law judge's ruling on the motion to dismiss the complaint or any part of the complaint in accordance with § 13.219(b).

§ 13.209 Answer.

(a) *Writing required.* A respondent must file in the FAA Hearing Docket a written answer to the complaint, or may file a written motion pursuant to § 13.208 or § 13.218 instead of filing an answer, not later than 30 days after service of the complaint. The answer must be dated and signed by the person responding to the complaint. An answer must be typewritten or legibly handwritten.

(b) *Filing.* A person filing an answer or motion under paragraph (a) of this section must follow the filing instructions in § 13.210.

(c) *Service.* A person filing an answer or a motion under paragraph (a) of this section must serve a copy of the answer or motion in accordance with the service instructions in § 13.211.

(d) *Contents.* An answer must specifically state any affirmative defense that the respondent intends to assert at the hearing. A person filing an answer may include a brief statement of any relief requested in the answer. The person filing an answer may recommend a location for the hearing when filing the answer.

(e) *Specific denial of allegations required.* A person filing an answer must admit, deny, or state that the person is without sufficient knowledge or information to admit or deny, each allegation in the complaint. All allegations in the complaint not specifically denied in the answer are deemed admitted. A general denial of the complaint is deemed a failure to file an answer.

(f) *Failure to file answer.* A person's failure to file an answer without good cause will be deemed an admission of the truth of each allegation contained in the complaint.

§ 13.210 Filing of documents.

(a) *General rule.* Unless provided otherwise in this subpart, all documents in proceedings under this subpart must be tendered for filing with the FAA Hearing Docket.

(b) *Methods of filing.* Filing must be by email, personal delivery, mail, or fax.

(c) *Address for filing.* A person filing a document with the FAA Hearing Docket must use the address identified for the method of filing as follows:

(1) *If delivery is in person, or by expedited or overnight express courier service.* Federal Aviation Administration, 600 Independence Avenue SW, Wilbur Wright Building—Suite 2W100, Washington, DC 20597; Attention: FAA Hearing Docket, AGC–70.

(2) *If delivery is via U.S. mail, or U.S. certified or registered mail.* Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; Attention: FAA Hearing Docket, AGC–70, Wilbur Wright Building—Suite 2W100.

(3) *If delivery is via email or fax.* The email address and fax number for the FAA Hearing Docket, made available on the FAA Office of Adjudication website.

(d) *Date of filing.* If a document is filed by fax or email, the date of filing is the date the email or fax is sent. If a document is filed by personal delivery, the date of filing is the date that personal delivery is accomplished. If a document is filed by mail, the date of filing is the date shown on the certificate of service, the date shown on the postmark if there is no certificate of service, or the mailing date shown by other evidence if there is no certificate of service or postmark.

(e) *Form.* Each document must be typewritten or legibly handwritten.

(f) *Contents.* Unless otherwise specified in this subpart, each document must contain a short, plain statement of the facts on which the person's case rests and a brief statement of the action requested.

(g) *Requirement to file an original document and number of copies.* A party must file an original document and one copy when filing by personal delivery or by mail. Only one copy must be filed if filing is accomplished by email or fax.

(h) *Filing by email.* A document that is filed by email must be attached as a PDF file to an email. The document must be signed in accordance with § 13.207. The email message does not constitute a submission, but serves only to deliver the attached PDF file to the FAA Hearing Docket.

§ 13.211 Service of documents.

(a) *General.* A person must serve a copy of all documents on each party and the administrative law judge, if assigned, at the time of filing with the FAA Hearing Docket except as provided otherwise in this subpart.

(b) *Service by the FAA Hearing Docket, the administrative law judge, and the FAA decisionmaker.* The FAA Hearing Docket, the administrative law judge, and the FAA decisionmaker must send documents to a party by personal delivery, mail, fax, or email as provided in this section.

(c) *Methods of service*—(1) *General.* A person may serve any document by email, personal delivery, mail, or fax.

(2) *Service by email.* Service of documents by email is voluntary and requires the prior consent of the person to be served by email. A person may retract consent to be served by email by filing a written retraction with the FAA Hearing Docket and serving it on the other party and the administrative law judge. A document that is served by email must be attached as a PDF file to an email message.

(d) *Certificate of service.* A certificate of service must accompany all documents filed with the FAA Hearing Docket. The certificate of service must be signed, describe the method of service, and state the date of service.

(e) *Date of service.* If a document is served by fax or served by email, the date of service is the date the email or fax is sent. If a document is served by personal delivery, the date of service is the date that personal delivery is accomplished. If a document is mailed, the date of service is the date shown on the certificate of service, the date shown on the postmark if there is no certificate of service, or the mailing date shown by other evidence if there is no certificate of service or postmark.

(f) *Valid service.* A document served by mail or personal delivery that was properly addressed, was sent in accordance with this subpart, and that was returned as unclaimed, or that was refused or not accepted, is deemed to have been served in accordance with this subpart.

(g) *Additional time after service by mail.* Whenever a party must respond within a prescribed period after service by mail, 5 days are added to the prescribed period.

(h) *Presumption of service.* There is a presumption of service where a party or a person, who customarily receives mail, or receives it in the ordinary course of business, at either the person's residence or the person's principal place of business, acknowledges receipt of the document.

§ 13.212 Computation of time.

(a) This section applies to any period of time prescribed or allowed by this subpart, by notice or order of the administrative law judge, or by any applicable statute.

(b) The date of an act, event, or default is not included in a computation of time under this subpart.

(c) The last day of a time period is included unless it is a Saturday, Sunday, or a Federal holiday. If the last day is a Saturday, Sunday, or Federal holiday, the time period runs until the end of the next day that is not a Saturday, Sunday, or Federal holiday.

§ 13.213 Extension of time.

(a) The parties may agree to extend for a reasonable period the time for filing a document under this subpart. The party seeking the extension of time must submit a draft order to the administrative law judge to be signed by the administrative law judge and filed with the FAA Hearing Docket. The administrative law judge must sign and issue the order if the extension agreed to by the parties is reasonable.

(b) A party may file a written motion for an extension of time. A written motion for an extension of time must be filed with the FAA Hearing Docket in accordance with § 13.210. The motion must be filed no later than seven days before the document is due unless good cause for the late filing is shown. The party filing the motion must serve a copy of the motion in accordance with § 13.211. The administrative law judge may grant the extension of time if good cause for the extension is shown.

(c) If the administrative law judge fails to rule on a motion for an extension of time by the date the document was due, the motion for an extension of time is deemed granted for no more than 20 days after the original date the document was to be filed.

§ 13.214 Amendment of pleadings.

(a) *Filing and service.* A party must file the amendment with the FAA Hearing Docket and must serve a copy of the amendment on the administrative law judge, if assigned, and on all parties to the proceeding.

(b) *Time.* (1) Not later than 15 days before the scheduled date of a hearing, a party may amend a complaint or an answer without the consent of the administrative law judge.

(2) Less than 15 days before the scheduled date of a hearing, the administrative law judge may allow amendment of a complaint or an answer only for good cause shown in a motion to amend.

(c) *Responses.* The administrative law judge must allow a reasonable time, but not more than 20 days from the date of filing, for other parties to respond if an amendment to a complaint, answer, or other pleading has been filed with the FAA Hearing Docket and served on the administrative law judge and other parties.

§ 13.215 Withdrawal of complaint or request for hearing.

At any time before or during a hearing, an agency attorney may withdraw a complaint or a party may withdraw a request for a hearing without the consent of the administrative law judge. If an agency attorney withdraws the complaint or a party withdraws the request for a hearing and the answer, the administrative law judge must dismiss the proceedings under this subpart with prejudice.

§ 13.216 Waivers.

Waivers of any rights provided by statute or regulation must be in writing or by stipulation made at a hearing and entered into the record. The parties must set forth the precise terms of the waiver and any conditions.

§ 13.217 Joint procedural or discovery schedule.

(a) *General.* The parties may agree to submit a schedule for filing all prehearing motions, conducting discovery in the proceedings, or both.

(b) *Form and content of schedule.* If the parties agree to a joint procedural or discovery schedule, one of the parties must file the joint schedule setting forth the dates to which the parties have agreed, in accordance with § 13.210, and must also serve a copy of the joint schedule in accordance with § 13.211. The filing of the joint schedule must include a draft order establishing a joint schedule to be signed by the administrative law judge.

(1) The joint schedule may include, but need not be limited to, requests for discovery, objections to discovery requests, responses to discovery requests to which there are no objections, submission of prehearing motions, responses to prehearing motions, exchange of exhibits to be introduced at the hearing, and a list of witnesses that may be called at the hearing.

(2) Each party must sign the joint schedule.

(c) *Time.* The parties may agree to submit all prehearing motions and responses and may agree to close discovery in the proceedings under the joint schedule within a reasonable time before the date of the hearing, but not later than 15 days before the hearing.

(d) *Joint scheduling order.* The joint schedule filed by the parties is a proposed schedule that requires approval of the administrative law judge to become the joint scheduling order.

(e) *Disputes.* The administrative law judge must resolve disputes regarding discovery or disputes regarding compliance with the joint scheduling order as soon as possible so that the parties may continue to comply with the joint scheduling order.

(f) *Sanctions for failure to comply with joint schedule.* If a party fails to comply with a joint scheduling order, the administrative law judge may impose any of the following sanctions, proportional to the party's failure to comply with the order:

(1) Strike the relevant portion of a party's pleadings;

(2) Preclude prehearing or discovery motions by that party;

(3) Preclude admission of the relevant portion of a party's evidence at the hearing; or

(4) Preclude the relevant portion of the testimony of that party's witnesses at the hearing.

§ 13.218 Motions.

(a) *General.* A party applying for an order or ruling not specifically provided in this subpart must do so by filing a motion in accordance with § 13.210. A party must serve a copy of each motion in accordance with § 13.211.

(b) *Form and contents.* A party must state the relief sought by the motion and the particular grounds supporting that relief. If a party has evidence in support of a motion, the party must attach any supporting evidence, including affidavits, to the motion.

(c) *Filing of motions.* A motion made prior to the hearing must be in writing. Unless otherwise agreed by the parties or for good cause shown, a party must file any prehearing motion not later than 30 days before the hearing in the FAA Hearing Docket in accordance with § 13.210, and must serve a copy on the administrative law judge, if assigned, and on each party in accordance with § 13.211. Motions introduced during a hearing may be made orally on the record unless the administrative law judge directs otherwise.

(d) *Responses to motions.* Any party may file a response, with affidavits or other evidence in support of the response, not later than 10 days after service of a written motion on that party. When a motion is made during a hearing, the response may be made at the hearing on the record, orally or in writing, within a reasonable time determined by the administrative law judge.

(e) *Rulings on motions.* The administrative law judge must rule on all motions as follows:

(1) *Discovery motions.* The administrative law judge must resolve all pending discovery motions not later than 10 days before the hearing.

(2) *Prehearing motions.* The administrative law judge must resolve all pending prehearing motions not later than 7 days before the hearing. If the administrative law judge issues a ruling or order orally, the administrative law judge must serve a written copy of the ruling or order, within 3 days, on each party. In all other cases, the administrative law judge must issue rulings and orders in writing and must serve a copy of the ruling or order on each party.

(3) *Motions made during the hearing.* The administrative law judge must issue rulings and orders on oral motions. Oral rulings or orders on motions must be made on the record.

(f) *Specific motions.* The motions that a party may file include but are not limited to the following:

(1) *Motion to dismiss for insufficiency.* A respondent may file a motion to dismiss the complaint for insufficiency instead of filing an answer. If the administrative law judge denies the motion to dismiss the complaint for insufficiency, the respondent must file an answer not later than 10 days after service of the administrative law judge's denial of the motion. A motion to dismiss the complaint for insufficiency must show that the complaint fails to state a violation of a provision of the Federal aviation statute listed in the first sentence in 49 U.S.C. 46301(d)(2) or in 49 U.S.C. 47531, or any implementing rule, regulation, or order, or a violation of the Federal hazardous materials transportation statute, 49 U.S.C. 5121–5128, or any implementing rule, regulation, or order.

(2) *Motion to dismiss.* A party may file a motion to dismiss, specifying the grounds for dismissal. If an administrative law judge grants a motion to dismiss in part, a party may appeal the administrative law judge's ruling on the motion to dismiss under § 13.219(b).

(i) *Motion to dismiss a request for a hearing.* An agency attorney may file a motion to dismiss a request for a hearing instead of filing a complaint. If the motion to dismiss is not granted, the agency attorney must file the complaint in the FAA Hearing Docket and must serve a copy of the complaint on the administrative law judge and on each party not later than 10 days after service of the administrative law judge's ruling or order on the motion to dismiss. If the motion to dismiss is granted and the proceedings are terminated without a hearing, the respondent may appeal to the FAA decisionmaker under § 13.233. If required by the decision on appeal, the agency attorney must file a complaint in the FAA Hearing Docket and must serve a copy of the complaint on the administrative law judge and each party not later than 10 days after service of the FAA decisionmaker's decision on appeal.

(ii) *Motion to dismiss a complaint.* A respondent may file a motion to dismiss a complaint instead of filing an answer, including a motion to dismiss a stale complaint or allegations as provided in § 13.208. If the motion to dismiss is not granted, the respondent must file an answer in the FAA Hearing Docket and must serve a copy of the answer on the administrative law judge and on each party not later than 10 days after service of the administrative law judge's ruling or order on the motion to dismiss. If the motion to dismiss is granted and the proceedings are terminated without a hearing, the agency attorney may file an appeal in the FAA Hearing Docket under § 13.233 and must serve each other party. If required by the FAA decisionmaker's decision on appeal, the respondent must file an answer in the FAA Hearing Docket, and must serve a copy of the answer on the administrative law judge and on each party not later than 10 days after service of the decision on appeal.

(3) *Motion for a more definite statement.* A party may file a motion for a more definite statement of any pleading which requires a response under this subpart. A party must set forth, in detail, the indefinite or uncertain allegations contained in a complaint or response to any pleading and must submit the details that the party believes would make the allegation or response definite and certain.

(i) *Complaint.* A respondent may file a motion requesting a more definite statement of the allegations contained in the complaint instead of filing an answer. If the administrative law judge grants the motion, the agency attorney must supply a more definite statement not later than 15 days after service of the ruling granting the motion. If the agency attorney fails to supply a more definite statement, the administrative law judge may strike the allegations in the complaint to which the motion is directed. If the administrative law judge denies the motion, the respondent must file an answer in the FAA Hearing Docket and must serve a copy of the answer on the administrative law judge and on each party not later than 10 days after service of the order of denial.

(ii) *Answer.* An agency attorney may file a motion requesting a more definite statement if an answer fails to respond clearly to the allegations in the complaint. If the administrative law judge grants the motion, the respondent must supply a more definite statement not later than 15 days after service of the ruling on the motion. If the respondent fails to supply a more definite statement, the administrative law judge may strike those statements in the answer to which the motion is directed. The respondent's failure to supply a more definite statement may be deemed an admission of unanswered allegations in the complaint.

(4) *Motion to strike.* Any party may make a motion to strike any insufficient allegation or defense, or any redundant, immaterial, impertinent, or scandalous matter in a pleading. A party must file a motion to strike before a response is required under this subpart or, if a response is not required, not later than 10 days after service of the pleading. A motion to strike must be filed in the FAA Hearing Docket and served on the

administrative law judge, if assigned, and on each other party.

(5) *Motion for decision.* A party may make a motion for decision, regarding all or any part of the proceedings, at any time before the administrative law judge has issued an initial decision in the proceedings. The administrative law judge must grant a party's motion for decision if the pleadings, depositions, answers to interrogatories, admissions, matters that the administrative law judge has officially noticed, or evidence introduced during the hearing shows that there is no genuine issue of material fact and that the party making the motion is entitled to a decision as a matter of law. The party making the motion for decision has the burden of showing that there is no genuine issue of material fact disputed by the parties.

(6) *Motion for disqualification.* A party may file a motion for disqualification in the FAA Hearing Docket and must serve a copy on the administrative law judge and on each party. A party may file the motion at any time after the administrative law judge has been assigned to the proceedings but must make the motion before the administrative law judge files an initial decision in the proceedings.

(i) *Motion and supporting affidavit.* A party must state the grounds for disqualification in a motion for disqualification, including, but not limited to, a financial or other personal interest that would be affected by the outcome of the enforcement action, personal animus against a party to the action or against a group to which a party belongs, prejudgment of the adjudicative facts at issue in the proceeding, or any other prohibited conflict of interest. A party must submit an affidavit with the motion for disqualification that sets forth, in detail, the matters alleged to constitute grounds for disqualification.

(ii) *Response.* A party must respond to the motion for disqualification not later than 5 days after service of the motion for disqualification.

(iii) *Decision on motion for disqualification.* The administrative law judge must render a decision on the motion for disqualification not later than 15 days after the motion has been filed. If the administrative law judge finds that the motion for disqualification and supporting affidavit show a basis for disqualification, the administrative law judge must withdraw from the proceedings immediately. If the administrative law judge finds that disqualification is not warranted, the administrative law judge must deny the motion and state the grounds for the denial on the record. If the administrative law judge fails to rule on a party's motion for disqualification within 15 days after the motion has been filed, the motion is deemed granted.

(iv) *Appeal.* A party may appeal the administrative law judge's denial of the motion for disqualification in accordance with § 13.219(b).

(7) *Motions for reconsideration of an initial decision, order dismissing a complaint, order dismissing a request for hearing or order dismissing a request for hearing and answer.* The FAA decisionmaker may treat motions for reconsideration of an initial decision, order dismissing a complaint, order dismissing a request for hearing, or order dismissing a request for hearing and answer as a notice of appeal under § 13.233, and if the motion was filed within the time allowed for the filing of a notice of appeal, the FAA decisionmaker will issue a briefing schedule.

§ 13.219 Interlocutory appeals.

(a) *General.* Unless otherwise provided in this subpart, a party may not appeal a ruling or decision of the administrative law judge to the FAA decisionmaker until the initial decision has been entered on the record. A decision or order of the FAA decisionmaker on the interlocutory appeal does not constitute a final order of the Administrator for the purposes of judicial appellate review as provided in § 13.235.

(b) *Interlocutory appeal for cause.* If a party orally requests or files a written request for an interlocutory appeal for cause, the proceedings are stayed until the administrative law judge issues a decision on the request. Any written request for interlocutory appeal for cause must be filed in the FAA Hearing Docket and served on each party and on the administrative law judge. If the administrative law judge grants the request, the proceedings are stayed until the FAA decisionmaker issues a decision on the interlocutory appeal. The administrative law judge must grant the request if a party shows that delay of the appeal would be detrimental to the public interest or would result in undue prejudice to any party.

(c) *Interlocutory appeals of right.* If a party notifies the administrative law judge of an interlocutory appeal of right, the proceedings are stayed until the FAA decisionmaker issues a decision on the interlocutory appeal. A party may file an interlocutory appeal of right, without the consent of the administrative law judge, before an initial decision has been entered in the case of:

(1) A ruling or order by the administrative law judge barring a person from the proceedings;

(2) Failure of the administrative law judge to dismiss the proceedings in accordance with § 13.215; or

(3) A ruling or order by the administrative law judge in violation of § 13.205(b).

(d) *Procedure.* A party must file a notice of interlocutory appeal, with supporting documents, with the FAA Hearing Docket, and must serve a copy of the notice and supporting documents on each party and the administrative law judge not later than 10 days after the administrative law judge's decision forming the basis of an interlocutory appeal of right, or not later than 10 days after the administrative law judge's decision granting an interlocutory appeal for cause, as appropriate. A party must file a reply, if any, with the FAA Hearing Docket, and serve a copy on each party and the administrative law judge not later than 10 days after service of the appeal. The FAA decisionmaker must render a decision on the interlocutory appeal on the record and as a part of the decision in the proceedings, within a reasonable time after receipt of the interlocutory appeal.

(e) *Summary rejection.* The FAA decisionmaker may reject frivolous, repetitive, or dilatory appeals, and may issue an order precluding one or more parties from making further interlocutory appeals in a proceeding in which there have been frivolous, repetitive, or dilatory interlocutory appeals.

§ 13.220 Discovery.

(a) *Initiation of discovery.* Any party may initiate discovery described in this section without the consent or approval of the administrative law judge at any time after a complaint has been filed in the proceedings.

(b) *Methods of discovery.* The following methods of discovery are permitted under this section: Depositions on oral examination or written questions of any person; written interrogatories directed to a party; requests for production of documents or tangible items to any person; and requests for admission by a party. A party must not file written interrogatories and responses, requests for production of documents or tangible items and responses, and requests for admission and response with the FAA Hearing Docket or serve them on the administrative law judge. In the event of a discovery dispute, a party must attach a copy of the relevant documents in support of a motion made under this section.

(c) *Service on the agency.* A party must serve each discovery request directed to the agency or any agency employee on the agency attorney of record.

(d) *Time for response to discovery requests.* Unless otherwise directed by this subpart or agreed by the parties, a party must respond to a request for discovery, including filing objections to a request for discovery, not later than 30 days after service of the request.

(e) *Scope of discovery.* Subject to the limits on discovery set forth in paragraph (f) of this section, a party may discover any matter that is not privileged and that is relevant to any party's claim or defense, including the existence, description, nature, custody, condition, and location of any document or other tangible item and the identity and location of any person having knowledge of discoverable matter. A party may discover facts known, or opinions held, by an expert who any other party expects to call to testify at the hearing. A party has no ground to object to a discovery request on the basis that the information sought would not be admissible at the hearing.

(f) *Limiting discovery.* The administrative law judge must limit the frequency and extent of discovery permitted by this section if a party shows that—

(1) The information requested is cumulative or repetitious;

(2) The information requested can be obtained from another less burdensome and more convenient source;

(3) The party requesting the information has had ample opportunity to obtain the information through other discovery methods permitted under this section; or

(4) The method or scope of discovery requested by the party is unduly burdensome or expensive.

(g) *Confidential orders.* A party or person who has received a discovery request for information that is related to a trade secret, confidential or sensitive material, competitive or commercial information, proprietary data, or information on research and development, may file a motion for a confidential order in the FAA Hearing Docket in accordance with § 13.210, and must serve a copy of the motion for a confidential order on each party and on the administrative law judge in accordance with § 13.211.

(1) The party or person making the motion must show that the confidential order is necessary to protect the information from disclosure to the public.

(2) If the administrative law judge determines that the requested material is not necessary to decide the case, the administrative law judge must preclude any inquiry into the matter by any party.

(3) If the administrative law judge determines that the requested material may be disclosed during discovery, the administrative law judge may order that the material may be discovered and disclosed under limited conditions or may be used only under certain terms and conditions.

(4) If the administrative law judge determines that the requested material is necessary to decide the case and that a confidential order is warranted, the administrative law judge must provide:

(i) An opportunity for review of the document by the parties off the record;

(ii) Procedures for excluding the information from the record; and

(iii) Order that the parties must not disclose the information in any manner and the parties must not use the information in any other proceeding.

(h) *Protective orders.* A party or a person who has received a request for discovery may file a motion for protective order in the FAA Hearing Docket and must serve a copy of the motion for protective order on the administrative law judge and each other party. The party or person making the motion must show that the protective order is necessary to protect the party or the person from annoyance, embarrassment, oppression, or undue burden or expense. As part of the protective order, the administrative law judge may:

(1) Deny the discovery request;

(2) Order that discovery be conducted only on specified terms and conditions, including a designation of the time or place for discovery or a determination of the method of discovery; or

(3) Limit the scope of discovery or preclude any inquiry into certain matters during discovery.

(i) *Duty to supplement or amend responses.* A party who has responded to a discovery request has a duty to supplement or amend the response, as soon as the information is known, as follows:

(1) A party must supplement or amend any response to a question requesting the identity and location of any person having knowledge of discoverable matters.

(2) A party must supplement or amend any response to a question requesting the identity of each person who will be called to testify at the hearing as an expert witness and the subject matter and substance of that witness's testimony.

(3) A party must supplement or amend any response that was incorrect when made or any response that was correct when made but is no longer correct, accurate, or complete.

(j) *Depositions*—(1) *Form.* A deposition must be taken on the record and reduced to writing. The person being deposed must sign the deposition unless the parties agree to waive the requirement of a signature.

(2) *Administration of oaths.* Within the United States, or a territory or possession subject to the jurisdiction of the United States, a party must take a deposition before a person authorized to administer oaths by the laws of the United States or authorized by the law of the place where the examination is held. In foreign countries, a party must take a deposition in any manner allowed by the Federal Rules of Civil Procedure.

(3) *Notice of deposition.* A party must serve a notice of deposition, stating the time and place of the deposition and the name and address of each person to be examined, on the person to be deposed, the administrative law judge, and each party not later than 7 days before the deposition. The notice must be filed in the FAA Hearing Docket simultaneously. A party may serve a notice of deposition less than 7 days before the deposition only with consent of the administrative law judge. The party noticing a deposition must attach a copy of any subpoena *duces tecum* requesting that materials be produced at the deposition to the notice of deposition.

(4) *Use of depositions.* A party may use any part or all of a deposition at a hearing authorized under this subpart only upon a showing of good cause. The deposition may be used against any party who was present or represented at the deposition or who had reasonable notice of the deposition.

(k) *Interrogatories.* A party, the party's attorney, or the party's representative may sign the party's responses to interrogatories. A party must answer each interrogatory separately and completely in writing. If a party objects to an interrogatory, the party must state the objection and the reasons for the objection. An opposing party may use any part or all of a party's responses to interrogatories at a hearing authorized under this subpart to the extent that the response is relevant, material, and not repetitious.

(1) A party must not serve more than 30 interrogatories to each other party. Each subpart of an interrogatory must be counted as a separate interrogatory.

(2) A party must file a motion for leave to serve additional interrogatories on a party with the administrative law judge before serving additional interrogatories on a party. The

administrative law judge may grant the motion only if the party shows good cause.

(l) *Requests for admission.* A party may serve a written request for admission of the truth of any matter within the scope of discovery under this section or the authenticity of any document described in the request. A party must set forth each request for admission separately. A party must serve copies of documents referenced in the request for admission unless the documents have been provided or are reasonably available for inspection and copying.

(1) *Time.* A party's failure to respond to a request for admission, in writing and signed by the attorney or the party, not later than 30 days after service of the request, is deemed an admission of the truth of the statement or statements contained in the request for admission. The administrative law judge may determine that a failure to respond to a request for admission is not deemed an admission of the truth if a party shows that the failure was due to circumstances beyond the control of the party or the party's attorney.

(2) *Response.* A party may object to a request for admission and must state the reasons for objection. A party may specifically deny the truth of the matter or describe the reasons why the party is unable to truthfully deny or admit the matter. If a party is unable to deny or admit the truth of the matter, the party must show that the party has made reasonable inquiry into the matter or that the information known to, or readily obtainable by, the party is insufficient to enable the party to admit or deny the matter. A party may admit or deny any part of the request for admission. If the administrative law judge determines that a response does not comply with the requirements of this paragraph (l)(2) or that the response is insufficient, the matter is deemed admitted.

(3) *Effect of admission.* Any matter admitted or deemed admitted under this section is conclusively established for the purpose of the hearing and appeal.

(m) *Motion to compel discovery.* A party may make a motion to compel discovery if a person refuses to answer a question during a deposition, a party fails or refuses to answer an interrogatory, if a person gives an evasive or incomplete answer during a deposition or when responding to an interrogatory, or a party fails or refuses to produce documents or tangible items. During a deposition, the proponent of a question may complete the deposition or may adjourn the examination before making a motion to compel if a person refuses to answer. Any motion to compel must be filed with the FAA Hearing Docket and served on the administrative law judge and other parties in accordance with §§ 13.210 and 13.211, respectively.

(n) *Failure to comply with a discovery order.* If a party fails to comply with a discovery order, the administrative law judge may impose any of the following sanctions proportional to the party's failure to comply with the order:

(1) Strike the relevant portion of a party's pleadings;

(2) Preclude prehearing or discovery motions by that party;

(3) Preclude admission of the relevant portion of a party's evidence at the hearing; or

(4) Preclude the relevant portion of the testimony of that party's witnesses at the hearing.

§ 13.221 Notice of hearing.

(a) *Notice.* The administrative law judge must provide each party with notice of the date, time, and location of the hearing at least 60 days before the hearing date.

(b) *Date, time, and location of the hearing.* The administrative law judge to whom the proceedings have been assigned must set a reasonable date, time, and location for the hearing. The administrative law judge must consider the need for discovery and any joint procedural or discovery schedule submitted by the parties when determining the hearing date. The administrative law judge must give due regard to the convenience of the parties, the location where the majority of the witnesses reside or work, and whether the location is served by a scheduled air carrier.

(c) *Earlier hearing.* With the consent of the administrative law judge, the parties may agree to hold the hearing on an earlier date than the date specified in the notice of hearing.

§ 13.222 Evidence.

(a) *General.* A party is entitled to present the party's case or defense by oral, documentary, or demonstrative evidence, to submit rebuttal evidence, and to conduct any cross-examination that may be required for a full and true disclosure of the facts.

(b) *Admissibility.* A party may introduce any oral, documentary, or demonstrative evidence in support of the party's case or defense. The administrative law judge must admit any relevant oral, documentary, or demonstrative evidence introduced by a party, but must exclude irrelevant, immaterial, or unduly repetitious evidence.

(c) *Hearsay evidence.* Hearsay evidence is admissible in proceedings governed by this subpart. The fact that evidence submitted by a party is hearsay goes only to the weight of the evidence and does not affect its admissibility.

§ 13.223 Standard of proof.

The administrative law judge must issue an initial decision or must rule in a party's favor only if the decision or ruling is supported by, and in accordance with, the reliable, probative, and substantial evidence contained in the record. In order to prevail, the party with the burden of proof must prove the party's case or defense by a preponderance of reliable, probative, and substantial evidence.

§ 13.224 Burden of proof.

(a) Except in the case of an affirmative defense, the burden of proof is on the agency.

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

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

§ 13.225 Offer of proof.

A party whose evidence has been excluded by a ruling of the administrative law judge may offer the evidence for the record on appeal.

§ 13.226 Public disclosure of information.

(a) The administrative law judge may order that any information contained in the record be withheld from public disclosure. Any party or interested person may object to disclosure of information in the record by filing and serving a written motion to withhold specific information in accordance with §§ 13.210 and 13.211 respectively. A party may file a motion seeking to protect from public disclosure information contained in a document that the party is filing at the same time it files the document. The person or party must state the specific grounds for nondisclosure in the motion.

(b) The administrative law judge must grant the motion to withhold if, based on the motion and any response to the motion, the administrative law judge determines that: Disclosure would be detrimental to aviation safety; disclosure would not be in the public interest; or the information is not otherwise required to be made available to the public.

§ 13.227 Expert or opinion witnesses.

An employee of the agency may not be called as an expert or opinion witness for any party other than the

FAA in any proceeding governed by this subpart. An employee of a respondent may not be called by an agency attorney as an expert or opinion witness for the FAA in any proceeding governed by this subpart to which the respondent is a party.

§ 13.228 Subpoenas.

(a) *Request for subpoena.* The administrative law judge, upon application by any party to the proceeding, may issue subpoenas requiring the attendance of witnesses or the production of documents or tangible things at a hearing or for the purpose of taking depositions, as permitted by law. A request for a subpoena must show its general relevance and reasonable scope. The party must serve the subpoena on the witness or the holder of the documents or tangible items as permitted by applicable statute. A request for a subpoena must be filed and served in accordance with §§ 13.210 and 13.211, respectively. Absent good cause shown, the filing and service must be completed as follows:

(1) Not later than 15 days before a scheduled deposition under the subpoena; or

(2) Not later than 30 days before a scheduled hearing where attendance at the hearing is sought.

(b) *Motion to quash or modify the subpoena.* A party, or any person upon whom a subpoena has been served, may file in the FAA Hearing Docket a motion to quash or modify the subpoena and must serve a copy on the administrative law judge and each party at or before the time specified in the subpoena for compliance. The movant must describe, in detail, the basis for the motion to quash or modify the subpoena including, but not limited to, a statement that the testimony, document, or tangible evidence is not relevant to the proceeding, that the subpoena is not reasonably tailored to the scope of the proceeding, or that the subpoena is unreasonable and oppressive. A motion to quash or modify the subpoena will stay the effect of the subpoena pending a decision by the administrative law judge on the motion.

(c) *Enforcement of subpoena.* Upon a showing that a person has failed or refused to comply with a subpoena, a party may apply to the appropriate U.S. district court to seek judicial enforcement of the subpoena.

§ 13.229 Witness fees.

(a) *General.* The party who applies for a subpoena to compel the attendance of a witness at a deposition or hearing, or the party at whose request a witness appears at a deposition or hearing, must pay the witness fees described in this section.

(b) *Amount.* Except for an employee of the agency who appears at the direction of the agency, a witness who appears at a deposition or hearing is entitled to the same fees and allowances provided for under 28 U.S.C. 1821.

§ 13.230 Record.

(a) *Exclusive record.* The pleadings, transcripts of the hearing and prehearing conferences, exhibits admitted into evidence, rulings, motions, applications, requests, briefs, and responses thereto, constitute the exclusive record for decision of the proceedings and the basis for the issuance of any orders in the proceeding. Any proceedings regarding the disqualification of an administrative law judge must be included in the record. Though only exhibits admitted into evidence are part of the record before an administrative law judge, evidence proffered but not admitted is also part of the record on appeal, as provided by § 13.225.

(b) *Examination and copying of record.* The parties may examine the record at the FAA Hearing Docket and may obtain copies of the record upon payment of applicable fees. Any other person may obtain copies of the releasable portions of the record in accordance with applicable law.

§ 13.231 Argument before the administrative law judge.

(a) *Arguments during the hearing.* During the hearing, the administrative law judge must give the parties a reasonable opportunity to present arguments on the record supporting or opposing motions, objections, and rulings if the parties request an opportunity for argument. The administrative law judge may request written arguments during the hearing if the administrative law judge finds that submission of written arguments would be reasonable.

(b) *Final oral argument.* At the conclusion of the hearing and before the administrative law judge issues an initial decision in the proceedings, the administrative law judge must allow the parties to submit oral proposed findings of fact and conclusions of law, exceptions to rulings of the administrative law judge, and supporting arguments for the findings, conclusions, or exceptions. At the conclusion of the hearing, a party may waive final oral argument.

(c) *Post-hearing briefs.* The administrative law judge may request written post-hearing briefs before the administrative law judge issues an initial decision in the proceedings if the administrative law judge finds that submission of written arguments would be reasonable. If a party files a written post-hearing brief, the party must include proposed findings of fact and conclusions of law, exceptions to rulings of the administrative law judge, and supporting arguments for the findings, conclusions, or exceptions. The administrative law judge must give the parties a reasonable opportunity, but not more than 30 days after receipt of the transcript, to prepare and submit the briefs. A party must file and serve any post-hearing brief in in accordance with §§ 13.210 and 13.211, respectively.

§ 13.232 Initial decision.

(a) *Contents.* The administrative law judge must issue an initial decision at the conclusion of the hearing. In each oral or written decision, the administrative law judge must include findings of fact and conclusions of law, as well as the grounds supporting those findings and conclusions, for all material issues of fact, the credibility of witnesses, the applicable law, any exercise of the administrative law judge's discretion, and the amount of any civil penalty found appropriate by the administrative law judge. The administrative law judge must also include a discussion of the basis for any order issued in the proceedings. The administrative law judge is not required to provide a written explanation for rulings on objections, procedural motions, and other matters not directly relevant to the substance of the initial decision. If the administrative law judge refers to any previous unreported or unpublished initial decision, the administrative law judge must make copies of that initial decision available to all parties and the FAA decisionmaker.

(b) *Oral decision.* Except as provided in paragraph (c) of this section, at the conclusion of the hearing, the administrative law judge's oral initial decision and order must be on the record.

(c) *Written decision.* The administrative law judge may issue a written initial decision not later than 30 days after the conclusion of the hearing or submission of the last post-hearing brief if the administrative law judge finds that issuing a written initial decision is reasonable. The administrative law judge must serve a copy of any written initial decision on each party.

(d) *Reconsideration of an initial decision.* The FAA decisionmaker may treat a motion for reconsideration of an initial decision as a notice of appeal

under § 13.233, and if the motion was filed within the time allowed for the filing of a notice of appeal, the FAA decisionmaker will issue a briefing schedule, as provided in § 13.218.

(e) *Order assessing civil penalty.* Unless appealed pursuant to § 13.233, the initial decision issued by the administrative law judge is considered an order assessing civil penalty if the administrative law judge finds that an alleged violation occurred and determines that a civil penalty, in an amount found appropriate by the administrative law judge, is warranted. The administrative law judge may not assess a civil penalty exceeding the amount sought in the complaint.

§ 13.233 Appeal from initial decision.

(a) *Notice of appeal.* A party may appeal the administrative law judge's initial decision, and any decision not previously appealed to the FAA decisionmaker on interlocutory appeal pursuant to § 13.219, by filing a notice of appeal in accordance with § 13.210 no later than 10 days after entry of the oral initial decision on the record or service of the written initial decision on the parties. The party must serve a copy of the notice of appeal on each party in accordance with § 13.211. A party is not required to serve any documents under § 13.233 on the administrative law judge.

(b) *Issues on appeal.* In any appeal from a decision of an administrative law judge, the FAA decisionmaker considers only the following issues:

(1) Whether each finding of fact is supported by a preponderance of reliable, probative, and substantial evidence;

(2) Whether each conclusion of law is made in accordance with applicable law, precedent, and public policy; and

(3) Whether the administrative law judge committed any prejudicial errors.

(c) *Perfecting an appeal.* Except as follows in paragraphs (c)(1) and (2) of this section, a party must perfect an appeal to the FAA decisionmaker no later than 50 days after entry of the oral initial decision on the record or service of the written initial decision on the parties by filing an appeal brief in accordance with § 13.210 and serving a copy on every other party in accordance with § 13.211.

(1) *Extension of time by agreement of the parties.* The parties may agree to extend the time for perfecting the appeal with the consent of the FAA decisionmaker. If the FAA decisionmaker grants an extension of time to perfect the appeal, the FAA decisionmaker must serve a letter confirming the extension of time on each party.

(2) *Written motion for extension.* If the parties do not agree to an extension of time for perfecting an appeal, a party desiring an extension of time may file a written motion for an extension in accordance with § 13.210 and must serve a copy of the motion on each party under § 13.211. Any party may file a written response to the motion for extension no later than 10 days after service of the motion. The FAA decisionmaker may grant an extension if good cause for the extension is shown in the motion.

(d) *Appeal briefs.* A party must file the appeal brief in accordance with § 13.210 and must serve a copy of the appeal brief on each party in accordance with § 13.211.

(1) A party must set forth, in detail, the party's specific objections to the initial decision or rulings in the appeal brief. A party also must set forth, in detail, the basis for the appeal, the reasons supporting the appeal, and the relief requested in the appeal. If the party relies on evidence contained in the record for the appeal, the party must specifically refer to the pertinent evidence contained in the transcript in the appeal brief.

(2) The FAA decisionmaker may dismiss an appeal, on the FAA decisionmaker's own initiative or upon motion of any other party, where a party has filed a notice of appeal but fails to perfect the appeal by timely filing an appeal brief with the FAA decisionmaker.

(e) *Reply brief.* Except as follows in paragraphs (e)(1) and (2) of this section, any party may file a reply brief in accordance with § 13.210 not later than 35 days after the appeal brief has been served on that party. The party filing the reply brief must serve a copy of the reply brief on each party in accordance with § 13.211. If the party relies on evidence contained in the record for the reply, the party must specifically refer to the pertinent evidence contained in the transcript in the reply brief.

(1) *Extension of time by agreement of the parties.* The parties may agree to extend the time for filing a reply brief with the consent of the FAA decisionmaker. If the FAA decisionmaker grants an extension of time to file the reply brief, the FAA decisionmaker must serve a letter confirming the extension of time on each party.

(2) *Written motion for extension.* If the parties do not agree to an extension of time for filing a reply brief, a party desiring an extension of time may file a written motion for an extension in accordance with § 13.210 and must serve a copy of the motion on each party in accordance with § 13.211. Any party choosing to respond to the motion must file and serve a written response to the motion no later than 10 days after service of the motion The FAA decisionmaker may grant an extension if good cause for the extension is shown in the motion.

(f) *Other briefs.* The FAA decisionmaker may allow any person to submit an *amicus curiae* brief in an appeal of an initial decision. A party may not file more than one brief unless permitted by the FAA decisionmaker. A party may petition the FAA decisionmaker, in writing, for leave to file an additional brief and must serve a copy of the petition on each party. The party may not file the additional brief with the petition. The FAA decisionmaker may grant leave to file an additional brief if the party demonstrates good cause for allowing additional argument on the appeal. The FAA decisionmaker will allow a reasonable time for the party to file the additional brief.

(g) *Number of copies.* A party must file the original plus one copy of the appeal brief or reply brief, but only one copy if filing by email or fax, as provided in § 13.210.

(h) *Oral argument.* The FAA decisionmaker may permit oral argument on the appeal. On the FAA decisionmaker's own initiative, or upon written motion by any party, the FAA decisionmaker may find that oral argument will contribute substantially to the development of the issues on appeal and may grant the parties an opportunity for oral argument.

(i) *Waiver of objections on appeal.* If a party fails to object to any alleged error regarding the proceedings in an appeal or a reply brief, the party waives any objection to the alleged error. The FAA decisionmaker is not required to consider any objection in an appeal brief, or any argument in the reply brief, if a party's objection or argument is based on evidence contained on the record and the party does not specifically refer to the pertinent evidence from the record in the brief.

(j) *FAA decisionmaker's decision on appeal.* The FAA decisionmaker will review the record, the briefs on appeal, and the oral argument, if any, when considering the issues on appeal. The FAA decisionmaker may affirm, modify, or reverse the initial decision, make any necessary findings, or remand the case for any proceedings that the FAA decisionmaker determines may be necessary. The FAA decisionmaker may assess a civil penalty but must not

assess a civil penalty in an amount greater than that sought in the complaint.

(1) The FAA decisionmaker may raise any issue, on the FAA decisionmaker's own initiative, that is required for proper disposition of the proceedings. The FAA decisionmaker will give the parties a reasonable opportunity to submit arguments on the new issues before making a decision on appeal. If an issue raised by the FAA decisionmaker requires the consideration of additional testimony or evidence, the FAA decisionmaker will remand the case to the administrative law judge for further proceedings and an initial decision related to that issue. If an issue raised by the FAA decisionmaker is solely an issue of law, or the issue was addressed at the hearing but was not raised by a party in the briefs on appeal, a remand of the case to the administrative law judge for further proceedings is not required but may be provided in the discretion of the FAA decisionmaker.

(2) The FAA decisionmaker will issue the final decision and order of the Administrator on appeal in writing and will serve a copy of the decision and order on each party. Unless a petition for review is filed pursuant to § 13.235, a final decision and order of the Administrator will be considered an order assessing civil penalty if the FAA decisionmaker finds that an alleged violation occurred and a civil penalty is warranted.

(3) A final decision and order of the Administrator after appeal is precedent in any other civil penalty action. Any issue, finding or conclusion, order, ruling, or initial decision of an administrative law judge that has not been appealed to the FAA decisionmaker is not precedent in any other civil penalty action.

§ 13.234 Petition to reconsider or modify a final decision and order of the FAA decisionmaker on appeal.

(a) *General.* Any party may petition the FAA decisionmaker to reconsider or modify a final decision and order issued by the FAA decisionmaker on appeal from an initial decision. A party must file a petition to reconsider or modify in accordance with § 13.210 not later than 30 days after service of the FAA decisionmaker's final decision and order on appeal and must serve a copy of the petition on each party in accordance with § 13.211. A party is not required to serve any documents under this section on the administrative law judge. The FAA decisionmaker will not reconsider or modify an initial decision and order issued by an administrative law judge that has not been appealed by any party to the FAA decisionmaker.

(b) *Number of copies.* The parties must file the original plus one copy of the petition or the reply to the petition, but only one copy if filing by email or fax, as provided in § 13.210.

(c) *Contents.* A party must state briefly and specifically the alleged errors in the final decision and order on appeal, the relief sought by the party, and the grounds that support the petition to reconsider or modify.

(1) If the petition is based, in whole or in part, on allegations regarding the consequences of the FAA decisionmaker's decision, the party must describe these allegations and must describe, and support, the basis for the allegations.

(2) If the petition is based, in whole or in part, on new material not previously raised in the proceedings, the party must set forth the new material and include affidavits of prospective witnesses and authenticated documents that would be introduced in support of the new material. The party must explain, in detail, why the new material was not discovered through due diligence prior to the hearing.

(d) *Repetitious and frivolous petitions.* The FAA decisionmaker will not consider repetitious or frivolous petitions. The FAA decisionmaker may summarily dismiss repetitious or frivolous petitions to reconsider or modify.

(e) *Reply petitions.* Any party replying to a petition to reconsider or modify must file the reply in accordance with § 13.210 no later than 10 days after service of the petition on that party, and must also serve a copy of the reply on each party in accordance with § 13.211.

(f) *Effect of filing petition.* The filing of a timely petition under this section will stay the effective date of the FAA decisionmaker's decision and order on appeal until final disposition of the petition by the FAA decisionmaker.

(g) *FAA decisionmaker's decision on petition.* The FAA decisionmaker has discretion to grant or deny a petition to reconsider. The FAA decisionmaker will grant or deny a petition to reconsider within a reasonable time after receipt of the petition or receipt of the reply petition, if any. The FAA decisionmaker may affirm, modify, or reverse the final decision and order on appeal, or may remand the case for any proceedings that the FAA decisionmaker determines may be necessary.

§ 13.235 Judicial review of a final decision and order.

(a) In cases under the Federal aviation statute, a party may seek judicial review of a final decision and order of the Administrator, as provided in 49 U.S.C. 46110(a), and, as applicable, in 49 U.S.C. 46301(d)(7)(D)(iii), 46301(g), or 47532.

(b) In cases under the Federal hazardous materials transportation statute, a party may seek judicial review of a final decision and order of the Administrator, as provided in 49 U.S.C. 5127.

(c) A party seeking judicial review of a final order issued by the Administrator may file a petition for review in the United States Court of Appeals for the District of Columbia Circuit or in the United States Court of Appeals for the circuit in which the party resides or has its principal place of business.

(d) The party must file the petition for review no later than 60 days after service of the Administrator's final decision and order.

§ 13.236 Alternative dispute resolution.

Parties may use mediation to achieve resolution of issues in controversy addressed by this subpart. Parties seeking alternative dispute resolution services may engage the services of a mutually acceptable mediator. The mediator must not participate in the adjudication under this subpart of any matter in which the mediator has provided mediation services. Mediation discussions and submissions will remain confidential consistent with the provisions of the Administrative Dispute Resolution Act and other applicable Federal laws.

Issued under authority provided by 49 U.S.C. 106(f) and 44701(a) in Washington, DC, on or about August 17, 2021.

Steve Dickson,

Administrator.

[FR Doc. 2021–19948 Filed 9–30–21; 8:45 am]

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Part III

Department of Justice

Drug Enforcement Administration

Pharmacy 4 Less; Decision and Order; Notice

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 18–41]

Pharmacy 4 Less; Decision and Order

On July 5, 2018, a former Assistant Administrator of the Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause (hereinafter, OSC) to Pharmacy 4 Less, (hereinafter, Respondent) of Altamonte Springs, Florida. Administrative Law Judge Exhibit (hereinafter, ALJ Ex.) 1, (OSC) at 1. The OSC proposed to revoke its DEA Certificate of Registration (hereinafter, COR) No. FP5459082, and deny any pending applications for renewal or modification of such registration pursuant to 21 U.S.C. 823(f) and 824(a)(4) for the reason that Respondent's ''continued registration is inconsistent with the public interest.'' *Id.*

In response to the OSC, Respondent timely requested a hearing before an Administrative Law Judge. ALJ Ex. 2. The hearing in this matter was held in Orlando, Florida, on November 5–7, 2018, and continued in Arlington, Virginia, on February 25, 2019. On May 22, 2019, Administrative Law Judge Mark M. Dowd (hereinafter, the ALJ) issued the Recommended Rulings, Findings of Fact, Conclusions of Law and Decision (hereinafter, Recommended Decision or RD), and on June 11, 2019, the Government timely filed exceptions (hereinafter, Govt Exceptions) to the Recommended Decision. On June 23, 2019, the Respondent filed what it styled as a response to the Government's Exceptions (hereinafter, Resp Exceptions).*[A] According to the ALJ, the Respondent Pharmacy did not request an extension of time to file exceptions, nor did it request an extension of time to file a response to the Government's Exceptions pursuant to 21 CFR 1316.66(c). *See* ALJ Transmittal Letter dated June 25, 2019. Even though Respondent did none of those things, I have decided to address the Exceptions filed by Respondent as part of my review of the record.*[B] Having reviewed the entire record, I find the Respondent's Exceptions are without merit and I adopt the ALJ's rulings, findings of fact, as modified, conclusions of law and recommended sanction with minor modifications, where noted herein.*[C]

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby revoke DEA Certificate of Registration No. FP5459082 issued to Pharmacy 4 Less. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(f), I hereby deny the pending application for renewal or modification of this registration by Pharmacy 4 Less in Florida. This Order is effective November 1, 2021.

Anne Milgram,
Administrator.

The Government's Exceptions

The Government, though in agreement with much of the ALJ's opinion, filed exceptions to the RD on June 11, 2019. The Government described its primary concern as being delay caused by the ALJ's conditional admission of documents and proffer testimony, and asked that I ''specify the manner in which the ALJ is to balance the risk of delay with the risk of being reversed, and to, where appropriate, allow only limited proffers.'' Govt Exceptions, at 3. The presiding ALJ has the ''duty to conduct a fair hearing, to take all necessary action to avoid delay, and to maintain order'' and has the power to ''[r]eceive, rule on, exclude, or limit evidence.'' 21 CFR 1316.52 and (f). In other words, he possesses discretion to ''regulate the course of the hearing.'' 5 U.S.C. 556(c)(5) (West 2021). As such, I decline to broadly instruct ALJs in the manner requested by the Government.

Next, the Government alleged that the ALJ erroneously admitted Respondent Exhibits 18–37, which consisted of due diligence files for the patients at issue in this case which had been updated by Respondent after the dates relevant to this case (and after a Government subpoena for these same records). Govt Exceptions, at 3–6. The Government conceded that the records could have been relevant to establish remedial measures taken by Respondent Pharmacy, but argues that they would have been relevant only if Respondent Pharmacy first accepted responsibility for its actions. *Id.* The Government alleges that the ALJ's admission of RX 18–37, even conditionally, was improper without Respondent first establishing responsibility or proffering that acceptance of responsibility was forthcoming. As I have already discussed, I decline to instruct the ALJs on how to balance the risk of delay against the need to receive evidence as it lies within their discretion, because every case will be different. Here, the ALJ ultimately found that the Respondent Pharmacy did not accept responsibility for its actions, but it would have been difficult for the ALJ to have reached that conclusion at the beginning of the evidentiary hearing.

The remainder of the Government's exceptions are addressed in the relevant sections of the RD as footnoted below.

The Respondent's Exceptions

On June 23, 2019, the Respondent filed its exceptions to the Recommended Decision. Exceptions ''shall include a statement of supporting reasons for such exceptions, together with evidence of record (including specific and complete citations of the pages of the transcript and exhibits) and citations of the authorities relied upon.'' 21 CFR 1316.66. For the most part, the Respondent's Exceptions not only fail to comply with this regulatory requirement, but also lack evidentiary support in the Administrative Record. Some of Respondent's Exceptions *[D] repeat facts which were already raised at the hearing in this matter and addressed by the ALJ in the adopted Recommended Decision herein.

Most of Respondent's Exceptions introduce evidentiary facts that Respondent Pharmacy appears to be offering to establish remedial measures.*[E] Many of these facts are not

*[A] Despite the title, Respondent's filing appears to assert its own Exceptions to the RD rather than respond to the Government's Exceptions.

*[B] My decision to consider the Respondent's Exceptions is based on the particular circumstances of this case, including but not limited to, the withdrawal of Respondent's counsel after the conclusion of the hearing.

*[C] I have made minor modifications to the RD. I have substituted initials or titles for the names of witnesses and patients to protect their privacy, I have corrected an occasional citation, and I have made minor, non-substantive, grammatical changes. Where I have made substantive changes, omitted language for brevity or relevance, or where I have added to or modified the ALJ's opinion, I have noted the edits with an asterisk, and I have included specific descriptions of the modifications in brackets following the asterisk or in footnotes marked with an asterisk and a letter.

*[D] Respondent's Exceptions ¶ 1 asserting that starting doses for opioid patients were not high and that the Pharmacy had detailed medical records; ¶ 7 regarding the initial inventory; ¶ 8 asserting the accuracy of the perpetual inventory; ¶ 12 claiming the opioid naivety red flag was resolved by checking e-FORCSE. Respondent's Exceptions, at 2–3.

*[E] Respondent's Exceptions ¶ 4 asserting that the pharmacy can now bill insurance companies and that 80% of the Schedule II controlled substances prescriptions it fills are through insurance now; ¶ 5 asserting the pharmacy now fills only 10% of the Schedule II controlled substances prescriptions it was filling in 2015 and 2016, admitting they filled too many Schedule II prescriptions in the past and claiming they are not ''extremely due diligent in filling;'' ¶ 6 asserting that the pharmacy does not fill prescriptions from a neighboring pain doctor who will not share medical records; ¶ 7 asserting that Respondent Pharmacy passed every Department of Health inspection from 2015 to 2019; ¶ 9 asserting that Patient A.R. has been discharged; ¶ 11 asserting

supported by the record and were not under oath or subject to cross examination when they were presented for the first time in Respondent's Exceptions. Moreover, where a registrant has not accepted responsibility it is not necessary to consider evidence of the registrant's remedial measures. *Jones Total Health Care Pharmacy, L.L.C. & SND Health Care, L.L.C.,* 81 FR 79188, 79202–03 (2016).'' As Respondent Pharmacy has failed to unequivocally accept responsibility for its actions, the purported remedial measures offered by Respondent in its Exceptions, even if they were part of the evidentiary record, would have no impact on my decision in this case.

Similarly, the Respondent's Exceptions contained a number of factual assertions regarding Owner Richard Sprys' purported work with law enforcement bodies to report illegal pharmacy operations and provide testimony, seemingly for the DEA in one instance, to hold those pharmacies accountable. *Id.* at 3. None of these facts were given under oath and none were subject to cross-examination; therefore, they are simply not part of the evidentiary record. Even if Respondent's assertions had been appropriately submitted through testimonial evidence, they could only have been relevant in assessing whether Respondent Pharmacy could be entrusted with a registration. Here, as Respondent Pharmacy has failed to unequivocally accept responsibility for its actions, such assertions would have had no impact on my decision.

The remainder of the Respondent's Exceptions are addressed in their relevant sections of the Recommended Decision as footnoted below.

The decision below is based on my consideration of the entire administrative record, including all of the testimony, admitted exhibits, and the oral and written arguments of both parties. I adopt the ALJ's Recommended Decision with noted modifications.

Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge

The Assistant Administrator, Drug Enforcement Administration (DEA), issued an Order to Show Cause,[1] dated July 5, 2018, seeking to deny the Respondent's Certificate of Registration, number FP5459082, on the ground that the Respondent's registration would be inconsistent with the public interest, pursuant to 21 U.S.C. 824(a)(4), and as defined in 21 U.S.C. 823(f). The Respondent requested a hearing on August 2, 2018,[2] and prehearing proceedings were initiated.[3] A hearing was conducted in this matter on November 5–7, 2018, in Orlando, Florida, and resumed on February 25, 2019, at the DEA Hearing Facility in Arlington, Virginia.

The issue ultimately to be adjudicated by the Administrator,[*F] with the assistance of this Recommended Decision, is whether the record as a whole establishes by a preponderance of the evidence that the Respondent's subject registration with the DEA should be revoked pursuant to 21 U.S.C. 824(a)(4).

After carefully considering the testimony elicited at the hearing, the admitted exhibits, the arguments of counsel, and the record as a whole, I have set forth my recommended findings of fact and conclusions of law below.

The Allegations

In the OSC, the Government contends that the DEA should revoke the Respondent's DEA COR because it failed to comply with 21 U.S.C. 824(a)(4) and its registration is inconsistent with the public interest, *see* 21 U.S.C. 823(f). Specifically, the Government alleges the following:

1. The Respondent failed to ensure that it only filled prescriptions issued for legitimate medical purposes and repeatedly filled prescriptions in the face of obvious red flags of diversion, in violation of both federal and state law (including 21 CFR 1306.06, 1306.04(a); *Wheatland Pharmacy,* 78 FR 69411, 69445 (2013); Fla. Admin. Code r. 64B16–27.810, 64B16–27.831[4]), specifically from at least October 27, 2015 to at least June 19, 2017, to at least ten different patients. ALJ Ex. 1 at ¶¶ 2–4.

2. The Respondent routinely filled Schedule II controlled substances without resolving the ''red flag'' of patients with ''very high starting dosages,'' both with respect to the individual dose being prescribed and with respect to the number of tablets being prescribed, which is potentially fatal for a patient. ALJ Ex. 1 at ¶ 5.

3. The Respondent routinely filled controlled substance prescriptions without resolving the ''red flag'' of immediate release pain medication over long periods of time. A chronic pain patient should be moved to a long acting medication. ALJ Ex. 1 at ¶ 6.

4. The Respondent routinely filled controlled substance prescriptions without resolving the ''red flag'' of extremely high cash prices. ALJ Ex. 1 at ¶ 7.

5. The Respondent routinely filled prescriptions without resolving the ''red flag'' for patients who traveled long distances to visit the Respondent's pharmacy. ALJ Ex. 1 at ¶ 8.

6. The Respondent would fill prescriptions without resolving the ''red flag'' for drug combinations that needed to be questioned, such as the combination of buprenorphine and oxycodone. ALJ Ex. 1 at ¶ 9.

Treatment of Patients

Patient A.E.

From November 19, 2015, to at least June 1, 2017, the Respondent filled at least 21 prescriptions for hydromorphone for A.E. outside the usual course of professional practice, in violation of 21 CFR 1306.06, and in violation of its corresponding responsibility under 21 CFR 1306.04(a). Specifically:

a. A.E.'s prescriptions were for 84 tablets of hydromorphone 8 mg, which is a large amount of tablets at the highest dosage strength.

b. A.E. filled his prescriptions for short acting hydromorphone since at least November 19, 2015, even though hydromorphone is not prescribed for long-term use or chronic conditions.

c. A.E. paid cash for his prescriptions at inflated prices, paying $500.00 for 84 tablets of hydromorphone 8 mg, approximately $5.95 per pill, at a time when legitimate pharmacies were charging approximately $1.50.

Patient A.R.

From March 17, 2016, to at least June 7, 2017, the Respondent filled at least 17 prescriptions for oxycodone for A.R. outside the usual course of professional practice, in violation of 21 CFR 1306.06, and in violation of its corresponding responsibility under 21 CFR 1306.04(a). Specifically:

a. A.R. filled his prescriptions for immediate release oxycodone since at least March 17, 2016, even though oxycodone is not prescribed for long-term use or chronic conditions.

b. A.R. drove extremely long distances to fill oxycodone prescriptions. A.R. drove approximately 37 miles southwest to visit the prescribing doctor, an additional 17.9 miles further southwest

that Patient A.V. was successfully taken off of opioids. Resp Exceptions, at 2–3.

[1] ALJ Ex. 1.

[2] ALJ Ex. 2.

[3] ALJ Ex. 3.

[*F] All references to ''Acting Administrator'' have been changed to ''Administrator.''

[4] It was noted that there was a scrivener's error by the Government citing to r. 64B16–27.821. The Government later corrected the cite to reflect the correct citation to r. 64B16–27.831.

to the Respondent's pharmacy, an additional 45.4 miles to A.R.'s home, for a total of 97.3 miles round-trip to fill the oxycodone prescriptions.

Patient A.V.

From April 12, 2016, to at least April 10, 2017, the Respondent filled at least 9 prescriptions for buprenorphine and at least 12 prescriptions for oxycodone for A.V. outside the usual course of professional practice, in violation of 21 CFR 1306.06, and in violation of its corresponding responsibility under 21 CFR 1306.04(a). Specifically:

a. A.V.'s prescriptions were for 112 tablets of oxycodone 20 mg and 60 tablets buprenorphine 8 mg, which are large amounts of tablets at a high dosage strength.

b. A.V. was filling prescriptions for opioid withdrawal at the same time he was filling a prescription for an opioid.

c. A.V. filled his prescriptions for short acting oxycodone since at least April 12, 2016, even though oxycodone was not prescribed for long-term use or chronic conditions.

Patient B.F.

From October 27, 2015, to at least May 15, 2017, the Respondent filled at least 17 prescriptions for hydromorphone and at least 5 prescriptions for oxycodone for B.F. outside the usual course of professional practice, in violation of 21 CFR 1306.06, and in violation of its corresponding responsibility under 21 CFR 1306.04(a). Specifically:

a. B.F.'s prescriptions were for 84 tablets of hydromorphone 8 mg, which is a large amount of tablets at the highest dosage strength.

b. B.F. filled his prescriptions for short acting hydromorphone since at least October 27, 2015, even though hydromorphone is not prescribed for long-term use or chronic conditions.

c. B.F. paid cash for his prescriptions at inflated prices, paying $490.00 for 84 tablets of hydromorphone 8 mg, approximately $5.93 per pill, at a time when legitimate pharmacies were charging approximately $1.50.

Patient B.N.

From January 22, 2016, to at least June 2, 2017, the Respondent filled at least 9 prescriptions for hydromorphone and at least 10 prescriptions for oxycodone for B.N. outside the usual course of professional practice, in violation of 21 CFR 1306.06, and in violation of its corresponding responsibility under 21 CFR 1306.04(a). Specifically:

a. B.N.'s prescriptions were for 100 tablets of hydromorphone 8 mg, which is a large amount of tablets at the highest dosage strength. In September 2016, B.N. switched to 120 tablets of oxycodone 30 mg, which is an even higher number of tablets at the highest dosage strength of oxycodone.

b. B.N. filled his prescriptions for immediate release oxycodone and hydromorphone since at least January 22, 2016, even though oxycodone and hydromorphone are not prescribed for long-term use or chronic conditions.

c. B.N. paid cash for his prescriptions at inflated prices, paying up to $640.00 for 100 tablets of hydromorphone 8 mg, approximately $6.40 per pill, at a time when legitimate pharmacies were charging approximately $1.50. Similarly, B.N. paid prices up to $650.00 for 120 tablets of oxycodone 30 mg, approximately $5.51 per pill, at a time when legitimate pharmacies were charging approximately $0.90 per tablet.

Patient K.Y.D.[5]

From February 4, 2016, to at least June 12, 2017, the Respondent filled at least 17 prescriptions for oxycodone and at least 17 prescriptions for morphine sulfate for K.Y.D. outside the usual course of professional practice, in violation of 21 CFR 1306.06, and in violation of its corresponding responsibility under 21 CFR 1306.04(a). Specifically:

a. K.Y.D.'s prescriptions for hydromorphone were for 84 tablets of oxycodone 30 mg, which is a large amount of tablets at the highest dosage strength.

b. K.Y.D. paid cash for his prescriptions at inflated prices, paying up to $290.00 for 84 tablets of oxycodone 30 mg, approximately $3.45 per tablet, at a time when legitimate pharmacies were charging approximately $0.90 per tablet.

Patient K.E.D.

From October 26, 2015, to at least June 7, 2017, the Respondent filled at least 20 prescriptions for oxycodone for K.E.D. outside the usual course of professional practice, in violation of 21 CFR 1306.06, and in violation of its corresponding responsibility under 21 CFR 1306.04(a). Specifically:

a. K.E.D.'s prescriptions for oxycodone were for 112 tablets of oxycodone 20 mg, which is a large amount of tablets at a high dosage strength.

b. K.E.D. filled his prescriptions for immediate release oxycodone since at least October 26, 2015, even though oxycodone is not prescribed for long-term use or chronic conditions.

c. K.E.D. paid cash for his prescriptions at inflated prices, paying up to $430.00 for 112 tablets of oxycodone, approximately $3.83 per tablet, at a time when legitimate pharmacies were charging approximately $0.90 per tablet.

Patient R.R.

From October 28, 2015, to at least May 30, 2017, the Respondent filled at least 21 prescriptions for oxycodone for R.R. outside the usual course of professional practice, in violation of 21 CFR 1306.06, and in violation of its corresponding responsibility under 21 CFR 1306.04(a). Specifically:

a. R.R.'s prescriptions for oxycodone were for 112 tablets of oxycodone 15 mg, which is a large amount of tablets at a high dosage strength.

b. R.R. filled his prescriptions for immediate release oxycodone since at least October 28, 2015, even though oxycodone is not prescribed for long-term use or chronic conditions.

Patient R.V.

From November 17, 2015, to at least June 19, 2017, the Respondent filled at least 21 prescriptions for oxycodone for R.V. outside the usual course of professional practice, in violation of 21 CFR 1306.06, and in violation of its corresponding responsibility under 21 CFR 1306.04(a). Specifically:

a. R.V.'s prescriptions for oxycodone were for 112 to 120 tablets of oxycodone 20 mg, which is a large amount of tablets at a high dosage strength.

b. R.V. filled her prescriptions for immediate release oxycodone since at least November 17, 2015, even though oxycodone is not prescribed for long-term use or chronic conditions.

Patient V.W.

From November 30, 2015, to at least May 31, 2017, the Respondent filled at least 20 prescriptions for oxycodone for V.W. outside the usual course of professional practice, in violation of 21 CFR 1306.06, and in violation of its corresponding responsibility under 21 CFR 1306.04(a). Specifically:

a. V.W.'s prescriptions for oxycodone were for 84 to 112 tablets of oxycodone 15 mg, which is a large amount of tablets at a high dosage strength.

[5] There are two patients with the same initials, K.D. In pretrial filings, the Government and Respondent referred to these patients as K.D.1 and K.D.2. However, the Government and Respondent referred to different patients as K.D.1 and K.D.2 (*i.e.,* the Government's K.D.1 was Respondent's K.D.2). At the hearing, the parties discussed this issue and decided to refer to these two patients by the first two letters in their first name. All of the Government's pre-trial filings referring to K.D.1 are now discussed as K.Y.D. All of the Government's pre-trial findings referring to K.D.2 are now discussed as K.E.D. The opposite is true for the Respondent.

b. V.W. filled his prescriptions for immediate release oxycodone since at least November 30, 2015, even though oxycodone is not prescribed for long-term use or chronic conditions.

c. V.W. paid cash for his prescriptions at inflated prices, paying up to $400.00 for 112 tablets of oxycodone, approximately $3.57 per tablet, at a time when legitimate pharmacies were charging approximately $0.90 per tablet.

Recordkeeping Violations

1. The Respondent did not have an initial inventory, when requested by DEA during an on-site inspection of June 6, 2017, in violation of 21 CFR 1304.11(b).

2. The Respondent's biennial inventory failed to indicate whether it was taken at the opening or closing of business as required by 21 CFR 1304.11(a).

3. The Respondent's pharmacist on duty, Amy Mincy, stated that the biennial inventory was performed over several days, in violation of 21 CFR 1304.11(a).

4. The Respondent's pharmacist on duty during the June 6, 2017 on-site inspection admitted to using the pharmacy owner's, Mr. Richard Sprys, CSOS credentials to order controlled substances in violation of 21 CFR 1311.30(a) & (c).

5. The Respondent's receiving records showed that the Respondent failed to create an electronically linked record of a quantity and date received for its controlled substances in violation of 21 CFR 1305.22(g). The Respondent also possessed 89 invoices without the date of receipt recorded in violation of 21 CFR 1304.22(c).

The Hearing

Preliminary Matters

At the outset of the hearing, the Government confirmed that it was not going forward with pursuing any independent violation against the Respondent for a delay by the Respondent in complying with the July 2018 administrative subpoena. Tr. 14–15.[6] This Tribunal also noticed the Government that if it intended to assert a new allegation or expand the charges, it must inform this Tribunal at the time the new matter is broached at the hearing. *Id.* at 15–16. This would also give the Respondent the opportunity to either litigate the issue by consent or to object to the new allegation. *Id.* at 15–16. No supplemental allegations were broached by the Government.

The Respondent noted that they would be withdrawing their motion to suppress evidence, a motion that this tribunal had only preliminarily ruled upon. *Id.* at 17; ALJ Ex. 35. This Tribunal noted that the preliminary evidentiary rulings were for guidance and that the parties would still need to make their objections at the time of the hearing to preserve those objections. Tr. 17. The Respondent further requested that this Tribunal take official notice of 21 CFR 1304.21(a) and 21 U.S.C. 827(a)(3), to which this Tribunal acceded. *Id.* at 17–18. Next, the Respondent made preliminary objections as to authentication, failure to meet the business records exception, and improper burden shifting as to Government's Proposed Exhibits 9, 11, and 13. *Id.* at 18–19. This Tribunal carried those objections over to the hearing. *Id.* at 19. Then, the Respondent clarified that Government's Proposed Exhibit 25 had been ruled inadmissible and excluded.[7] *Id.* at 20. The Respondent then discussed a number of other matters related to proposed exhibits, which will be later discussed. *Id.* at 20–22. Finally, the Respondent objected to Government's Proposed Exhibit 26, which objection was also carried to the hearing. *Id.* at 23.

Government's Opening Statement

In the Government's Opening Statement, it previewed that the DEA conducted an audit of Pharmacy 4 Less on June 6, 2017. *Id.* at 25. The Government intended to explain the on-site audit through the testimony of DI1, including the findings from the audit, and explain the record keeping and regulatory violations that were discovered. *Id.* at 25. The Government also intended to offer the testimony of Dr. Hamilton regarding his review of the prescriptions and due diligence files that Pharmacy 4 Less maintained and how the Respondent filled prescriptions for controlled substances without resolving red flags. *Id.* at 25. Finally, the Government argued that the Respondent had not accepted responsibility for any of the alleged violations. *Id.* at 25–26.

Respondent's Opening Statement

In the Respondent's Opening Statement, it described Pharmacy 4 Less as a small, independent pharmacy. *Id.* at 27. Pharmacy 4 Less has two pharmacists and a low volume of patients. *Id.* at 27. The Respondent contrasted it from Publix, the pharmacy where Dr. Hamilton is employed. *Id.* at 27–28. The Respondent stated that Pharmacy 4 Less cannot purchase in volume like other retail pharmacies, and cannot sell at the same prices as other larger pharmacies. *Id.* at 28.

The Respondent described Mr. Richard Sprys, the owner and operator of Pharmacy 4 Less. *Id.* at 28. The Respondent detailed Mr. Sprys' community involvement in his capacity as a pharmacist, and how he has previously testified as a witness in several cases for the Government in whistleblower cases against pharmacies. *Id.* at 28. The Respondent further asserted that Mr. Sprys has always attempted to cooperate with the Government, including the process involving the July 9, 2018 administrative subpoena. *Id.* at 28–29. The Respondent also described Ms. Amy Mincy, another pharmacist that works at Pharmacy 4 Less, including her extensive background and experience as a pharmacist. *Id.* at 30.

The Respondent described the June 6, 2017 on-site inspection of Pharmacy 4 Less. *Id.* at 29. The Respondent asserted that the DEA diversion investigators related to Ms. Mincy, the pharmacist on-site at the time of the inspection, that the inspection would only last ten to fifteen minutes when the inspection actually lasted over six hours. *Id.* at 29.

The Respondent asserted that the Government's portrayal that the Respondent has not accepted responsibility is misplaced. *Id.* at 30. The Respondent stated that they submitted a corrective action plan (which the DEA rejected), they have modified their behavior, they have reduced the number of patients they see and fill prescriptions for, and they have implemented a number of other remedial changes. *Id.* at 30.

The Respondent further described the treatment of patients when they visit Pharmacy 4 Less. *Id.* at 30–32. The Respondent asserted that each patient receives specialized attention by the pharmacists because of Pharmacy 4 Less's small size. *Id.* at 31. The Respondent also stated that not only does Pharmacy 4 Less contact patients' doctors to resolve red flags, but Pharmacy 4 Less goes beyond that of other pharmacies because they will request and keep medical records of their patients to assist in the resolution of red flags. *Id.* at 31–32.

Finally, the Respondent stressed that while Pharmacy 4 Less may not be

[6] Tr.—Refers to the hearing transcript. The number(s) immediately following refer to the transcript page numbers.

[7] GX 25 consisted of over 1000 pages of an Excel spreadsheet involving records of patients additional to the ten patients who are the subject of the allegations. GX 25 was ruled inadmissible as generally irrelevant. The Government was permitted to reconstitute the exhibit reflecting only the ten subject patients. The Government's substitute exhibit was introduced as GX 35.

perfect, they keep their practice above-average. *Id.* at 32. The Respondent maintains that before and after the DEA on-site inspection, Pharmacy 4 Less has a clean record with the Florida Department of Health for their on-site inspections. *Id.* at 32.

Government's Case in Chief

The Government presented its case in chief through the testimony of two witnesses. First, the Government presented the testimony of a Diversion Investigator (hereinafter DI1). Secondly, the Government presented the testimony of its expert, Dr. Thomas D. Hamilton.

Diversion Investigator DI1

DI1 has been a Diversion Investigator for approximately seven years. *Id.* at 33. He is currently assigned to the Orlando District Office, in Orlando, Florida. *Id.* at 33. DI1 described his training and experience at the DEA Academy and in the field at the Baltimore and Orlando offices, including experience in at least 50–70 pharmacy investigations. *Id.* at 34–35.

DI1 first met with the staff at Pharmacy 4 Less on June 6, 2017. *Id.* at 37. He explained that Diversion Investigators [8] were doing regulatory inspections and Pharmacy 4 Less was randomly picked for a regulatory inspection. *Id.* at 37. When they arrived, the DIs showed their credentials and presented Ms. Amy Mincy, a pharmacist at Pharmacy 4 Less, with a DEA Form 82 Notice of Inspection.[9] *Id.* at 37–38; GX 30.[10] The form was signed by Ms. Mincy and the DIs began their on-site inspection. Tr. 38–39.

The DIs began by asking questions about Pharmacy 4 Less's customer base and prescriptions, and looked at the prescriptions records, log books, and other required records. *Id.* at 39. When DI1 asked Ms. Mincy about inventories, she could not locate the initial inventory; so Mr. Richard Sprys, the owner of Pharmacy 4 Less, was contacted via speakerphone by Ms. Mincy to determine where the initial inventory could be located. *Id.* at 39–40.[11] DI1 asked Mr. Sprys over the phone if Pharmacy 4 Less had an initial inventory, and Mr. Sprys replied that it did not. *Id.* at 40.

DI1 next inquired as to whether Pharmacy 4 Less had performed a biennial inventory. *Id.* at 40–41. Ms. Mincy provided DI1 with a document purported to be a biennial inventory. *Id.* at 41. DI1 concluded that the document did not comply with DEA regulations as the purported biennial inventory did not include a statement that it had been completed either at the opening or closing of business.[12] *Id.* at 41–42. Further, DI1 claimed that Ms. Mincy had indicated that she had completed it over several days. *Id.* at 41. DI1 indicated that biennial inventories need to be completed either at the opening or closing of business and it needs to be notated on the biennial inventory. *Id.* at 41–42. DI1 claimed that during this exchange, Ms. Mincy said, ''what was [I] supposed to do, shut down the pharmacy?'' *Id.* at 42. As part of his later audit of the pharmacy's inventories, DI1 did not use the biennial inventory because he could not verify its accuracy due to the issues he had discovered during his review. *Id.* at 56, 61, 66, 154–56.

DI1 then inquired of Ms. Mincy as to recordkeeping and CSOS records.[13] *Id.* at 42. DI1 asked Ms. Mincy how Pharmacy 4 Less documents and records their ordering of controlled substances and validation of a prescription's legitimacy. *Id.* at 43.[14] When DI1 asked Ms. Mincy to produce the CSOS records (including records of receipt for Schedule 2s), he observed that Ms. Mincy proceeded to a laptop in the pharmacy to log into the CSOS system. *Id.* at 45. DI1 asked Ms. Mincy if she had her own CSOS credentials (which DI1 asserted is required for anyone accessing the CSOS system and cannot be shared with anyone else). *Id.* at 46. In response, Ms. Mincy stated she did not have her own credentials and did not have a power of attorney for anyone else's credentials. *Id.* at 46. Ms. Mincy stated to DI1 that she was using Mr. Richard Sprys credentials to log onto CSOS. *Id.* at 46.

DI1 later contacted Mr. Chris Jewell, one of the personnel in charge of the CSOS system at DEA Headquarters, to determine which personnel at Pharmacy 4 Less had access to the CSOS system. *Id.* at 47–48. Mr. Jewell ran a report and the report stated that Ms. Mincy received her own CSOS credentials in July 2018. *Id.* at 48–49; GX 29.[15]

DI1 described the audit [16] of Pharmacy 4 Less's records and inventories.[17] Tr. 53–85, 919–26; GX 4, 31, 32.[18] DI1 conducted an audit of Pharmacy 4 Less's records and inventories at a starting date of January 1, 2017. Tr. 55–56. DI1 selected this date because Pharmacy 4 Less maintained handwritten Schedule 2 controlled substance logs, there was no initial inventory, and the investigating DIs were unsure of how accurate the biennial inventory was. *Id.* at 56, 61. For example, DI1 had used the pharmacy's handwritten perpetual inventory forms for Methadone 10 mg tablets and Oxycodone 30 mg tablets during the audit, which had been provided to DI1 by Ms. Mincy during the on-site inspection on June 6, 2017. *Id.* at 56–60; GX 31, 32.[19]

DI1 explained that under DEA regulations, records need to be readily retrievable and maintained at the pharmacy. Tr. 86. It does not satisfy the regulations that records may later be retrieved. *Id.* at 86. He discovered that

[8] DI1 was accompanied by Group Supervisor DI2 during the on-site inspection. Tr. 41.

[9] A Notice of Inspection is a DEA Form evidencing a voluntary consent to search.

[10] GX—Government's Exhibit.

[11] Richard Sprys was not present at Pharmacy 4 Less during the on-site inspection on June 6, 2017. Tr. 40.

[12] *See* 21 CFR 1304.11(a).

[13] CSOS—Controlled Substance Ordering System.

[14] DI1 asserted during his testimony that when a pharmacy orders and receives controlled substances on-site, they are required to notate that they received them with the date and the initials of the person that received them. Tr. 44.

[15] The Respondent objected to admission of GX 29 on the basis of lack of authentication and not meeting the exception of a business record. Tr. 49. DI1 made it clear that he did not personally produce this record, but requested it from Mr. Jewell. *Id.* at 49–50. This Tribunal noticed that it appears to be a government record and did not appear to have any indication of inaccuracy or unreliability. *Id.* at 50. The Respondent argued that portions of the document appeared to have inaccuracies as related to Mr. Sprys, but agreed that if the Government was only offering the document as related to Ms. Mincy, it would not object if the rest of the document was blackened out to only show Ms. Mincy's records. *Id.* at 50–52. The Government agreed that it was only offering the document for Ms. Mincy's records on the top line and would not object to blackening out Mr. Spry's records. *Id.* at 51–52. This Tribunal admitted GX 29 on that basis as altered and is only considering GX 29 for the top line as related to Ms. Mincy's records. *Id.* at 51–52.

[16] The audit occurred both at the pharmacy and later during a review of Pharmacy 4 Less's records. Tr. 100.

[17] DI1 was later asked about his receipt and possession of records obtained from the pharmacy during the June 6, 2017 on-site inspection. Tr. 949–54; Proposed RX 10 (not offered into evidence) (The Government also had a standing objection to this line of questioning as outside the scope of redirect examination. Tr. 951.). Proposed RX 10 was a DEA–12, a receipt of items taken by the DIs after their inspection. Tr. 951. The DEA–12 forms indicated that the DEA had taken possession of six California folders containing C–2 prescriptions, and 13 manila folders containing C–2 invoices. Tr. 951–53.

[18] The Government initially offered GX 4 during the first portion of the hearing in Orlando, Florida. Tr. 67. The Respondent conducted voir dire and objected that it was unreliable. Tr. 68–81. This Tribunal initially admitted the exhibit. Tr. 81–85. However, this Tribunal reconsidered its ruling and found that GX 4 in its then present condition would not be helpful to the factfinder. Tr. 146. This Tribunal then afforded the Government the opportunity to resubmit GX 4 at a later time. Tr. 146–48. During the portion of the hearing in Arlington, Virginia, the Government reintroduced a corrected version of GX 4. Tr. 925. The Respondent did not object and the corrected version of GX 4 was admitted. Tr. 925–26.

[19] For a full discussion of how DI1 conducted his audit, *see* Tr. 61–67.

Pharmacy 4 Less did not have readily retrievable records available during the June 6, 2017 on-site inspection. *Id.* at 87.[20]

Following the June 6, 2017 on-site inspection, DIs[21] returned to Pharmacy 4 Less again on June 21, 2017. *Id.* at 88. Ms. Mincy was again at the pharmacy, and Mr. Richard Sprys joined them later that day. *Id.* at 88. DI1 stated that he discussed his findings from the initial on-site inspection and audit (including the invoices and prescriptions) with Mr. Sprys and Ms. Mincy during this second visit. *Id.* at 88. During the discussion, DI1 asked Mr. Sprys and Ms. Mincy how they determined whether prescriptions were for a legitimate medical purpose, based on a review of the records the DIs had retrieved during the first on-site inspection. *Id.* at 89–90. The pharmacists (both Mr. Sprys and Ms. Mincy) responded that they checked E–FORCSE, the Florida prescription monitoring program website, and that they would verify prescriptions by contacting the doctor's office and/or requesting patient medical files. *Id.* at 90–91. When asked how this information is documented, one of the pharmacists (DI1 could not remember if it was Mr. Sprys or Ms. Mincy) provided a red folder that they maintained. *Id.* at 91–92. The red folder contained screenshots from the computer system, Rx30.[22] Tr. 92. The red folder contained information related to multiple patients. Tr. 93, 119–31; GX 5, 7, 13, 17, 21, 23. DI1 did not find any ''due diligence files'' for Patients A.V., B.F., K.Y.D., or R.R. in the files provided to him by Pharmacy 4 Less. Tr. 131–36.

The following day on June 22, 2017, an administrative subpoena was served on Pharmacy 4 Less, requesting hard copy prescriptions for all Schedules 2–5 controlled substance prescriptions from October 2015 through June 22, 2017, all controlled substance prescription data from Rx30, and all due diligence patient files. Tr. 93–94; GX 2. Pharmacy 4 Less complied by delivering a gray tote container that contained ''California'' folders filled with Schedule 2 hard copy prescriptions, a thumb drive containing all Rx30 data, and the red folder seen during the June 21 on-site inspection. *Id.* at 96. The Schedules 3–5 prescriptions were delivered to the DIs by Pharmacy 4 Less at an unidentified later date. *Id.* at 97. The red folder contained screenshots from the Rx30 program. *Id.* at 96. The red folder also contained the pharmacists' notes on patients, referred to as ''due diligence files.'' *Id.* at 96–97. The ''California'' folders were organized by prescription number, which DI1 sorted through to locate prescriptions for the 10 charged patients at issue in this case. Tr. 97–111; GX 6, 8, 10, 12, 14, 16, 18, 20, 22, 24.[23] DI1 also discussed the Rx30 data retrieved from the thumb drive related to the 10 charged patients. Tr. 111–16; GX 35, 36.[24]

Diversion Investigators (the DIs were not identified by DI1) returned to Pharmacy 4 Less during approximately February 2018. Tr. 136. During this visit, DI1 acquired copies of invoices for controlled substances. Tr. 136. DI1 noted that a few of these invoices violated DEA regulations by failing to provide a date of receipt.[25] thnsp;*G Tr. 136–39.

Another administrative subpoena was served on Pharmacy 4 Less on July 9, 2018. Tr. 95; GX 3.

DI1 was recalled during the second portion of the hearing at the DEA Hearing Facility in Arlington, Virginia. DI1 credibly explained the purpose of the corrected GX 4, and how he arrived at his results during his audit of the pharmacy's records and inventories. Tr. 919–26. DI1 also testified to GX 38—Redacted (Initial Response from Florida E–FORCSE reflecting only the 10 charged patients) and GX 40 (A declaration by DI3 as to an administrative subpoena sent to the Florida E–FORCSE for user history), which was introduced at the second portion of the hearing. Tr. 929–36.[26] DI3 was asked by DI1 to send an administrative subpoena to the Florida E–FORCSE program to request a user history report. *Id.* at 929–30. Based on a follow-up request by DI1, the Florida E–FORCSE personnel reviewed their system to see when Mr. Sprys and Ms. Mincy had accessed the Florida PDMP to look up patients. Tr. 931–32; GX 40, Att. C.

DI1 also offered three arrest records for Patient K.Y.D. Tr. 937; GX 41–43. The arrest records were produced from ''*arrest.org,*'' a public website where members of the public can retrieve arrest information about individuals, which DI1 occasionally uses in the course of his employment. *Id.* at 938–39. DI1 indicated that this website is a tool that pharmacists or doctors can utilize to look up patients to see if they have ever been arrested for controlled substance violations. *Id.* at 940. According to the records, Patient K.Y.D. had previously been arrested on December 31, 2015, for possession of oxycodone with an intent to sell. *Id.* at 940; GX 43. Patient K.Y.D. had also previously been arrested on May 2, 2016, for operating with a suspended license, possession of Schedule 2 controlled substances, and possession of a Schedule 4 controlled substance. Tr. 941; GX 41. Finally, Patient K.Y.D. had also previously been arrested on February 25, 2017, for possession of a Schedule 2 controlled substance and resisting an officer without violence. Tr. 941–42; GX 42.[27]

Dr. Thomas Hamilton, Pharm. D.

Dr. Hamilton received his Doctor of Pharmacy degree at Nova Southeastern University in Fort Lauderdale. Tr. 167. He has worked as a pharmacist for 18 years. *Id.* at 169; GX 27. After being licensed in 1999, he worked for a short time at a small pharmacy before beginning full-time at Publix pharmacy as a pharmacist. Tr. 172. He served in

[20] DI1 explained that ''readily retrievable'' means that when DIs go into a pharmacy to perform an audit or to review a record, the pharmacy should be able to provide those records within a reasonable time. Tr. 87.

[21] DI1 noted that on this second visit, he was present, along with DI Debbie George, Group Supervisor Linda Stocum, and Division Program Manager of the State of Florida, Susan Langston. Tr. 88.

[22] Rx30 is a computer software that Pharmacy 4 Less used to maintain their inventory, the dispensing of controlled substances, and as DI1 testified, patient profile screens where the pharmacist can input notes about the patient, including information about the patient, treatment, injuries, and other diagnosis notes. Tr. 92–93. The Respondent identified this as the patient record maintenance form (PRM). *Id.* at 93.

[23] These exhibits were admitted with the qualification that these exhibits only contained the Schedule 2 hard copy prescriptions for each of the 10 charged patients, not all of the prescriptions. Tr. 102–11. [The Government noted, that ''some of the prescriptions here are not Schedule 2s, but [the Government did] not litigat[e] those prescriptions,'' and they are therefore not relevant to the Government's *prima facie* case. Tr. 103.]

[24] GX 35 is a narrowed version of Government's Proposed Exhibit 25, which was previously ruled inadmissible during prehearing proceedings. GX 35 only included information related to the 10 charged patients. Tr. 116–18. *See* ALJ Ex. 32.

[25] The Respondent conducted voir dire of DI1 on this point and argued that 21 CFR 1305 only applies to Schedule 2 controlled substances. Tr. 140–45. For further analysis, *see infra* section ''Date of Receipt on Invoices.''

*G DI clarified his testimony to say that ''only a few of them actually contained the . . . date of receipt;'' specifically, there were only ''four that contain[ed] the actual date of receipt,'' and ''eighty-five'' were not properly dated. Tr. 137–38.

[26] GX 38—Redacted was admitted and substituted in place of the original GX 38. Tr. 934. GX 40, p. 1, Att. A, and Att. C. were also admitted into evidence. Tr. 935–36.

[27] The Respondent objected and argued that the arrest records were unreliable and irrelevant to this matter. This Tribunal found that these records were available to the public, and not being offered for the truth of the matter of the arrests, but as a resource that an individual such as a doctor or pharmacist would be confronted with if they accessed this website. They were admitted over objection. Tr. 942–43. Reviewing such arrest websites is not required by the relevant standard of care, nor is it something that Dr. Hamilton or the other pharmacists did at Publix Pharmacies. Tr. 1022–23.

various capacities at Publix, including Pharmacist, Assistant Manager of the Pharmacy, and Pharmacy Manager. GX 27. He also served as a ''fixer,'' or a temporary Pharmacy Manager, who would ''clean up'' pharmacies. Tr. 169. Dr. Hamilton later transitioned to a Pharmacy Supervisor, in which he oversaw up to 40–45 *[H] pharmacies, in hiring, firing and daily operations. Tr. 170. Additionally, Dr. Hamilton evaluated stand-alone, independent pharmacies for purchase by Publix Supermarkets. *Id.* at 170. This evaluation included review of the drug invoices, the filled prescriptions, and the nature of the pharmacy's overall business. *Id.* at 170–71. In order to spend more time with his young family, Dr. Hamilton decreased his responsibilities with the company, gave up his supervisory role, and now serves as a Pharmacy Manager of a single pharmacy with Publix. *Id.* at 286–87.

In connection with the investigation into Pharmacy 4 Less, Dr. Hamilton reviewed the materials sent to him by the Government, which included prescriptions (front and back), related patient medical notes, and patient addresses. *Id.* at 177, 380–81. Additionally, Dr. Hamilton reviewed prescription pricing via GoodRx. *Id.* at 177–78. Dr. Hamilton noticed ''red flags'' in connection with the reviewed prescriptions. *Id.* at 178. ''Red flags'' are concerns resulting from the review of the prescription. *Id.* at 178–79. These concerns can be resolved through some investigation by the pharmacist, such as speaking with the patient, reviewing the medical history, or checking with the prescriber. *Id.* at 179. Dr. Hamilton noted that the resolution of the ''red flag'' had to be documented in the file as part of the Florida Standard of Care,*[I] noting, ''[i]f it's not documented, there's no evidence that . . . it was resolved *[or a phone call was made, or an answer was given].'' *Id.* at 179–81, 306, 318, 337, 1006–11, 1016.[28]

Dr. Hamilton indicated the source of pharmacy standards in Florida included ''Florida Regulation 64B,''[29] and guidance from the National Board of Pharmacy Association. *Id.* at 180, 351–58. Dr. Hamilton noted these standards are enforced by the Board of Pharmacy in Florida. *Id.* at 180.

Dr. Hamilton explained that if the prescription involved a controlled substance, that in itself was a red flag. *Id.* at 182. The strength of medication and the duration of the medication therapy was a concern, which needed to be addressed. *Id.* The pricing structure of the controlled substance represented a concern, as well as the distance of travel. *Id.* at 182, 360–61.

Dr. Hamilton noted ''red flags'' in a prescription to Patient A.E., for 84 tablets of 8 mg. of hydromorphone. *Id.* at 183–84; GX. 6, pp. 1–2, GX. 5; RX 18, pp. 1–2, RX 19.[30] Dr. Hamilton noted that 8 mg was the highest dosage made of hydromorphone, a Schedule 2 controlled substance. Tr. 184. Further, the number of dosage units prescribed, 84, was also concerning. *Id.* at 184. Dr. Hamilton noted that, based on the records, the first ''red flag'' involving a dangerously high dosage level, had not been resolved. *Id.* at 186. Dr. Hamilton noted the absence of any information relating to the patient's prescribing history suggesting the patient was acclimated to this significant dosage, and not ''opiate naïve'' to this dosage. *Id.* at 188–90, 316–17. Dr. Hamilton indicated the Florida standard of care required the starting date of the prescribed medication to be disclosed on the face of the prescription or in a note readily available to the pharmacist. *Id.* at 186–87, 350–51, 392–94. Dr. Hamilton acknowledged that a pharmacist had access to the Florida PDMP, or ''E–FORCSE'' database, which contained prescribing history. *Id.* at 348–49.

Dr. Hamilton noted that an identical prescription for hydromorphone was issued to A.E. for two more consecutive months. Tr. 191–92; GX 6, pp. 3–6. Dr. Hamilton noted the Florida standard of care regarding ''individualization'' required that the pharmacist consider whether an extended high dosage of controlled medication should be continued or should be reduced. Tr. 192–93. Dr. Hamilton expected to see a reduction in dosage over time, or an explanation by the pharmacist for continuing to dispense the same high dosage. *Id.* at 1013–14. Dr. Hamilton noted there was no evidence that any reevaluation of the patient's continued need for this strong medication had been made. *Id.* at 193. The fact that the patient was on immediate release tablets further heightened the ''red flag.'' GX 28, p. 6. Dr. Hamilton explained that immediate release tablets typically addressed acute versus chronic or long-term conditions, as suggested here by ongoing prescriptions for hydromorphone. Tr. 193–94, 1013–14. This ''red flag'' was not resolved on the face of the prescription, or in the medical notes. Tr. 194; GX 5, GX 6, pp. 5–6. Dr. Hamilton was also concerned by the cash purchase of the prescription and the ''extremely high prices'' paid, of $5.95 per pill. Tr. 194, 199; GX, 28, p. 6.

Dr. Hamilton explained that medications are typically priced at the ''average wholesale price'' plus 20%. Tr. 195. Dr. Hamilton explained that the appropriate price *[J] of 8 mg. of hydromorphone was $1.50 per tablet. He cautioned that this was an approximation by reviewing pharmacy prices in his area, both of big chain pharmacies as well as independents. *Id.* at 195, 326, 330–31. Dr. Hamilton opined that prices per pill from wholesalers would be fairly consistent across the state. *Id.* at 195, 1011–13. However, he noted that, at the retail level, the purchase of just a few pills could result in an extremely high price per pill versus the purchase of a large number of pills. Tr. 198.

On rebuttal, Dr. Hamilton compared versions of the same medical records as to A.E. *See* GX 5 and RX 18, 19. After pointing out differences in the two versions, and granting the reliability of the Respondent's versions, Dr. Hamilton opined that considering the GX 18, 19 version, his previous opinions as to A.E.'s dispensing remained the same. Tr. 957–65. As related to the differences

*[H] Amended pursuant to Tr. 170.

*[I] Throughout the case, the Government's expert and all parties appear to have used the phrases ''standard of care'' and ''corresponding responsibility'' and ''standard of pharmacy practice'' interchangeably. The testimony regarding the requirement to resolve red flags is clearly related to Respondent Pharmacy's corresponding responsibility under 21 CFR 1306.04. The interchangeable use of this terminology does not impact my ultimate finding that Respondent Pharmacy failed to resolve red flags in contravention of Respondent's corresponding responsibility under 21 CFR 1306.04 and outside the usual course of professional practice in violation of 21 CFR 1306.06. For consistency purposes, I will use the language regarding standard of care to encompass the standard of pharmacy practice and corresponding responsibility herein.

[28] *[Omitted for clarity. The ALJ found that the Government did not allege a separate violation regarding the documentation of the resolution of red flags, but instead chose to consider such lack of documentation as an inference supporting a finding that the red flag was not resolved. In this case, I find that the Government's expert credibly testified that documenting the resolution of red flags was required by the standard of professional practice in Florida. Furthermore, the issue of whether documentation was required by the standard of practice in Florida was thoroughly addressed by both parties at the hearing. *See id.* 179–81, 434–38, 1007–08. I find that it is unimportant to find an independent violation related to the lack of documentation, because such lack of documentation already supports the overall finding that Respondent filled these alleged prescriptions in violation of its corresponding responsibility and outside the usual course of professional practice in Florida.]

[29] *See* West's Florida Administrative Code, Title 64. Department of Health, Subtitle 64b16, Chapter 64B16–27—Pharmacy Practice.

[30] Dr. Hamilton compared GX 5 with RX 18.

*[J] Dr. Hamilton referred to it as ''the market retail price.'' Tr. 195.

between the Government and Respondent versions of the same records, Dr. Hamilton conceded that the Respondent versions could be updated versions of the Government versions. *Id.* at 1019–20. Dr. Hamilton observed that updating medical records was required by the standard of care. *Id.* at 1020.

Turning to patient A.R., Dr. Hamilton noted a prescription for 112 tablets of 15 mg of oxycodone represented several ''red flags'', citing significant dosage, high quantity, frequency of prescribed usage (4 times daily), and high price.[31] *Id.* at 204–05, 329; GX 8, pp. 1–2; RX 20. Dr. Hamilton was unable to find that these ''red flags'' were resolved on the face of the prescription or on the ''information sheet'' within the patient record. Tr. 205–06; GX 7. Dr. Hamilton explained that, although the patient's ''information sheet'' contained information relating to diagnoses and medical conditions, it did not include information justifying the long-term use of the subject oxycodone prescription. Tr. 206, 329–30; GX 28, pp. 12–14. As relates to price per pill, Dr. Hamilton estimated the retail price to be approximately 90 cents. Tr. 330–31. The next prescription for A.R. also involved 15 mg of oxycodone, but for 140 tablets at a directed frequency of 5 times per day at a price of $350. Tr. 207–08; GX 8, pp. 3–4. Dr. Hamilton noted the distance between A.R.'s residence and the prescribing doctor's office and Pharmacy 4 Less. Tr. 208. Dr. Hamilton estimated A.R. lived approximately 40 miles from the prescribing doctor, and another 13 miles further to the subject pharmacy. *Id.* at 209. Dr. Hamilton indicated this distance represented a ''red flag,'' which went unresolved within the subject records. Tr. 209–10, 332–37; GX 7, GX 8, p. 3.

The next two prescriptions for A.R., which Dr. Hamilton indicated disclosed the same ''red flags'' were identical prescriptions for 15 mg of oxycodone, for 140 tablets, but at a price of $340. Tr. 212–14; GX 8, pp. 5–6, 33–34. *[Omitted based on further review of the record]. Dr. Hamilton opined the subject oxycodone prescriptions for A.R. remained unresolved within the records reviewed, and were thus below the standard of care in Florida. Tr. 215–16; GX 7.

On rebuttal, Dr. Hamilton compared versions of the same medical records as to A.R. *See* GX 7 and RX 20, 21. After pointing out differences in the two versions, and granting the reliability of the Respondent's versions, Dr. Hamilton opined that considering the GX 20 and 21 version, his previous opinions as to A.R.'s dispensing remained the same. Tr. 965–69.

As to Patient B.F., Dr. Hamilton reviewed a series of prescriptions for hydromorphone 8 mg, 84 count, 3 times daily. Tr. 216–22; GX 12, pp. 13–14, 17–18, 21–22, 25–26; RX 24. The ''red flags'' revealed included the controlled substance itself, the dosage at the highest available, the high quantity (84 tablets), the immediate release, the ongoing length of time it is being prescribed, and the high price ($490).[32] Tr. 216–22.

On rebuttal, Dr. Hamilton evaluated the Respondent's sponsored versions of medical records as to B.F., RX 24, 25. Dr. Hamilton noted references to a discharge date of May 15, 2017, a reference to liver cancer, stage 3, and the last fill of the subject prescription on May 15, 2017. Tr. 976–77. Even granting the reliability of the records, Dr. Hamilton stuck with his original opinions as to B.F.'s dispensing. *Id.* at 975–80.

As to Patient B.N., Dr. Hamilton identified ''red flags'' related to a series of prescriptions for hydromorphone. *Id.* at 223. The first was of 8 mg, 90 count, priced at $580. Tr. 222–23; GX 14, pp. 1–2; GX 13; RX 26. Dr. Hamilton reiterated the hydromorphone itself represented an unresolved ''red flag,'' as well as the dosage, quantity and cost. Tr. 223, 226. The second and third prescriptions for hydromorphone, again with the same unresolved a ''red flags,'' involved 8 mg, 100 count, priced at $640. Tr. 224–28; GX 14, pp. 3–6; GX 13. The fourth hydrocodone prescription, again with the same unresolved ''red flags,'' involved 8 mg, 100 count, priced at $600. Tr. 229–30; GX 14, pp. 15–16. This prescription prompted an additional ''red flag'' as it represented ongoing prescribing of hydromorphone without demonstrated justification. Tr. 230. Dr. Hamilton reviewed a prescription for oxycodone, 30 mg (the highest dosage available), 120 count, priced at $600. *Id.* at 231–32. Dr. Hamilton opined the medication itself represented a ''red flag,'' as well as the dosage, the quantity and the cost. *Id.;* GX 14, pp. 19–20, GX 13. Additionally, transitioning from hydromorphone to oxycodone required an explanation, which was not contained within the records reviewed by Dr. Hamilton. Tr. 232. A second prescription for oxycodone for B.N., for 30 mg, quantity 40, had the same unresolved ''red flags.'' Tr. 233; GX 14, pp. 21–22. As this represented the second consecutive prescription for oxycodone, an additional ''red flag'' was raised regarding the ongoing unjustified prescribing. Tr. 233–34. The next two oxycodone prescription for B.N. involving the same unresolved ''red flags,'' involved 30 mg, 120 count, priced at $600.*[K] Tr. 234–36; GX 13; GX 14, pp. 23–24, 37–38.

[31] Patient A.R. paid $280 for 112 pills of oxycodone in connection with this prescription, or $2.50 per pill. *[Later, Patient A.R. paid between $340 and $350 for 140 pills of oxycodone, or approximately $2.43–$2.50 per pill. GX 8, at 3–6, 33–34.]

[32] Eighty-four tablets at $490 equals $5.83 per tablet. *[The ALJ then found that Dr. Hamilton estimated the expected retail price to be $0.90 per pill citing to Tr. 218–22 and GX 28, p. 11, but the record does not support this finding. Dr. Hamilton originally testified that hydromorphone had an estimated retail price of $0.90, Tr. 218; however, after he refreshed his recollection with his expert report he stated, ''I might have misspoke at $0.90. It's a little bit more expensive for [D]ilaudid, or [h]ydromorphone . . . .'' Tr. 222. Dr. Hamilton's export report stated that the estimated retail price of hydromorphone was approximately $1.50 per pill. GX 28, at 11. Dr. Hamilton also testified elsewhere in the record that the market retail price for hydromorphone was $1.50 per pill. *See e.g.* Tr. 195–97. Moreover, albeit in a different context, Dr. Hamilton testified that to the extent numbers appearing in his expert report differed from numbers to which he was testifying based on his recollection, the numbers in the expert report would be ''[m]ore accurate.'' Tr. 209. Based on the entirety of the record, I find that Dr. Hamilton estimated the expected retail price of hydromorphone to be $1.50 per pill.]

[*K] Dr. Hamilton also testified that additional prescriptions falling between the November 11, 2016, and June 2, 2017, prescriptions had the same unresolved ''red flags.'' Tr. 236.

On rebuttal, Dr. Hamilton compared versions of the same medical records as to B.N., GX 13 and RX 26, 27. After pointing out differences in the two versions, and granting the reliability of the Respondent's versions, Dr. Hamilton opined that considering the RX 26 and 27 version, his previous opinions as to B.N.'s dispensing remained the same. Tr. 980–85.

As to patient K.Y.D., Dr. Hamilton identified a series of oxycodone prescriptions with unresolved ''red flags.'' Tr. 237; GX16, pp. 1–2, 5–6, 9–10, 63–64; RX 30, 31, pp. 2–4. The first three involved a dosage of 30 mg, quantity 84, price $290. Tr. 237–39 *[For these prescriptions, Dr. Hamilton testified that the red flags included the highest strength dosage, high quantity, frequency of prescribed usage (3 times daily), and high price.] By the third prescription, it also triggered an additional ''red flag'' involving the ongoing unjustified prescribing of oxycodone. Tr. 239. The fourth example for the identical prescription triggered the same unresolved ''red flags.'' [*L] *Id.* at 240.

On rebuttal, Dr. Hamilton evaluated the Respondent's sponsored versions of medical records as to K.Y.D., RX 30, 31. Dr. Hamilton noted references to a discharge date of June 12, 2017. Tr. 990–91. Even granting the reliability of the records, Dr. Hamilton stuck with his original opinions as to K.Y.D.'s dispensing. Tr. 990–94.

As to Patient K.E.D., Dr. Hamilton determined there were unresolved ''red flags'' involved in a series of oxycodone prescriptions. The first was for 20.5 mg, quantity 112, for $430. Tr. 241–45; GX 17, GX 18, pp. 1–2, 3–4, 5–6, 41–42; RX 28, RX 29, p. 2. For the first, the dosage of 20.5 mg represents a dosage outside common dosage units, and would have been a compounded dosage, a ''red flag'' in itself. Tr. 242. *[Additionally, Dr. Hamilton noted that the quantity, and price were unresolved red flags for this prescription. *Id.*] The second and third oxycodone prescription noted were for 20 mg, 112 quantity, priced at $430. Tr. 244–45. Again, the medication itself represented a ''red flag,'' as well as the dosage, quantity and price. Tr. 245. The fourth oxycodone prescription was identical to the second and third, except that the price was $400. Tr. 245–46. *[In addition to the ''red flags'' identified with the prior two prescriptions,] the fourth prescription triggered the ''red flag'' of an extended prescription without apparent justification.[*M] *Id.* at 246.

On rebuttal, Dr. Hamilton compared versions of the same medical records as to K.E.D. *See* GX 17; RX 28, 29. After pointing out differences in the two versions, and granting the reliability of the Respondent's versions, Dr. Hamilton opined that considering the RX 28 and 29 version, his previous opinions as to K.E.D.'s dispensing remained the same. Tr. 986–90.

As to Patient R.R., Dr. Hamilton identified a series of oxycodone prescriptions, each which involved unresolved ''red flags.'' Tr. 247–50; GX 20, pp. 1–6, 41–42; RX 32, p. 1; RX 33, p. 5. The first prescription was of 18 mg, 112 quantity, priced at $250. Tr. 247. The first ''red flag'' is that the dosage has been compounded, without explanation. *Id.* The high quantity is a ''red flag,'' as well as the high price paid. *Id.* The second and third prescriptions involved 15 mg, quantity of 112, priced at $270. Tr. 248. The fourth prescription is identical to the second and third, except for the price was $260. Tr. 249–50. The third and fourth prescriptions *[had the same unresolved red flags as the earlier prescriptions, and] additionally triggered a ''red flag'' as extended prescriptions without apparent justification.[*N] *Id.*

On rebuttal, Dr. Hamilton evaluated the Respondent's sponsored versions of medical records as to R.R. *See* RX 32, 33. Dr. Hamilton noted references to a discharge date of May 2, 2017, yet another prescription fill on May 30, 2017. Tr. 994–95. Even granting the reliability of the records, Dr. Hamilton stuck with his original opinions as to R.R.'s dispensing. *Id.* at 994–97.

As to Patient R.V., Dr. Hamilton identified a series of oxycodone prescriptions, each which involved unresolved ''red flags.'' Tr. 251–56; GX 21; GX 22, pp. 27–28, 31–32, 34–35, 78–79; RX 34, p. 1; RX 35. The first prescription was for 20 mg, 112 quantity, priced at $340. Tr. 251; GX 28. The first ''red flag'' was the high dosage. Tr. 251. The next ''red flag'' was the quantity. *Id.* And the third was the high price paid. *Id.* *[Dr. Hamilton testified that there was no evidence on either the face of the prescription or in the patient record for R.V. that these ''red flags'' were resolved. *Id.* at 251–52.] The second prescription was identical to the first *[and had the same unresolved ''red flags.'']. *Id.* at 253. The third was identical to the first two, except that it was priced at $310. *Id.* The third prescription *[had the same unresolved red flags as the earlier prescriptions, and] had the additional ''red flag'' as an extended prescription without apparent justification. *Id.* The fourth prescription for oxycodone was of 20 mg, quantity 120, priced at $340 *[and had the same unresolved red flags as the third].[*O] *Id.* at 254–55.

On rebuttal, Dr. Hamilton compared versions of the same medical records as to R.V. *See* GX 21 and RX 34, 35. After pointing out differences in the two versions, and granting the reliability of the Respondent's versions, Dr. Hamilton opined that considering the RX 34 and 35 version, his previous opinions as to R.V.'s dispensing remained the same. Tr. 997–1001.

As to Patient V.W., Dr. Hamilton identified a series of oxycodone prescriptions, each which involved unresolved ''red flags.'' Tr. 256–60; GX 23, GX 24, pp. 1–2, 3–4, 5–6, 41–42; RX 36. The first prescription was for 15 mg, quantity of 84, priced at $300. Tr. 256. The first ''red flag'' was the relatively high dosage. Tr. 256. The next ''red flag'' was the quantity. *Id.* And the third was the high price paid. *Id.* The second prescription involved 15 mg, quantity 112, priced at $400. Tr. 257. The third prescription was identical to the second, but was priced at $350. Tr. 258. The third prescription had *[the same unresolved ''red flags'' as prior prescriptions based on the dose and quantity] and additional [unresolved] ''red flags'' *[because the prescription was written for four times a day and filled for only three times a day and] as an extended prescription without apparent justification. *Id.* The fourth prescription was identical to the third, except priced at $285. *Id.* at 259. *[The fourth prescription shared the ''red flags'' arising based on the dose, quantity, price, and ''length of time for immediate-release medication.'' [*P] *Id.* at 259–60.

[*L] Dr. Hamilton also testified that additional prescriptions issued between March 31, 2016, and June 12, 2017, had the same unresolved ''red flags.'' Tr. 241.

[*M] Dr. Hamilton testified collectively regarding the remaining prescriptions in GX 18 issued between December 21, 2015, and June 7, 2017, and opined that there were similar red flags for all of those prescriptions and that none of those red flags were resolved. Tr. 246.

[*N] Dr. Hamilton testified collectively regarding the remaining prescriptions in GX 20 issued between December 21, 2015, and May 30, 2017, and opined that there were similar red flags for all of those prescriptions and that none of those red flags were resolved. Tr. 250.

[*O] Dr. Hamilton testified collectively regarding the remaining prescriptions in GX 22 issued between January 11, 2016, and June 19, 2017, and opined that there were similar red flags for all of those prescriptions and that none of those red flags were resolved. Tr. 255.

[*P] Dr. Hamilton testified collectively regarding the remaining prescriptions in GX 24 issued between January 25, 2016, and May 21, 2017, and opined that each had the same red flags as the fourth prescription discussed herein and that none of those red flags were resolved. Tr. 260.

On rebuttal, Dr. Hamilton compared versions of the same medical records as to V.W. *See* GX 23 and RX 36, 37. After pointing out differences in the two versions, and granting the reliability of the Respondent's versions, Dr. Hamilton opined that considering the RX 36 and 37 version, his previous opinions as to R.V.'s dispensing remained the same. Tr. 1001–04.

As to Patient A.V., Dr. Hamilton discovered a series of controlled substance prescriptions that were filled by Pharmacy 4 Less despite unresolved ''red flags.'' Tr. 261–67; GX 10, pp. 1–2, 3–4, 5–6, 9–10, 15–16, 37–38, 41–42, 43–44, 45–46, 47–48, 59–60; RX 22. The first such prescription involved 29 tablets of 8 mg of buprenorphine. Tr. 261–62. The second prescription, filled 9 days after the buprenorphine was filled, involved 112 tablets of oxycodone, 20 mg each, priced at $290. Tr. 262. The oxycodone prescription itself presented ''red flags,'' which needed to be resolved, as discussed earlier, including the drug itself, the large quantity, the relatively high dosage, and the price. *Id.* Additionally, Dr. Hamilton observed the 20 mg oxycodone was being prescribed in conjunction with the buprenorphine. *Id.* at 263. Buprenorphine is used to wean someone off of an opiate, such as oxycodone. *Id.* The prescribing of buprenorphine along with an opioid prescription creates a ''red flag,'' which needs to be resolved. *Id.* at 262–63. The acceptable protocol would be to introduce the buprenorphine as the dosage of oxycodone is reduced, until the oxycodone is completely replaced by the buprenorphine. *Id.* at 262–65. Here, the buprenorphine is introduced, yet nine days later the 20 mg of oxycodone was filled, which is inconsistent with the typical detoxification protocol, and can present some contraindication issues. *Id.* at 266–67. Additionally, detoxification would require physician monitoring. *Id.* at 265. Dr. Hamilton noted there was no indication in the reviewed records [*Q] *[that the ''red flag'' was resolved]. *Id.* at 265–66. Another 8 mg buprenorphine prescription of 60 tablets was filled almost two months after the first buprenorphine prescription. *Id.* at 267–68. On the same day, a second identical prescription for 20 mg of oxycodone was filled, triggering the same set of ''red flags'' as previously described *[and, according to Dr. Hamilton, there was no documentation that those ''red flags'' were resolved]. *Id.* at 268–69. This second prescription for oxycodone,[*R] *[according to Dr. Hamilton, raised the same unresolved ''red flags'' as the first one, and an additional unresolved ''red flag'' because the medication dosage and frequency remained unchanged and ''[y]ou would see a de-escalation of medication with a patient going through detox.'' *Id.* at 268–69. The next month saw a repeat of an 8 mg buprenorphine prescription *[for 60 tablets], along with a 20 mg prescription for oxycodone, thus repeating the same unresolved ''red flags.'' *Id.* at 271–72. Less than one month later, dual prescriptions for 8 mg of buprenorphine and 20 mg of oxycodone were filled, repeating the same unresolved ''red flags'' as described earlier. *Id.* at 271–73. Additionally, as to the oxycodone, the repeated prescribing created the unresolved ''red flag'' related to *[the length of time] without a reduction in dosage. *Id.* at 273–74. Dr. Hamilton addressed another set of dual prescriptions for 8 mg of buprenorphine and 20 mg of oxycodone, thus repeating the same unresolved ''red flags'' discussed earlier.[*S] *Id.* at 274–77.

On rebuttal, Dr. Hamilton evaluated the Respondent's sponsored versions of medical records as to A.V. *See* RX 22, 23. Dr. Hamilton noted references to a consultation with Dr. Seaford, to ''tapering'' and to ''detox.'' Tr. 970–72. Even granting the reliability of the records, Dr. Hamilton stuck with his original opinions as to A.V.'s dispensing. *Id.* at 970–75.

Again on rebuttal, Dr. Hamilton confirmed that nothing in the testimony of Mr. Parrado or Ms. Mincy has caused Dr. Hamilton to change his previously offered opinions in this case. *Id.* at 1004–05. Dr. Hamilton did agree with Mr. Parrado's observation that it was proper to fill a pain prescription up to a month after the patient was released from the hospital. *Id.* at 1017. Dr. Hamilton further commended the Respondent's practices of maintaining medical records within their pharmacy files. *Id.* at 1015–16.

Respondent's Case in Chief

The Respondent presented its case through the testimony of two witnesses. First, the Respondent presented the testimony of Ms. Amy Mincy (Ms. Mincy). Second, the Respondent presented the testimony of its expert, Robert M. Parrado (Mr. Parrado).

Ms. Amy Mincy, R.Ph.[33]

Ms. Mincy testified to the following. Several of Ms. Mincy's claims were contested by the government and will be discussed later. As background, Ms. Mincy graduated from Mercer University in Atlanta, Georgia, and has been a pharmacist since 1983. Tr. 569. She is licensed in the State of Florida and has inactive licenses in Tennessee and Virginia. *Id.* She has worked for a number of pharmacies for varying lengths of time, including independent pharmacies, as a relief pharmacist, and as a pharmacy consultant, over the course of her career. *Id.* at 569–76, 579–83; RX 1.[34] She has also previously been disciplined by the Florida Board of Pharmacy for filling a prescription for her mother, was placed on probation, and successfully completed the terms of her probation in 1998. *Id.* at 579–82. She began working as a pharmacist at Pharmacy 4 Less in January 2016. *Id.* at 576–77. She is one of two pharmacists that works at Pharmacy 4 Less, along with Mr. Sprys. *Id.* at 577. She works at Pharmacy 4 Less four days per week, Monday through Thursday, with Mr. Sprys working on Friday. *Id.* at 822.

Ms. Mincy was working as the pharmacist on duty at Pharmacy 4 Less on June 6, 2017, when the DEA conducted its on-site inspection at the pharmacy. *Id.* at 584. She testified that DI1 and another Diversion Investigator (hereinafter DI2) arrived at the pharmacy sometime between 10:00 a.m.–12:00 p.m. that day. *Id.* at 585. She did not know the DEA was planning to conduct the on-site inspection that day. *Id.* at 585–86. She was told that the inspection would take between 20–30 minutes or up to an hour. *Id.* at 586.[35] She related that Mr. Sprys' son, William Sprys, was also in the pharmacy. *Id.* at

[*Q] The ALJ found that ''Dr. Hamilton noted that there was no indication in the reviewed records that the physician was monitoring any attempted detoxification.'' I have omitted the finding because I do not see support for it in the record and find it to be irrelevant. The record is clear that Dr. Hamilton did not see any documentation of resolution of the ''red flag,'' which is ultimately the fact at issue in this case.

[*R] The ALJ found that the second prescription ''highlighted the 'red flag' relating to the absence of any evaluation as to the reduction in the dosage or frequency of the oxycodone.'' I have revised this finding to quote Dr. Hamilton.

[*S] Dr. Hamilton testified collectively regarding the remaining prescriptions for buprenorphine and oxycodone in GX 10 issued between August 2, 2016, and February 13, 2017, and opined that each oxycodone prescription had the same red flags as the other oxycodone prescriptions discussed herein and that there was no documentation that these red flags were resolved. Tr. 276.

[33] Ms. Mincy testified the entire day of November 7, 2018. She was recalled to the stand during the second portion of the hearing at the DEA Hearing Facility in Arlington, Virginia on February 25, 2019, for the remainder of her testimony.

[34] Ms. Mincy's CV was admitted over objection with the corrections noted through Ms. Mincy's testimony. Tr. 584.

[35] When asked, Ms. Mincy said that it was primarily DI1 that spoke to her and asked her questions during the inspection. Tr. 586. She stated that DI2 was primarily observing. Tr. 587.

587. William Sprys acts as the administrator for the pharmacy, but is not a registered pharmacist, so he primarily handles clerical administrative duties. *Id.* at 587–88.

During the inspection, Ms. Mincy was handed a DEA Form 82, Notice of Inspection. Tr. 589; GX 30. She was uneasy about consenting to an inspection because she only works as an independent contractor at Pharmacy 4 Less, not as a regular employee. Tr. 590–91. She asked to contact Mr. Richard Sprys to ask about the form and whether she should consent and sign the form. *Id.* at 591–92. She had William Sprys contact Mr. Richard Sprys on the telephone because Richard was out of the country at the time of the inspection. *Id.* at 592. The DIs were also present during the telephone call. *Id.* She spoke to Mr. Richard Sprys on speakerphone about the DEA inspection and the DIs request to inspect the pharmacy. *Id.* Mr. Sprys then gave permission and directed Ms. Mincy to sign the form. *Id.* at 592–93. Ms. Mincy then signed the Form 82. Tr. 594.

After signing the form, Ms. Mincy was taken into a separate room in the pharmacy. *Id.* at 596. DI1 asked to see the pharmacy's perpetual inventory. *Id.* at 598. DI1 proceeded to count pills of controlled substances contained in the pharmacy. *Id.* DI1 asked for the perpetual inventory pages for January 1, 2017, through June 6, 2017. Tr. 604–05. The perpetual inventory was handwritten and was designed to keep track of the pharmacy's prescription inventory. Tr. 630–31; RX 31 (Methadone), 32 (Oxycodone).

He then requested the pharmacy's biennial inventory. Tr. 605–06, 773–74; GX 37; RX 38.[36] The pharmacy keeps its inventories in a binder that is located inside the locked medication room. Tr. 607. The Respondent's version of the biennial inventory indicated that it was completed on April 26, 2017, at 8:00 a.m. by Ms. Mincy and Mr. Sprys. *Id.* at 617–18, 767–73; RX. 38, pp. 1, 2, 3, 8–16. The inventory was completed by entering the drug room, verifying the number of pills, scanning the prescription bottles, and verifying their entry into the pharmacy's computer system. Tr. 626–27. Ms. Mincy testified she completed the biennial inventory in about three hours. *Id.* at 628. Ms. Mincy indicated her understanding that the biennial inventory must be completed either in the morning before the start of business or at the end of the day at the close of business, and that it was completed before the opening of business. *Id.* at 620–21, 817–19. The biennial inventory was kept inside a binder with the C–2 perpetual inventory. *Id.* at 622. The biennial inventory was later sent by the pharmacy to DI1 after he left it at the pharmacy following the inspection. *Id.* at 638–42; 782–88. She indicated she was not aware that a biennial inventory containing Schedule 2 prescriptions needed to be separate from an inventory containing Schedules 3 through 5 prescriptions. *Id.* at 818. To complete the biennial inventory, she would open the narcotic cabinet and would hand-count the Schedule 2 pills inside. *Id.* at 820–21.

For the inventories in the pharmacy, Ms. Mincy would keep a perpetual inventory of the prescriptions that had been filled. *Id.* at 628–34; GX 31, 32. The perpetual inventories were usually filled out by Ms. Mincy, but were sometimes updated by Mr. Sprys. Tr. 628–29. Every time a prescription was filled, it would be noted by either Mr. Sprys or Ms. Mincy so that they could keep up with their inventory that was on hand. *Id.* at 631. These were provided by Ms. Mincy to DI1 when he asked to see the pharmacy's inventory to determine if it was correct. *Id.* at 634–35. Ms. Mincy explained from the perpetual inventories how it can be determined how many pills were currently in the inventory. *Id.* at 635.

DI1 also asked to see the pharmacy's computer software, including print-outs and reports. *Id.* at 609–11. DI1 then requested to inspect the pharmacy's CSOS system. *Id.* at 612–13. CSOS is the pharmacy's electronic controlled substance ordering system. *Id.* at 611, 865–66. The pharmacy uses the CSOS system sourced through AmerisourceBergen. *Id.* at 612. Ms. Mincy showed DI1 the steps to order, but could not order because she did not have CSOS credentials at the time of the inspection. *Id.* at 613, 839–40, 867. Each authorized user receives an individual code that must be kept confidential to that user. *Id.* at 613. When showing the program to DI1, Ms. Mincy stated she did not put in any credentials because she did not have any at the time. *Id.* at 615, 867–68. DI1 then accused her of ordering with Mr. Richard Spry's credentials, which she promptly denied. *Id.* at 615. DI1 then proceeded to take all the original copies of the pharmacy's Schedule 2 prescriptions and some of the Schedules 3–5 prescriptions from January 1, 2017, to June 6, 2017. *Id.* at 615–17, 891–93, 894–96; RX 59, 60.[37] Ms. Mincy could not explain how there were differences between the original copy of RX 59 she had maintained at the pharmacy and the version that the Government had introduced into evidence, as the version the Government had seized on June 6, 2017. Tr. 901–903; *compare* GX 26, pg. 50 *with* RX 59.

Ms. Mincy would use the Florida E–FORCSE system as part of her resolution of red flags. Tr. 642–43. It is used to assist medical personnel in keeping track of medications individuals are taking. *Id.* at 642, 870–71. It contains a log of a patient's controlled substances that are disbursed from a prescription written by a doctor and filled by a pharmacist. *Id.* Pharmacies upload prescriptions daily into the E–FORCSE system. *Id.* at 643. E–FORCSE contains prescriptions for Schedules 2–4 controlled substances. *Id.* Ms. Mincy would use it daily and prior to every fill of a new prescription for clients. *Id.* at 643. E–FORCSE allows a pharmacist to immediately access a patient's name, date of birth, address, and the aforementioned prescriptions. *Id.* at 645. It also allows a pharmacist to see which pharmacies a patient goes to, or if the patient is doctor shopping or trying to fill prescriptions early. Tr. 645.

At the pharmacy each morning, either Mr. Sprys or Ms. Mincy would log on to the E–FORCSE system and it would be left open on the computer to be accessed. *Id.* at 871. Ms. Mincy understood that when E–FORCSE started, it was permissible to use another person's login since the pharmacy manager or pharmacist would log in first thing in the morning and it could be used throughout the day under that person's login information. *Id.* at 903–908.[38] The login systems for CSOS and E–FORCSE are two separate systems. *Id.* at 872. CSOS is regulated directly by the DEA and individual authorization and access has to be

[36] Each version was admitted following the Government's voir dire and request to admit GX 37 if this Tribunal were to admit RX 38. The Government agreed to redact the pricing information contained at the Respondent's request. Tr. 775–82. However, the Government later requested to withdraw the original GX 37 and offer an alternative version of GX 37, with only pages 1–7 considered for record. Tr. 912–17.

[37] Testimony related to RX 59 and 60 were objected to by the Government for lack of notice and being beyond the scope of cross-examination that was conducted on November 7, 2018. This Tribunal permitted the Respondent to make a record of the testimony for the Administrator's consideration, but sustained the Government's objection as to being beyond the scope of cross examination. Tr. 885–91, 893, 896–900.

[38] Ms. Mincy explained that this is why sometimes another person's E–FORCSE number would appear on the search records when she had actually done the search. Tr. 908–09. There was further testimony about the pharmacy's use of E–FORCSE and Ms. Mincy's understanding of its use, along with discussion about proposed RX 57. Tr. 903–09. However, proposed RX 57 was later withdrawn by the Respondent and GX 38 (redacted) was used instead after its introduction during DI1's rebuttal testimony. Tr. 927–34; 1024–25.

granted by the DEA. *Id.* at 872. Ms. Mincy had a key and certificate specific to her that had to be used to access the CSOS system. *Id.* at 872. On the other hand, E–FORCSE could be properly accessed by either Mr. Sprys or Ms. Mincy and could be left open on the computer for either person to access. *Id.* at 872.

Ms. Mincy would turn away patients if she found discrepancies on the E–FORCSE, and did so, up to 10 to 12 times per month. *Id.* at 646. She would turn them away if she suspected their ID was not legitimate, if they were also filling their prescriptions somewhere else, if it appeared they were doctor shopping, or if there were signs of diversion or abuse. *Id.* at 647. She would also call the patient's doctor and discuss the patient's medical needs and the prescriptions that had been provided to her. *Id.* at 648. She would send patients away if there were discrepancies between the identification provided and the information provided on the prescription. *Id.* at 648. She would also look to see if any of the patients had overdosed, which would help her determine whether to fill a prescription. *Id.* at 841. She would also investigate whether there was any indication that any of the patients were selling their prescribed medications. *Id.* at 841–45.[39] She would then place a sticker on the prescription to signify that she had resolved any potential red flags for the prescription. *Id.* at 648–49, 827–28.

Ms. Mincy was familiar with each of the 10 charged patients in this matter. *Id.* at 649. She has filled prescriptions for controlled substances for each of the 10 subject patients. *Id.* at 830. She would try to resolve red flags for each of the 10 subject patients by using the previously discussed methods, including determining whether any of them were opiate naïve.[*T] *Id.* at 813–14. One way she would do so was by accessing E–FORCSE. *Id.* at 814, 831.[40] Her E–FORCSE number is *[redacted]. *Id.* at 831. She conceded there was no documentary evidence that indicated that any of the subject ten patients started at lower doses of opioids, including oxycodone and hydromorphone, and worked their way up because they become opioid tolerant. *Id.* at 815–16. She had medical release forms for Patient K.Y.D., but not for the other 9 charged patients. *Id.* at 828–29. Ms. Mincy confirmed she had previously reviewed E–FORCSE in relation to the 10 charged patients. *Id.* at 875–79. Ms. Mincy indicated that while the policy at the pharmacy was presently (at the time of the hearing) to run each controlled substance patient through E–FORCSE, it had previously been only to run each Schedule 2 prescription. *Id.* at 880–81.

The pharmacy used the Rx30 computer software to fill prescriptions. *Id.* at 650. This was an internal system the pharmacy used to collect information, such as patient's names, addresses, phone numbers, allergies, and diagnostic codes. *Id.* at 650–51, 687–90; *see, e.g.,* GX 5; RX 18, p. 1; RX 19. It is also used to input information related to the patient's doctor, prescriptions, directions for the prescriptions, and number of days for the supply. Tr. 652. Each prescription was entered into the program one at a time, even if the doctor had put multiple substances on a single prescription form. *Id.* at 652–53. The Rx30 program would flash red with an alert if there was a contra-indication that something in the prescription did not match with the information on file to let Ms. Mincy know that some follow up was necessary. *Id.* at 652–54.

The pharmacy maintained patient record maintenance files through their internal system. *Id.* at 687–90, 706–09, 713–16, 722–31, 733–67; RX 18–37. These records were also used to maintain due diligence on the pharmacy's patients and resolve red flags as they arose. *Id.* at 707–08, 840–41.

Ms. Mincy had been present at Pharmacy 4 Less during inspections by the Florida Department of Health, including on February 28, 2017. *Id.* at 657–58. Ms. Mincy assisted the DOH inspector throughout the state inspections. *Id.* at 659–60. There were no deficiencies found during the February 28, 2017 inspection. *Id.* at 662; RX 15. She was also present during an inspection of the pharmacy on September 5, 2017. Tr. 669, 674. This inspection was done by the Board of Pharmacy. *Id.* at 667, 671–72. Ms. Mincy was given an inspection report at the end of that inspection, although the inspection report appeared to be incomplete. Tr. 675–81; RX 14.

At the end of the DEA inspection, DI1 took ten ''California folder'' files of Schedule 2 prescriptions dated between January 1, 2017, through June 6, 2017. Tr. 799–801. A ''California file'' consists of bundles of prescriptions that the pharmacy keeps for its records. *Id.* at 801. DI1 later requested twenty-four additional ''California files'' from Mr. Sprys. *Id.* at 801–02. The pharmacy kept a receipt that documented originals of the Schedule 2 prescriptions in the pharmacy. Tr. 802–03; RX 12.

Ms. Mincy was present during the inventory taken by DI1 on June 6, 2017. Tr. 835. She signed a DEA closing inventory sheet, confirming that the drug counts were correct. Tr. 835–37; GX 39.[41]

Mr. Robert M. Parrado, BPharm., R.Ph.

Robert Parrado graduated from the University of Florida in 1970 with a B.S. in Pharmacy. Tr. 401. Mr. Parrado has been licensed in Florida as a Pharmacist since 1971. *Id.;* RX 5, at 1. He was formerly licensed as a Consulting Pharmacist by the State of Florida up until 1989, which involved work with institutional facilities. Tr. 401; RX5, at 1. Mr. Parrado has received several awards over the years: The R.Q. Richards Award from the Florida Pharmacy Association for pharmaceutical public relations, and the Generation Rx Award in the field of prescription drug abuse and drug diversion from Cardinal Health. Tr. 402. He is presently President and CEO of Parrado Pharmacy Consultants, Inc., which involves pharmacy consulting with pharmacies, pharmacists, and with government agencies. *Id.* at 402–03; RX 5. Mr. Parrado previously worked for CVS Pharmacy from 2000 to 2009 as a Pharmacist. Tr. 403. For nine months in 2007, Mr. Parrado was a Regional Acquisition Specialist, involved in acquiring independent pharmacies by CVS. *Id.* Prior to working for CVS, Mr. Parrado worked for approximately three years for Eckerd Drugs and Albertson's. *Id.* at 404. Previously, Mr. Parrado worked for St. Joseph's Hospital as an Inpatient Staff Pharmacist, during which time he consulted with physicians on a daily basis. *Id.* Prior to St. Joseph's, Mr. Parrado was the Director of Pharmacy at Centro Hispano Hospital in Tampa. *Id.* at 404–05. Prior to that, for a few months, Mr. Parrado worked as a Pharmacist at SupeRx Drugs. *Id.* at 405.

From 2001 to 2004, Mr. Parrado was a member of the Florida Board of

[39] The Government confronted Ms. Mincy with arrest records of Patient K.Y.D. during its cross-examination. She was surprised to hear that he had been arrested on December 31, 2015, for possession of oxycodone with intent to sell, and later arrested on February 25, 2017, for possession of a Schedule 2 controlled substance. She said he had later been discharged as a patient and that he was unruly. Tr. 845–84; GX 41–43.

[*T] Ms. Mincy, responded ''No'' to the question ''Did you ever fill any prescription the first time for a patient where it was contra-indicated for the amount because a patient might have been opiate naïve?'' Tr. 649–50.

[40] When asked, Ms. Mincy stated that she had not printed out any documents from E–FORCSE that would show she had looked at the 10 charged patients. Tr. 814–15.

[41] While she could not recall signing the inventory sheet, she stated that it was her signature on the document. Tr. 837.

Pharmacy. *Id.* at 406. From 2003 to 2009, he was on the Board's Accreditation Council on Pharmacy Education. *Id.* As such, Mr. Parrado was involved in the accreditation of Florida schools of pharmacy. *Id.* While on the Board, Mr. Parrado was on the Rules Committee. *Id.* at 407. He also served on the Legislative Affairs Committee, which wrote proposed legislation for presentation to the Florida Department of Health, and for consideration by the Florida legislature. *Id.* During 2004, Mr. Parrado was Chairman of the Florida Board of Pharmacy. *Id.* at 408. Since 2001, Mr. Parrado has been a perpetual member of the National Association of Boards of Pharmacy. *Id.* Mr. Parrado was a member of the National ''Rules Committee,'' which developed ''model rules'' for consideration by individual states. *Id.* at 408–09. For 18 months, ending in 2001, Mr. Parrado was President-elect of the Florida Pharmacy Association. *Id.* at 409. Later, Mr. Parrado served as Speaker of the House of Delegates for the Association. *Id.* at 410. Since 2014, Mr. Parrado has been guest lecturer on pharmacy law at the University of South Florida College of Pharmacy. *Id.* As part of a recurring continuing education course, Mr. Parrado taught ''Resolving Red Flags, Allowing Patients to Legally Obtain Their Lawful Medical Prescriptions.'' *Id.* at 411. He has taught this course at universities, to county and state pharmacy associations, and other professional organizations. *Id.* at 411–12. He has presented to various professional organizations a course on ''Identifying Drug Diversion.'' *Id.* at 412. Mr. Parrado has testified as an expert witness previously, including an estimated eight or nine times as an expert called by DEA. *Id.* at 414–16.

Mr. Parrado had last prescribed a controlled substance approximately three or four years prior to the instant hearing when working as a substitute pharmacist at Genoa Healthcare. *Id.* at 418. Regarding his most recent dispensing of opioids on a regular basis, Mr. Parrado estimated it to be 2011. *Id.* at 419. Mr. Parrado was certified as a pharmacy expert. *Id.* at 431.

As relates to opioid naïve patients, Mr. Parrado described various scenarios in which a patient, even one who has been dispensed opioids in the past but who has been deprived of opioids for a month or two, can become dangerously opioid naïve. *Id.* at 433. To ensure a patient prescribed opioids is not opioid naïve, Mr. Parrado described several tools available to the pharmacist. *Id.* at 433–34. The pharmacist should ask a number of questions to alleviate concerns. *Id.* at 434. He can also reference the E–FORCSE database. *Id.*

Mr. Parrado was critical of the limited records Dr. Hamilton reviewed to form his opinion in this case. *Id.* at 434. Mr. Parrado suggested he would have asked the DEA to share more documentation with him than was shared with Dr. Hamilton. *Id.* at 443.

As related to resolving red flags, Mr. Parrado opined that in addition to consulting the E–FORCSE database, a pharmacist may obtain medical records directly from the physician, or access the ''patient record maintenance'' from the Rx30 computer program. *Id.* at 435–36. As to Dr. Hamilton's opinion that the resolution of ''red flags'' had to be documented under Florida law, either on the prescription or somewhere else readily available to the pharmacist, Mr. Parrado disagreed, claiming there was no such requirement under Florida law. *Id.* at 434, 438. Mr. Parrado conceded documenting the resolution of ''red flags'' may represent the ''best practice.'' *U *Id.* at 434. As to the subject documentation, Mr. Parrado observed that most pharmacists do ''document somewhat.'' *Id.* at 435. Most document on the back of the prescription. *Id.* However, if that wasn't possible, Mr. Parrado opined that it was acceptable to ''document'' in a card file system, or in the ''note'' field on your computer system. *Id.* Mr. Parrado also noted he created a computer program, called ''Red Flag Resolver,'' which would preserve such documentation on the computer server. *Id.* Mr. Parrado suggested diagnostic codes could be used on the prescription to demonstrate the medication was justified on the basis of the medical condition. *Id.*

Mr. Parrado explained that to resolve any red flag regarding ''immediate release'' medication, the physician can be consulted. *Id.* at 447–48. Mr. Parrado noted that ''immediate release'' medications are cheaper than the extended release versions, and that the insurance company may not pay for extended release. *Id.* at 448.

Mr. Parrado also disagreed with Dr. Hamilton's estimated price for each pill of oxycodone at .90 cents. *Id.* at 449. Mr. Parrado suggested the price of Schedule 2 controlled substances are often inflated to accommodate the added expenses inherent in dispensing them, such as additionally scrutiny, legwork, record-keeping, and inventories. *Id.* Mr. Parrado conceded that pharmacy pricing was very competitive. *Id.* at 449–50. Mr. Parrado explained that insurance issues can explain why a pharmacy may only accept cash payments *V *[omitted]. *Id.* at 450–51. Mr. Parrado explained that ''cash'' in the pharmacy business may include by credit card or even by check. *Id.* at 460.

The only explanations Mr. Parrado could give for a pharmacy charging different prices for the same medication was a potential higher cost from a different wholesaler, the use of discount coupons, or indigent pricing programs. *Id.* at 451–52.

Regarding inordinate travel to fill a prescription, Mr. Parrado agreed it was a red flag, which needed to be resolved. *Id.* at 453. *[But Mr. Parrado did not go on to opine as to whether or not the red flag was resolved with regard to the patient file for A.R. at issue in this case. *Id.*] As to the 8.5 mg prescription for hydromorphone, Mr. Parrado did not recognize it as requiring any investigation.*W *Id.* at 454. Prescriptions for compounded medications are a normal part of pharmacy work. *Id.* at 453–54; GX 12, p. 17–18.

As to Patient B.F., who was apparently suffering from stage 3 hepatic cancer, Mr. Parrado opined that absent an inconsistent physical presentation by the patient at the pharmacy, the diagnosis itself resolved any ''red flag'' created by the large amount of opioids prescribed. *Id.* at 455–56.

Mr. Parrado disagreed with Dr. Hamilton's concept of the ''minimum standard of care,'' which Dr. Hamilton attributed to both the Florida Administrative Code, specifically ''Florida Regulation 64B,''[42] and guidelines from the National Board of Pharmacy Association. *Id.* at 180, 351–58. Mr. Parrado understood the ''minimum standard of care'' as a violation of a law or rule of the Pharmacy Act, or of the Florida

*U Mr. Parrado testified that there is ''no regulation that says you have to document . . . It may be a best practice to do that. But it [does not] say you have to.'' Tr. 434. When asked by the ALJ whether ''documenting the resolution of this red flag issue might be the best practice,'' Mr. Parrado testified ''It might be, [it is] a good, I do it.'' *Id.* at 436. Later, Mr. Parrado testified that, ''[y]ou have to resolve the flag . . . . Does it say anywhere that you have to document it? No. Should you? Of course. How are you going to remember; how is your partner coming going to know, because there [are] many pharmacists coming in and out of the pharmacy.'' *Id.* at 438.

*V The ALJ further found that the insurance issues can explain why a customer would pay cash. That portion of the finding is neither relevant to the alleged conduct nor did I find support for it in the record. Tr. 450–51.

*W Mr. Parrado did not testify in the positive or the negative regarding the need for an investigation, and he was never asked whether an 8.5 mg prescription for hydromorphone raised a red flag that needed to be resolved. Tr. 454.

[42] *See* West's Florida Administrative Code, Title 64. Department of Health, Subtitle 64b16, Chapter 64B16–27—Pharmacy Practice.

Administrative Code. *Id.* at 456. Mr. Parrado did not recognize any violation of the Florida minimum standard of care by Pharmacy 4 Less in the documents he reviewed and interviewing the two pharmacists involved. *Id.* at 456–58. Mr. Parrado reviewed favorable Florida Department of Health Inspection Reports dated February 28, 2017, September 5, 2017. *Id.* at 475–80, 546; RX 14, 15, 16, 17. One of the documents Mr. Parrado reviewed at Pharmacy 4 Less was their biennial inventory completed April 26, 2017. Tr. 489.

Mr. Parrado disagreed with Dr. Hamilton's opinion that 84 or 112 opioid tablets, *[for 30 mg of oxycodone,] represented ''red flags,'' which needed to be resolved. *Id.* at 461–63. He did not consider these to be inordinate amounts. *Id.* at 463.

Mr. Parrado agreed that the simultaneous prescribing of oxycodone and buprenorphine to Patient A.V. represented a ''red flag'' which needed to be resolved. *Id.* at 463. Mr. Parrado was able to resolve it by reviewing the PRM records. *Id.* at 464. It revealed the pharmacy had contacted the physician, who advised he was attempting to wean the patient off of the oxycodone. *Id.* at 463–65.

In reviewing the PRM for each of the ten subject patients, Mr. Parrado found evidence that Pharmacy 4 Less contacted or attempted to contact the physician in each of ten cases to resolve red flags, and that each ''red flag'' described by Dr. Hamilton was properly resolved. *Id.* at 490–92.

Mr. Parrado found none of the dosage units inordinately high, not even the 8 mg of hydromorphone. *Id.* at 491. He actually deemed 15 to 20 mg of oxycodone a ''very low dose,'' in contrast to Dr. Hamilton's assertion that those doses were relatively high. *Id.* at 510. As to the high prices charged, Mr. Parrado disagreed that the subject prices were suspiciously high. *Id.* at 492–93, 534. Mr. Parrado explained that following the crackdown on ''pill mills'' in Florida, opioids became more difficult for patients to obtain. *Id.* at 457, 539. They may have to travel to multiple pharmacies to even find the medication, so they would be willing to pay higher prices for them. *Id.* at 457, 539.

Mr. Parrado did not address the ''red flag'' described by Dr. Hamilton for the ongoing opioid prescriptions without considering a reduction in dosage, ''individualization.'' [*X] *Id.* at 492.

On cross-examination, Mr. Parrado was confronted with Florida Administrative Code Section 64(B)16–27.800, requiring pharmacies to maintain patient records. *Id.* at 495–96. It specifically requires the pharmacy to ''provide for the immediate retrieval of information necessary for the dispensing pharmacist to identify previously dispensed drugs at the time a new or refill prescription is presented for dispensing,'' *[and requires that a ''reasonable effort is made to obtain, record and maintain . . . pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.'' Tr. 496.]

Mr. Parrado indicated the ''red flag'' identified by Dr. Hamilton regarding whether patients could be opioid naïve had been resolved by the subject pharmacists. *Id.* at 497. Mr. Parrado learned this by interviewing the pharmacists, and being satisfied with the steps they *[told Mr. Parrado that they generally] took, including checking with the PDMP. *Id.* at 496–99.

Mr. Parrado did not observe the ten patients increasing their dosage above the norm. *Id.* at 511. Most appeared to remain at ''maintenance levels.'' *Id.* at 511–12.

As to Patient R.V., who, according to the pharmacy notes, was suffering from a neoplasm, Mr. Parrado was not ''concerned'' by a medical record from the pain doctor, which described her condition as cervicalgia resulting from a ''fender bender.'' *Id.* at 516–22, 549; RX 34, p. 1, RX 35, p. 2.

As to Patient B.F., who Mr. Parrado testified was suffering from liver cancer, however, Mr. Parrado was unable to identify the cancer diagnosis by virtue of the diagnostic codes contained in the records. *Id.* at 514. However, he recalled seeing the cancer diagnosis in a medical note. *Id.* at 513–16.

Regarding RX 22, pp. 2–3; GX 10, Mr. Parrado discovered the pharmacists resolved the red flag by speaking with the subject pharmacists, who advised they confirmed they contacted the physician, who advised he was weaning the patient off of oxycodone with buprenorphine. Tr. 522–25. However, in GX 10, it appears the buprenorphine was prescribed for sciatica pain. *Id.* at 524–25. Mr. Parrado dismissed the medical codes as likely erroneous, choosing to rely on the conversation between the pharmacist and the physician. *Id.* at 525–26. As to the nearly one year period of *[unchanged strength] oxycodone prescriptions from April 12, 2016 to April 10, 2017, in conjunction with the buprenorphine intervention, Mr. Parrado recognized it to be a red flag, which would require the pharmacist to investigate by contacting the physician, pursuant to Fla. Admin. Code § 16–27.810. Tr. 526–27. *[Mr. Parrado did not testify specifically as to whether or not this ''red flag'' was in fact resolved with a call to the physician. Tr. 527.]

As to Patient R.R., who apparently suffered a ''broken back'' and fractured tibia from a car accident, Mr. Parrado was not concerned that the patient was discharged from the hospital on May 2, 2017, yet the final prescription was issued on May 30, 2017. *Id.* at 527–28, 551; RX 32, pp. 1–2. Mr. Parrado did not consider a prescription issued a month after discharge unusual, and assumed the patient had not yet found another doctor. Tr. 528. Mr. Parrado was not concerned by the medical report denying any surgical history for R.R., as it was not contradictory of the above pharmacy notes, explaining a broken tibia does not necessarily require surgery. Tr. 529.

As to Patient A.E., although Mr. Parrado reviewed the relevant medical records, which contained some obvious contradictions, including the patient claiming a pain level of 10 of 10, yet the physical examination by the physician showed no physical restrictions. *Id.* at 532. Mr. Parrado did not appear to have evaluated the substance of the medical records, but only the fact that the pharmacist had obtained the records and verified the patient was being treated for pain.[*Y] Tr. 529–32; RX 18, RX 19, pp. 2, 3.

As to Patient K.E.D., who was reportedly suffering from ''chronic pain'' as the result of a ''severe auto accident,'' yet the medical records deny past hospitalization, Mr. Parrado focused on the key findings of ''chronic pain'' and ''auto accident'' and not on contradictions in the medical records. Tr. 532–33, 552; RX 28, 29, p. 3.

As to Patient A.R., who apparently drove 45.4 miles *[one way] to see his physician and to obtain his medications at Pharmacy 4 Less, Mr. Parrado did not find that distance unusual, citing the difficulty in locating pharmacies which carried opioids. Tr. 539. Mr. Parrado conceded he has testified in other cases that driving 40 miles was a red flag. *Id.* at 541–42. Mr. Parrado distinguished his prior testimony as the distance was also part of a suspicious pattern. *Id.* at 542.

[*X] Though Mr. Parrado did not specifically address this red flag, he did testify generally that assuming there were red flags with every one of the patients, those red flags ''seemed to be'' resolved in every case and that he ''saw documentation where they had written down the resolutions.'' Tr. 492.

[*Y] Mr. Parrado testified, that he was not considering the medical records with specificity for their content, but ''was looking to see that they had gotten something from the doctor to help them resolve [red flags]. . . . [he] considered the fact that they had [the medical record], and that the doctor was treating pain and that they had gotten that.'' Tr. 532.

Mr. Parrado conceded that dual prescriptions for hydromorphone and methadone represented a red flag, but one which could be resolved by contacting the physician. *Id.* at 542–43. As to Patient B.F., Mr. Parrado did not consider multiple different opioid prescriptions concerning, explaining that physicians often try different medications to find an effective treatment. *Id.* at 543–44; RX 24, pp. 2–3. Further, Mr. Parrado did not view the simultaneous prescription of methadone and hydromorphone concerning, as methadone could be used as an extended release reliever, while the hydromorphone was an immediate release. *Id.* at 544. Mr. Parrado conceded he had testified previously that that combination was a red flag, but a resolvable red flag. *Id.*

As to Patient A.V., the prescription bore a code for sciatica. *Id.* at 545. Mr. Parrado [*Z] *[testified that the diagnostic code for sciatica was inherently reliable because it was handwritten as opposed to created by a computer.] *Id.* at 545–46, 551; GX 10, p. 15.

Mr. Parrado testified that ''due diligence files'' in a pharmacy would include all information used by the pharmacists to resolve red flags. Tr. 546.

Mr. Parrado's Sur-Rebuttal Testimony

During the second part of the hearing, the Respondent recalled Mr. Parrado to give sur-rebuttal testimony to the Government's rebuttal case. The Government objected to the testimony by Mr. Parrado and argued that sur-rebuttal testimony was not permitted by the rules. *Id.* at 1027. This Tribunal sustained the government's objection, but permitted the Respondent to continue questioning Mr. Parrado to make his record for the Administrator's consideration should the Administrator find this Tribunal's evidentiary ruling in error. *Id.* at 1028–29.

This Tribunal instructed the parties to brief the issue as to the propriety of sur-rebuttal testimony. In their Posthearing Brief, the Government concedes that there is no express prohibition of sur-rebuttal testimony, however, the regulations provide that unduly repetitious testimony will not be admitted. Govt Posthearing Brief at 46–47; 21 CFR 1316.59(a). The Government argues that the Respondent did not identify what was being proffered and the additional testimony ''was doing nothing more than seeking to bolster [the Respondent's] case.'' Govt Posthearing Brief at 46.

Upon a review of the Government's brief and the transcript of the proceedings, I find that sustaining the Government's objection to sur-rebuttal testimony was ill-advised. Although there is no relevant regulation or rule authorizing sur-rebuttal, neither is there a regulation or rule authorizing rebuttal testimony.[43] However, the Attorney General's Manual on the APA finds in Presentation of Evidence, Section 7 (c) that ''[e]very party shall have the right to present his case or defense by oral or documentary evidence, to submit rebuttal evidence, and to conduct such cross-examination as may be required for a full and true disclosure of the facts.'' Accordingly, this Tribunal recommends that the Administrator find the subject ruling in error and fully consider Mr. Parrado's sur-rebuttal testimony as direct evidence, to the extent it does not exceed the scope of rebuttal evidence.[44]

On sur-rebuttal, in explaining the differences between the Government's and the Respondent's versions of the medical record exhibits, Mr. Parrado affirmed the propriety of updating pharmacy records as relevant information is learned. *Id.* at 1029–30. Mr. Parrado further affirmed the propriety of including Schedules 3–5 prescriptions within the pharmacy records to reflect the totality of the dispensing, and not just the Schedule 2 prescriptions.[*AA] *Id.* at 1033–34.

Mr. Parrado further opined that many of the medical conditions and diagnoses noted in Pharmacy 4 Less files, ''chronic pain, cancer, neoplasms, broken backs'' are conditions which cannot be treated by surgery, but rather by opioid therapy. *Id.* at 1029–31. The dosage and frequency of such opioid therapy is designed to permit the patient to operate at a normal level. *Id.* at 1032. As to Dr. Hamilton's expectation of the tapering down of opioid doses, Mr. Parrado noted tapering in chronic pain patients was often difficult and ineffective. *Id.* at 1036. Finally, Mr. Parrado offered that the Respondent issued a below average number of oxycodone tablets as compared to other Florida pharmacies during the relevant period. *Id.* at 1037–40. Mr. Parrado conceded there were no pharmacy records explaining that the long distances traveled by customers of the Respondent was due to pharmacies going out of business. *Id.* at 1041. Nor did Mr. Parrado observe records in this case suggesting patients could not afford extended release medications. *Id.* at 1041.

The Facts

Stipulations of Fact

The Government and the Respondent, through counsel, have agreed to thirteen stipulations, which I recommend be accepted as fact in these proceedings:

1. Pharmacy 4 Less, LLC, is registered with the DEA to handle controlled substances under Schedules II to V under DEA COR No. FP5459082. Its registered address is: 805 Douglas Avenue, Suite 159, Altamonte Springs, Florida 32714.

2. Pharmacy 4 Less's COR was issued on February 2, 2018.

3. Richard Sprys, R.Ph., C.Ph., is the owner and manager of Pharmacy 4 Less.

4. Amy Mincy, R.Ph., is a pharmacist at Pharmacy 4 Less.

5. On June 6, 2017, DEA conducted an audit of Pharmacy 4 Less.

6. Proposed Government's Exhibit 2 is a true and correct copy of the June 22, 2017 Administrative Subpoena served upon Pharmacy 4 Less.

7. Pharmacy 4 Less completed its compliance with the administrative subpoena on July 11, 2017.

8. DEA served Pharmacy 4 Less with an Order to Show Cause on July 5, 2018.

9. Pharmacy 4 Less submitted a Corrective Action Plan to John J. Martin, Assistant Administrator for the Diversion Control Division of DEA, on July 31, 2018.

10. Pharmacy 4 Less submitted a Request for Hearing to the Office of the Administrative Law Judges at DEA Headquarters on August 1, 2018.

11. On August 8, 2018, Mr. Martin denied Respondent's request to discontinue or defer administrative proceedings.

12. Ms. Amy Mincy signed the DEA Form 82, Notice of Inspection of Controlled Premises on behalf of Pharmacy 4 Less during the June 6, 2017 on-site inspection. Tr. 38.

13. RX 19, 21, 23, 25, 27, 29, 31, 33, 35, 37 were supplied to the DEA in response to the July 9, 2018 administrative subpoena. Tr. 812–13.

[*Z] The ALJ found that Mr. Parrado was not concerned by the sciatica code, as errors happen. I understand, and have edited this finding accordingly, Mr. Parrado's testimony to be that here the sciatica code was inherently reliable because it was handwritten rather than generated by a computer error, which he previously testified occurs frequently. Tr. 545.

[43] The Agency has permitted and considered surrebuttal evidence in the past. *Flavio D. Gentile,* M.D.; 55 FR 3113 (1990).

[44] Sur-rebuttal evidence is permitted to confront the opposing party's rebuttal evidence.

[*AA] Mr. Parrado testified that when considering the ''total profile'' of all prescriptions for these patients, ''the patients were getting all their medications there . . . . [that is] what you want. . . . You [do not] want him just buying controls from you because now you [do not] know what else is going on with that patient. . . . It essentially resolved that red flag'' meaning the person is not ''just trying to obtain narcotics from [the pharmacy].'' Tr. 1033–34.

Findings of Fact

The factual findings below are based on a preponderance of the evidence, including the detailed, credible, and competent testimony of the aforementioned witnesses, the exhibits entered into evidence, and the record before me.

1. The Respondent currently holds active COR FP5459082. ALJ Ex. 1.

2. DI1 conducted an on-site inspection of Pharmacy 4 Less on June 6, 2017. Tr. 37.

3. Pharmacy 4 Less was randomly picked for regulatory inspection by the DEA. Tr. 37.

4. Ms. Amy Mincy signed the Notice of Inspection presented to her by DI1. Tr. 38–39; GX 30.

5. Ms. Mincy could not locate an initial inventory, and Mr. Richard Sprys confirmed via speakerphone with DI1 that Pharmacy 4 Less did not have an initial inventory. Tr. 39–40.

6. Ms. Mincy provided DI1 with a purported biennial inventory, but, *[according to DI1,] it did not indicate whether it had been completed either at the opening or closing of business. Tr. 41–42; GX 37.

7. When asked about the pharmacy's CSOS system, Ms. Mincy demonstrated to DI1 how the pharmacy ordered controlled substances on the system. Tr. 43–45.

8. DI1 contacted Mr. Chris Jewell, one of the personnel in charge of the CSOS system at DEA Headquarters. Mr. Jewell ran a report which stated that Ms. Mincy received her own CSOS credentials in July 2018. Tr. 47–49; GX 29.

9. DI1 conducted an audit of Pharmacy 4 Less's records and inventories. Tr. 53–93, 919–26; GX 4, 31, 32. DI1 selected a starting date of January 1, 2017, due to discrepancies in the biennial inventory, the lack of an initial inventory, and Pharmacy 4 Less maintained handwritten Schedule 2 controlled substance logs. Tr. 56, 61.

10. DI1 and other personnel returned to Pharmacy 4 Less on June 21, 2017. Both Ms. Mincy and Mr. Sprys were present. Tr. 88–89.

11. DI1 asked Ms. Mincy and Mr. Sprys how they determined whether prescriptions were for a legitimate medical purpose. Both pharmacists responded they would check E–FORCSE and that they would verify prescriptions by contacting the patients' doctors. The DIs were provided with a red folder that contained screenshots from the pharmacy's computer system, Rx30. Tr. 89–92. The red folder contained screenshots from the Rx30 program. *Id.* at 96. The red folder also contained the pharmacists' notes on patients, referred to as ''due diligence files.'' *Id.* at 97.

12. On June 22, 2017, an administrative subpoena was issued to Pharmacy 4 Less, requesting hard copy prescriptions for all Schedules 2–5 controlled substance prescriptions from October 2015 through June 22, 2017, all controlled substance prescription data from Rx30, and all due diligence patient files. *Id.* at 93–94; GX 2. Pharmacy 4 Less complied by delivering a gray tote container that contained ''California'' folders filled with Schedule 2 hard copy prescriptions, a thumb drive containing all Rx30 data, and the red folder seen during the June 21 on-site inspection. *Id.* at 96. The Schedules 3–5 prescriptions were delivered to the DIs by Pharmacy 4 Less at an unidentified later date. *Id.* at 97.

Treatment of Patient A.E.

13. Pharmacy 4 Less dispensed hydromorphone 8 mg to Patient A.E. on 21 occasions between November 19, 2015, and June 1, 2017. GX 6.

14. On November 19, 2015, Pharmacy 4 Less dispensed Patient A.E. 84 tablets of hydromorphone 8 mg without determining whether Patient A.E. was opioid naïve. Tr. 183–86; GX 28, p. 6; GX 37, p. 11.

15. Between November 19, 2015, and June 1, 2017, Pharmacy 4 Less, on 21 separate occasions, dispensed hydromorphone 8 mg tablets to Patient A.E. at a price of approximately $5.95 per tablet, even though other retail pharmacies were selling hydromorphone 8 mg at approximately $1.50 per tablet. Tr. 195–99; 200–03; GX 28, pp. 6–7.

16. Between December 17, 2015, and June 1, 2017, Pharmacy 4 Less, on 20 separate occasions, dispensed hydromorphone to Patient A.E. without determining why hydromorphone was being prescribed on a long-term basis without the presence of a long-acting pain medication. Tr. 192–95; 200–03; GX 28, p. 6.

Treatment of Patient A.R.

17. Pharmacy 4 Less dispensed oxycodone 15 mg to Patient A.R. on 17 occasions between March 17, 2016, and June 7, 2017; GX 8.

18. On March 17, 2016, Pharmacy 4 Less dispensed Patient A.R. 112 tablets of oxycodone 15 mg without determining whether Patient A.R. was opioid naïve. Tr. 205–07; GX 28, p. 12.

19. Between March 17, 2016, and June 7, 2017, Pharmacy 4 Less, on 17 separate occasions, dispensed oxycodone 15 mg tablets to Patient A.R. at a price of approximately $2.23 to $2.50 per tablet, even though other retail pharmacies were selling oxycodone 15 mg at approximately $0.90 per tablet at the time. Tr. 205–07, 212–14; GX 28, pp. 12–13.

20. Between May 11, 2016, and June 7, 2017, Pharmacy 4 Less, on 15 separate occasions, dispensed oxycodone 15 mg to Patient A.R. without determining why oxycodone was being prescribed on a long-term basis without the presence of a long-acting pain medication. Tr. 212–14, GX 28 p. 12.

21. Between March 17, 2016, and June 7, 2017, Pharmacy 4 Less, on 17 separate occasions, dispensed oxycodone 15 mg tablets to Patient A.R., even though Pharmacy 4 Less's records do not show that Pharmacy 4 Less ever addressed why Patient A.R. traveled southwest approximately 37 miles from his house in Daytona Beach, Florida to his doctor's office in Sanford, Florida; traveled approximately 15 miles further southwest to buy his controlled substances from Pharmacy 4 Less, and then returned approximately 45 miles northeast to his home in Daytona Beach, Florida. Tr. 207–14, 334–35, GX 28, p. 13.

Treatment of Patient A.V.

22. Pharmacy 4 Less dispensed buprenorphine and/or oxycodone to Patient A.V. on 14 occasions between April 12, 2016, and April 10, 2017. GX 10.

23. On March 17, 2016, Pharmacy 4 Less dispensed Patient A.V. 112 tablets of oxycodone 20 mg without determining whether Patient A.V. was opioid naïve. Tr. at 262, 267–68; GX 28, p. 8.

24. Between April 12, 2016, and February 13, 2017, on 8 separate occasions, Pharmacy 4 Less filled prescriptions for Patient A.V. for 112 tablets of oxycodone 20 mg, an opioid, within nine days of filling a prescription for 29–60 tablets of buprenorphine 8 mg, a controlled substance used to treat opioid addiction. Seven of the eight fills took place on the same day. Tr. at 261–76; GX 28, p. 8.

25. Between April 21, 2016, and April 10, 2017, Pharmacy 4 Less, on 12 separate occasions, dispensed oxycodone 20 mg tablets to Patient A.V. at a price of approximately $2.59 per tablet, even though other retail pharmacies were selling oxycodone 20 mg at approximately $1.25 per tablet at the time. Tr. at 262–76; GX 28, pp. 8–9.

26. Between July 5, 2016, and April 10, 2017, Pharmacy 4 Less, on 10 separate occasions, dispensed oxycodone to Patient A.V. without determining why oxycodone was being

prescribed on a long-term basis without the presence of a long-acting pain medication. Tr. at 268–76; GX 28, p. 8.

Treatment of Patient B.F.

27. Pharmacy 4 Less dispensed hydromorphone to Patient B.F. on 17 occasions between October 27, 2015, and May 15, 2017. GX 12.

28. On October 27, 2015, Pharmacy 4 Less dispensed Patient B.F. 64 tablets of hydromorphone 8 mg without determining whether Patient B.F. was opioid naïve. Tr. at 217–18; GX 28, p. 10; GX 38, p. 5.

29. Between November 24, 2015, and May 15, 2017, Pharmacy 4 Less, on 16 separate occasions, dispensed hydromorphone 8 mg tablets to Patient B.F. at a price of approximately $5.70 to $5.83 per tablet, even though other retail pharmacies were selling hydromorphone 8 mg at approximately $1.50 per tablet at the time. Tr. at 218–22; GX 28, p. 11.

30. Between December 30, 2015, and May 15, 2017, Pharmacy 4 Less, on 15 separate occasions, dispensed hydromorphone to Patient B.F. without determining why hydromorphone was being prescribed on a long-term basis without the presence of a long-acting pain medication. Tr. 219–22; GX 28, p. 10.

Treatment of Patient B.N.

31. Pharmacy 4 Less dispensed either hydromorphone or oxycodone to Patient B.N. on 19 occasions between January 22, 2016, and June 2, 2017. GX 14.

32. On January 22, 2016, Pharmacy 4 Less dispensed to Patient B.N. 90 tablets of hydromorphone 8 mg without determining whether Patient B.F. was opioid naïve. Tr. 222–27; GX 28, p. 14.

33. Between January 22, 2016, and August 15, 2016, Pharmacy 4 Less, on nine separate occasions, dispensed hydromorphone 8 mg tablets to Patient B.N. at a price of approximately $5.95 to $6.45 per tablet, even though other retail pharmacies were selling hydromorphone 8 mg at approximately $1.50 per tablet at the time. Tr. 222–35; GX 28, p. 15.

34. Between September 9, 2016, and June 2, 2017, Pharmacy 4 Less, on ten separate occasions, dispensed oxycodone 30 mg tablets to Patient B.N. at a price of approximately $5.00 per tablet, even though other retail pharmacies were selling oxycodone 30 mg tablets at approximately $0.90 per tablet at the time; Tr. 232–35; GX 28, p. 15.

35. Between March 15, 2016, and June 2, 2017, Pharmacy 4 Less, on 17 separate occasions, dispensed hydromorphone and oxycodone to Patient B.N. without determining why hydromorphone and oxycodone were being prescribed on a long-term basis without the presence of a long-acting pain medication. Tr. 222–35; GX 28, pp. 14–15.

Treatment of Patient K.E.D.

36. Pharmacy 4 Less dispensed oxycodone to Patient K.E.D. on 21 occasions between October 26, 2015, and June 7, 2017. GX 18.

37. On October 26, 2015, Pharmacy 4 Less dispensed to Patient K.E.D. 112 tablets of oxycodone 20.5 mg without determining whether Patient K.E.D. was opioid naïve. Tr. 241–44; GX 28, p. 16; GX 38, p. 7.

38. Between October 26, 2015, and June 7, 2017, Pharmacy 4 Less, on 21 separate occasions, dispensed oxycodone 20 mg tablets to Patient K.E.D. at a price of approximately $3.57 to $3.84 per tablet, even though other retail pharmacies were selling oxycodone 20 mg at approximately $0.90 per tablet at the time. Tr. 241–47; GX 28, p. 17.

39. Between December 21, 2015, and June 7, 2017, Pharmacy 4 Less, on 19 separate occasions, dispensed oxycodone to Patient K.E.D. without determining why oxycodone was being prescribed on a long-term basis without the presence of a long-acting pain medication. Tr. 244–47; GX 28, pp. 16–17.

Treatment of Patient K.Y.D.

40. Pharmacy 4 Less dispensed oxycodone to Patient K.Y.D. on 17 occasions between February 4, 2016, and June 12, 2017. GX 16.

41. On February 4, 2016, Pharmacy 4 Less dispensed to Patient K.Y.D. 84 tablets of oxycodone 30 mg without determining whether Patient K.Y.D. was opioid naïve. Tr. 237–38; GX 28, p. 20.

42. Between February 4, 2016, and June 12, 2017, Pharmacy 4 Less, on 17 separate occasions, dispensed oxycodone 30 mg tablets to Patient K.Y.D. at a price of approximately $3.45 per tablet, even though other retail pharmacies were selling oxycodone 30 mg at approximately $0.90 per tablet at the time. Tr. 237–41; GX 28, pp. 20–21.

43. Between March 31, 2016, and June 12, 2017, Pharmacy 4 Less, on 15 separate occasions, dispensed oxycodone to Patient K.Y.D. without determining why oxycodone was being prescribed on a long-term basis without the presence of a long-acting pain medication. Tr. 237–41; GX, p. 20.

Treatment of Patient R.R.

44. Pharmacy 4 Less dispensed oxycodone to Patient R.R. on 21 occasions between October 28, 2015, and May 30, 2017. GX 20.

45. On October 28, 2015, Pharmacy 4 Less dispensed to Patient R.R. 112 tablets of oxycodone 18 mg without determining whether Patient R.R. was opioid naïve. Tr. 247–50; GX 28, p. 18; GX 38, p. 8.

46. Between November 23, 2015, and May 30, 2017, Pharmacy 4 Less, on 20 separate occasions, dispensed oxycodone 15 mg tablets [*BB] to Patient R.R. at a price of approximately $2.28 to $2.41 per tablet, even though other retail pharmacies were selling oxycodone 15 mg at approximately $0.90 per tablet at the time. Tr. 247–50; GX 28, p. 19.

47. Between December 21, 2015, and May 30, 2017, Pharmacy 4 Less, on 19 separate occasions, dispensed oxycodone to Patient R.R. without determining why oxycodone was being prescribed on a long-term basis without the presence of a long-acting pain medication. Tr. 248–50; GX 28, pp. 18–19.

Treatment of Patient R.V.

48. Pharmacy 4 Less dispensed oxycodone to Patient R.V. on 22 occasions between November 17, 2015, and June 19, 2017. GX 22.

49. On November 17, 2015, Pharmacy 4 Less dispensed to Patient R.V. 112 tablets of oxycodone 20 mg without determining whether Patient R.V. was opioid naïve. Tr. 251–53; GX 28, p. 22; GX 38, p. 7.

50. Between November 17, 2015, and June 19, 2017, Pharmacy 4 Less, on 21 separate occasions,[45] dispensed oxycodone 20 mg tablets [*CC] to Patient R.V. at a price of approximately $2.23 to $3.04 per tablet, even though other retail pharmacies were selling oxycodone 20 mg at approximately $0.90 per tablet at the time. Tr. 251–55; GX 28, pp. 22–23.

51. Between January 11, 2016, and June 19, 2017, Pharmacy 4 Less, on 20 separate occasions, dispensed oxycodone to Patient R.V. without determining why oxycodone was being prescribed on a long-term basis without the presence of a long-acting pain medication. Tr. 252–55; GX 28, p. 22.

Treatment of Patient V.W.

52. Pharmacy 4 Less dispensed oxycodone to Patient V.W. on 21 occasions between November 30, 2015, and May 31, 2017. GX 24.

[*BB] Additionally, on October 28, 2015, Pharmacy 4 Less, dispensed oxycodone 18 mg tablets to Patient R.R. at a price of approximately $2.23.

[45] The Government is not alleging that the price charged on March 27, 2017 was unreasonable.

[*CC] Except for on April 22, 2017, when Oxycodone 15 mg was dispensed at a price of $2.23 per tablet. GX 22, p. 71.

53. On November 30, 2015, Pharmacy 4 Less dispensed to Patient V.W. 84 tablets of oxycodone 15 mg without determining whether Patient V.W. was opioid naïve. Tr. 256–57; GX 28, p. 24; GX 38, p. 9.

54. Between November 30, 2015, and May 31, 2017, Pharmacy 4 Less, on 21 separate occasions, dispensed oxycodone 15 mg tablets to Patient V.W. at a price of approximately $2.54 to $3.57 per tablet, even though other retail pharmacies were selling oxycodone 15 mg at approximately $0.90 per tablet at the time. Tr. 256–60; GX 28, pp. 24–25.

55. Between January 25, 2016, and May 31, 2017, Pharmacy 4 Less, on 19 separate occasions, dispensed oxycodone to Patient V.W. without determining why oxycodone was being prescribed on a long-term basis without the presence of a long-acting pain medication. Tr. 258–60; GX 28, pp. 24.

Recordkeeping

56. Pharmacy 4 Less did not have an initial inventory readily available during DI1's on-site inspection. Tr. 39–40.

57. [According to DI1, the copy of Pharmacy 4 Less's biennial inventory that he viewed in-person during the inspection on June 6, 2017, did not notate whether the inventory was completed at the opening or closing of business. Tr. 41–42.] *DD

58. Pharmacy 4 Less's biennial inventory (apparently revised sometime after June 6, 2017) did not indicate whether it was conducted at the ''close'' or ''opening of business,'' instead listing the time that it was completed. *Compare* GX 37, p. 2 *with* RX 38, p. 1. *[Specifically, the content appeared on a blank document that Ms. Mincy described as a cover page with handwriting stating ''Biennial Inventory; Completed April 26, 2017; 8AM'' and with signatures by both pharmacists. *Id.* The cover page was included in a fax to DI1 from Respondent pharmacy on June 7, 2017.] *EE

59. Pharmacy 4 Less's records were inaccurate, and included shortages and overages. GX 4. Specifically, the shortages and overages are as follows

a. Oxycodone 15 mg: Shortage of 73 tablets
b. Oxycodone 20 mg: Shortage of 212 tablets
c. Oxycodone 30 mg: Shortage of 731 tablets
d. Hydromorphone 8 mg: Shortage of 149 tablets
e. Methadone 10 mg: Overage of 1,488 tablets
f. Suboxone 8 mg/2 mg: Overage of 224 tablets
g. Carisoprodol 350 mg: Shortage of 526 tablets

60. Pharmacy 4 Less's [invoices] *FF did not include the date the order was received for 84 invoices. Tr. 137–38; GX 26.

Analysis

Credibility Analysis of Fact Witnesses

Ability To Recall Events

DI1

Generally speaking, individuals experiencing an event out of the ordinary, such as an on-site inspection as occurred here, are likely to have a better memory of those events than the Government Diversion Investigator, who performs similar inspections on any number of clinics. It seems to me, all other factors being equal, it would be easier for a DI to forget or confuse events than the person inspected. However, in this matter, DI1 presented an overall clear description of events surrounding the June 6, 2017, and June 21, 2017 on-site inspections of Pharmacy 4 Less.

DI1 occasionally had difficulty recalling the specific individual who responded to his questions. *See, e.g.,* Tr. 90–91. This cuts slightly against his reliability. However, he was generally able to recall the key events as to what had occurred during the on-site inspections and the substance of the relevant conversations. His testimony is also generally corroborated by the documentary evidence.

Further, DI1 demonstrated a basic understanding of the relevant DEA regulations as provided in the Code of Federal Regulations in order to properly perform his duties.[46] He had some difficulty citing specific relevant provisions of the CFR when asked, which is quite understandable. However, part of DI1's testimony involved an issue contested by the Respondent regarding the necessity of the date of receipt on invoices maintained by the pharmacy, which this Tribunal finds necessary to separately analyze and discuss.[47] Tr. 136–39.

Based on a complete review of DI1's presentation of testimony, ability to recall events, and comparison with the other evidence, I find his testimony to be credible and should be afforded considerable weight.

Ms. Amy Mincy

Ms. Amy Mincy's credibility presents more of a challenge for this Tribunal to address. During the first portion of the hearing in Orlando, Florida, Ms. Mincy appeared on the stand for the entire duration of the third day of testimony. At the beginning of her testimony, Respondent's counsel attempted to cover Ms. Mincy's professional background and C.V. Ms. Mincy struggled greatly remembering details about pharmacies where she had previously worked, and other details about her own professional background. While the transcript does not fully capture Ms. Mincy's difficulties in discussing her background, there are indications within the transcript that demonstrate these issues.[48]

*DD Finding of fact modified for clarity.

*EE There is insufficient information in the record for me to conclusively determine whether or not the cover page was attached to the biennial inventory at the time of DEA's inspection. On the one hand, I fully credit DI1's testimony that the biennial inventory did not notate whether the inventory was ''completed at either the opening or closing of business.'' Tr. 41–42. However, I cannot tell whether DI was testifying that the specific words ''opening or closing of business'' did not appear on the biennial inventory (which I agree is true) or if he was testifying that the cover page at GX 37, p. 2 was not included on the biennial inventory that DI1 was handed on the date of the inspection. If DI1's testimony meant the latter, it was unclear, and unfortunately, the biennial inventory was not seized during the inspection. Instead, the biennial inventory was faxed to DI1 the following day and the cover page was included. Notably, Mr. Sprys was out of the country at the time of the inspection and subsequent fax. As Mr. Spry's signature appears on the biennial inventory cover page that was faxed, it does not seem implausible to conclude that the cover page existed prior to Mr. Sprys leaving the country and prior to the inspection. Therefore, I cannot find substantial evidence to support the Government's allegation that the biennial inventory lacked the notation regarding whether it was conducted at the opening or closing of business.

*FF Modified because he ALJ referred to these documents as ''222 Forms,'' but I find that they are more accurately described as ''invoices.''

[46] While this Tribunal heard testimony from DI1 about the regulations, it does not rely on DI1's understanding of the regulations in this Recommended Decision.

[47] *See infra* at section ''Date of Receipt on Invoices.''

[48] ''MR. INDEST: And since she's having a little bit of difficulty remembering some of these, I'd like the clerk to give her the hearing book and let her, if she needs to refer to the CV.

THE WITNESS: I'm good.

MR. INDEST: No, let's have it in front of you so we've got the dates right and everything, okay?'' Tr. 571.

''Q Okay, but where did you work next after that? Where did you work next? If you're having trouble remembering, if you need to refresh your recollection, please look at the CV because you're taking a long, long pause before you answer my questions. This might help speed things up.'' Tr. 572–73.

''Q Okay, and did you work as a pharmacy consultant after that?

A For some places, yes.

Q According to your CV, Ms. Mincy, listen, these are simple straightforward questions, and if you can't remember the answers.'' Tr. 573.

''MR. INDEST: Your Honor, I'd like the record to reflect I'm asking the questions and she's taking a long, long pause.'' Tr. 574.

Following the testimony of Ms. Mincy's background, Respondent's counsel moved on to the facts of this matter. Throughout her testimony, Ms. Mincy appeared to encounter great difficulty in remembering details of the June 6, 2017 on-site inspection. While Ms. Mincy appeared to remember some details, her presentation and delivery of those details appeared sometimes confused and disoriented. Throughout the direct examination, I noticed that Respondent's counsel had trouble eliciting answers from Ms. Mincy about the June 6, 2017 on-site inspection.[49] Further, Respondent's counsel made a number of statements on the record that demonstrated his difficulty in eliciting testimony from Ms. Mincy, leading to a number of objections by Government counsel for leading the witness.[50] While understandable that a lay witness may have some difficulties due to being nervous or anxious about her time on the witness stand, Ms. Mincy's inability to answer questions posed by her own attorney suggest issues with Ms. Mincy's ability to reliably recall events one would expect to be otherwise fairly memorable. Her presentation in Orlando clearly diminishes her reliability as a witness, especially as relates to her Orlando testimony.

During the second portion of the hearing in Arlington, Virginia, Ms. Mincy appeared to be more relaxed on the stand, which appeared to increase her ability to recall and to reliably convey her perception of the relevant events.

Overall, I find that the reliability of her testimony was significantly diminished by her inability to recall details about both her own personal history and those surrounding the events of the on-site inspections at Pharmacy 4 Less.[51]

The parties only presented one fact witness each as to the events surrounding the on-site inspections at Pharmacy 4 Less. It will therefore be necessary for me to compare and weigh the testimony of DI1 and Ms. Mincy regarding the factual circumstances surrounding the on-site inspections of Pharmacy 4 Less and the subsequent investigation.[52] Physical evidence is more corroborative of DI1's testimony than that of Ms. Mincy's. When their testimony is in conflict, I find that it is proper to give greater weight to the testimony of DI1 over that of Ms. Mincy.

Motivation to Color Testimony

DI1, as a public servant, typically has no personal stake in the outcome of the instant inspection or in the revocation of the Respondent's Registration. The instant investigation was initiated at random. I noted no animus on his part as to the Respondent, its owner, or employees. Although he may be viewed as being part of the prosecution team, I saw no indication from his testimony that any partiality interfered with his reliable testimony.

On the other hand, Ms. Mincy appeared to be very defensive of Pharmacy 4 Less and the pharmacy's practices. As one of the two pharmacists on staff at the pharmacy, the investigation directly implicates her practices and her employment at the pharmacy. I suspect that she would be more likely to color her testimony than would DI1.

Ms. Mincy made statements during her testimony that make her motivation to color her testimony more likely. When confronted about the testimony of DI1, recalling statements made by Ms. Mincy during the June 6, 2017 on-site inspection, Ms. Mincy seemed to personalize the conflict. Ms. Mincy claimed that DI1 would have been ''lying,'' or that ''he was confused.'' Tr. 823–25. Ms. Mincy said that DI1 ''was like a kid in a candy store.'' *Id.* at 824–25. She said that ''the longer he was there and the more he got access to, the wilder and crazier he got.'' *Id.* at 825. Ms. Mincy described her interactions with DI1 as ''tormenting'' and ''almost, like, harassment'' of the Respondent. *Id.* at 825–26. While Ms. Mincy may have been testifying as to how she felt during the surprise on-site inspection with DI1, this colorful language, along with her description and characterization of the inspection, makes her testimony suspect as a possible attempt to improperly discredit DI1's testimony and his characterization of the on-site inspection.[53] In combination with the previous discussion of Ms. Mincy's ability to recall events, I find that Ms. Mincy has more motivation to color her testimony than DI1.

Credibility Analysis of Expert Witnesses and Opinions

The relevant standard of care may be established by an expert witness through his experience in the field, and through his reliance upon and application of state and federal professional standards. *[Omitted for brevity.]

Dr. Thomas Hamilton, Pharm.D.

Dr. Hamilton testified as the Government's expert witness in this matter. Dr. Hamilton was offered and was qualified as an expert in the practice of pharmacy in Florida. Tr. 174. Dr. Hamilton has worked as a pharmacist for 18 years. *Id.* at 167–69. His experience includes time at a small pharmacy before moving to work full-time as a pharmacist for Publix, where he has served in a variety of roles, including as a Pharmacist, the Assistant Manager of the Pharmacy, and as the Pharmacy Supervisor. He has served as a ''fixer'' or temporary Pharmacy Manager in order to ''clean up'' pharmacies. *Id.* at 169. In his role as Pharmacy Supervisor, he was in charge of overseeing up to 60 pharmacies, and his duties included the hiring and firing of employees, and overseeing daily operations. *Id.* at 170. Additionally, Dr. Hamilton evaluated stand-alone, independent pharmacies for purchase

[49] ''ADMIN. LAW JUDGE DOWD: And I know you're having some difficulty with Ms. Mincy, but try not to lead, Mr. Indest.'' Tr. 588.

[50] ''MR. MANN: She needs to answer his questions and not listen to him repeat the answers to her.

MR. INDEST: Your Honor, she's having a very difficult time answering these questions.

ADMIN. LAW JUDGE DOWD: It is what it is. But I'm going to sustain the objection as to leading.

MR. INDEST: And, Your Honor, with that understanding, a witness that is hard to answer the questions should be given some, the counsel should be given some leeway to at least get the basic information.

ADMIN. LAW JUDGE DOWD: I think I've given you leeway, Mr. Indest.

MR. INDEST: Okay, thank you.

ADMIN. LAW JUDGE DOWD: We have to have the testimony come from the witness.

MR. INDEST: Okay, we'll try.'' Tr. 595–96.

[51] In its Posthearing Brief, the Government argues that Ms. Mincy's false testimony should not be credited. Govt Posthearing Brief at 33–36. The Government argues that she ''lied'' about checking E–FORCSE every time before she filled a prescription. I will not go to the extreme the Government suggests, especially in light of Ms. Mincy's demonstrated memory deficits. *[However, I do find that when comparing the testimony to GX 38, Ms. Mincy overstated her use of E–FORCSE and that her credibility on the subject is diminished. Remainder of footnote omitted for brevity.]

[52] As to the lack of corroboration of portions of Ms. Mincy's testimony, the owner of Pharmacy 4 Less and the only other pharmacist at the pharmacy, Mr. Richard Sprys, had the ability to corroborate crucial details about the pharmacy Ms. Mincy's testimony about the pharmacy's operations, details regarding the June 6, 2017 phone call, and the June 21, 2017 on-site inspection. However, neither the Government nor the Respondent decided to call Mr. Sprys as a witness during the hearing. This Tribunal will not question either parties' trial strategy or determination of which witnesses to call, and notes that neither party has suggested any inference should be drawn regarding the failure to present evidence through Mr. Sprys. As such, we are without the benefit of Mr. Sprys testimony and are left only with the testimony evidence of DI1 and Ms. Mincy.

[53] In its Posthearing Brief, the Government asserts that Ms. Mincy's testimony should be discredited when it is contradicted by DI1. Govt Posthearing Brief at 37. While I cannot reach the Government's assertion that Ms. Mincy is ''lying,'' I have already found that greater weight will be given to DI1's testimony whenever there is conflict between DI1 and Ms. Mincy's testimony.

by Publix. This evaluation included review of the drug invoices, filled prescriptions and the nature of each pharmacy's overall business. *Id.* at 170–71. In order to spend more time with his young family, Dr. Hamilton decreased his responsibilities with the company, gave up his supervisory role, and now serves as a Pharmacy Manager of a single pharmacy. *Id.* at 286–87.

During the hearing in this matter, Dr. Hamilton reviewed a number of materials provided to him by the DEA, including prescriptions (front and back), related patient medical notes, and patient addresses. *Id.* at 177, 380–81. Additionally, Dr. Hamilton reviewed prescription pricing via GoodRX. *Id.* at 177–78. Dr. Hamilton also prepared an expert report in this matter based on the information and materials provided to him. GX 28.

In general, Dr. Hamilton provided detailed assessments of each of the 10 charged patients in this matter. He detailed his review of the prescriptions provided for each of the 10 charged patients and any ''red flags'' that he noticed through his review. His explanation that ''red flags'' can be resolved through a review of the prescription and some investigation, including speaking with the patient, reviewing medical history, or speaking with the prescriber, were all consistent with his ultimate opinions in this matter. His opinions in this matter were bolstered by his knowledge and experience in this field, as well as his knowledge of ''Florida regulation 64B'' and guidance provided by the National Board of Pharmacy Association, which provide the source of pharmacy standards of care in Florida. *Id.* at 180, 351–58.

On cross-examination, Dr. Hamilton's credibility was bolstered by his willingness to provide straightforward answers that were consistent with those opinions he had provided on direct examination. Dr. Hamilton conceded that he only reviewed the documents provided to him by the Government, but he was present throughout the hearing and was present to observe the testimony from the Respondent's witnesses. He indicated, when recalled during the Government's rebuttal case, that even after hearing the testimony and opinions from the Respondent's witnesses, his opinions in this matter had not changed. Tr. 1005. Further, Dr. Hamilton demonstrated objectivity. While Dr. Hamilton had differing opinions from Mr. Parrado in a variety of subjects, he was willing to concede areas in which he agreed with Mr. Parrado and did not appear to form opinions solely to favor the Government.

Overall, I find Dr. Hamilton's testimony and opinions in this matter to be credible and reliable.

Mr. Robert Parrado, BPharm., R.Ph.

Mr. Parrado testified as the Respondent's expert witness in this matter. Mr. Parrado was offered and qualified as a pharmacy expert. *Id.* at 431. Mr. Parrado has an extensive history in the pharmacy field. He appears to be approaching legend status in the field in Florida. He has been a licensed pharmacist in Florida since 1971. He was formerly licensed as a Consulting Pharmacist by the State of Florida until 1989. He has received numerous awards during his career. He is currently President and CEO of Parrado Pharmacy Consultants, Inc., which involves consulting with pharmacies, pharmacists, and with government agencies. *Id.* at 399–402; RX 5. He has previously worked at several pharmacies.

From 2001 to 2004, Mr. Parrado was a member of the Florida Board of Pharmacy. From 2003 to 2009, he was on the Board's Accreditation Council in Pharmacy Education. While on the Board, Mr. Parrado also served on the Rules Committee and the Legislative Affairs Committee. During 2004, Mr. Parrado was Chairman of the Florida Board of Pharmacy. Since 2001, Mr. Parrado has been a perpetual member of the National Association of Boards of Pharmacy. Mr. Parrado was a member of the National ''Rules Committee'' which developed ''model rules'' for consideration by individual states. *Id.* at 409. For 18 months, ending in 2001, Mr. Parrado was President-elect of the Florida Pharmacy Association. Later, Mr. Parrado served as Speaker of the House of Delegates for the Association.

Since 2014, Mr. Parrado has been guest lecturer on pharmacy law at the University of Florida College of Pharmacy. *Id.* at 410. As part of a recurring continuing education course, Mr. Parrado taught ''Resolving Red Flags, Allowing Patients to Legally Obtain Their Lawful Medical Prescriptions.'' *Id.* at 411. He has also presented to various professional organizations a course on ''Identifying Drug Diversion.'' *Id.* at 412. Mr. Parrado has testified as an expert witness previously, including an estimated eight or nine times as an expert called by DEA in these administrative proceedings. *Id.* at 414–16.

It is undisputed that Mr. Parrado has an extensive and impressive background in the pharmacy field. In particular, Mr. Parrado has a vast amount of experience in the practice of pharmacy within the state of Florida. His experience as a member of the Board of Pharmacy, including as a member of the Rules and Legislative Affairs Committees and as the Chairman of the Board, are highly instructive as to the Florida standard of care and those regulations governing Florida pharmacists. Mr. Parrado even noted that he was a co-author of Rule 64B16–27.831, which is the Florida state requirement that pharmacists question prescriptions that may not be valid and only fill the prescriptions if the pharmacist is able to validate the prescription. *Id.* at 420.

As it has been noted, Mr. Parrado has previously testified in similar DEA administrative proceedings. In *Superior Pharmacy I and II,* the Agency found that the ALJ in that matter properly qualified Mr. Parrado as an expert witness in that proceeding given his extensive experience in the pharmacy field. *See Superior Pharmacy I and II,* 81 FR 31,309, 31,322 n.16 (2016). Mr. Parrado was also previously certified as an expert in community pharmacy practice. *Hills Pharmacy, LLC,* 81 FR 49,815, 49,820 (2016). The Agency also gave credit to Mr. Parrado's expertise in *Edge Pharmacy,* 81 FR 72,092 (2016). As such, I further find that Mr. Parrado's background and expertise is more than sufficient to lend weight towards his testimony in this matter.

In this matter, Mr. Parrado provided generally reliable statements as to his review of the materials and his ultimate opinions. He testified that he had reviewed not only the Respondent's exhibits, but also was provided and reviewed the DEA's exhibits. Tr. 432. Mr. Parrado suggested that if he were in Dr. Hamilton's position, he would have asked the Government to provide more documentation.[54] As to ultimate opinions, while Dr. Hamilton generally provided specific answers to the questions posed by the parties, Mr.

[54] There was a question as to what requirement, if any, an expert witness has in requesting additional documents. Mr. Parrado indicated that it was his experience from *Superior Pharmacy I and II* that he should request more documents. Respondent's counsel argued that *Superior Pharmacy I and II* holds that if information to resolve red flags is not documented in materials provided to the expert, the additional documentation should be requested and provided to the expert if it exists. Tr. 444–45. The Government's objection to the question was sustained and the parties were invited to brief this issue in their Posthearing Brief. The Government argues in its Posthearing Brief that *Superior Pharmacy I and II* do not stand for the argument that the Respondent asserted. Govt Posthearing Brief at 42–43. Upon a review of *Superior Pharmacy I and II,* this Tribunal agrees with that assessment. It was not established that *Superior Pharmacy I and II* have created such an obligation on the part of an expert witness to request additional documentation.

Parrado would occasionally provide more summary or conclusory opinions to the questions posed to him. For example, Mr. Parrado gave the blanket conclusory opinion that based on the discussions between Mr. Parrado and Mr. Sprys and Ms. Mincy, of which there was no record or report, Mr. Parrado opined that in every instance of a red flag, they properly resolved the red flag prior to dispensing the subject controlled substance.

There were also a number of disagreements between Dr. Hamilton and Mr. Parrado in a number of areas, which will be discussed *infra.*

However, Mr. Parrado's testimony was diminished by his failure to include important details as to the bases of his opinions in this matter. First, Mr. Parrado failed to disclose that he interviewed Mr. Sprys and Ms. Mincy in forming his opinions in this matter. Tr. 497–500, 504–06. As bases for his opinions and having testified as an expert in a number of these proceedings, Ms. Parrado should be well aware of his obligations and the necessity to disclose the bases of his opinions, particularly if interviewing witnesses in this matter formed the bases of his opinions. My Order for Prehearing Statements specifically requires witnesses who rely on hearsay statements to identify those individuals in the prehearing statement. ALJ Ex. 3. Mr. Parrado's opinions were further diminished by the fact that Mr. Sprys did not testify, so he could not be subject to cross-examination on this issue. Therefore, Mr. Parrado's subject opinions are based on hearsay statements that were not subject to cross-examination. The Government was given an opportunity to cross examine Ms. Mincy. Additionally, Mr. Parrado testified that Ms. Mincy and Mr. Sprys confirmed to him that checking the E–FORCSE database was instrumental in their resolving certain red flags. As GX 38 reveals, Mr. Sprys and Ms. Mincy's access of the E–FORCSE was not as diligent as claimed. *See infra* section ''Opioid Tolerance High Starting Dosages.'' This suggests that Mr. Parrado's opinions in this regard are diminished by less than reliable claims made to him by Mr. Sprys and Ms. Mincy. Additionally, as there was little or no documentary support for Mr. Sprys and Ms. Mincy's claims to Mr. Parrado that they appropriately resolved each of the subject red flags, one would have to credit them with extraordinary memory, based on specific events over a few year period which the record does not establish.

Secondly, when cross-examined about his conclusions regarding the distance traveled by Patient A.R., Mr. Parrado was asked why he did not provide certain details about his opinions in his expert report. Tr. 540–41. When asked why he didn't put anything in his report about the pharmacist's relationship with Patient A.R., he stated ''I didn't see cause for that. My eloquence is not that great.'' These statements further diminish Mr. Parrado's bases for his opinions in this matter. Further, there was an inconsistency in Mr. Parrado's evaluation. In defending the Respondent's resolution of red flags, Mr. Parrado often relied on the PRM records maintained in the pharmacy file to justify the resolution. However, in instances where the PRM did not establish justification of the red flag, Mr. Parrado dismissed this fact and credited the Respondent's resolution by virtue of the mere effort of contacting the physician. This is contrary to the pharmacist's corresponding responsibility. The pharmacist must resolve red flags. An unsuccessful attempt to resolve red flags is insufficient.

However, overall, I do not find that Mr. Parrado was disingenuous or lacking candor in his testimony, even when he occasionally failed to answer questions in a direct manner or to provide notice of all facts and materials upon which he relied in making his opinions. I do find his testimony to be generally credible and reliable, to the extent the information upon which he relied was accurate.

As to both experts in this matter, I consider their opinions and the merits of each when weighing the factors and the law. Here, the experts had differing strengths. Mr. Parrado has a tremendous amount of experience in Florida Pharmacy law and practice, while Dr. Hamilton seems to have the edge regarding existing pharmacy practice and market forces. However, as with any battle of experts, it is the expert's justification, or explanation for his opinion, which is key. As developed in detail *infra,* generally Dr. Hamilton's justifications and explanations for his opinions appeared more consistent with existing market forces, the relevant law, and Agency precedent than those of Mr. Parrado.

*[Omitted for clarity.]

Conflicting Findings of Dr. Hamilton and Mr. Parrado

Florida Minimum Standard of Care

Dr. Hamilton provided testimony that he understood the Florida minimum standard of care to be guided by the Florida Administrative Code, specifically ''Regulation 64B'' and guidelines provided by the National Board of Pharmacy Association. Tr. 180–81. Specifically, Dr. Hamilton noted that the Florida standard of care included responsibilities not specifically included within the relevant Florida regulations. *Id.* at 1007–08. On the other hand, Mr. Parrado testified that he understood the minimum standard of care to be set strictly and exclusively by the [Florida] Pharmacy Act or the Florida Administrative Code. *Id.* at 456. Further, the experience that Mr. Parrado has in the creation and implementation of these standards give his testimony significant weight in determining the import and scope of Florida law.*[GG]

A careful review of Florida law and regulations guiding the practice of pharmacy within the State of Florida shows that the practice is generally guided by Chapter 465 of the Florida Pharmacy Act,[55] and Florida Administrative Code rule 64B16, which governs pharmacy practice. Based strictly on this review, Mr. Parrado's testimony as to the law and regulations governing the practice of pharmacy in Florida appears to be correct. While Dr. Hamilton may also be correct about the guidelines set by the National Board of Pharmacy Association that have guided the State of Florida in its implementation of laws and regulations setting the minimum standard of care, it cannot be ascertained from the literal text of relevant Florida regulations where the Association's guidelines have been given any legal force beyond those provided for in the statutes and regulations cited to by Mr. Parrado. *[However, I likewise find no support for the proposition that Florida law encompasses the entirety of the standard of care in the State of Florida. Here, Mr. Parrado testified that Florida pharmacists are required to take thirty hours of continuing education every two years, and that ''two of those hours have to be on the . . . opioid abuse and resolving red flags.'' Tr. 413. In this case, I find that Florida state law can be reasonably interpreted to support both Dr. Hamilton's and Mr. Parrado's testimony.]

Mr. Parrado's testimony would generally be credited as to the governing laws and regulations within the Florida Pharmacy Act and the Florida Administrative Code. *[And Dr. Hamilton's testimony would generally be credited as to the usual course of existing pharmacy practice.] However, individual scrutiny will be given to the sections of the Florida Administrative

*[GG] Sentence was relocated for clarity.

[55] Fla. Stat. § 465.001 *et seq.*

Code under which the Government has raised allegations against the Respondent for failing to meet the minimum standard of care.

Requirement To Document Resolution of Red Flags

Dr. Hamilton provided testimony that resolution of each ''red flag'' had to be documented somewhere in a patient's file to demonstrate that the ''red flag'' had been resolved. He noted that this would be required under the Florida standard of care and that ''[i]f [it is] not documented, there's no evidence that . . . it was resolved.'' *Id.* at 179–81. Dr. Hamilton conceded that although this requirement was not specifically written in the relevant Florida regulations, it was without question required in the context of the Florida regulations as part of the Florida standard of care. *Id.* at 1007–08.

Despite its obvious logic, Mr. Parrado disagreed with Dr. Hamilton's assertion that such documentation is required in Florida. Mr. Parrado conceded that documenting the resolution of ''red flags'' may represent ''best practice,'' including that he would also do it as a pharmacist, but that it is not required under Florida law or the standard of care. He provided that most pharmacists complete at least some kind of documentation to indicate resolution of ''red flags.'' He also stated that he had created a computer program called ''Red Flag Resolver'' to assist pharmacists in documenting the resolution of red flags in their own practice.

*[Omitted. Here both experts agree that documentation of red flag resolution is not explicitly required by Florida law. However, the regulations generally support the testimony of Dr. Hamilton regarding the importance of documentation in the usual course of professional practice in Florida. *See also Suntree Pharmacy and Suntree Medical Equipment, L.L.C.,* 85 FR 73,753, 73,772.*HH thnsp;56]

Therefore, under Florida regulations and findings of the Agency on this issue, I credit Dr. Hamilton's testimony that pharmacists are required under the Florida standard of care to document the resolution of ''red flags.''

Pricing of Prescriptions *II

Dr. Hamilton expressed concerns that *[the patients' willingness to pay cash for these] *JJ highly priced prescriptions was a ''red flag'' that should be addressed. Dr. Hamilton indicated that it does not make sense that a patient would continue to go to a pharmacy that is charging high prices when there are pharmacies that sell the same medications for much less. Tr. 194. For example, high prices were a red flag for Patient A.E. (paying up to $500 a month) because A.E. was paying up to $5.95 per pill *[in cash when he could have gotten the controlled substances elsewhere for 1.50 per pill]. Tr. 199; GX 28, pp. 6–7. He opined that patients do not want to pay more than they have to, and if the same prescription was offered at a lower price at a different pharmacy, the patient would have gone to that other pharmacy. Tr. 199. Dr. Hamilton also noted he has observed different pricing schemes for the same prescriptions for the same person, *[paying cash] for which he could not provide a rational explanation. *Id.* at 203–04.

Mr. Parrado disagreed with Dr. Hamilton's assertion that the prices on the prescriptions should be much lower than that charged by Pharmacy 4 Less. He opined that every pharmacy can determine their own prices, which may be more expensive when filling a controlled substance prescription based on the added work load (including checking E–FORCSE, better maintenance of records, and additional inventories). *Id.* at 449. He stated that pharmacy pricing can be very competitive. *Id.* at 450. The only explanations Mr. Parrado could give for a pharmacy charging different prices for the same medication was a potential higher cost from a different wholesaler, the use of discount coupons, or indigent pricing programs. *Id.* at 451–52. There was no evidence offered that these exceptional circumstances existed here.

As to Mr. Parrado's claim that opioids had become scarce, difficult to locate, and involved additional expense to the pharmacies, thus warranting higher prices, neither party introduced documentary evidence to support or to counter this claim. *Id.* at 451–52, 539. Mr. Parrado did not offer the actual reason the Respondent charged the prices they did, or whether the Respondent recognized their prices were significantly higher than other like-situated pharmacies. For example, we don't know if there was a pharmacy much closer to the patients' homes or doctor offices charging less, from any direct evidence. We are left with conflicting, sometimes anecdotal, evidence by Mr. Parrado and Dr. Hamilton.

Dr. Hamilton personally surveyed pharmacy prices in his area, near Fort Lauderdale, while Pharmacy 4 Less is located just north of Orlando. *Id.* at 178. Dr. Hamilton's formula to determine average prices by large and small pharmacies involved a survey of wholesale prices of opioids sold to pharmacies, generally increased by 20% for pharmacy mark up, does not rebut the justifying explanations given by Mr. Parrado. To be more accurate, the survey should have been limited to small pharmacies. However, Dr. Hamilton's reliance upon a GoodRx program to determine prices charged by pharmacies for opioids does provide objective support for his assertions that the prices charged by Pharmacy 4 Less for the various subject opioids were considerably in excess of what other pharmacies were charging. *Id.* at 177–78.

Based on a review of this record, I find that Dr. Hamilton provided a more reliable basis in support of his opinion of unusually high prices of opioids charged by Pharmacy 4 Less than the uncorroborated and more anecdotal and historical explanations given by Mr. Parrado. I do not discount the market forces cited by Mr. Parrado, although I reject the extent to which he opined they affected the prices charged by the Respondent.

Having found that Respondent's *[cash-paying patients at issue in this case were paying] unusually high prices for the subject opioids, triggering a red flag, the next inquiry is whether the Respondent resolved the red flag. There was no evidence introduced that the Respondent performed any inquiry or investigation as to why the subject patients were willing to pay such high *[cash] prices for the subject opioids. Dr. Hamilton's opinion that this red flag repeatedly went unresolved is fully supported by this record.

*HH In *Suntree,* the Respondent implied that the Government's expert's ''inability to draw a solid conclusion as to where the requirement to document the resolution of red flags is written somehow demonstrated that there is no such requirement in the standard of practice.'' *Id.* The Acting Administrator rejected that reasoning and found ''that Florida state law can be reasonably interpreted to support [the Government expert's] testimony, but that her testimony [was] independently credible that documentation of the resolution of red flags is a requirement of the practice of pharmacy in the State of Florida.'' *Id.* I find the same. Here, Dr. Hamilton clearly testified that the resolution of the ''red flag'' had to be documented in the file as part of the Florida Standard of Care, noting, ''[i]f it's not documented, there's no evidence that . . . it was resolved, or a phone call was made, or an answer was given.'' *Id.* at 179–80; *see also id.* at 306, 318, 337, 1006–11, 1016.

56 *[Omitted text where original footnote was included.]

*II I have made modifications as indicated throughout this section to more directly address the issue in this case—that the patients identified in the OSC were paying cash, and excessively high prices at that, for controlled substances which created a red flag.

*JJ *See infra* n. NN.

Long Distances Traveled by Patients

Both Dr. Hamilton and Mr. Parrado agreed that long distances traveled by patients to fill their prescriptions at Pharmacy 4 Less was a ''red flag'' that needed to be resolved before the prescription was filled. *Id.* at 209–10, 453. As to Patient A.R., Dr. Hamilton gave the opinion that there were multiple red flags. *Id.* at 209. He said that the distance from A.R.'s home to the physician was a red flag because A.R. had to explain the reason to be going to that physician. Further, the distance from the physician to the pharmacy is a red flag, because it was taking A.R. even further away from A.R.'s home, approximately 50 miles from his home. A.R. needed to explain why he was traveling so far to fill the subject prescriptions. *Id.* at 209–10. Dr. Hamilton first opined that this red flag was not resolvable, but later conceded that there may be circumstances in which it could be resolved, but that it would need to be notated in the pharmacy file. *Id.* at 210.

Mr. Parrado gave the opinion that while the long distance traveled would be a red flag, it was one that could be resolved. *Id.* at 453. He said that it only needed to be resolved once as long as the pharmacist knew the patient and knew why they are coming to the pharmacy. Further, he stated that it would not need to be re-resolved each time if the patient was ''coming from the same place, he's seeing the same doctors, coming to the same pharmacy.'' *Id.* at 453. When asked about this red flag on cross-examination, Mr. Parrado said that from his review, Patient A.R. appeared to have a relationship with a pharmacy that would fill his prescriptions when it was difficult to find places to fill prescriptions. *Id.* at 539. He observed that Pharmacy 4 Less had developed a relationship with A.R., was monitoring and checking up on him, and gave all other indications which would resolve that red flag, in his opinion. *Id.* at 539.

While there appears to be no dispute that long distances traveled can constitute a red flag, there is a dispute as to its resolution in this matter. Mr. Parrado claimed that in his review, he believed this red flag had been resolved. Mr. Parrado based his finding on A.R. having developed a relationship with the Respondent and the difficulty in locating pharmacies which carried opioids. Mr. Parrado's finding appears to rely significantly on a scarcity of pharmacies carrying opioids. Based on the existing record, such scarcity has not been directly established. That the Respondent pharmacy has developed a relationship with A.R. would certainly not justify the first few dispensing without resolving the distance traveled red flag. In the absence of any other evidence resolving this red flag, I credit Dr. Hamilton's testimony that even if the red flag is resolvable, it was not resolved in this case.

Opioid Tolerance and High Starting Dosages

I did not recognize significant disagreement between Dr. Hamilton and Mr. Parrado regarding the red flag evident at the initial dispensing of any significant strength of opioids. Dr. Hamilton testified that a high initial opioid prescription is a red flag that must be resolved. He asserted that if a starting dose is too high and a pharmacist fails to identify the patient as being opioid naïve to that dosage level, the prescription could potentially prove to be fatal. *Id.* at 188. While Mr. Parrado did not appear to disagree that this is a red flag that should be resolved, he differed in his assessment of the patients in this matter receiving high starting dosages such that they would fail to meet the minimum standard of care. For example, when asking about prescribing 84 pills of oxycodone 30 mg to a patient, Dr. Hamilton testified that it would have been too high of a starting dosage for some of the charged patients. On the other hand, Mr. Parrado observed that there is no upper limit on the quantity that can be prescribed to a patient or how many milligrams. He stated that each would depend on the patient and their individual tolerance level. *Id.* at 461–62. Their previous opioid medication levels would fairly suggest their level of tolerance. Essentially, Mr. Parrado took the position that initial subject opioid dispensing of a significant dosage represented a red flag, which was resolvable. I do not recognize significant conflict between the two experts in this regard.

The credibility of Ms. Mincy's testimony as relates to her investigating the opioid naiveté of the 10 subject patients deserves some analysis. Here, Ms. Mincy testified that she used E–FORCSE at the pharmacy to look at patients' histories and records before filling a prescription. *Id.* at 643. She indicated that she uses it daily and prior to every fill of a new prescription of her patients. *Id.* She even stated that E–FORCSE ''is the best system to resolve red flags, in [her] opinion.'' *Id.* at 645. She made multiple comments about the usefulness of the E–FORCSE system and how she uses it on a daily basis during her work in the pharmacy. Finally, she indicated that she uses it before she fills every controlled substance prescription. *Id.* at 645–46.

The Government introduced evidence of the E–FORCSE searches conducted by Pharmacy 4 Less between January 1, 2015, and June 6, 2017, for the 10 charged patients in this matter. GX 38. For six patients, A.E., B.F., K.E.D., R.R., R.V., and V.W., this exhibit shows that Pharmacy 4 Less conducted initial opioid fills for the six patients, but did not run a search on E–FORCSE on the corresponding date of the fill. For example, Patient A.E. first filled a prescription on November 19, 2015, but Pharmacy 4 Less did not check E–FORCSE for Patient A.E. until April 7, 2016. GX 38, p. 11. Apart from being able to run checks through E–FORCSE, Pharmacy 4 Less did not introduce any evidence that it otherwise completed or documented its resolution of any potential red flags for Patient A.E before doing an initial fill of the prescription. The evidence shows this to be true for Patients B.F., K.E.D., R.R., R.V., and V.W., as well. GX 38.

The E–FORCSE records introduced do substantiate that either Ms. Mincy or Mr. Sprys checked the E–FORCSE database for the initial opioid dispensing for the following subject patients: A.R. on March 16, 2016; A.V. on April 21, 2016; B.N. on January 22, 2016; and K.Y.D. on February 4, 2016. *See* GX 38; RX 21, p. 4, 23, p. 3, 27, p. 3, 31, p. 7. However, Ms. Mincy conceded there was no documentary evidence that indicated that any of the subject ten patients started at lower doses of opioids, including oxycodone and hydromorphone, and worked their way up because they become opioid tolerant. Tr. 815–16. To the extent that Mr. Parrado credited Ms. Mincy's and Mr. Sprys' claims that they checked E–FORCSE to resolve opioid naïveté for the six patients noted above, this significantly diminishes Mr. Parrado's opinion.

The E–FORCSE records further belie Ms. Mincy's claim that she checked the E–FORCSE prior to filling each prescription. Tr. 645–46; GX 38. According to my math, of the 190 charged dispensed prescriptions within the subject record, the Respondent checked the E–FORCSE database 31 times, or 16.3% of the time. Ms. Mincy later testified that she checked E–FORCSE for each Schedule 2 prescription, and only recently began checking it for all controlled substance prescriptions. This significantly diminishes Ms. Mincy's reliability as a witness.

Findings as to Allegations

The Government alleges that the Respondent's COR should be revoked because the Respondent failed to ensure that it only filled prescriptions issued for legitimate medical purposes, and within the course of professional practice, in violation of its corresponding responsibility, and repeatedly filled prescriptions in the face of obvious red flags of diversion, and its registration would be inconsistent with the public interest, as provided in 21 U.S.C. 824(a)(4) and 21 U.S.C. 823(f), and in violation of state law under the Florida Administrative Code and state requirements for the minimum standard of care.

In the adjudication of a revocation or suspension of a DEA COR, DEA has the burden of proving that the requirements for such revocation or suspension are satisfied. 21 CFR 1301.44(e) (2010). Where the Government has sustained its burden and made its *prima facie* case, a respondent must both accept responsibility for her actions and demonstrate that she will not engage in future misconduct. *Patrick W. Stodola, M.D.,* 74 FR 20,727, 20,734 (2009). Acceptance of responsibility and remedial measures are assessed in the context of the ''egregiousness of the violations and the [DEA's] interest in deterring similar misconduct by [the] Respondent in the future as well as on the part of others.'' *David A. Ruben, M.D.,* 78 FR 38,363, 38,364 (2013). Where the Government has sustained its burden, that registrant must present sufficient mitigating evidence to assure the Administrator that he can be entrusted with the responsibility commensurate with such a registration. *Medicine Shoppe-Jonesborough,* 73 FR 364, 387 (2008).*KK

The Agency's conclusion that ''past performance is the best predictor of future performance'' has been sustained on review in the courts, *Alra Labs., Inc.* v. *DEA,* 54 F.3d 450, 452 (7th Cir. 1995), as has the Agency's consistent policy of strongly weighing whether a registrant who has committed acts inconsistent with the public interest has accepted responsibility and demonstrated that he or she will not engage in future misconduct. *Hoxie,* 419 F.3d at 482–83; *see also Ronald Lynch, M.D.,* 75 FR 78,745, 78,754 (2010) (holding that the Respondent's attempts to minimize misconduct undermined acceptance of responsibility); *George C. Aycock, M.D.,* 74 FR 17,529, 17,543 (2009) (finding that much of the respondent's testimony undermined his initial acceptance that he was ''probably at fault'' for some misconduct); *Krishna-Iyer,* 74 FR at 463 (noting, on remand, that despite the respondent's having undertaken measures to reform her practice, revocation had been appropriate because the respondent had refused to acknowledge her responsibility under the law); *Med. Shoppe–Jonesborough,* 73 FR at 387 (noting that the respondent did not acknowledge recordkeeping problems, let alone more serious violations of federal law, and concluding that revocation was warranted).

The burden of proof at this administrative hearing is a preponderance-of-the-evidence standard. *Steadman* v. *SEC,* 450 U.S. 91, 100–01 (1981). The Administrator's factual findings will be sustained on review to the extent they are supported by ''substantial evidence.'' *Hoxie,* 419 F.3d at 481. The Supreme Court has defined 'substantial evidence' as such relevant evidence as a reasonable mind might accept as adequate to support a conclusion. *Consolidated Edison Co. of New York* v. *National Labor Relations Board,* 305 U.S. 197, 229, 59 S.Ct. 206, 217 (1938). While ''the possibility of drawing two inconsistent conclusions from the evidence'' does not limit the Administrator's ability to find facts on either side of the contested issues in the case, *Shatz* v. *U.S. Dep't of Justice,* 873 F.2d 1089, 1092 (8th Cir. 1989); *Trawick,* 861 F.2d at 77, all ''important aspect[s] of the problem,'' such as a respondent's defense or explanation that runs counter to the Government's evidence, must be considered. *Wedgewood Vill. Pharmacy* v. *DEA,* 509 F.3d 541, 549 (D.C. Cir. 2007); *Humphreys* v. *DEA,* 96 F.3d 658, 663 (3rd Cir. 1996). The ultimate disposition of the case must be in accordance with the weight of the evidence, not simply supported by enough evidence to justify, if the trial were to a jury, a refusal to direct a verdict when the conclusion sought to be drawn from it is one of fact for the jury. *Steadman,* 450 U.S. at 99 (internal quotation marks omitted).

Regarding the exercise of discretionary authority, the courts have recognized that gross deviations from past agency precedent must be adequately supported, *Morall,* 412 F.3d at 183, but mere unevenness in application does not, standing alone, render a particular discretionary action unwarranted. *Chein* v. *DEA,* 533 F.3d 828, 835 (D.C. Cir. 2008) (citing *Butz* v. *Glover Livestock Comm'n Co.,* 411 U.S. 182, 188 (1973)). It is well-settled that since the Administrative Law Judge has had the opportunity to observe the demeanor and conduct of hearing witnesses, the factual findings set forth in this recommended decision are entitled to significant deference, *Universal Camera Corp.* v. *NLRB,* 340 U.S. 474, 496 (1951), and that this recommended decision constitutes an important part of the record that must be considered in the Administrator's decision. *Morall,* 412 F.3d at 179. However, any recommendations set forth herein regarding the exercise of discretion are by no means binding on the Administrator and do not limit the exercise of that discretion. 5 U.S.C. 557(b) (2006); *River Forest Pharmacy, Inc.* v. *DEA,* 501 F.2d 1202, 1206 (7th Cir. 1974); *Attorney General's Manual on the Administrative Procedure Act* 8 (1947).

Red Flags of Diversion

The Government has alleged that Pharmacy 4 Less failed to resolve and document ''red flags'' of diversion outside the usual course of professional practice (21 CFR 1306.06) and the pharmacy's corresponding responsibility (21 CFR 1306.04(a)) and in violation of meeting the Florida minimum standard of care under Florida law.

High Starting Dosages

The Government has alleged that Pharmacy 4 Less routinely filled Schedule 2 controlled substances for patients with high starting dosages, including both the dosage being prescribed and the number of tablets being prescribed.

The Government presented evidence by Dr. Hamilton that the initial starting dosages for at least six of the charged patients (Patients A.E., B.F., K.E.D., R.R., R.V., and V.W.) were too high and potentially fatal to opioid naïve patients. Dr. Hamilton gave his opinion that the starting dosages for these charged patients were too high given the nature of the patients' medical records and other documents that he had reviewed. Mr. Parrado appeared to agree with Dr. Hamilton that it is necessary to determine whether a patient is opioid naïve and that it should be factored into the determination of what a proper starting dosage would be, but disagreed that the starting dosages were necessarily too high. Both experts agreed that in order to determine if a patient is opioid naïve, a pharmacist can check E–FORCSE, talk to the patient, consult with the prescribing doctor, or take other steps the pharmacist determines to be necessary.

Here, Ms. Mincy testified that she used E–FORCSE at the pharmacy to look at patients' histories and records before

*KK Text omitted for brevity.

filling a prescription. Tr. 643. She indicated that she uses it daily and prior to every fill of a new prescription of her patients. *Id.* She even stated that E–FORCSE ''is the best system to resolve red flags, in [her] opinion.'' *Id.* at 645. She made multiple comments about the usefulness of the E–FORCSE system and how she uses it on a daily basis during her work in the pharmacy. Finally, she indicated that she uses it before she fills every controlled substance prescription. *Id.* at 645–46.

The Government introduced evidence of the E–FORCSE searches conducted by Pharmacy 4 Less between January 1, 2015, and June 6, 2017, for the 10 charged patients in this matter. GX 38. For the six patients previously mentioned, this exhibit shows that Pharmacy 4 Less conducted initial opioid fills for the six patients, but did not run a search on E–FORCSE on the corresponding date of the fill. For example, Patient A.E. first filled a prescription on November 19, 2015, but Pharmacy 4 Less did not check E–FORCSE for Patient A.E. until April 7, 2016. GX 38, p. 11. Apart from being able to run checks through E–FORCSE, Pharmacy 4 Less did not introduce any evidence that it otherwise completed or documented its resolution of any potential red flags for Patient A.E before doing an initial fill of the prescription. The evidence shows this to be true for Patients A.E., B.F., K.E.D., R.R., R.V., and V.W. GX 38.

Therefore, the Government has met its burden of proof as to this allegation as to these six patients.

As to the remaining four subject patients, the E–FORCSE records introduced reflect that either she or Mr. Sprys checked the E–FORCSE database for the first charged prescriptions for the following subject patients:[*LL] A.R. on March 16, 2016; A.V. on April 21, 2016; B.N. on January 22, 2016; and K.Y.D. on February 4, 2016. *See* GX 38; RX 21, p. 4, RX 23, p. 3, RX 27, p. 3, RX 31, p. 7. Ms. Mincy conceded there was no documentary evidence that indicated that any of the subject ten patients started at lower doses of opioids, including oxycodone and hydromorphone, and worked their way up because they become opioid tolerant. Tr. 815–16. *[Consistent with Dr. Hamilton's testimony, I find that Respondent acted outside of the usual course of professional practice and in violation of its corresponding responsibility when it failed to resolve and/or to document resolution of the opioid naïveté red flag as to each of the ten patients at issue in this case.][*MM]

[Cash Paid and] Excessive Pricing [*NN]

The Government has alleged that Pharmacy 4 Less routinely filled controlled substance prescriptions *[for patients who were paying cash at] extremely high prices.

As previously discussed, I credit Dr. Hamilton's opinion that Pharmacy 4 Less charged unusually high prices. Using his calculations in relation to large and small pharmacies, and his findings as to average prices charged in the surrounding area, Dr. Hamilton determined that there is generally only a slight difference between large and small pharmacies prices, with the difference generally amounting to a few dollars per prescription. *Id.* at 194–98. However, the Government's evidence suggests that Pharmacy 4 Less was charging prices much higher than that expected by a pharmacy within the surrounding area, whether it be a small independent pharmacy or a large retail pharmacy. *[Most concerning, the patients at issue in this case were paying for these over-priced controlled substances with cash which created a red flag. When Dr. Hamilton was asked at the hearing what he meant by the red flag he labeled ''paid cash, extremely high prices'' in his report, *see* GX 28, at 6, Dr. Hamilton explained that absent diversion, ''[t]here is no reason for a . . . patient to continue to go to a pharmacy that has'' ''extremely high prices when there [are] pharmacies that would sell it for much less.'' *Id.* at 194.]

While the Respondent put on evidence by Mr. Parrado as to the excessive pricing, I note that Mr. Parrado did not reveal the actual reasons the Respondent charged such prices, nor reveal similar prices by pharmacies closer to the subject patients' homes or physicians. *[Mr. Parrado further testified that some pharmacies only take cash, they ''do not take insurance . . . it's hard to get on some of these insurance networks,[*OO] then [you are] subject to their audits.'' Tr. 450.] I have found that his opinions on this allegation were more anecdotal and historical, and did not provide a sufficient basis to completely refute Dr. Hamilton's more objective and timely analysis.

Therefore, I find that the Government has met its burden of proof as to this allegation. The record establishes that the Respondent's *[patients at issue in this case paid cash at] prices that were noticeably higher than market forces would explain and sufficient to create a red flag. However, the record does not support a finding that the Respondent prices were exorbitant to the extent those transactions represented ''knowing'' diversion by the Respondent.

I do not find that solely on the basis of the high prices charged by the Respondent that Pharmacy 4 Less knowingly issued the prescriptions without a legitimate medical purpose. In their Posthearing Brief, the Government argues that ''[w]here a pharmacy is consistently charging exorbitant prices, DEA 'may properly draw the inference that the pharmacy is charging those prices because it knows it is supplying persons who are seeking the drugs to either abuse them or divert them to others.' *Jones Total Health Care Pharmacy, LLC,* 81 FR 79,188, 79,199–200 (2016).'' Govt Posthearing Brief at 39–40. The Government argues that, while there may be some variance in pricing, which the Administrator in *Jones Total Health Care* acknowledged, ''exceeding the average retail price by more than 200% at times is not what one would expect to find at a legitimate pharmacy.'' Govt Posthearing Brief at 31. As noted in *Jones Total Health Care,* the view that prices charged by a

[*LL] In its exceptions, the Government argued that merely running a name through E–FORCSE was insufficient to resolve the opioid naïve red flag, and that the pharmacist needed to affirmatively review the report, determine that the report addressed the red flag, and document the resolution. Govt Exceptions, at 9–10. I agree with the Government's position, but do not find that the ALJ erred. The ALJ considered the E–FORCSE records along with Ms. Mincy's testimony that she was using E–FORSCE to resolve the red flag in exactly the manner the Government said was required. There are credibility issues with Ms. Mincy's testimony, but ultimately, the ALJ in a different section of the RD found that Respondent Pharmacy's failure to document resolution of this red flag demonstrated a violation of its corresponding responsibility. *Infra* section ''Failure to Document Resolution of Red Flags.'' I have modified this section of the RD to clarify that the ALJ found that the Respondent Pharmacy's failure to document resolution of this red flag demonstrated a violation of Respondent Pharmacy's corresponding responsibility and was outside the usual course of pharmacy practice.

[*MM] This replaces the ALJ's original finding that the Government failed to carry its burden that the opioid naïveté red flag went unresolved for four of the ten patients.

[NN] Throughout the testimony in this case and in its Posthearing Brief, the Government emphasized the excessively high prices charged by the pharmacy. However, the Government's expert also opined that the customer's cash payment at excessively high prices created red flags that were not resolved prior to dispensing. *See also* OSC, at 3–7; Govt Supp. Prehearing, at 7–15 GX 28, at 5–6; Tr. 194–98. I have made modifications throughout this section as noted in brackets to account for the ''cash payment'' portion of the issue.

[*OO] In its exceptions, Respondent asserted that ''[i]t takes almost 2 years for a new pharmacy to be accepted by all insurance companies.'' Respondent's Exceptions, at ¶ 3. Though this specific factual assertion lacks evidence in the record, I find it is in line with Mr. Parrado's anecdotal testimony which was properly considered by the ALJ in reaching his decision.

pharmacy in excess of average prices can support an inference that the pharmacy knew the prescriptions were not being issued for a legitimate medical purpose. *Jones Total Health Care,* 81 FR at 79,200 (citing *United States* v. *Leal,* 75 F.3d 219, 223 (6th Cir. 1996); *United States* v. *Cooper,* 868 F.2d 1505, 1512 (6th Cir. 1989); *United States* v. *Hayes,* 595 F.2d 258, 261 (5th Cir. 1979)).

Here, no direct evidence was offered by either party regarding the prices actually charged by alternate pharmacies near the patients' homes or physician's offices. *[Absent additional and more specific evidence,][*PP] I find that an inference based solely on the higher prices charged herein *[omitted] that Pharmacy 4 Less knowingly filled the prescriptions without a legitimate medical purpose, would not be warranted. *[Still, as I found above, the record establishes that the Respondent's patients at issue in this case paid cash at prices sufficiently high to create red flags, which were not resolved. And there is sufficient evidence to support a finding that the pharmacists who filled those prescriptions without documenting resolution of those red flags violated their corresponding responsibility due to their willful blindness to the prescriptions' potential illegitimacy. *See Suntree,* 85 FR at 73,770.]

Long-Term Fill for Immediate Release Pain Medication

The Government has alleged that Pharmacy 4 Less routinely filled controlled substance prescriptions for immediate release pain medication over long periods of time.

Dr. Hamilton testified that a patient receiving short-acting medications over a long period of time is a red flag that must be resolved before the prescription is filled. He stated that immediate-release medication should not be taken over long periods of time, with the medication being ''immediate-release for a reason.'' Tr. 193. He further testified that if it is prescribed over a long period of time, there needs to be documentation from the physician about the patient as to why a long-acting medication failed or other circumstance that would demonstrate why a short-acting medication was being prescribed over a long-period of time. *Id.* at 194.

The Respondent did not present evidence to directly counter the Government's evidence. Mr. Parrado agreed that this was a red flag that needed to be resolved. He only generally asserted that the physician determines what medication the patient will be on, that many insurance companies will not pay for extended release medication, and the charged patients may have had insurances that did not cover them. *Id.* at 447. However, he did counter that oxycodone can be used for extended periods of time, based upon academic literature, and that there was no set duration of time which oxycodone should stop being used. *Id.* at 447. He did concede that as a pharmacist, he questioned whether a short acting versus a long acting prescription was properly prescribed. *Id.* at 447–48. Without evidentiary corroboration,[*QQ] Mr. Parrado's testimony in this regard is little more than speculation. It does not meaningfully counter Dr. Hamilton's subject opinion.

Therefore, I find that the Government has met its burden of proof as to this allegation. *[Specifically, I find that Respondent pharmacy acted outside of the usual course of professional practice and in contravention of its corresponding responsibility when it failed to resolve and/or document resolution of the red flag arising from long-term use of immediate-release pain medications.]

Long Distance Traveled by Patient A.R.

The Government has alleged that Pharmacy 4 Less filled prescriptions for Patient A.R., who traveled long distances (fifty miles from his home) to fill his prescriptions.

Both Dr. Hamilton and Mr. Parrado agreed that long distances traveled by patients to fill their prescriptions at Pharmacy 4 Less was a ''red flag'' that needed to be resolved before the prescription was filled. *Id.* at 209–10, 453. As previously discussed, while there appears to be no dispute that long distances traveled can constitute a red flag, Dr. Hamilton and Mr. Parrado did disagree about the potential for resolution of the red flag in this matter as to Patient A.R. However, Mr. Parrado again gave general opinions on this matter as to why Patient A.R. may have been traveling such long distances to fill his prescriptions at Pharmacy 4 Less. Without proper documentation to show if Pharmacy 4 Less even attempted to resolve such a red flag, Mr. Parrado's assertions remain speculative and cannot be definitively shown.[57] Further, I find that the distances traveled by Patient A.R. were long enough that Dr. Hamilton's opinion is to be credited that this is a red flag that needed resolution, which Pharmacy 4 Less has failed to do.

Therefore, I find that the Government has met its burden of proof as to this allegation. *[Specifically, I find that Respondent pharmacy acted outside of the usual course of professional practice and in contravention of its corresponding responsibility when it failed to resolve and/or to document resolution of the red flag arising from the long distance A.R. traveled to fill his prescription.]

Drug Combination Prescriptions

The Government has alleged that Pharmacy 4 Less filled prescriptions for drug combinations that needed to be questioned. In particular, the Government has alleged that Pharmacy 4 Less improperly filled prescriptions for Patient A.V. that combined buprenorphine along with oxycodone.

Dr. Hamilton testified that buprenorphine issued with oxycodone presents a red flag that needs to be resolved. *Id.* at 263–76. He explained that buprenorphine is a medication used for opiate withdrawal, and issuing it along with oxycodone, an opioid, would present a red flag because the opioid would no longer be of any use. *Id.* at 263. He testified that when these combinations are used, it would be expected to see that the patient, would *[within a few days to a few weeks, *Id.* at 974] be weaned off of the opioid and it would be substituted with the buprenorphine. *Id* at 263. Dr. Hamilton indicated that he did not see any evidence that Pharmacy 4 Less had resolved this red flag before issuing the prescriptions to Patient A.V. *Id.* at 266. When confronted with the Respondent sponsored PRM file, which included references to tapering the patient off of opioids, Dr. Hamilton opined that such cryptic reference was insufficient to resolve the red flag or be sufficient documentation within the pharmacy record. *Id.* at 972. *[Specifically, Dr. Hamilton testified that ''the note says that the . . . physician is tapering the patient off of medications that [he is] addicted to, but [there is] a continuation of the oxycodone fill in the same amounts, same quantity, same timeframe. It continues over the course of the whole year.'' *Id.* It is clear from

[*PP] Original text modified for clarity and brevity.

[*QQ] In its Exceptions, Respondent asserted that ''[p]atients are on immediate release because the price of long term is 3 to 5 times as much and their insurance does not pay for it. Almost all patients had forms that we filled out and signed for reimbursement from their insurance companies.'' Resp Exceptions, at ¶ 2. This factual assertion, again without evidence in the record to support it, fails to qualify as the evidentiary corroboration needed to establish Dr. Parrado's testimony as anything other than speculation.

[57] Mr. Parrado testified that all of the red flags were resolved to his satisfaction by his speaking with Ms. Mincy and Mr. Sprys, as their explanations resolved all of the charged red flags. Without more specificity, I cannot attribute significant probative value to this blanket opinion.

Dr. Hamilton's testimony that the drug combination red flag arises twice in this case: first, when the buprenorphine and oxycodone are prescribed together; and again, when the drug combination continues over time without tapering.]

Mr. Parrado agreed with Dr. Hamilton that this drug combination is a red flag ''that [he] would have wanted to look into very carefully.'' *Id.* at 463. However, Mr. Parrado indicated that he believed the red flag had been resolved because he found that Pharmacy 4 Less had contacted Patient A.V.'s doctor, in which the doctor explained that he was trying to get A.V. off of the oxycodone by intermittently using buprenorphine. *Id.* at 463–64. When I asked where Mr. Parrado had seen this red flag resolved in the records he reviewed, he stated that he had seen it in the patient's record maintenance folder. *Id.* at 464; RX 22, 23.

Upon a review of the evidence, I find that Patient A.V.'s patient record maintenance file maintained by Pharmacy 4 Less does give some indication that Pharmacy 4 Less contacted A.V.'s doctor. In the Patient Memo, it states ''PATIENT DC'D 4/17/17 CONTINUED DETOX WITH COM. DRUGS FOR HIS SPECIFIC LEVEL OF ADDICTION TAPERING PER DR. W SEIFERT—MD CONSULTED AND RESULTED IN CONTINUED THERAPY.'' RX 22, p. 1.[*RR] However, what cannot be ascertained is when this information was entered into the system.

It is clear from at least the face of the prescriptions that Pharmacy 4 Less did not provide additional documentation beyond what is shown in the patient record maintenance file. With the impossibility of determining when this information was entered, it cannot be definitively ascertained whether Pharmacy 4 Less resolved the *[initial] red flag at the time the prescriptions were issued or whether this information was inserted at a later time. *[However, even if the Respondent Pharmacy did resolve the initial red flag arising from the drug combination, there is no evidence in the record that the red flag arising from the continual prescribing of the drug combination without proper tapering was resolved.

Therefore, I find that the Government has met its burden of proof as to this allegation by establishing that Respondent Pharmacy failed to resolve the red flag of arising from the long-term use of this drug combination without tapering.][*SS]

Failure To Document Resolution of Red Flags

I have presented my findings as to each of the five allegations set out by the Government as to Pharmacy 4 Less's failure to resolve red flags. The Government has argued that not only has Pharmacy 4 Less failed to resolve these red flags, but their failure to document resolution of red flags warrants an inference that the red flag was never resolved.

As I have already discussed, *[Omitted. I credit Dr. Hamilton's testimony that pharmacists are required under the course of professional practice in Florida to document the resolution of ''red flags.'']*[TT] As such, I make my recommendation that the Administrator find Pharmacy 4 Less was required to document the resolution of red flags, and that it failed to do so.

During the hearing, Mr. Parrado provided testimony about the Florida laws and regulations that underpin the standard of care for Florida pharmacists. As one of the individuals involved with the drafting of Florida regulations in question, he gave insightful comments about the creation and basis for the rules. However, as I noted during the hearing, Mr. Parrado's comments were instructive, but not dispositive. Tr. 468. I am foremost guided by the text of the law and regulations,*[UU] *[and by the Government's expert testimony regarding the standard of care in the State of Florida.]

Based upon the evidence provided, I find that Pharmacy 4 Less has failed to document or show other evidence that demonstrates resolution of the red flags [58] as alleged by the Government in the previous five allegations, excluding the *[allegation related to the initial red flag arising from] Patient A.V.'s prescribed drug combination.*[VV]

Recordkeeping Violations

Initial Inventory

The Government has charged that Pharmacy 4 Less did not have an initial inventory in violation of 21 CFR 1304.11(b). Section 1304.11(b) provides that ''[e]very person required to keep records shall take an inventory of all stocks of controlled substances on hand on the date he/she first engages in the . . . distribution, or dispensing of controlled substances. . . .''

The Government provided the testimony of DI1 that on June 6, 2017, during the on-site inspection, DI1 asked Ms. Mincy if Pharmacy 4 Less had an initial inventory. Tr. 39. When asked, Ms. Mincy could not locate the initial inventory and did not know where it was, and contacted Mr. Sprys to ask about the initial inventory. *Id.* at 39–40. This was done in the presence of DI1 and DI2. Tr. 39. DI1 explained to Mr. Sprys what an initial inventory was and asked if Pharmacy 4 Less had one, to which Mr. Sprys stated that he did not. Tr. 40. *[Omitted for brevity.]

The Respondent did not put on any evidence to confront this allegation,*[WW] although the Respondent, during cross-examination of DI1, questioned whether DI1 spoke to Mr. Sprys over the telephone regarding the initial inventory. Tr. 154.

As noted, the Government has the burden of proof in these proceedings to prove the charges alleged in the OSC and those later raised in the prehearing statements. The Government must meet its burden by a preponderance of the evidence for its burden to be satisfied as to each allegation. Here, the Government produced the testimony of DI1 that Ms. Mincy did not know where the initial inventory was, and that Mr. Sprys indicated that the pharmacy did

*[RR] The Government argued in its exceptions that the ALJ improperly relied on RX 22 because the exhibit was admitted only conditionally and the condition for its admission was ultimately not met. While I understand the Government's argument regarding reliance on the exhibit in this way, the ALJ did not rely on RX 22 standing alone, rather he relied on it as support for Mr. Parrado's opinion which was that the Respondent Pharmacy had contacted the patient's physician and resolved the initial red flag. Ultimately, in light of the preponderance of the evidence, RX 22 is of little importance to the finding on this red flag.

*[SS] I have omitted the ALJ's original finding in Respondent's favor based on his uncertainty over whether or not the Respondent had resolved the initial drug combination red flag as may have been documented in RX 22. The ALJ did not evaluate the red flags that arose as a result of the continued filling of the drug combination prescriptions without signs of proper tapering, and having so evaluated them, I have reached a different result.

*[TT] *See also supra* ''Requirement to Document Resolution of Red Flags.''

*[UU] Omitted for clarity.

[58] Further, the Government offered evidence that DI and the rest of his team did ask Ms. Mincy if they documented their resolution of red flags and where they did so. DI was provided documents by the Respondent at DI's request upon which records were identified that failed to indicate the resolution of red flags. *[This footnote was relocated for preservation after the original text to which it referenced was omitted].

*[VV] Omitted, for brevity, the inference that Respondent Pharmacy's failure to document resolution of the red flags supported a finding that the red flags were in fact not resolved. Here, there is ample evidence of red flags that were unresolved and/or undocumented.

*[WW] In its exceptions, Respondent claimed that it opened in 2015 with ''zero narcotics'' and that ''[t]his report was shown to DEA agents on initial inspection in 2015.'' Resp Exceptions, at ¶ 7. This assertion is not supported by the evidentiary record. Moreover, the reference to ''this report'' is ambiguous and may or may not refer to an initial inventory, but even if an initial inventory was taken, there is no assertion that Respondent had an initial inventory during the 2017 inspection. This exception is simply without merit.

not have one. This evidence went essentially uncontested.

The Agency has previously found that ''testimony alone provides substantial evidence'' to support a finding that a registrant failed to properly prepare records. *Jones Total Health Care Pharmacy, L.L.C., & SND Health Care, L.L.C.,* 81 FR 79,188, 79,191 (2016), *pet. for rev. denied,* 881 F.3d 823 (11th Cir. 2018). The Agency rejected the respondent's argument that because the DEA bears the burden of proof, it must provide independent evidence towards such allegations. *Id.*

As previously discussed, I find that DI1's testimony in these proceedings was credible and indicated trustworthiness. The Government has submitted testimonial proof sufficient to satisfy its burden, that the Respondent did not have an initial inventory. Further, while the Respondent has no burden to disprove the Government's allegation, it would not benefit the Respondent to withhold such a document if such document existed. Based on DI1's testimony and the lack of physical evidence presented by either party, I find that the Government has met its burden to show that the Respondent has failed to keep an initial inventory as required under § 1304.11(b).

Biennial Inventory

The Government has charged that Pharmacy 4 Less failed to indicate whether the biennial inventory was taken at the opening or closing of business as required by 21 CFR 1304.11(a). Section 1304.11(a) provides, in part, that ''[t]he inventory may be taken either as of opening of business or as of the close of business on the inventory date and it shall be indicated on the inventory.''

The Government presented testimony from DI1 that the biennial inventory was provided to him by Ms. Mincy during the June 6, 2017 on-site inspection. DI1 testified that the biennial inventory given to him did not meet the requirements as set in the DEA regulations. Tr. 41. One failing that DI1 noted was that, by Ms. Mincy's statements, the biennial inventory was not completed during a single day, but over the course of several days. Tr. 41. Another defect was that there was no notation on the biennial inventory as to whether it was completed at the opening or closing of business. *Id.* at 41–42. DI1 was unsure about the accuracy of the biennial inventory due to these issues, which caused him not to use it as part of his audit of the pharmacy's inventory. *Id.* at 56, 61, 66, 154–56.

The Respondent presented testimony from Ms. Mincy that DI1 had asked to see the biennial inventory, which she produced and gave him a copy. *Id.* at 605. She indicated that the biennial inventory was located in a binder in the locked medication room along with the perpetual inventory. *Id.* at 607, 622–23. Ms. Mincy testified that on June 6, 2017, she gave DI1 the biennial inventory at the pharmacy. *Id.* at 773–74. She indicated that he had left it at the pharmacy after the inspection, and that he called back looking for it because he had forgotten to take it with him. *Id.* at 774.

The Respondent then introduced a copy of the biennial inventory. RX 38. The exhibit included a cover sheet that noted that the biennial inventory was completed on April 26, 2017, at 8:00 a.m., and was completed by Ms. Mincy and Mr. Sprys. Tr. 617–18, 767–68; RX 38, p. 1. The following page was the actual first page of the printed out biennial inventory. Tr. 619, 767; RX 38, p. 2. The remaining pages are all part of the biennial inventory, and the printout indicates a date of April 26, 2017. Tr. 620–22; RX 38, pp. 2–16. The exhibit contains handwriting that indicates that the biennial inventory was completed on April 26, 2017, at 8:00 a.m. and was signed by Mr. Sprys and Ms. Mincy. Tr. 767–69; RX 38, pp. 1, 2, 8.

Ms. Mincy testified that the biennial inventory had been completed at 8:00 a.m. because it must be completed in the morning before business or at the end of the day at the close of business to avoid discrepancies in the pharmacy's counts. Tr. 620. She further testified that she and Mr. Sprys had signed and dated the biennial inventory to validate that the information was true and correct, and that she had completed it during that date and time. *Id.* at 624–25. She indicated that it took her approximately three hours to complete the biennial inventory, so she would have arrived at the pharmacy at approximately 5:00 a.m. *Id.* at 628. She testified that she personally prepared both reports contained within the biennial inventory, and personally entered all of the information herself on the date listed on the form. *Id.* at 772. As for the date indicated at the top of each page, Ms. Mincy stated that it reflects the date on which the report was run. *Id.* at 772–73; RX 38, pp. 2–7, 9–16.

The Government conducted a voir dire of Ms. Mincy as to RX 38. Tr. 774. She testified that RX 38 was a true and correct copy of what she had given DI1 on June 6, 2017, and that there had not been any alterations made to the document after she gave it to him. *Id.* at 774–75. She claimed that no one had written on the document to include the handwriting at the top of RX 38, p. 2 after she had given it to DI1 or after it had been faxed to him. *Id.* at 775. She testified that the biennial inventory had later been faxed to DI1 by Bill Sprys. *Id.* at 776–77. The Government showed Ms. Mincy another version of a copy of the biennial inventory that did not contain the handwriting written on RX 38. *Id.* at 778–81. The Government's copy was admitted as GX 37. Ms. Mincy indicated that there must be two versions of the inventory, one labeled complete and one that was not labeled. *Id.* at 780.

The Government later conducted cross-examination of Ms. Mincy about the biennial inventory. *Id.* at 817. She admitted that while the biennial inventory did not indicate that it was conducted at the close of business, she asserted that it was completed before the opening of business at 8:00 a.m. *Id.* at 817. When asked on cross-examination, she changed her earlier testimony to say that she completed the biennial inventory from 6:00 a.m. to 8:00 a.m. on April 26, 2017, an hour later than she had previously indicated. *Id.* at 822.

Ms. Mincy was also confronted with statements DI1 testified she had said during the inspection. When asked if she had said during the on-site inspection that she had completed the inventory over the course of several days, she claimed that DI1 was confused. *Id.* at 823–24. When asked if she had said that she would have to shut down the pharmacy to do the biennial inventory, she said that DI1 misunderstood. *Id.* at 825.

Based on both parties' assertions, DI1 left the biennial inventory at the pharmacy after the on-site inspection. At that point, DI1 did not have a copy of the biennial inventory. I noted during the course of the hearing that DI1 had testified Ms. Mincy had provided a document that was represented as a biennial inventory, but that it didn't qualify because there was no indication that the document was prepared on a single occasion, so he left it at the pharmacy because he would not use it as part of his audit. Tr. 155.*XX

At the outset, I note the immediate differences between GX 37 and RX 38 as highlighted by the Government. Both GX 37, p. 7, and RX 38, p. 2, present similarly printed material, but RX 38 contains handwritten material at the top of the page that purports to show that the biennial inventory was completed on ''4/26/17'' at ''8AM'' and is contains signatures purported to be Ms. Mincy

*XX Paragraph relocated for clarity.

and Mr. Sprys. The Government represents that GX 37 is the biennial inventory that was faxed to DI1 from Bill Sprys at Pharmacy 4 Less on the day following the June 6, 2017 on-site inspection. While it cannot be ascertained when exactly the handwritten material was included on RX 38, p.2, I find it inescapable that the handwritten notes were added after the inventory was faxed to the government. This is further supported by the assertion from Ms. Mincy that she did not appear to know where the handwritten notes came from.*YY Tr. 786–88. In sum, the handwriting on RX 38 demonstrates that it is more likely that DI1 was provided a clean copy by the Respondent through the fax on June 7, 2017, and the handwriting on RX 38 was written at a later time.[59] *ZZ I credit DI1's testimony as to the statements made during the June 6, 2017 on-site inspection, as well as the lack of indication on the biennial inventory when the inventory had taken place.

*[I agree with the ALJ's credibility finding regarding the handwriting on GX 37, p. 7 and RX 38, p.2. However, I also note that both the copy of the biennial inventory faxed to the Government, GX 37, p. 2, and the copy maintained by Respondent, RX 38, p. 1, contained what Ms. Mincy described as a ''cover page'' which stated ''Biennial Inventory, completed 4/26/17, 8am'' and was signed by both Ms. Mincy and Mr. Spry. Tr. 617–18. While the cover sheet contained the same information written in GX 37, p. 7 and RX 38, p. 2, there is simply insufficient information in the record for me to determine whether or not this ''cover page'' was attached to the Biennial Inventory at the time of inspection. Accordingly, I cannot say that there is enough evidence to support a violation of 1304.11(a). As my finding differs from the ALJ's in this regard, the remainder of the ALJ's discussion on this topic is omitted. Even without this violation, there is more than enough evidence on the record to indicate that Respondent pharmacy's registration is inconsistent with the public interest.

Therefore, I find that the Government has not established by sufficient evidence that Respondent's biennial inventory failed to comply with the requirements of 21 CFR 1304.11(a) as alleged.]

Ms. Mincy's Access to CSOS

The Government has charged that during DEA's review of Pharmacy 4 Less's CSOS, Ms. Mincy admitted to using Mr. Spry's CSOS credentials to order controlled substances in violation of 21 CFR 1311.30(a), (c). Section 1311.30(a) provides that ''[o]nly the certificate holder may access or use his or her digital certificate and private key.'' Section 1311.30(c) provides that ''[a] certificate holder must ensure that no one else uses the private key. While the private key is activated, the certificate holder must prevent unauthorized use of that private key.''

The Government presented credible testimony from DI1 that he asked Ms. Mincy how Pharmacy 4 Less documents and records their ordering of controlled substances and validation of a prescription's legitimacy. Tr. 43.[60] DI1 testified that he observed Ms. Mincy proceeded to a laptop in the pharmacy to log into the CSOS system. *Id.* at 45. DI1 asked Ms. Mincy if she had her own CSOS credentials (which DI1 asserted is required for anyone accessing the CSOS system and cannot be shared with anyone else). *Id.* at 46. DI1 testified that Ms. Mincy stated she did not have her own credentials and did not have a power of attorney for anyone else's credentials. *Id.* Ms. Mincy stated to DI1 that she was using Mr. Richard Sprys credentials to log onto CSOS. *Id.* The Government put on further evidence that DI1 later contacted Mr. Chris Jewell, one of the personnel in charge of the CSOS system at DEA Headquarters, to determine which personnel at Pharmacy 4 Less had access to the CSOS system. *Id.* at 47–48. Mr. Jewell ran a report and the report stated that Ms. Mincy only received her own CSOS credentials in July 2018, after the on-site inspection. *Id.* at 48–49; GX 29.[61]

The Respondent presented testimony from Ms. Mincy that she was asked by DI1 to look at the pharmacy's CSOS system. *Id.* at 612–13. The pharmacy uses the CSOS system sourced through AmerisourceBergen. *Id.* at 612. Ms. Mincy testified that she showed DI1 the steps to order, but could not order because she did not have CSOS credentials at the time of the inspection. *Id.* at 613, 839–40, 867. *[During her testimony, Ms. Mincy went into some detail explaining how the system worked; *AAA she testified that she logged into AmerisourceBergen and demonstrated how controlled substances could be added to an order without the CSOS credentials. *Id.* at 840, 867. She explained that upon completion of the order, Schedule III–V medications are submitted to AmerisourceBergen, but that Schedule II controlled substances are not submitted without taking extra steps to verify the CSOC certificate. *Id.* at 867.] When showing the program to DI1, Ms. Mincy stated she did not put in any credentials *[to complete the process of ordering Schedule II controlled substances], because she did not have any at the time. *Id.* at 615, 867–68. Ms. Mincy stated she then heard DI1 say that she had been ordering with Mr. Spry's credentials, which she followed up by telling him that was not correct. Tr. 615.

It is extremely difficult to reconcile the testimony and evidence presented by the parties regarding this allegation. On one hand, the Government presented testimony of DI1 indicating that he observed Ms. Mincy log onto the CSOS system, and that Ms. Mincy stated during the on-site inspection that she had ordered controlled substances using Mr. Sprys' credentials. On the other hand, the Respondent presented testimony of Ms. Mincy that [she logged in to the AmerisourceBergen system, not CSOS,] that she never [said she was using Mr. Sprys' credentials,] and that she told DI1 that his assertion was not correct. Both versions cannot be correct. Based on the previous analysis of the witnesses' credibility, DI1's version is [generally] more credible, considering Ms. Mincy's memory issues and motivation to color her testimony. *[However, Ms. Mincy testified in much greater detail than DI regarding the system and the steps she took to demonstrate it to DI, and this testimony was not addressed by DI when he later took the stand as a rebuttal witness. The Agency is clear that CSOS is the ''only method for ordering Schedule I and II controlled substances electronically,'' and can be used for other Schedules, but there is no information on the record about at what point during the purchasing process the credentials are necessary. *https://www.deaecom.gov/*

*YY Furthermore, I do not find credible Ms. Mincy's assertion that there were two or three versions of the inventory, one labeled complete and others that were not labeled. *[Content was moved for clarity.]

[59] In their Posthearing Brief, the Government asserts that Ms. Mincy has intentionally backdated documents, including RX 38. Govt Posthearing Brief, at 36. As discussed, I cannot determine exactly who added the additional handwriting included on RX 38 or when it was added, and cannot accept the Government's assertion that it was, in fact, Ms. Mincy who backdated it after it had been delivered to the Government.

*ZZ The preceding sentence and the following sentence were relocated for clarity.

[60] DI1 asserted during his testimony that when a pharmacy orders and receives controlled substances on-site, they are required to notate that they received them with the date and the initials of the person that received them. Tr. 44.

[61] *See supra* n.15.

*AAA Respondent, in its exceptions, made additional factual assertions regarding Mr. Sprys' ability to access CSOS and order controlled substances, which are not only missing from the evidentiary record but are entirely irrelevant to the issue at hand and have no impact on my decision in this case. Resp Exceptions, at ¶ 10.

qanda.html.[*BBB] Further had Ms. Mincy actually purchased controlled substances using the CSOS account during the inspection, I find it confusing that the Government did not include evidence related to such purchase.

Despite the credibility issues present in this case,[*CCC] the Government's evidence lacked basic information regarding the CSOS system and what the DI actually observed (as opposed to what he heard Ms. Mincy say) that led to his conclusion that Ms. Mincy had used Mr. Sprys' credentials to log into the CSOS system. Without that information it is difficult to determine the weight of the evidence, and as the Government has the burden of proof, I simply cannot find substantial evidence to support violations of § 1311.30 (a) & (c).]

Electronically Linked Record of Quantity and Date Received

The Government has charged that Pharmacy 4 Less's receiving records showed that Pharmacy 4 Less failed to create an electronically linked record of a quantity and date received for its controlled substances in violation of 21 CFR 1305.22(g). Section 1305.22(g) provides that ''[w]hen a purchaser receives a shipment, the purchaser must create a record of the quantity of each item received and the date received. The record must be electronically linked to the original order and archived.''

After a thorough review of the evidence and testimony presented by the parties, I have found a lack of any evidence presented towards this charge by the Government. While the DI1 extensively testified about the Government's charge of a lack of a date of receipt on the pharmacy's invoices, the Government did not probe into the allegation that Pharmacy 4 Less failed to create electronically linked records under § 1305.22(g). While DI1 indicated that Pharmacy 4 Less did not have PDF copies of the CSOS records, he did testify that the CSOS is online and can be a totally electronic record. Tr. 44–45. However, there was no evidence that Pharmacy 4 Less had failed to create an electronically linked record of any shipments of controlled substances.

However, the Respondent, while brief, presented some evidence of their compliance with § 1305.22(g). The Respondent presented testimony by Ms. Mincy towards two inspections at Pharmacy 4 Less by the Florida Department of Health Investigative Services. Tr. 658–81; RX 14, 15. One inspection report, dated February 28, 2017, before the DEA's on-site inspection, indicated that the investigator from the Florida Department of Health had found that Pharmacy 4 Less was compliant with the requirement that ''DEA 222 forms properly completed or records of receipt of CSOS orders electronically completed, archived and retrievable.'' Tr. 661; RX 15, p. 2. This requirement then directly cites to 21 CFR 1305.22(g). RX 15, p. 2. The second inspection report, dated September 5, 2017, after the DEA's on-site inspection, indicated that the investigator from the Florida Department of Health again found that Pharmacy 4 Less was compliant with the requirement under § 1305.22(g). RX 14, p. 2.

While the Respondent's evidence will ultimately go towards the analysis of Factor Two under the public interest factors, it is also relevant to rebut the Government's charge under § 1305.22(g). While the DIs may have had some indication that Pharmacy 4 Less was not in compliance with the requirements under § 1305.22(g), the record is void of any testimony or evidence to support such a charge. Further, the Respondent has offered evidence, at least from the viewpoint of an inspector with the Florida Department of Health, that Pharmacy 4 Less was in compliance with the requirements under § 1305.22(g) before and after the DEA's on-site inspection. Therefore, I find that the Government has not met their burden of proof as to this allegation.

Date of Receipt on Invoices

The Government has charged that Pharmacy 4 Less possessed 85 invoices without the date of receipt recorded in violation of 21 CFR 1304.22(c). Section 1304.22(c) provides, in part, that ''[e]ach person registered or authorized to dispense or conduct research with controlled substances shall maintain records with the same information required of manufacturers pursuant to paragraph (a)(2)(i), (ii), (iv), (vii), and (ix) of this section. In addition, records shall be maintained of the number of units or volume of such finished form dispensed, including the name and address of the person to whom it was dispensed, the date of dispensing, the number of units or volume dispensed, and the written or typewritten name or initials of the individual who dispensed or administered the substance on behalf of the dispenser.''

I note at the outset that a review of the Government's charge in the OSC and in their Prehearing Statements presents a problem. Upon a careful review of the language of § 1304.22(c), it becomes apparent to me that this section has no requirement that the pharmacy must indicate a date of receipt of controlled substances. Section 1304.22(c) relates to ''Records for dispensers and researchers'' and requires certain records be maintained, both those provided in § 1304.22(c) and those required under § 1304.22(a)(2)(i), (ii), (iv), (vii), and (ix). None of these subsections indicate any requirement to maintain a date of receipt.

I find that the Government's subject allegation does not cite to a regulation which proscribes the conduct alleged. Substituting a different regulation post-hearing would create daunting notice and due process issues. To allow the Government to do so would create an improper burden-shifting beyond those recognized by the APA and the fundamental tenets of notice and due process. *See Farmacia Yani,* 80 FR 29,053, 29,059–60 (2015). One of the fundamental tenets of Due Process is that an Agency must provide a Respondent with notice of those acts which the Agency intends to rely on in seeking the revocation of its registration so as to provide a full and fair opportunity to challenge the factual and legal basis for the Agency's action. *See NLRB* v. *I.W.G., Inc.,* 144 F.3d 685, 688–89 (10th Cir. 1998); *Pergament United Sales, Inc.* v. *NLRB,* 920 F.2d 130, 134 (2d Cir. 1990). Because the Government apparently did not allege in the Order to Show Cause or in its Prehearing Statements the applicable citation to the law on which it bases its allegation, before proceeding to address whether the evidence supports the Government's factual contention, it is necessary determine whether the Government otherwise provided adequate notice of its intent to litigate the issue. *See* 5 U.S.C. 554(b) (''Persons entitled to notice of an agency hearing shall be timely informed of . . . the matters of fact and law asserted.''). ''The primary function of notice is to afford [a] respondent an opportunity to prepare a defense by investigating the basis of the

[*BBB] ''What is a CSOS Certificate? A CSOS Certificate is a digital identity issued by the DEA's CSOS Certification Authority (CSOS CA) that allows for electronic ordering for Schedule I and II (as well as III–V) controlled substances. A CSOS Certificate is the digital equivalent of the identification information contained on a DEA Form-222. CSOS Certificates are issued to *individuals* and are required for electronic ordering of Schedule I and II controlled substances.''

[*CCC] The Recommended Decision stated that ''it is more believable than not, from this record, that Ms. Mincy was given access to Mr. Sprys' digital certificate and private key. Despite her contractor status, she ran the pharmacy Monday through Thursday. She used Mr. Sprys' credentials to log onto the CSOS system in the presence of DI1, before she had her own credentials.'' Although I agree with the ALJ's credibility findings generally, I believe that the Government could have easily produced evidence to support this claim, and I decline to find a violation.

complaint and fashioning an explanation that refutes the charge of unlawful behavior.'' *Pergament United Sales,* 920 F.2d at 135 (citation omitted). While the issue of whether an allegation ''has been fully and fairly litigated [by consent] is so peculiarly fact-bound as to make every case unique,'' *id.* at 136, ''the simple presentation of evidence important to an alternative [allegation] does not satisfy the requirement'' that a respondent be afforded with a full and fair opportunity to litigate the alternative allegation. *I.W.G.,* 144 F.3d at 688 (quoting *NLRB* v. *Quality C.A.T.V., Inc.,* 824 F.2d 542, 547 (7th Cir. 1987) (citation omitted)).

From the outset, the Government has consistently cited to § 1304.22(c) as the basis of this charge for Pharmacy 4 Less failing to record the date of receipt on 85 invoices. However, as discussed, § 1304.22(c) does not contain any such requirement. In this proceeding, it is not the responsibility of the Respondent, this Tribunal, or the Administrator to substitute a different regulation than charged to fit the evidence the Government has presented.[62] The Government has been given multiple opportunities to amend its pleadings, but it has not done so.

[Moreover, the record does not support a finding that the issue was litigated by consent.] To further confuse the matter, the Respondent conducted voir dire of DI1 as to GX 26. The Respondent questioned whether the federal regulations require that invoices had to be signed and dated by the person receiving the controlled substances shipment. Tr. 141. DI1 stated that while he could not accurately quote the regulations off the top of his head, he had a general understanding that the regulations required these things. *Id.* at 140–41. The Respondent then argued that if the Government were offering GX 26 to prove a violation of § 1305, the exhibit should not be admitted because § 1305 only requires a signature and date by the receiver for Schedule 2 controlled substances.[63] *Id.* at 142. The Government responded that it offered the entire exhibit into evidence for all controlled substances, but stated that it may have cited an improper section and would limit their ability to prove that charge. *Id.* at 142–43. The Respondent argued that the Government cited to § 1305.22 throughout the Order to Show Cause, the Government's Prehearing Statement, and the Government's Supplemental Prehearing Statement, and that they had been given notice of their citation mistake by the Tribunal during the prehearing conference. *Id.* at 143. The Government said that it may have intended to limit itself to strictly Schedule 1 and 2 controlled substances, but that it could not cite that at that moment. Tr. 144. [Here, although Respondent pharmacy clearly believed that the § 1304.22 citation in the OSC was incorrect, they proceeded with the litigation believing that the Government had intended to cite § 1305.22(g).[*DDD] [64] 21 CFR 1305.22 deals strictly with electronic (as opposed to paper) orders for Schedules I and II controlled substances (as opposed to Scheduled III–V), so it also does not provide a legal basis for the allegation that Respondent violated the law by failing to record a receipt date on its paper invoices. I suspect the Government intended to charge Respondent with a violation of § 1304.21,[*EEE] but I will not consider it based on lack of notice.]

While the Government has presented a sufficient amount of evidence towards their allegation that Pharmacy 4 Less possessed invoices without the date of receipt (as the Government claims the cited regulation requires), the Respondent has consistently objected to the Government's legal basis for its allegation [and there has been no notice of a proper legal basis.] Therefore, I find that the Government cannot sustain their burden in their allegation under § 1304.22(c) as charged. [Therefore, it is not necessary to review the evidence and testimony in support of this allegation, and I have omitted it accordingly.]

Inaccurate Inventory

The Government has charged that Pharmacy 4 Less maintained an inaccurate inventory [*FFF] in violation of 21 CFR 1304.22(c). Section 1304.22(c) again provides, in part, that ''[e]ach person registered or authorized to dispense or conduct research with controlled substances shall maintain records with the same information required of manufacturers pursuant to paragraph (a)(2)(i), (ii), (iv), (vii), and (ix) of this section.[[*GGG]] In addition, records shall be maintained of the number of units or volume of such finished form dispensed, including the name and address of the person to whom it was dispensed, the date of dispensing, the number of units or volume dispensed, and the written or typewritten name or initials of the individual who dispensed or administered the substance on behalf of the dispenser.''

The Government included this new charge, after the issuance of the Order to Show Cause, in its Prehearing Statement. The Government's Supplemental Prehearing Statement states that ''DI1 will testify that he conducted an audit of Pharmacy 4 Less's inventory, and found that it was inaccurate, a violation of 21 CFR 1304.22(c). The way that the audit was performed depended on the controlled substance involved. For Schedule II Controlled Substances, Pharmacy 4 Less maintained a handwritten perpetual inventory which was used to audit the controlled substances with a start date

[62] ''[I]t is the Government's obligation as part of its burden of proof and not the ALJ's responsibility to sift through the records and highlight that information which is probative of the issues in the proceeding.'' *Top RX Pharmacy,* 78 FR 26,069, 26070 n.7 (2013) (quoting *Gregg & Son Distribs.,* 74 FR 17,517–18 n.1 (2009)); *James William Eisenberg, M.D.,* 77 FR 45,663, 45,674 n.47 (2012).

[63] Upon review of the OSC and the Government's Prehearing Statements, I believe that the Respondent misstated § 1305 as the basis for this charge and questioned DI1 on the basis of a regulation not charged. The Government charged a failure to indicate a date of receipt under § 1304.22.

[*DDD] [This text was relocated for clarity.] When I later asked about § 1305.22, DI1 was provided a copy of the Code of Federal Regulations to determine if it was the section that requires a person receiving a shipment of controlled substances must initial and date. Tr. 163. While looking at the regulations, DI1 indicated that it was not § 1305.22. Tr. 163–64. He stated that § 1305.22 refers to the procedure for filling electronic orders, which refers to CSOS. Tr. 164–65. After looking through the regulations, he indicated that he didn't know the actual regulation, but that § 1305.22 was not what he was talking about. Tr. 165.

[64] The following morning on the second day of the hearing, before the start of testimony, I inquired with the Government as to whether they still intended to include all scheduled controlled substances or limit the evidence to only those invoices including Schedules 1 and 2 controlled substances. The Government indicated that they wanted to proceed with all scheduled controlled substances. The Respondent objected and again raised his argument that § 1305 only provides requirements for Schedules 1 and 2 controlled substances. However, upon a review of the hearing transcripts, I have found that these conversations were not recorded and transcribed. This recitation of the discussion is from my memory, but should be provided in the context of the analysis as to any ultimate due process concerns.

[*EEE] At one point, DI identified and read 21 CFR 1304.21(d) into the record, but agreed that section did not require the recording of the date of receipt (and he did not identify 1304.21(a) which does require pharmacies to keep records regarding the date of receipt of controlled substances). Tr. 164. Ultimately DI's testimony was that he did not know which regulation required pharmacies to document the date controlled substances were received. Tr. 165.

[*FFF] The Government's reference to an ''inaccurate inventory'' in this section does not seem to refer to any specific inventory document such as the initial inventory, biennial inventory, or even the perpetual inventory. Rather, the Government seems to be using the phrase generally to state that the Pharmacy's records and the quantity of controlled substances on hand at the pharmacy did not align.

[*GGG] These required records include, amongst other things, the name, quantity, and strength of controlled substances and the number of units that are acquired to inventory or distributed or disposed. *Id.*

of January 1, 2017. For other controlled substances, the start of business was used. Among other inaccuracies, DI1's audit found that Pharmacy 4 Less had a shortfall of 731 tablets of oxycodone 30 mg, a shortfall of 526 tablets of carisoprodol 350 mg, and a surplus of 1,488 tablets of methadone HCL 10 mg. DI1 will authenticate his computation chart. DI1 will also authenticate the handwritten oxycodone and methadone perpetual inventories that were used to conduct the oxycodone and methadone audits.'' Government's Supplemental Prehearing Statement, at 4–5.

During the Prehearing Conference, I inquired with the Government as to the addition of this new allegation and whether they intended this to act as a new charge. The Government said that it did intend it as a new charge. The Respondent objected and argued that it should not be required to answer to charges not listed in the Order to Show Cause. I informed the Respondent as to the Agency's liberal notice requirements and provided them with the opportunity to address any new allegations in a Supplemental Prehearing Statement provided the Government amended or added to its new allegation. I find the Government provided sufficient notice to satisfy due process as to this supplemental charge.

In the Respondent's Amended Supplemental Prehearing Statement, the Respondent not only offered a proposed stipulation that their inventory was correct, but also indicated that Ms. Mincy's proposed testimony would include testimony that Pharmacy 4 Less's inventory was accurate. As it will be discussed, Respondent both cross-examined DI1 on his audit of Pharmacy 4 Less's inventory, as well as provided testimony from Ms. Mincy about the pharmacy's inventory.

The Government presented evidence from DI1 about the audit he conducted of Pharmacy 4 Less's perpetual inventories in order to find if their inventories were accurate. As previously noted, DI1 did not use either an initial inventory or biennial inventory as the starting point for the audit.*[HHH] DI1 created a computation chart of the controlled substances in order to conduct an audit of the pharmacy's inventories. GX 4.

DI1 indicated January 1, 2017, as the starting point for the audit. Tr. 55. This date was selected because it was the date in which the pharmacy had used in its handwritten Schedule 2 controlled substance inventories. Tr. 56; GX 31, 32. These include the perpetual inventory form for Methadone 10 mg tablets (GX 31) and Oxycodone 30 mg tablets (GX 32). *Id.* at 57. He testified that he used the pharmacy's inventories and made sure that the inventories received or filled prior to January 1, 2017 were correct to use as a starting point. *Id.* at 61–62. Then he would take records from the pharmacy for the period of the audit and correlate those with invoices and any other records showing when the pharmacy had received additional controlled substances. *Id.* at 62. Once those numbers were verified, DI1 then looked at what the pharmacy had on hand according to their records, took all the received controlled substances within that timeframe, and then added those numbers together to find a total accountable number. *Id.* at 63.

DI1 then determined how many controlled substances Pharmacy 4 Less actually had on site during the June 6, 2017 on-site inspection. *Id.* This was done by hand counting the tablets located on hand in the pharmacy at the time of the inspection. *Id.* He also determined the number of sales for each controlled substance during the audit period by looking at documentation provided to him by Ms. Mincy. *Id.* at 63–64. DI1 then added up the total number of the inventory that had been counted in the store on June 6 and the sales that had been accounted for by the records to determine the total amount of tablets accounted for. *Id.* at 65. DI1 then compared the ''total accountable for'' number and the ''total accounted for'' number to determine if there was a shortfall or surplus, indicated as the ''total difference.'' *Id.* The same process was completed for Schedules 3 through 5 controlled substances, but the starting number at the beginning of business was zero because the pharmacy had no controlled substances on hand when they started as a pharmacy. *Id.* at 66.

As previously noted, the Respondent conducted a cross-examination as to the computation chart revealing some formatting errors. This Tribunal allowed the Government to substitute a more legible copy of it. Tr. 919–26. A check of the mathematics done within GX 4 demonstrate that the mathematics have been done correctly and demonstrate discrepancies between the pharmacy's records as used by DI1 and the amount that DI1 accounted for during his count at the pharmacy during his on-site inspection.

The Respondent presented testimony from Ms. Mincy about the pharmacy's inventories. Ms. Mincy confirmed that DI1 had asked to see the pharmacy's biennial and perpetual inventories,*[III] along with DI1 and DI2 conducting a pill count during the June 6, 2017 on-site inspection.*[JJJ]

Based on the testimony and evidence presented by the parties, I find the audit conducted by DI1 to be consistent with his portrayal of events during the June 6, 2017 on-site inspection and that it credibly shows discrepancies between the records maintained by the pharmacy and the actual count of tablets as determined by DI1. For example, DI1's calculations determined that Pharmacy 4 Less has 1,488 more tablets of Methadone HCL 10 mg on hand than was provided for in their records. This large of a disparity between the amount counted and the records show that it cannot be the result of miscounting the tablets on hand at the pharmacy during the on-site inspection.

While Ms. Mincy may have testified to her role at the pharmacy in maintaining the supplies and inventories, I find, in light of my previous reliability analysis of Ms. Mincy, that her explanations regarding inventory procedure and practice do not overcome the Government's evidence showing the pharmacy inventories were inaccurate. The failure of the pharmacy to maintain an initial inventory and failure to maintain an accurate biennial inventory, along with the great potential for error that a handwritten perpetual inventory provides, also lend weight to the Government's allegation that Pharmacy 4 Less maintained inaccurate inventories.

*[The Government has demonstrated that Respondent's on-hand inventory had overages and shortages when compared to Respondent's records at the time of the inspection. The Agency has found that such overages and shortages create a risk for diversion. It is clear that

*[HHH] Respondent argued during the hearing that there is no requirement to maintain a perpetual inventory and that the perpetual inventory was thus an improper document upon which to base the audit. Tr. 18, 58, 630–31, 925. I agree that Respondent was not required to create a perpetual inventory. However, what matters here is that Respondent could not account for a significant number of controlled substances by adequate documentation. *See Ideal Pharmacy Care, Inc., d/b/a Esplanade Pharmacy,* 76 FR 51,415, 51,416 (2011). These significant variances were present both where the perpetual inventory was used in the audit and where it was not. Notably, Respondent Pharmacy made no attempt to rebut the government's *prima facie* case demonstrating inaccurate recordkeeping aside from bald assertions that its on-hand inventory was accurate.

*[III] Ms. Mincy testified that the perpetual inventory was a handwritten document. Tr. 631. As for its purpose, she stated ''[e]very time we fill a prescription we like to note it so that we can keep up with our inventory on hand, to make sure that we are keeping enough drugs in stock like for the next day, you know, we [do not] want to run out.'' *Id.*

*[JJJ] Omitted information regarding the biennial inventory for brevity and inserted information regarding the perpetual inventory.

there were unexplained discrepancies between Respondent's records and the amount of inventory on hand. Such discrepancies provide substantial evidence that Respondent has violated 21 CFR 1304.22(c). See *e.g., Ester Mark, M.D.,* 56 FR 16,760, 16,774 (2021); *Wayne Pharmacy,* 85 FR 63,579, 63,582 (2020).]

Government's Burden of Proof and Establishment of a Prima Facie Case

Based upon my review of each of the allegations by the Government, it is necessary to determine if it has met its *prima facie* burden of proving the requirements for a sanction pursuant to 21 U.S.C. 824(a). At the outset, I find that the Government has demonstrated and met its burden of proof in support of revocation through its case that the Respondent has failed to resolve red flags of diversion and document the resolution of red flags of diversion. Further, the Government has additionally demonstrated, that Pharmacy 4 Less has violated certain recordkeeping requirements of the Code of Federal Regulations. Inasmuch as the Government has established by a preponderance of the evidence that the Respondent *[acted outside of the usual course of professional practice and beneath the applicable standard of care in the state of Florida, and] violated federal laws relating to controlled substances on numerous occasions,*KKK it has met its *prima facie* burden of proving that the requirements for a sanction pursuant to 21 U.S.C. 824(a) are satisfied.

Public Interest Determination: The Standard

Pursuant to 21 U.S.C. 823(f) (2006 & Supp. III 2010), the Administrator[65] may revoke a DEA Certificate of Registration if persuaded that the maintaining such registration would be inconsistent with the public interest. Evaluation of the following factors have been mandated by Congress in determining whether maintaining such registration would be inconsistent with the ''the public interest'':

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The [registrant's] experience in dispensing, or conducting research with respect to controlled substances.

(3) The [registrant's] conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.

21 U.S.C. 823(f).

''These factors are . . . considered in the disjunctive.'' *Robert A. Leslie, M.D.,* 68 FR 15,227, 15,230 (2003). Any one or a combination of factors may be relied upon, and when exercising authority as an impartial adjudicator, the Agency may properly give each factor whatever weight it deems appropriate in determining whether a registrant's registration should be revoked. *Id.* (citation omitted); *David H. Gillis, M.D.,* 58 FR 37,507, 37,508 (1993); *see also Morall* v. *DEA,* 412 F.3d 165, 173–74 (D.C. Cir. 2005); *Henry J. Schwarz, Jr., M.D.,* 54 FR 16,422, 16,424 (1989). Moreover, the Agency is ''not required to make findings as to all of the factors,'' *Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005); *see also Morall,* 412 F.3d at 173, and is not required to discuss consideration of each factor in equal detail, or even every factor in any given level of detail. *Trawick* v. *DEA,* 861 F.2d 72, 76 (4th Cir. 1988) (holding that the Administrator's obligation to explain the decision rationale may be satisfied even if only minimal consideration is given to the relevant factors, and that remand is required only when it is unclear whether the relevant factors were considered at all). The balancing of the public interest factors ''is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest . . . .'' *Jayam Krishna-Iyer, M.D.,* 74 FR 459, 462 (2009).

Factors 2 and 4: Experience in Dispensing, and Compliance With Applicable State, Federal, or Local Laws Relating to Controlled Substances

The Government's case invoking the public interest factors of 21 U.S.C. 823(f) seeks the revocation of the Respondent's COR based primarily on conduct most aptly considered under Public Interest Factors 2 and 4.[66] *LLL [67] [68] [69]

*[Factors Two and Four are often analyzed together. *See, e.g., Fred Samimi, M.D.,* 79 FR 18,698, 18,709 (2014); *John V. Scalera, M.D.,* 78 FR 12,092, 12,098 (2013). Under Factor Two, the DEA analyzes a registrant's ''experience in dispensing . . . controlled substances.'' 21 U.S.C. 823(f)(2). Factor Two analysis focuses on an applicant's acts that are inconsistent with the public interest, rather than on an applicant's neutral or positive acts and experience.*MMM *Randall L. Wolff, M.D.,* 77 FR 5106, 5121 n.25 (2012) (explaining that ''every registrant can undoubtedly point to an extensive body of legitimate prescribing over the course of [the registrant's] professional career'') (quoting *Jayam Krishna-Iyer, M.D.,* 74 FR 459, 463 (2009)). Similarly, under Factor Four, the DEA analyzes an applicant's compliance with federal and state controlled substance laws. 21 U.S.C. 823(f)(4). Factor Four analysis focuses on violations of state and federal laws and regulations. *Volkman* v. *DEA,* 567 F.3d 215, 223–24 (6th Cir. 2009) (citing *Gonzales* v. *Oregon,* 546 U.S. 243, 272, 274 (2006)); *see Joseph Gaudio, M.D.,* 74 FR 10,083, 10,090–91 (2009).]

Here, Pharmacy 4 Less provided evidence of its compliance with state and federal law through the introduction of two Florida Department of Health Inspection reports.[70] RX 14, 15. One of the reports, dated February 28, 2017, occurred before the June 6, 2017 on-site inspection by the DEA. RX 15. The report appears to show that Pharmacy 4 Less was in compliance with all applicable portions of the state inspector's report, which not only cites to Florida administrative regulations, but also to federal regulations. While the thoroughness and thus full significance of the Florida state inspections cannot be gleaned from the inspection reports, and the Florida inspector cannot be held to determine compliance with federal regulations in the same manner as DEA DIs, it is sufficient evidence to show that the Florida inspector not only determined at least some sufficient maintenance of required standards under federal regulations, but particularly with Florida administrative regulations under Florida state law. This gives indication that Pharmacy 4 Less was in compliance with, at a minimum,

*KKK Omitted text for clarity.

[65] This authority has been delegated pursuant to 28 CFR§ 0.100(b) and 0.104 (2008).

[66] 21 U.S.C. 823(f)(2), (4). There is nothing in the record to suggest that a state licensing board made any recommendation regarding the disposition of the Respondent's DEA COR (Factor 1). Likewise, the record contains no evidence that the Respondent has been convicted of (or charged with) a crime related to controlled substances (Factor 3).

*LLL For brevity and keeping with recent cases, I have removed the legal standard used originally by the ALJ throughout this section to analyze Factors 2 and 4 and have replaced it with this text.

[67] *[Omitted text where footnote was included.]

[68] *[Omitted text where footnote was included.]

[69] *[Omitted text where footnote was included.]

*MMM As it is not relevant, I have removed the ALJ's analysis regarding the history of Pharmacy 4 Less and its impact on the local community which, according to the ALJ, was based on very little evidence in the record.

[70] *[Omitted text where footnote was included.]

applicable Florida state law (based on the requirements by the State of Florida Department of Health Investigative Services) before the DEA's on-site inspection.

Further, Pharmacy 4 Less also introduced a second state report dated September 5, 2017, which occurred after the DEA's on-site inspection. RX 14. The report has a few discrepancies when compared to RX 15. The second report does not appear to be completely filled out, particularly at the end of the second page. Further, it does not have a signature page as that provided for in RX 15. However, when comparing both documents, it is clear that RX 14 was completed by a computer or some sort of electronic device, while RX 15 was completed by hand. This second report also demonstrates, in the same manner as RX 15, that the Florida inspector not only found Pharmacy 4 Less to be compliant with some federal regulations, but particularly with sections of Florida administrative regulations.

Both of these reports weigh in favor of Pharmacy 4 Less as evidence of their compliance with federal and state law, as determined by inspectors from the Florida Department of Health Investigative Services. [However, the reports are not dispositive of the issues in this case, in particular the resolution of red flags, and the specific allegations in this case must still be addressed.]

Standard of Care as to Charged Violations *NNN

A physician's standard of care for prescribing is guided by federal and state law. ''A prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice.'' 21 CFR 1306.06. [According to the CSA's implementing regulations, a lawful controlled substance order or prescription is one that is ''issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.'' 21 CFR 1306.04(a). While the ''responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, . . . a corresponding responsibility rests with the pharmacist who fills the prescription.'' *Id.* The regulations establish the parameters of the pharmacy's corresponding responsibility.

An order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription within the meaning and intent of . . . 21 U.S.C. 829 . . . and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

Id. ''The language in 21 CFR 1306.04 and caselaw could not be more explicit. A pharmacist has his own responsibility to ensure that controlled substances are not dispensed for non-medical reasons.'' *Ralph J. Bertolino, d/b/a Ralph J. Bertolino Pharmacy,* 55 FR 4729, 4730 (1990) (citing United *States* v. *Hayes,* 595 F.2d 258 (5th Cir. 1979), *cert. denied,* 444 U.S. 866 (1979); *United States* v. *Henry,* 727 F.2d 1373 (5th Cir. 1984) (reversed on other grounds)). As the Supreme Court explained in the context of the CSA's requirement that schedule II controlled substances may be dispensed only by written prescription, ''the prescription requirement . . . ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse . . . [and] also bars doctors from peddling to patients who crave the drugs for those prohibited uses.'' *Gonzales* v. *Oregon,* 546 U.S. 243, 274 (2006).

To prove a pharmacist violated her corresponding responsibility, the Government must show that the pharmacist acted with the requisite degree of scienter. *See* 21 CFR 1306.04(a) (''[T]he person *knowingly* filling [a prescription issued not in the usual course of professional treatment] . . . shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.'') (emphasis added). DEA has also consistently interpreted the corresponding responsibility regulation such that ''[w]hen prescriptions are clearly not issued for legitimate medical purposes, a pharmacist may not intentionally close his eyes and thereby avoid [actual] knowledge of the real purpose of the prescription.'' *Bertolino,* 55 FR at 4730 (citations omitted); *see also JM Pharmacy Group, Inc. d/b/a Pharmacia Nueva and Best Pharmacy Corp.,* 80 FR 28667, 28670–72 (2015) (applying the standard of willful blindness in assessing whether a pharmacist acted with the requisite scienter). Pursuant to their corresponding responsibility, pharmacists must exercise ''common sense and professional judgment'' when filling a prescription issued by a physician. *Bertolino,* 55 FR at 4730. When a pharmacist's suspicions are aroused by a red flag, the pharmacist must question the prescription and, if unable to resolve the red flag, refuse to fill the prescription. *Id.; Medicine Shoppe-Jonesborough,* 300 F. App'x 409, 412 (6th Cir. 2008) (''When pharmacists' suspicions are aroused as reasonable professionals, they must at least verify the prescription's propriety, and if not satisfied by the answer they must refuse to dispense.'').

Finally, ''[t]he corresponding responsibility to ensure the dispensing of valid prescriptions extends to the pharmacy itself.'' *Holiday CVS,* 77 FR at 62341 (citing *Med. Shoppe—Jonesborough,* 73 FR at 384; *United Prescription Servs., Inc.,* 72 FR 50397, 50407–08 (2007); *EZRX, L.L.C.,* 69 FR 63178, 63181 (2004); *Role of Authorized Agents in Communicating Controlled Substance Prescriptions to Pharmacies,* 75 FR 61613, 61617 (2010); *Issuance of Multiple Prescriptions for Schedule II Controlled Substances,* 72 FR 64921, 64924 (2007) (other citations omitted)). The DEA has consistently held that the registration of a pharmacy may be revoked as the result of the unlawful activity of the pharmacy's owners, majority shareholders, officers, managing pharmacist, or other key employee. *EZRX, L.L.C.,* 69 FR at 63181; *Plaza Pharmacy,* 53 FR 36910, 36911 (1988). Similarly, ''[k]nowledge obtained by the pharmacists and other employees acting within the scope of their employment may be imputed to the pharmacy itself.'' *Holiday CVS,* 77 FR at 62341.

In this matter, the Government did not allege that Respondent dispensed the subject prescriptions having actual knowledge that the prescriptions lacked a legitimate medical purpose. Instead, the Government alleged that Respondent violated the corresponding responsibility regulation for each of the patients at issue in this matter by filling prescriptions ''in the face of [numerous] red flags for which there [was] no evidence that they were ever resolved.'' Govt Prehearing, at 8, and 9–14. Agency decisions have consistently found that prescriptions with the same red flags at issue here were so suspicious as to support a finding that the pharmacists who filled them violated the Agency's corresponding responsibility rule due to actual knowledge of, or willful blindness to, the prescriptions' illegitimacy. 21 CFR 1306.04(a); *see, e.g., Pharmacy Doctors Enterprises d/b/a Zion Clinic Pharmacy,* 83 FR 10876, 10898, *pet. for rev. denied,* 789 F. App'x 724 (11th Cir. 2019) (long distances; pattern prescribing; customers with the same street address presenting the same prescriptions on the same day; drug cocktails; cash payments; early refills); *Hills Pharmacy,* 81 FR 49816, 49836–39

*NNN The added text in this section clarifies the analysis of a pharmacist's corresponding responsibility under 21 CFR 1306.04(a).

(2016) (multiple customers presenting prescriptions written by the same prescriber for the same drugs in the same quantities; customers with the same last name and street address presenting similar prescriptions on the same day; long distances; drug cocktails); *The Medicine Shoppe,* 79 FR 59504, 59507, 59512–13 (2014) (unusually large quantity of a controlled substance; pattern prescribing; irregular dosing instructions; drug cocktails); *Holiday CVS,* 77 FR 62316, 62317–22 (2012) (long distances; multiple customers presenting prescriptions written by the same prescriber for the same drugs in the same quantities; customers with the same last name and street address presenting virtually the same prescriptions within a short time span; payment by cash); *East Main Street Pharmacy,* 75 FR 66149, 66163–65 (2010) (long distances; lack of individualized therapy or dosing; drug cocktails; early fills/refills; other pharmacies' refusals to fill the prescriptions). Here, the Government established the presence of red flags on the prescriptions that Respondent Pharmacy filled.]

Further, under Florida law, [which is supportive of the applicable standard of care in Florida,] a pharmacist is required to conduct a prospective drug use review before filling or refilling any prescription for controlled substances. Fla. Admin. Code r. 64B16–27.810. Florida also requires that pharmacists question prescriptions that may not be valid and only fill the prescriptions if the pharmacist is able to validate the prescription. Fla. Admin. Code r. 64B16–27.831.*OOO

This leads me to the conclusion that Pharmacy 4 Less *PPP has operated outside the usual course of professional practice (in violation of 21 CFR 1306.06) and in violation of its corresponding responsibility (in violation of 21 CFR 1306.04(a)). Further, as the Florida laws and regulations provide for the standards of practice for pharmacists and pharmacies, including requiring certain standards of review and documentation, I find that the charged regulations bear a substantial relationship to the CSA's purposes of drug abuse and diversion. As such, I find that Pharmacy 4 Less has failed to meet the standard of care as provided for under Florida law and regulations [and as I have found above].

In light of the record as to this factor, I find that the favorable evidence introduced through the Respondent is overwhelmed by the evidence introduced through the Government that the Respondent has failed to comply with federal *[omitted] law [and has violated its corresponding responsibility]. Therefore, I find [factors 2 and 4] significantly favor revoking the Respondent's registration.

Due Process Right of the Respondent

*[Omitted.] The Government asserts in its Posthearing Brief that Pharmacy 4 Less has been ''disingenuous'' during the course of this matter and should be penalized for its decision to file a motion to suppress, and to withhold subpoenaed records from the Government when it asserted HIPAA privacy issues and was preparing to contest the DEA's administrative subpoena in United States District Court. Govt Posthearing, at 44. *[Omitted. The ALJ found] that the Respondent's decision to contest the DEA's administrative subpoena should not be held against the Respondent as either an adverse inference or as an independent violation. [I decline to make any findings regarding the Government's argument and have omitted the analysis accordingly.]

Acceptance of Responsibility

The Government's *prima facie* burden having been met, the Respondent must present sufficient mitigating evidence to assure the Administrator that he can be entrusted with the responsibility incumbent with such registration. *Medicine Shoppe-Jonesborough,* 73 FR 364, 387 (2008), *Samuel S. Jackson,* 72 FR 23,848, 23,853 (2007).*QQQ This feature of the Agency's interpretation of its statutory mandate on the exercise of its discretionary function under the CSA has been sustained on review. *MacKay,* 664 F.3d at 822. As, past performance is the best predictor of future performance, DEA has repeatedly held that where an applicant has committed acts inconsistent with the public interest, the applicant must accept responsibility for his actions and demonstrate that he will not engage in future misconduct. *ALRA Labs, Inc.* v. *DEA,* 54 F.3d 450, 452 (7th Cir.1995); *Medicine Shoppe,* 73 FR 387; *see also Hoxie,* 419 F.3d at 483 (''admitting fault'' is ''properly consider[ed]'' by DEA to be an ''important factor[ ]'' in the public interest determination). So too, in making the public interest determination, ''this Agency places great weight on an [applicant's] candor, both during an investigation and in [a] subsequent proceeding.'' *Robert F. Hunt,* 75 FR 49,995, 50,004 (2010); *Hoxie,* 419 F.3d at 483.

While an applicant must accept responsibility and demonstrate that he will not engage in future misconduct in order to establish that his/her continued registration is consistent with the public interest, DEA has repeatedly held these are not the only factors that are relevant in determining the appropriate sanction. *See, e.g., Joseph Gaudio,* 74 FR 10,083, 10,094 (2009); *Southwood Pharmaceuticals, Inc.,* 72 FR 36,487, 36,504 (2007). The egregiousness and extent of an applicant's misconduct are significant factors in determining the appropriate sanction. *See Jacobo Dreszer,* 76 FR 19,386, 19,387–88 (2011) (explaining that a respondent can ''argue that even though the Government has made out a prima facie case, his conduct was not so egregious as to warrant revocation''); *Paul H. Volkman,* 73 FR 30,630, 30,644 (2008); *see also Gregory D. Owens,* 74 FR 36,751, 36,757 n.22 (2009). [Likewise, DEA considers its interest in deterring future misconduct by both the registrant as well as other registrants. *Ruben,* 78 FR at 38,364.] *RRR

The Respondent argued during the hearing that it had accepted responsibility by virtue of its submission of a corrective action plan (which the DEA rejected), modification of its behavior, a reduction in the number of patients they see and for whom it fills prescriptions, as well as the implementation of a number of other remedial changes. Tr. 30. However, no one from Pharmacy for Less has admitted any wrongdoing regarding the vast majority of infractions I found.

I find that Ms. Mincy, the only fact witness for the Respondent, did not accept responsibility for either her actions or on behalf of Pharmacy 4 Less. Additionally, I find that Ms. Mincy was sometimes a less than reliable witness. Although correcting violative behavior and practices is very important to establish acceptance of responsibility, conceding wrongdoing is critical to reestablishing trust with the Agency. *Holiday CVS, L.L.C.,* 77 FR 62,316, 62,346 (2012), *Daniel A. Glick, D.D.S.,* 80 FR 74,800, 74,801 (2015). As such, I find that Pharmacy 4 Less has failed to unequivocally accept any responsibility in this matter.[71]

*OOO Omitted, for brevity, text regarding the legal standard requiring a nexus between the state law that has been violated and the CSA's purpose of preventing drug abuse and diversion. I find that, here, Florida law was used to support determination of the standard of care, but that the Government did not allege independent violations of state law.

*PPP Omitted finding of a violation of Florida law.

*QQQ This sentence was relocated and replaced existing text for clarity and brevity.

*RRR Inserted text for completeness.

[71] During this proceeding, this Tribunal conditionally admitted RX 18–37 as potentially

Loss of Trust

Where the Government has sustained its burden and established that a registrant has committed acts inconsistent with the public interest, that registrant must present sufficient mitigating evidence to assure the Administrator that he can be entrusted with the responsibility commensurate with such a registration. *Medicine Shoppe-Jonesborough,* 73 FR 364, 387 (2008). Here, Pharmacy 4 Less has failed to establish that it can be entrusted with maintaining its registration.*SSS

[The CSA authorizes the Attorney General to ''promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under this subchapter.'' 21 U.S.C. 871(b). In efficiently executing the revocation and suspension authority delegated to me under the CSA for the aforementioned purposes, I review the evidence and argument Respondents submitted to determine whether or not they have presented ''sufficient mitigating evidence to assure the Administrator that [they] can be trusted with the responsibility carried by such a registration.'' *Samuel S. Jackson, D.D.S.,* 72 FR 23,848, 23,853 (2007) (quoting *Leo R. Miller, M.D.,* 53 FR 21,931, 21,932 (1988)). The issue of trust is necessarily a fact-dependent determination based on the circumstances presented by the individual respondent; therefore, the Agency looks at factors, such as the acceptance of responsibility and the credibility of that acceptance as it relates to the probability of repeat violations or behavior and the nature of the misconduct that forms the basis for sanction, while also considering the Agency's interest in deterring similar acts. *See Arvinder Singh, M.D.,* 81 FR 8247, 8248 (2016).

Regarding all of these matters, there is nothing in the record establishing that Respondent Pharmacy has accepted responsibility for its actions.] The Respondent's only fact witness, Ms. Mincy, conveyed that she was resentful at the Agency's intervention at the pharmacy. She seemed to maintain a confrontational attitude with DI1, suggesting he was harassing the Respondent and that he was lying during testimony. [The closest Respondent came to accepting responsibility was in its Exceptions, in which Respondent ''admit[ted] that [it was] filling too many c2 [Schedule II] prescriptions in the past.'' Resp Exceptions, at ¶ 5. Even if this admission were part of the evidentiary record, the entirety of the record lacks the unequivocal acceptance of responsibility necessary to establish Respondent' trustworthiness with a registration.

The egregiousness of Respondent Pharmacy's conduct and the interests of specific and general deterrence support a sanction of revocation. RD, at 99. Respondent Pharmacy filled many prescriptions over multiple years for these patients without resolving numerous red flags. There is nothing in the record that lends support to the proposition that Respondent Pharmacy's future behavior will deviate in any positive respect from its past behavior. Due to the fact that Respondent Pharmacy has accepted no responsibility nor offered any remedial measures,*TTT it has given me no reassurance that I can entrust it with a registration and no evidence that it will not repeat its egregious behavior.

Regarding general deterrence, the Agency bears the responsibility to deter similar misconduct on the part of others for the protection of the public at large. *David A. Ruben,* 78 FR at 38,385. Based on the number and egregiousness of the established violations in this case, a sanction less than revocation would send a message to the regulated community that compliance with the law is not a condition precedent to maintaining registration.

A balancing of the statutory public interest factors, coupled with consideration of Respondent Pharmacy's failure to accept responsibility, the absence of any evidence of remedial measures to guard against recurrence, and the Agency's interest in deterrence, support the conclusion that Respondent Pharmacy should not continue to be entrusted with a registration.]

As such, I find from the course of these proceedings that Pharmacy 4 Less has lost a significant amount of trust and has failed to prove to the Agency that it can be entrusted to maintain its COR in lawful fashion.

Recommendation

Considering the entire record before me, the conduct of the hearing, and observation of the testimony of the witnesses presented, I find that the Government has met its burden of proof and has established a *prima facie* case for revocation. Further, I find that the Respondent has not accepted responsibility, or presented sufficient evidence demonstrating that the Agency can entrust it to maintain its COR.

Therefore, I recommend the Respondent's DEA COR FP5459082 should be *revoked* and any pending applications for renewal or modification of such registration be *denied*.

Signed: May 22, 2019.

Mark M. Dowd,

U.S. Administrative Law Judge.

[FR Doc. 2021–21429 Filed 9–30–21; 8:45 am]

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related to remedial measures taken by the Respondent. *See* Tr. 702; 1047. As I find that the Respondent has failed to accept any responsibility, I find that RX 18–37 should not be considered by the Administrator towards remedial measures taken by the Respondent. *See Ajay S. Ahuja,* 84 FR 5479, 5498 n.33 (2019) (''[A] registrant does not accept responsibility for its actions simply by taking remedial measures. *Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 & 5195,* 77 FR 62,316, 62,346 (2012). Further, where a registrant has not accepted responsibility it is not necessary to consider evidence of the registrant's remedial measures. *Jones Total Health Care Pharmacy, L.L.C. & SND Health Care, L.L.C.,* 81 FR 79,188, 79,202–03 (2016)'').

*SSS For brevity and keeping with recent cases, I have modified the legal standard used originally by the ALJ regarding loss of trust and have replaced it with this text.

*TTT I have already addressed that Respondent Pharmacy presented factual assertions related to remedial measures for the first time in Respondent's Exceptions, but most of those facts are not supported by the record and were not under oath or subject to cross examination.

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October 12	Oct 27	Nov 2	Nov 12	Nov 16	Nov 26	Dec 13	Jan 10
October 13	Oct 28	Nov 3	Nov 12	Nov 17	Nov 29	Dec 13	Jan 11
October 14	Oct 29	Nov 4	Nov 15	Nov 18	Nov 29	Dec 13	Jan 12
October 15	Nov 1	Nov 5	Nov 15	Nov 19	Nov 29	Dec 14	Jan 13
October 18	Nov 2	Nov 8	Nov 17	Nov 22	Dec 2	Dec 17	Jan 18
October 19	Nov 3	Nov 9	Nov 18	Nov 23	Dec 3	Dec 20	Jan 18
October 20	Nov 4	Nov 10	Nov 19	Nov 24	Dec 6	Dec 20	Jan 18
October 21	Nov 5	Nov 12	Nov 22	Nov 26	Dec 6	Dec 20	Jan 19
October 22	Nov 8	Nov 12	Nov 22	Nov 26	Dec 6	Dec 21	Jan 20
October 25	Nov 9	Nov 15	Nov 24	Nov 29	Dec 9	Dec 27	Jan 24
October 26	Nov 10	Nov 16	Nov 26	Nov 30	Dec 10	Dec 27	Jan 24
October 27	Nov 12	Nov 17	Nov 26	Dec 1	Dec 13	Dec 27	Jan 25
October 28	Nov 12	Nov 18	Nov 29	Dec 2	Dec 13	Dec 27	Jan 26
October 29	Nov 15	Nov 19	Nov 29	Dec 3	Dec 13	Dec 28	Jan 27